1 PURPOSE

To describe the policies and procedures for developing, reviewing, revising, and distributing standard operating procedures (SOPs) for the Institutional Review Board (IRB) and Office of Human Research Protections (OHRP) at West Virginia University (WVU).

2 OVERVIEW

This SOP applies to all policies and procedures reviewed by VPR (Institutional Official or IO), WVU OHRP Director, WVU OHRP Assistant Director (OAD), WVU OHRP Continuous Improvement Manager (CIM), WVU OHRP staff, and approved by WVU IRB Leadership, the Vice President for Research (VPR), and any WVU administrative offices to which the SOP applies.

3 PROCEDURES

Procedure for Writing New Standard Operating Procedures

3.1. The WVU OHRP Director, with advice from IO, OAD, CIM, WVU OHRP staff, IRB Chairs, IRB Vice Chairs, IRB members, and/or PIs (as applicable), determines when a new SOP needs to be established. Designated OHRP staff are responsible for writing SOPs.

3.2. Any OHRP Staff member may draft an SOP based on his or her specialization. All SOPs should comply with federal, state, and institutional regulations.

3.3. As appropriate, the WVU OHRP staff distribute copies of newly drafted SOPs to designated IRB Chairs, IRB Vice Chairs, IRB members, and/or OHRP staff members for review.

3.4. If the SOP involves coordination with another WVU administrative office, the WVU OHRP Director or WVU OHRP staff cooperate with the administrative unit involved in drafting the SOP and route the SOP to the appropriate individual representing that office for approval.

3.5. The WVU OHRP staff ensure each SOP designates the most recent revision date, which serves as the currently effective date for the SOP.

3.6. Each SOP contains a version number, which indicates how many times since its origination, WVU OHRP staff have revised an SOP.

3.7. The IRB Chair(s), WVU's VPR, and any appropriate coordinating officials (when necessary) review the new or revised SOP. The SOP approval documentation is used to track new and revised SOP approvals. The SOP approval documentation will denote which SOP(s) were reviewed and approved, along with the original version number. The date that the VPR (IO) reviews and approves the SOP(s) should match the currently effective date of an SOP.

Dissemination of Standard Operating Procedures

3.8. The OAD or designee monitors the SOPs and disseminates new SOPs to all WVU OHRP staff members and to the IRB Chairs, Vice Chairs, or members if the SOP involves their activities.

3.9. WVU OHRP staff and/or IRB Chairs or designees are responsible for reviewing the new SOP, documenting their review, and returning it to the OAD within a reasonable amount of time.

3.10. The WVU OHRP maintains the most recent versions of all approved SOPs on the WVU OHRP website.

3.11. According to SOP 003 (Investigator and Key Personnel Responsibilities, Qualifications, and Training), PIs are responsible for reviewing and complying with ethical codes, IRB guidance documents, and WVU OHRP/IRB SOPs relevant to them, to professional practice, and to other applicable regulatory requirements (e.g., 45 CFR 46.114 – Cooperative Research Provision).

Revisions to Standard Operating Procedures

3.12. The WVU OHRP Director, with advice from VPR (IO), OAD, CIM, WVU OHRP staff, IRB Chairs, Vice Chairs, and/or IRB members, determines when to revise an existing SOP. In most cases, the OAD revises the SOP. The OAD may make minor administrative corrections without revising an SOP (e.g., typographical, formatting, or grammatical error). Any WVU OHRP staff member may draft revisions to an SOP based on his or her specialization. All SOP revisions should comply with federal, state, and institutional regulations.

3.13. In revising SOPs, WVU OHRP staff may consult with IRB Chairs and/or IRB members on IRB-related issues.

3.14. As appropriate, the OAD or designee circulates copies of newly revised SOPs to IRB Chairs, IRB members, and/or WVU OHRP staff for review.

3.15. If the revised SOP involves coordination with another WVU administrative office, the OAD or designee routes the SOP to the appropriate individual representing that office for review and approval.

3.16. The revised SOP is effective when the SOP documentation is approved by the WVU VPR (in coordination with IRB Chairs and any other coordinating officials [as necessary] on the date indicated).

3.17. The CIM or designee places an updated copy of a revised SOP in the WVU OHRP Sharepoint secured site where effective SOPs and SOP approval documentation are stored.

3.18. The CIM or designee informs WVU OHRP staff members of all changes in the SOPs relevant to their jobs.

3.19. The CIM or designee informs IRB members of all changes in SOPs relevant to their responsibilities and provides this information via virtual or in-person meetings, email, communication, presentations, and/or the OHRP website.

3.20. If an SOP impacts PIs or study personnel, the CIM or designee provides this information to them through the WVU OHRP website and may disseminate changes through various educational initiatives (e.g., emails, listserv announcements, newsletters, presentations, etc.).

Temporary Addendums for Transitional Periods or Emergency Situations

3.21. The WVU OHRP Director or designee has the authority to implement temporary contingency procedures that may veer from designated SOPs in emergency situations or during transitional periods.

3.22. The WVU OHRP Director or designee will document temporary contingency procedures and the period in which they are in effect via an SOP addendum to the applicable SOP. The addendum will be confirmed in writing (electronic or paper) by the WVU OHRP Director or designee.

Review of Standard Operating Procedures

3.23. The OAD or designee conducts a periodic review (once every three years or according to workload/need) of the continuing suitability of the SOPs.

3.24. WVU OHRP staff may review SOPs at any time for accuracy/applicability. The WVU IRB/OHRP staff obtain information necessary to update procedures through monitoring of sources including, but not limited to, the US Food and Drug Administration website and the Department of Health and Human Services.

3.25. If significant or applicable changes to procedures become necessary, the WVU OHRP Director, OAD, or designee revises the SOP in question as soon as possible, and the OAD or designee distributes the revisions to the IRB, WVU OHRP staff, and appropriate individuals representing coordinating administrative offices in a timely manner following the procedures outlined above. (See the section on *Revisions to Standard Operating Procedures*.)

Suspension or Deletion of an SOP

3.26. Upon consulting with IRB Chairs, the WVU OHRP Director or designee has the authority to suspend or delete an SOP in such circumstances as major policy deliberation, changes in institutional administration, or reorganization of departments, offices, or divisions with which the WVU OHRP and IRB have coordinated relationships or joint procedures.

3.27. When an SOP is suspended or becomes obsolete, the CIM or designee deletes the SOP, informs appropriate staff and/or IRB members, and ensures that WVU OHRP staff remove the SOP from the WVU OHRP website and database, and archive or delete it, as appropriate, and within WVU's institutional data destruction policies.

Record Keeping

3.28. The CIM or designee maintains copies of all current SOPs on the WVU OHRP Website and OHRP Sharepoint secured site. (See SOP 039: IRB Records and Data Information Management.)

4 REFERENCES

Not applicable

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/8/2021	New SOP

1 PURPOSE

1.1 This SOP describes the West Virginia University (WVU) Office of Human Research Protections and provides an overview of the organization's resources, staff, and reporting structure.

2 OVERVIEW

2.1 WVU has established the Office of Human Research Protections (WVU OHRP) to ensure compliance with policies and procedures to protect human subjects in research. WVU OHRP is a compliance department within the WVU Research Office. The primary responsibility of WVU OHRP is the operation of the human research protection program. (See SOP 002: Human Research Protection Program.)

2.2 WVU OHRP provides the written policies and procedures (Standard Operating Procedures, SOPs) for the WVU IRBs to review human subject research and general departmental and research support activities related to human subject protections for the institution. These activities include ensuring that systems and standard operating procedures are in place to support human subject protections while aiding the research community. WVU IRB and OHRP operations follow the criteria within the SOPs unless otherwise stated.

2.3 WVU OHRP has instituted standard procedures for determining when the human research protection program oversees activities. WVU OHRP facilitates the review and approval for and provides general support for human subject research for the Research Office and the institution. (See SOP 011: Human Subject Determination.)

3 RESOURCES

3.1 Through the Institutional Official, WVU OHRP has support for the required resources to perform the human research protection program's functions, including the IRB meetings online and in-person. (Resources include office space, meeting space, storage space, equipment, and electronic systems.) The resources provided include the WVU OHRP electronic submission management system, education program, quality improvement program, and community outreach. Resources are reviewed during the annual budget review process.

4 STAFF

4.1 The WVU OHRP Director selects employees for WVU OHRP to support the human research protection program, according to WVU Human Resources policies and procedures. Depending on the positions to be filled, qualifications to be considered in the selection of staff may include experience in:

- IRB Administration
- Regulatory Compliance

- Human Research Protections

4.2 Staff at the entry or clerical level must demonstrate the desire to learn, and be an active participant in, the regulatory, ethical, and procedural aspects that support a research protection program.

4.3 Through informal and formal training, the staff is provided with the opportunity to become knowledgeable about WVU's human research protections program and standard operating procedures.

4.4 The staff approved to review protocols are issued a Review Authorization Letter from the Institutional Official detailing the types of reviews they are authorized to complete.

4.5 The WVU OHRP Director supervises and evaluates staff on an annual basis, according to WVU Human Resources policies and procedures. The adequacy of personnel and non-personnel resources of the human research protections program is regularly assessed by the WVU OHRP Director and approved by the Institutional Official.

5 REPORTING STRUCTURE

5.1 WVU OHRP Staff reports to the Director (and, when applicable, the Assistant Director) and perform the tasks required to meet the mission of WVU OHRP and the human subject protection program.

5.2 WVU OHRP Assistant Director reports to the Director.

5.3 WVU OHRP Director reports to the Associate Vice President for Creative and Scholarly Activities.

5.4 WVU Associate Vice President for Creative and Scholarly Activities reports to the Vice President for Research, who serves as the Institutional Official.

6 REFERENCES

WVU Policies:
WVU Human Research Protection Policy Letter dated February 13, 2019
SOP 002: Human Research Protections Program
SOP 011: Human Subject Research Determination (NHSR)

Federal Regulations:
N/A

AAHRPP:
Standard I-1, A
Standard I-2

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/8/2021	New SOP

1 PURPOSE

1.1 This SOP provides an overview of West Virginia University's human research protections program known as the WVU Office of Human Research Protections (OHRP).

2 OVERVIEW

2.1 West Virginia University (WVU) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of WVU.

2.2 In the review and conduct of research, WVU staff's actions are guided by the ethical principles outlined in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, referred to as the *Belmont Report*: respect for persons, beneficence, and justice.

2.3 The WVU Office of Human Research Protections is a systemic and comprehensive program designed to afford protections to all human research participants. The actions of WVU staff will conform to the applicable federal, state, and local laws and regulations.

2.4 The WVU Human Research Protection Policy Letter delegates responsibility to the Vice President for Research (VPR), who serves as the Institutional Official (IO) to ensure appropriate authority and independence for the program. Through WVU OHRP and IO oversight, the WVU Office of Human Research Protections has sufficient resources to protect the rights and welfare of research participants for the research activities that WVU conducts or oversees.

2.5 WVU's transnational research activities are consistent with the ethical principles outlined in the program and meet equivalent levels of participant protection for the research conducted in WVU's principal locations while complying with local laws and considering cultural context.

2.6 Research that has been approved by a WVU IRB may be subject to further appropriate review and disapproval by officials of the institution. However, those officials may not approve the research if an IRB has not previously approved it.

3 RESPONSIBILITIES

3.1 The Institutional Official and those directly responsible for the human research protections program have the following responsibilities:

- Follow the WVU written policies and procedures (SOPs) that allow the WVU IRBs to function independently of other organizational entities in protecting research participants.

- Follow the written policies and procedures (SOPs) that specify the ethical standards and practices of the WVU human research protections program.
- Ensure that the SOPs are available to Sponsors, Researchers, Research Staff, research participants, and the WVU IRBs via the WVU OHRP website.
- Communicate changes in policies and procedures to sponsors, researchers, research staff, research participants, and the WVU IRBs via listserv announcements and the WVU OHRP website.
- Identify applicable laws in the localities where it conducts human research.
- Ensure that the WVU OHRP staff and the WVU IRB members consider the SOPs, institutional policy, federal/state law in the review and conduct of research and resolve differences between federal or national laws and local laws.
- Provide an educational program that contributes to improving the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
- Ensure that Federal funds administered by a federal department or agency may not be expended for research involving human subjects unless the requirements of the applicable WVU SOPs have been satisfied.
- Facilitate the operation of the WVU IRBs (membership management, meetings, and record management)
- Provide oversight for all human-subject, research-related activities (systems, SOPs, IRB, education)

4 REFERENCES

WVU Policies:
WVU Human Research Protection Policy Letter dated February 13, 2019
SOP 001 WVU OHRP Overview

Federal Regulations:
45 CFR 46.112
45 CFR 46.122

AAHRPP:
Element I.1.A, B, C, D, E, G
Standard I-2
Standard I-3
Element III.I.A

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/8/2021	New SOP
8/8/2022	Minor revisions to address AAHRPP Step 1 requirements. (Update to clarify communication process with research community)

1 PURPOSE

This SOP defines WVU-affiliated principal investigator (PI) and key personnel (hereafter called research staff) responsibilities, qualifications, and training requirements when conducting human subject research under the auspices of WVU IRBs.

2 GENERAL INFORMATION

2.1 PIs and research staff will adhere to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("Belmont Report") when conducting research involving human subjects.

2.2 All PIs and research staff will conduct research according to all applicable university policies and human research protections program policies, as well as federal, state, and local laws and guidance for the protection of human subjects in research. Researchers will also consider the applicable professional practice standards of their disciplines and other generally accepted good research practice guidelines in the development and performance of human research.

3 PRINCIPAL INVESTIGATOR RESPONSIBILITIES

3.1 Principal Investigator Qualifications, Oversight, and Training

3.1.1 PIs will have appropriate education, training, and experience to assume overall responsibility for the ethical conduct of human subject research. Training requirements include training in human subjects protection, as described on the WVU OHRP Training website. Additional training requirements may also apply for PIs receiving funding from select sponsors (e.g. NIH or NSF requirements for instruction in the responsible conduct of research for certain training grants or requirements for good clinical practice training for NIH awardees involved in NIH-funded clinical trials).

3.1.2 For purposes of WVU OHRP policy, only one individual is designated as the primary PI of a human research study. Other individuals can be listed as Co-PIs. Although these individuals are not the considered under local institutional policies as PI of the project, they can assist in managing research and can be designated by the PI to oversee the conduct of research and training of research staff. Please note that students and residents may not be PIs on protocols at WVU.

3.1.3 PIs are responsible for knowing when proposed activities are defined as "research involving human subjects" by WVU OHRP policy (SOP 011: Human Subject Determination) or by seeking guidance as appropriate. PIs will provide the IRB (or designees) with sufficient information and materials to make the determinations required by WVU OHRP policies. (See SOPs 011: Human Subject Research Determination (NHSR); 017: Exempt Protocols; 018: Expedited Protocols; 019:

Full Board; 020: Flex Protocols.) PIs will ensure that research does not begin until IRB approval or Exempt/Flex acknowledgment has been obtained.

3.1.4 PIs are responsible for adhering to WVU OHRP and WVU institutional policies in addition to reviewing IRB policies when WVU has determined to rely on an external IRB. (See SOP 010 Reliance and Single IRB.)

3.1.5 PIs are responsible for the selection and training of individuals who may assist with their research and will obtain IRB approval for the involvement of (and changes in) co-PIs and research staff when required by the protocol types. Training should provide staff with a general familiarity with the research methods and objectives (as applicable) and study-specific information relevant to the tasks to be performed.

3.1.6 PIs may delegate study-related tasks to appropriately qualified and trained study personnel. PIs will maintain oversight of, and retain ultimate responsibility for, the conduct of those who perform delegated functions.

3.1.7 PIs will ensure that all researchers assisting in the conduct of the research are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies of the institution and the reviewing IRB. PIs will keep co-PIs and research staff informed of any changes made to the research while the research is ongoing. If the PI oversees a multi-site research project, the PI is responsible for keeping co-PIs and research staff informed of any changes in the research or applicable laws, regulations, and policies of the WVU OHRP and WVU IRB.

3.1.8 PIs will ensure that they have sufficient time to properly conduct and/or supervise the proposed research and personnel and that adequate resources (e.g., qualified staff, facilities, medical/psychosocial services) are available to conduct the approved research safely.

3.1.9 If a PI leaves the university or is unavailable to conduct or supervise ongoing research personally (e.g., on sabbatical or extended leave), they must plan to amend (including a change in PI) or terminate the research, as appropriate. Primary research data and research-related records will be retained at the university unless otherwise agreed upon by West Virginia University. (See SOPs 038: Research Data Retention and 039: IRB Records.)

3.1.10 PIs, co-PIs and research staff will disclose all personal financial interests relevant to their institutional commitments, as required by regulations and university policy, and will work to eliminate or manage potential conflicts of interest when applicable. (See SOP 042: Conflicts of Interest.)

4 PRINCIPAL INVESTIGATORAND RESEARCH STAFF RESPONSIBILITIES

4.1.1 PIs are responsible for designing and conducting research in a manner that minimizes risks, including using sound research design and generally accepted scientific and/or scholarly standards. PIs performing research involving investigational drugs, biologics, or devices will comply with applicable FDA regulations and WVU OHRP policies. (See SOPs 022: Research Involving Investigational Drugs and 023: Research Involving Investigational Devices.)

4.1.2 PIs and research staff will perform the research as approved (or as determined Exempt or Flex review) and will follow the terms of an associated grant, contract, and/or signed funding agreement if any. Researchers will not make changes to the research or informed consent process unless approved by the IRB, except where necessary to eliminate apparent immediate hazards to participants, and will inform the IRB (and sponsor as applicable) of any change.

4.1.3 PIs will obtain continuing review and approval of ongoing, applicable research at the interval determined by the IRB to avoid expiration of IRB approval and cessation of all research activities.

5 PROTECTING THE RIGHTS, SAFETY, AND WELFARE OF RESEARCH PARTICIPANTS

5.1.1 PIs and research staff will recruit participants in a fair and equitable manner that avoids the potential for coercion and undue influence.

5.1.2 Using the IRB-approved consent process(es), PIs and research staff will obtain and document informed consent (unless waived) and HIPAA (Health Insurance Portability & Accountability Act) research authorization (when applicable) from participants or their legally authorized representatives before the participants' involvement in the research. PIs and research staff will provide participants or representatives sufficient opportunity to consider whether to participate and will ensure that participants' (or representatives') choices are voluntary and based upon informed decisions. (See SOP 012: Informed Consent.)

5.1.3 To minimize risks to participants, PIs and research staff will follow procedures to protect the privacy of participants and maintain the confidentiality of the research data. For greater than minimal risk research, PIs will appropriately monitor research data to ensure participant safety. (See SOP 036: Research Data Protection/HIPAA.)

5.1.4 When populations vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons are included in the research, PIs will provide additional required protections. (See SOPs 013: Vulnerable Populations, 014: Research Involving Children, 047: Research Involving Prisoners, and 048: Research Involving Pregnant Women.)

5.1.5 PIs and research staff will be available to participants to address concerns or complaints and to answer participants' questions during the research (typically via email or telephone but potentially via other electronic means, if appropriate security mechanisms are in place, as approved by the IRB). Researchers will involve the IRB (or designees) in their responses when appropriate.

5.1.6 During and following the conduct of the research, PIs will provide participants with significant new findings that may relate to the participant's well-being and/or willingness to continue to participate.

6 ADDITIONAL REQUIREMENTS FOR PRINCIPAL INVESTIGATORSFOLLOWING ICH-GCP GUIDANCE

6.1 Good Clinical Practice (GCP) guidance developed by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) defines the roles and responsibilities of IRBs, PIs, monitors, and sponsors in clinical trials involving human subjects. The responsibilities described by ICH-GCP guidance include requirements for PIs conducting clinical trials in addition to those of DHHS and FDA regulations and human research protection policies. For additional information on PI responsibilities required by ICH-GCP, please see the guidance provided on the WVU OHRP Training website.

6.2 All PIs conducting human subjects research at WVU who follow ICH-GCP guidance must also comply with other applicable WVU OHRP policies.

7 ADDITIONAL REQUIREMENTS FOR PRINCIPAL INVESTIGATORS WORKING WITH NON-AFFILATES

7.1 Principal investigators must comply with institutional policies and procedures related to oversight of non-affiliated personnel. Expectations vary by review type. In general, if reliance does not apply, non-affiliated personnel must seek IRB review and oversight at their local institutions. For individuals at organizations without an IRB or community members, the WVU PI is responsible for ensuring appropriate oversight and training. Reliance policies apply when applicable for expedited and full board protocols.

8 REFERENCES

WVU Policies:

SOP 010: Reliance and Single IRB
SOP 011: Human Subject Research Determination (NHSR)
SOP 013: Vulnerable Populations
SOP 014: Research Involving Children
SOP 017: Exempt Protocols
SOP 018: Expedited Protocols
SOP 019: Full Board Protocols
SOP 020: Flex Protocols
SOP 022: Research Involving Investigational Drugs
SOP 023: Research Involving Investigational Devices
SOP 036: Research Data Protection/HIPAA
SOP 038: Research Data Retention
SOP 039: IRB Records

SOP 042: Conflicts of Interest
SOP 047: Research Involving Prisoners
SOP 048: Research Involving Pregnant Women

Federal Regulations:
21 CFR 56.111
21 CFR 312
21 CFR 812
45 CFR 46.111

AAHRPP:
Standard III-1
Standard III-2

Guidance:
FDA Draft Guidance "Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of PIs" (05/10/2007)
ICH "Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance" (03/2018)
OHRP Frequently Asked Questions about Human Research "Investigator Responsibilities FAQs"

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/8/2021	New SOP
10/17/2024	Removed mention of non-affiliates in Section 1; added Section 7

IRB Authority, Membership and Responsibilities			
Document	**Version #**	**Effective Date**	**Page**
SOP 004	3.0	02-26-2025	Page 1 of 10

1 PURPOSE

This SOP describes the WVU onsite Institutional Review Board (IRB) authority, membership composition, membership selection process, and the WVU staff responsibilities related to the operation of the WVU IRBs.

2 SCOPE

The IRBs operated by West Virginia University

- WVU has established two internal Institutional Review Boards (IRB) to ensure human subjects' protection in research conducted under the auspices of WVU.
- The two WVU IRBs follow the same policies and procedures and are referred to as the IRBs within this document.
- Non-exempt human subjects research conducted under the auspices of WVU must be reviewed and approved by a WVU IRB before research can begin.
- WVU IRBs can serve as the single IRB of record for multi-site research projects.

WVU has agreements in place with central IRBs and enters into IRB Authorization Agreements (IAAs) via written documentation and single IRB platforms. (See SOP 010 Reliance and Single IRB.)

3 OVERVIEW

WVU IRB AUTHORITY

The IRB derives its authority from the HRPP institutional policy letter dated February 13, 2019. Under Federal Regulations, IRB authority includes:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of WVU.
2. To suspend or terminate approval of research not being conducted following the IRB's requirements or research that has been associated with unexpected serious harm to participants.
3. To observe or have a third party observe the consent process.
4. To observe or have a third party observe the conduct of research.

The research covered by this policy that has been approved by an IRB may be subject to further appropriate review and disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

WVU officials may strengthen requirements and/or conditions or add other modifications to secure WVU approval or approval by another WVU committee. Previously approved research proposals and/or consent forms must be re-approved by the IRB before initiating the modifications.

The WVU IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with the WVU IRB's requirements or research that has been associated with unexpected serious harm to participants. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the PI, appropriate institutional officials, and the department head. (See SOP 029 Suspension, Termination, Investigator Hold, Early Termination.)

Liability Coverage for IRB Members:

The institution's liability insurance policy covers employees and persons authorized to act on behalf of the institution for acts or omissions occurring within the scope of their employment or within the scope of the authorized activity.

4 RESPONSIBILITY

The Institutional Official (IO), the WVU OHRP Director, the IRB Chairs, and the members of the IRBs assume the following responsibilities:

- To ensure that IRB membership promotes respect for its advice and provide counsel in safeguarding human subjects' rights and welfare.
- To ensure that IRB members and Chairs have the professional competence necessary to review specific research activities. IRB members and Chairs are solicited from non-tenure track faculty/staff, tenure track faculty, and administrative staff. Individuals in a training role and students are not permitted to serve on the IRB.
- The IO is legally authorized to represent the institution for matters related to research conducted under the auspices of WVU, is the signatory official for all Assurances, and assumes the obligations of the Institution's Assurance. The IO may authorize a designee in writing for specific responsibilities/tasks to be carried out by alternate knowledgeable officials of the institution.

Institutional Official (IO):

- Provides oversight for research conducted under the auspices of WVU.
- Provides oversight and support for the WVU Institutional Review Boards.
- Ensures that the IRBs operate fairly and impartially and are immune to pressure by the institution's administration, PIs, and other professional and non-professional sources.

- Reviews membership and activity on at least an annual basis with the WVU OHRP Director to ensure adequate membership (refer to membership below) and the appropriate number of IRBs to support the volume and nature of the research for the institution.
- Appoints a Chair and Vice-Chair for each IRB to serve for renewable three-year terms in consultation with the WVU IRB Chairs and WVU OHRP Director.
- Reviews the performance of the WVU IRB Chairs on an annual basis and provides feedback as appropriate in consultation with the OHRP Director.
- Removes Chairs for reasons including (but not limited to) the following: if the Chair is not acting in accordance with the IRB's mission, following policies and procedures, has an excessive number of absences, or is not fulfilling the responsibilities of the Chair.

WVU OHRP Director (or designee):

Registration and Assurances:

- Maintains registration for the WVU IRBs with the Department of Health and Human Services.
- Updates the IRB Registration information within 90 days when the following changes occur.
    - Contact person who provided the IRB registration information
    - IRB chair with Federal OHRP
- Submits, implements, and maintains an approved Federal Wide Assurance (FWA) through the IO and the Department of Health and Human Services Office of Human Research Protection (OHRP).
- Appoints members (other than Chair and Vice Chair) to the Institutional Review Board to serve for renewable three-year terms in consultation with the WVU IRB Chairs and WVU OHRP Director.
- Communicates change in appointment of all IRB members and/or IRB Chairs/Vice Chairs to the research community by making the list available on the WVU OHRP website.
- Serves as the primary contact for the WVU Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.

WVU IRB Oversight\Membership Management

- Actively oversees and manages the membership roster to ensure the membership is adequate for the volume and type of research.
- Ensures written procedures for the review of research to ensure that the reviews are completed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required.
- Provides feedback regarding IRB member performance to the Chairs.
- Provides members with the results of the feedback.

- Reviews the activity of the IRBs on at least an annual basis, provides recommendations to the IO regarding IRB membership and the appropriate number of IRBs required to support the volume and nature of research for the institution.
- Ensures that IRB members are appropriately knowledgeable to review research per ethical standards and applicable regulations.
- Ensures the development and implementation of an educational plan for IRB members, staff, and researchers.
- Follows institutional and federal policy related to competing business interests and conflict of interest.
- Ensures the availability of alternates to take a member's place in the event of a prolonged absence.
- Recommends the appointment of members to serve for renewable three-year terms to the IO.
- Manage change in appointment of membership and chairs (including reappointment or removal).

IRB Chair(s):

The IRB Chairs should be highly respected individuals, from WVU or the community, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

IRB Chairs should also:

- Ensure that the actions of the IRBs are fair, impartial, and immune to pressure by the institution's administration, the PIs, and other professional and non-professional sources.
- Conduct the meetings and be a signatory for correspondence generated by the WVU human research protections program.
- Designate other members to perform duties, as appropriate, for review, signature authority, and other IRB functions, e.g., the Vice Chair and WVU OHRP Director.
- Advise the IO and the WVU OHRP Director regarding member performance and competence
- Conduct member evaluations and advises the IO and the WVU OHRP Director regarding member performance and competence.
- Consult with the WVU OHRP Director to designate one or more subcommittees to address complex issues, perform investigations, or develop policies/procedures.
- Solicit individuals from the organization or the community with competence in special areas to assist in reviewing issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to the current membership.
- Attend monthly Chair meetings to discuss events, IRB business, and new policies and procedures.
- Attend required training and presentations related to policy and regulatory changes.
- Follow institutional and federal policy related to competing business interests and conflicts of interest.
- Maintain the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.

IRB Vice Chair(s):

- The Vice Chair serves as the Chair of the IRB in the Chair's absence and has the same qualifications, authority, and duties as the Chair.

IRB Members:

- Attend the scheduled IRB meetings. If a member cannot attend a scheduled meeting, the IRB Chair and designated WVU OHRP staff member should be informed at least five days before the planned meeting (except in cases of emergency outside of the IRB member's control).
- Notify the WVU OHRP Director and the IRB Chair at least 30 days in advance for planned absences for extended periods, such as a sabbatical (except in cases of emergency outside of the IRB member's control).
- Review the materials at least one week before the meeting to facilitate full participation in the review (meeting materials will be sent before the meetings).
- Attend required training and presentations related to policy, procedure, and regulatory changes.
- Follow institutional and federal policy related to competing business interests and conflicts of interest.
- Maintain the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.
- Review (if needed) multiple protocols or other research items that require primary review.

Alternate Members:

The appointment and function of alternate members are the same as those for primary members.

- The expertise and perspective of the alternate member should be comparable to that of the primary member.
- The alternate member's role is to serve as a voting member of the IRB when the primary member is unavailable to attend a convened meeting.
- The alternate member will receive and review the same materials before the IRB meeting.
- The roster identifies the primary member(s)' qualifications for whom each alternate member with comparable qualifications may substitute.
- The alternate member will not be counted as a voting member unless the primary member is absent. The minutes will document when an alternate member replaces a primary member.
- Replacement members can be temporary, for the period of absence, or permanent if they are not returning to the IRB.
- Maintain the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.
- Review (if needed) multiple protocols or other research items that require primary review.

IRB Consultants:

- When necessary, the IRB Chair, designee, or WVU OHRP Director may solicit individuals from the institution or community with competence in special areas to assist in reviewing issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB.
- The use of consultants to review protocols or issues related to research will be coordinated by the IRB Chair in collaboration with the WVU OHRP staff.
- The essential information provided by consultants at meetings (for protocols being reviewed at convened meetings) will be documented in the minutes.
- Reviews provided by the consultant will be filed with the protocol.
- The consultant's findings will be presented to the IRB for consideration.
- If in attendance at a convened IRB meeting, consultants will provide consultation but cannot participate in or observe the vote.
- Consultants may not vote on protocol applications.
- Consultants can provide guidance and input regarding IRB operations and protocol review.

Ex Officio Members:

- Ex officio IRB members are non-voting members who serve as liaisons to ensure coordination among other research administrative units.
- Ex officio members can provide guidance and input regarding IRB operations and protocol review.
- Examples of ex officio members include but are not limited to: Investigational Drug Service (IDS) representative(s), OHRP Director, Radiation Safety representative(s), Legal Counsel, Institutional Biosafety Committee (IBC) representative(s), and Conflict of Interest (COI) representative(s), WVU Tissue Banks/Repositories authorized staff, etc.
- The VPR automatically reappoints ex officio members each year.

IRB Subcommittee:

In consultation with the WVU OHRP Director, the IRB Chair may appoint a subcommittee to address complex issues, perform investigations, or develop policies/procedures. The number and composition of the IRB Subcommittee members depend on the authority delegated by the IRB Chair. (For example, making recommendations versus decision-making authority).

- Review and interpret regulations to develop guides, policies, and procedures.
- Members of the IRB Subcommittee can include experienced IRB members, Ex Officio members, and/or consultants. These individuals should be matched as closely as possible with their field of expertise to

the research project assigned for review or the procedure to be developed. Ex Officio members and consultants are not voting members but can provide expertise as needed to the committee.

PROCEDURES

WVU IRB Composition:

The Chairs and WVU OHRP Director will work together to ensure that the following composition requirements are met for WVU IRBs:

- At least five members with varying backgrounds to promote the complete and adequate review of research activities commonly conducted by WVU.
- Members are sufficiently qualified in compliance with 45 CFR 46.107.
- Include persons with the knowledge to ascertain the acceptability of proposed research regarding institutional commitments, including policies and regulations, applicable law, and standards of professional conduct and practice.
- If research involving vulnerable populations is regularly reviewed, consideration will be given to adding members who are knowledgeable about and experienced in working with vulnerable populations (children, prisoners, pregnant women, handicapped, or mentally disabled persons).
- Includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
- Includes at least one unaffiliated and who is not part of the immediate family of a person who is affiliated with the institution.
- Includes one or more members who represent the general perspective of participants.
- Members cannot participate in the initial or continuing review of any protocol in which the member has a conflicting interest, except to provide the information requested by the IRB.
- Individuals with competence in special areas may be invited at the discretion of the IRB to assist in the review of issues that require expertise beyond or in addition to the available membership. These individuals may not vote. (See IRB Consultants section.)
- The membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB roster.
- Every effort will be made to ensure membership does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes; however, selection cannot be based on gender alone.
- Every effort will be made to ensure membership does not consist entirely of members of one profession.
- One member may satisfy more than one membership category.
- The WVU OHRP Director and WVU OHRP staff may be voting members of the IRB.

- The IRB has, and follows, written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge required to review the research protocol.
- On an annual basis, the IRB Chairs and the WVU OHRP Director will review the membership and composition of the IRB to determine if membership continues to meet regulatory and institutional requirements.

Membership Selection Considerations:

- Members are selected based on criteria outlined in 45 CFR 46.107.
- The structure and composition of the IRB must be appropriate to the volume and nature of the protocol applications.
- Every effort will be made to ensure membership knowledge for the type of research representing the majority of the research performed at WVU.
- Staff from the WVU Office of Sponsored Programs or Office of Innovation and Commericialization cannot serve as members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests.

Procedure to Appoint New Members:

Appointments are made for a renewable three-year period of service unless otherwise approved by the IO. Members may be re-appointed indefinitely. Any change in appointment, including reappointment or removal, requires written notification to the Chair. Members may resign by written notification to the Chair and/or WVU OHRP Director.

1. The Chair, Vice Chair, and/or the WVU OHRP staff identify a need for a new, replacement, or alternate member.
2. The members and Chairs may nominate candidates and send the nominees' names to the IO and/or the WVU OHRP Director.
3. The final decision in selecting a new member is made by the IO, in consultation with the Chair and the WVU OHRP Director.

Procedures to Engage Consultants:

1. The need is determined in advance of the board meeting by the Chair, designee, or the WVU OHRP Director by assessing the protocols scheduled to be reviewed at the convened meeting.

2. WVU OHRP will ensure that all relevant materials are provided to the consultant before the convened meeting.
3. Information and recommendations provided by consultants at meetings will be documented in the minutes (for protocols being reviewed at the convened IRB meeting).
4. Reviews provided by the consultants will be filed with the protocol.
5. The consultant's findings will be presented to the IRB, either in person or in writing. If in attendance at a convened meeting, the consultants cannot participate in or observe the vote.
6. Consultants may not vote on protocol applications.

Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

Procedure for Reporting and Investigating Allegations of Undue Influence:

1. If an IRB Chair, member, or staff person feels that any party has unduly influenced the IRB, a confidential report should be made to the IO.
2. The IO will appoint the appropriate staff to conduct an investigation.
3. If the claim is substantiated, corrective action will be taken as directed by the IO to prevent additional occurrences.

5 REFERENCES

WVU Policies:
WVU Human Research Protection Policy Letter dated February 13, 2019
SOP 010 Reliance and Single IRB
SOP 022 Research Involving Investigational Drugs
SOP 023 Research Involving Investigational Devices
SOP 029 Suspension, Termination and Investigator Hold
SOP 053 Emergency Use of Investigational Drugs, Devices, and Biologics

Federal Regulations:
45 CFR 46.107
45 CFR 46.113
45 CFR 46

AAHRPP:
Elements II.1.A, B, C, D, & E
Element III.1.E

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/8/2021	New SOP
8/8/2022	Minor revisions to address AAHRPP Step 1 requirements. (Added language describing who can serve as an IRB member.)
2/26/25	WVU IRB Composition and Member Selection updated to reference 45 CFR 46.107; change Office of Technology Transfer to Office of Innovation and Commericalization; remove Emergency IRB language.

Principal Investigators Transitioning Research To and From WVU			
Document	**Version #**	**Effective Date**	**Page**
SOP 005	3.0	09-13-2023	Page 1 of 2

1 Purpose

This SOP outlines the processes in place to bring human subjects research to WVU from another institution and to move human subjects research from WVU to another institution when Principal Investigators (PIs) begin employment with, or separate from, WVU.

2 Overview

A PI who moves human subjects research to or from WVU when external institutions are involved must review and follow this policy for each of the scenarios below.

Human Subjects Research Coming to WVU from Another Institution (PI begins employment with WVU):

- The incoming PI submits a written request to irb@mail.wvu.edu to consult with WVU OHRP staff regarding opening a research study at WVU.
- WVU OHRP staff may request a phone call/virtual meeting with the PI, the previous institution, or both.
- The incoming PI notifies the WVU Office of Sponsored Projects if the research is funded and whether any primary or subawards will be reassigned to WVU from another institution.
- The incoming PI, after consulting with WVU OHRP staff (and if applicable, the previous institution's IRB), submits a new, initial protocol to WVU's electronic IRB submission system. The type of protocol (Flex, Exempt, Expedited, Full Board, CIRB) will depend upon the nature of the research being conducted at WVU, research funding (if any), and whether other institutions are engaged in human subjects research.

Human Subjects Research Going to Another Institution from WVU (PI leaves WVU and the study IS NOT under the Single IRB Mandate):

- The departing PI submits a written request to irb@mail.wvu.edu to consult with WVU OHRP staff regarding moving the research from WVU to the new institution. WVU OHRP staff may request a phone call/virtual meeting with the PI, the new institution, or both.
- The departing PI notifies the WVU Office of Sponsored Projects if the research is funded and whether any primary or subawards will be reassigned from WVU to the new institution.
- The departing PI, after consulting with WVU OHRP staff and their new institution's IRB, submits an amendment in WVU's electronic submission system to change the PI on the study from that of the departing PI to an authorized WVU employee who can serve as the new WVU PI. This ensures the continuity of the research until the departing PI obtains IRB approval, if applicable, at their new institution.
- The departing PI is completely removed from the protocol in WVU's electronic IRB submission system.
- If the research **is not** continuing at WVU, the new PI of the WVU protocol closes the protocol within six (6) months of the departing PI's separation from WVU. Protocols not closed by the new PI within six (6) months may be closed administratively by WVU OHRP and/or the IRB.
- If the research **is** continuing at WVU, no additional action is required, and the research continues under the new PI and operates under WVU OHRP SOPs. If the departing PI and new institution are involved in the research, the new institution is responsible for the oversight of the research activities at their site.

- Departing PIs may continue to collaborate on research at WVU after their departure by obtaining authorization/approval from their new institution's IRB and providing documentation of this approval to WVU IRB.

Research Going to Another Institution (PI separates from WVU and the study IS under the Single IRB Mandate):

- The departing PI submits a written request to irb@mail.wvu.edu to consult with WVU OHRP staff regarding moving the research from WVU to the new institution. WVU OHRP staff may request a phone call/virtual meeting with the PI, the new institution, or both.
- The departing PI notifies the WVU Office of Sponsored Projects if the research is funded and whether any primary or subawards will be reassigned from WVU to the new institution.
- For research that falls under a single IRB mandate, WVU OHRP operates under SOP 010 Single IRB Reliance. The departing PI will follow this process for moving their research to the new institution.

Research Involving Special Circumstances:

- Under special circumstances, alternative arrangements to this policy may be approved on a limited case-by-case basis or by prior agreement.
- PIs who leave WVU and do not follow institutional policy and guidance regarding properly notifying WVU OHRP and moving their research may have their protocols at WVU assigned to an authorized PI who is willing to assume this responsibility or closed administratively without further notice.

History of Revisions to SOP

Effective Date	Nature of Revision(s)
04/28/22	New SOP
8/18/23	Clerical edits
9/13/23	Major edits to clarify PI responsibilities when transferring institutions

IRB Meeting Conduct			
Document	**Version #**	**Effective Date**	**Page**
SOP 006	2.0	08-08-2022	Page 1 of 3

1 PURPOSE

This SOP outlines procedures and responsibilities for conducting IRB meetings at WVU.

2 OVERVIEW

2.1 WVU IRBs have access to sufficient physical meeting space in the University building where WVU OHRP is located (when applicable).

2.2 WVU IRB meetings are held online as of March 2020 and will continue in an online or hybrid fashion for the foreseeable future. The video conferencing system used for the meetings is approved by the institution and is considered secure.

2.3 The WVU IRB members have access to the WVU OHRP staff as needed to support protocol reviews, recordkeeping, and meeting facilitation.

2.4 The IRB Chair conducts the meetings.

2.5 The IRB Chair must appoint someone to write and keep minutes.

2.6 Investigators (PIs) are responsible for submitting all needed materials in the timeframe designated by WVU OHRP and the WVU IRB.

2.7 WVU OHRP electronically delivers and/or makes accessible all meeting materials to IRB members at least five business days before the scheduled meeting.

2.8 The IRB Chair or OHRP Director (or designee) has the authority to approve guests, including the PI, to attend the meeting.

2.9 OHRP staff must ensure any guests of IRB meetings have signed confidentiality waivers.

2.10 The IRB Chair must verify the quorum before beginning each IRB meeting. This quorum must exist for all matters that are voted on. Quorum is defined as more than half the voting members and must include one member whose primary concern is not scientific. If a matter involves FDA-regulated research, a physician must be present. If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.

2.11 One unaffiliated member and at least one member representing the general perspective of participants (the same individual can serve in both capacities) will be present at all IRB meetings. Although the IRB may, on occasion, meet without this representation, individuals serving in this capacity must be present for at least 80% of all IRB meetings.

3 PROCEDURES

3.1 The agenda, submission materials, protocols, proposed informed consent forms, and other appropriate documents are available electronically to IRB members at least five days before the convened meeting. IRB members have sufficient time to review the material and can fully participate in each protocol submission review.

3.2 The IRB Chair will ensure that a quorum is present at the beginning of each meeting.

3.3 IRB members are considered present and can participate at a duly convened IRB meeting when either physically present or participating through electronic means (e.g., teleconferencing or video conferencing) which permits them to listen and speak during IRB deliberations and to vote.

3.4 When not physically present, the IRB member must receive the required materials before the scheduled meeting and must be able to participate actively and equally in all discussions.

3.5 Members participating through electronic means must vote according to procedure during the meeting using a planned method. Votes are taken within the video conferencing system polls feature that are pre-populated for each meeting. If a member has problems voting via the poll, they are instructed to verbally vote or submit their vote in the chat function. Votes are then documented in the meeting minutes.

3.6 The Chair or Vice Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict.

3.7 The IRB will review and discuss the IRB minutes from the previous meeting(s) and determine if there are any revisions. If there are none, the minutes will be accepted as presented and considered final. If it is determined that revisions or corrections are necessary, the minutes will be amended and presented at a future IRB meeting.

3.8 The IRB reviews all submissions for initial and continuing review, as well as requests for modifications.

3.9 The primary (and in some cases secondary) reviewers present an overview of the research and lead the discussion by discussing the regulatory criteria for approval within the various reviewer checklists. Primary and/or secondary reviewers utilize the Criteria for Approval checklist as a guide in making determinations at the convened meeting. (See SOP 006: Criteria for IRB Approval.)

3.10 All members present at a convened meeting have full voting rights, except in the cases of alternate members attending alongside full board members, cultural consultants, ex-officio members, or any member who discloses a conflict of interest (see SOP 004: IRB Membership, Authority, and Responsibilities). A majority of present voting members must vote for approval for the research to be approved.

3.11 PIs must leave the room or the online meeting room prior to the discussion and vote on their research.

3.12 WVU OHRP records the proceedings by taking and archiving minutes after each IRB meeting.

4 REFERENCES

WVU Policies:
SOP 006: Criteria for IRB Approval
SOP 019 Full Review

Federal Regulations:
45 CFR 46.109
21 CFR 56.109

AAHRPP:
Standard II.2.D

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP
8/8/2022	Minor revisions to address AAHRPP Step 1 requirements. (Added language regarding electronic voting.)

1 PURPOSE

This SOP describes the criteria for WVU IRB approval of protocols. Although it is not a requirement for an IRB member to complete the Criteria for Approval Checklist in the electronic system upon his or her review, the checklist is available for the IRB member to use as a guide while making determinations on any research under which these criteria must be satisfied.

2 GENERAL CONSIDERATIONS

2.1 These criteria must be satisfied for each review (initial, continuing, and amendments) for both expedited review and review by the convened IRB:

2.2 Risks to participants are minimized:

- By using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk; and
- Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes

2.3 Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the participant(s) would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

2.4 Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

2.5 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by the Federal Regulations.

2.6 When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.

2.7 When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

2.8 When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the protocol to protect the rights and welfare of these participants.

2.9 Risk/Benefit assessment: The goal of the assessment is to ensure that the risks to research participants posed by participation in the research are justified by the anticipated benefits to the participants or society.

2.10 Identify the risks associated with the research, as distinguished from the risks of standard procedures the participants would receive even if not participating in research;

2.11 Determine whether the risks are reasonable in relation to the benefits to participants, if any, and assess the importance of the knowledge to be gained.

2.12 Ensure that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

2.13 To assess the risk and benefits of the proposed research, the IRB must determine that:

- The research uses procedures consistent with sound research design;
- The research design is sound enough to reasonably expect the research to answer its proposed question; and
- The knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the IRB may draw on its knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review. When scientific review is conducted by an individual or entity external to the IRB, documentation that the above questions were considered must be provided to the IRB for review and consideration. Departmental scientific review is initiated when the electronic system sends notification to the administrative official responsible for the investigator's research unit that a new protocol was submitted. The administrative official then reviews and acknowledges the new protocol application and alerts WVU OHRP staff or the investigator listed as PI on the protocol if any issues are identified.

2.14 To approve research, the IRB determines that research studies have the resources necessary to protect participants, such as:

- Adequate time for the researchers to conduct and complete the research
- Adequate number of qualified staff
- Adequate facilities
- Access to a population that will allow recruitment of the necessary number of participants
- Availability of medical or psychosocial resources that participants might need as a consequence of the research

2.15 The IRB determines that the selection of participants is equitable with respect to gender, age, class, etc. by viewing the submitted protocol, and/or other research project materials. The IRB will not approve a protocol that does not provide adequately for the equitable selection of participants or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research. In making this determination, the IRB evaluates:

1. The purpose of the research;
2. The setting in which the research occurs;
3. The scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
4. The scientific and ethical justification for excluding classes of persons who might benefit from the research; and
5. The inclusion and exclusion criteria.

2.16 At the time of the continuing review the IRB will determine that the PI has followed the participant selection criteria that he/she originally set forth at the time of the initial IRB review and approval (See SOP 030: Continuing Review of Approved Research).

2.17 The IRB will ensure that informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 45 CFR 46.116 and 21 CFR 50.20. In addition, the IRB will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 60.27 (See also SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process).

2.18 For all research that is more than minimal risk, the researcher must submit a data safety monitoring plan. The initial plan submitted to the IRB should describe the procedures for safety monitoring, reporting of unanticipated problems involving risks to participants or others, descriptions of interim safety reviews and the procedures planned for transmitting the results to the IRB. This description should include information regarding an independent Data and Safety Monitoring Board (DSMB) if one exists, or an explanation of why an independent data safety monitor is not necessary. (See SOP 036: Research Data Protection and HIPAA for more information.)

2.19 The IRB must determine whether the activities in the research constitute an invasion of privacy. To make that determination, the IRB must obtain information regarding how the researchers are getting access to participants or their private, identifiable information and the participant's expectations of privacy in the situation. Researchers must have appropriate authorization to access the participants or their information. In developing strategies for the protection of participants' privacy, consideration should be given to:

1. Methods used to identify and contact potential participants
2. Settings in which an individual will be interacting with a researcher
3. Appropriateness of all personnel present for research activities
4. Methods used to obtain information about participants and the nature of the requested information
5. Information that is obtained about individuals other than the "target participants" and whether such individuals meet the regulatory definition of "human participant" (i.e., a participant provides information about a family member for a survey).

2.20 At the time of initial review, the IRB ensures that the privacy and confidentiality of research participants is protected. The IRB assesses whether there are adequate provisions to protect participant privacy and maintain confidentiality. The IRB does this through the evaluation of the methods used to obtain information:

- About participants;
- About individuals who may be recruited to participate in the research;
- The use of personally identifiable records; and
- The methods to protect the confidentiality of the research data.

The IRB will review all information received from the researcher(s) and determine whether the privacy and confidentiality of research participants is sufficiently protected. In some cases, the IRB may also

require that a Certificate of Confidentiality be obtained to provide additional protection for the participant.

In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would likely result from disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

2.21 At the time of initial review, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research (if applicable). The IRB may determine and require that, when appropriate, additional safeguards be put into place for vulnerable participants, such as those with impaired decision-making capacity.

3 ADDITIONAL CONSIDERATIONS

3.1. At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with the research protocols. Risks associated with the research will be classified as either "minimal" or "greater than minimal." The meeting minutes should reflect the IRB's determination regarding risk levels.

3.2. At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols. All protocols will be reviewed by the IRB at intervals appropriate to the degree of risk and based on SOP 021: Approval Period and Determination of Expiration. In some circumstances, a shorter review interval (i.e. biannually, quarterly, or after accrual of a specific number of participants) may be required (see 4.3). The meeting minutes will reflect the IRB's determination regarding review frequency.

3.3.Research that meets any of the following criteria could require review more than annually:

1. Significant risk to research participants (i.e. death, permanent or long-lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants.
2. Involvement of especially vulnerable populations likely to be participants to coercion (i.e. terminally ill).
3. History of serious or continuing non-compliance on the part of the PI.

Please note: This is not an exhaustive list. At any time, the IRB may determine that research meets criteria to require review more than annually.

The following factors will also be considered when determining which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to participants.
2. The likely medical condition of the proposed participants.
3. The overall qualifications of the PI and other members of the research team.
4. The specific experience of the responsible researcher and other members of the research team in conducting similar research.
5. The nature and frequency of adverse events observed in similar research at this and other institutions.
6. The novelty of the research making unanticipated adverse events more likely.

7. Any other factors that the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of participants either studied or enrolled. If a maximum number of participants studied or enrolled is used to define the approval period, it is understood that the approval period in no case can exceed one year and that the number of participants studied or enrolled determines the approval period only when that number of participants is studied or enrolled in less than one year. If an approval period of less than one year is specified by the IRB, the reason for more frequent review must be documented in the minutes.

3.4. The IRB recognizes that protecting the rights and welfare of participants sometimes requires that the IRB verify independently, utilizing sources other than the researcher that no material changes occurred during the IRB-designated approval period. Independent verification from sources other than the researcher may be necessary at times, for example, in cooperative studies or other multi-center research.

The IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

1. Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
2. Protocols conducted by researchers who have previously failed to comply with federal regulations and/or the requirements or determinations of the IRB.
3. Protocols subject to internal audit.
4. Whenever else the IRB deems verification from outside sources is relevant.

The following factors will also be considered when determining which studies require independent verification:

1. The probability and magnitude of anticipated risks to participants.
2. The likely medical condition of the proposed participants.
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period or may retrospectively require such verification at the time of continuing review, review of amendments, and/or unanticipated problems.

If any material changes have occurred without IRB review and approval, the IRB will decide on the corrective action to be taken.

3.5. In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required to reduce the possibility of coercion and undue influence.
Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular researcher or a research project.

3.6. The IRB follows and must adhere to applicable state and local laws in the jurisdictions where the research is taking place. The WVU OHRP and the IRB will rely on the WVU General Counsel for the interpretation and application of West Virginia State law and the laws of any other jurisdiction where research is conducted as they apply to human subject research. All consent forms must be consistent with applicable state and local laws.

3.7. Deception occurs when researchers provide false or incomplete information to participants. The IRB accepts the need for certain types of behavioral and social science studies (and in rare cases, biomedical research) to employ strategies that include deception. Employment of such strategies must, however, be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant may have declined to participate had they been informed of the true purpose of the research. Studies that use deception as part of their experimental design must meet all the requirements of 45 CFR §46.116(d), described below, and include a post-project debriefing unless an exception is granted by the IRB. If such an exception is requested, this will require full board review. If the research includes the use of deception, the investigator must:

1. Provide justification for the deception (e.g., why the research could not be conducted without deception);
2. Describe the manner of deception (e.g., the participants are not informed of the true intent of the research) and/or how the deception will take place (e.g., an associate will simulate an accident);
3. Note whether the deception results in an increased risk to participants (e.g., associates engage in a staged altercation, which could result in emotional upset) or the effect of the deception on a subject's willingness to participate in research;
4. Describe how any additional risks would be minimized; and
5. Offer the participant the option to withdraw their data from the research project in the debriefing script.

4 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 016: Documentation of the Informed Consent Process

SOP 021: Approval Period and Determination of Expiration
SOP 030: Continuing Review of Approved Research
SOP 036: Research Data Protection and HIPAA

Federal Regulations:
21 CFR 56.111
21 CFR 812
45 CFR 46.111

AAHRPP:
Element I.1.F
Standard II-2

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

IRB Determinations			
Document	**Version #**	**Effective Date**	**Page**
SOP 008	1.0	09-24-2021	Page 1 of 4

1 PURPOSE

This SOP describes the different determinations the IRB may make concerning all non-exempt human subjects research protocol applications.

2 OVERVIEW

2.1 It is the responsibility of the convened IRB or expedited IRB reviewer to make a determination within the scope of this SOP for all non-exempt human subjects research protocol applications.

2.2 It is the responsibility of all researchers, investigators, and persons under the auspices of WVU IRB to respect these IRB determinations.

2.3 Except for research waived under 45 CFR 46.101(i) or exempted under 45 CFR 46.104, the following actions will be taken by a vote of a majority of the regular and alternate members present at a convened meeting (See SOP 019: Full Board Protocols). Alternately, the IRB Chair, Vice Chair, or experienced reviewer designated by the IRB Chair may approve the research (See SOP 018: Expedited Protocols). When an application is reviewed using expedited procedures, the IRB Chair or designee may take any of the following actions except to defer for substantive issues or disapprove a study.

2.4 The IRB Chair or designee is responsible for ensuring the appropriateness of all IRB decisions and actions. The IRB Chair or designee may confer with the OHRP staff to verify that all IRB decisions and actions are based on institutional and regulatory requirements.

2.5 IRB decisions and actions voted on by the convened IRB are documented by using reviewer checklists and are included in the official minutes of the convened meeting approved by the IRB.

3 PROCEDURES

3.1 The IRB may take one of the following actions as a result of its review of research submitted for initial review or continuing review, including review of amendments. Actions are recorded in the minutes when reviewed by a full convened board. When an IRB Chair or designee takes one of the following actions as a result of his/her expedited review of research, it is recorded in the WVU electronic IRB system.

3.1.1 **Approval:** If the IRB approves an application as submitted, approval commences on that day. The application and accompanying documents are approved as submitted. The PI must receive an approval letter by WVU OHRP staff before any research activity can begin.

3.1.2 **Board Modification (Specific Minor Revisions):** The IRB may stipulate specific minor revisions to the protocol application and/or the informed consent form. The minor revisions can include wording changes, with replacement language provided. For protocol applications reviewed at a convened meeting, the required revisions are agreed upon at the meeting. For protocol applications reviewed under expedited review, the required revisions are designated by the reviewer(s). None of the required revisions may be related to the regulatory criteria for approval. The revisions are presented to the PI for incorporation by simple concurrence. The revisions must be made exactly as designated by the IRB or the reviewer(s).

To receive approval for a protocol deferred for non-substantive issues:

- Full Board Review: the PI's response, the revised protocol application, and the previously submitted protocol application are provided to the IRB Chair, Vice Chair, or a subcommittee of the IRB for review. The reviewer(s) may approve the protocol application upon receipt and approval of the revisions without further action by the IRB.
- Expedited Review: the PI's response, the revised protocol application, and the previously submitted protocol application are provided to the same reviewer (whenever possible) or to a subcommittee of the IRB for review. The reviewer(s) may approve the protocol application upon receipt and approve the revisions without further action by the IRB.

Approval of the protocol application will not be granted until all deficiencies, if any, are corrected to the satisfaction of the IRB or IRB reviewer(s). The date of approval for expedited protocol applications is the date conditions were determined to be met. This is considered the final date of initial approval. The date of approval for full board protocol applications is calculated based on the date of the last convened IRB meeting and not on the final date of initial approval.

3.1.3 **Deferred for Substantive Issues:** If the convened IRB requests substantive clarifications or modifications regarding the protocol application or the informed consent documents that are directly relevant to the determinations required by the IRB according to the regulations (See SOP 006: IRB Criteria for Approval), the protocol application is deferred pending subsequent review by the convened IRB that reviewed the protocol originally.

To receive approval for a protocol deferred for substantive issues:

- Full Board Review: the PI's response must be submitted for review at a subsequent, convened meeting of the same IRB (whenever possible). The WVU OHRP provides the IRB with the PI's response, the revised protocol application, and the previously submitted application. The PI's responsive material is placed on the agenda for re-review at the next available convened meeting.
- Expedited Review: the PI's response, the revised protocol application, and the previously submitted application are placed on the agenda for review by the full board at the next available convened meeting.

Approval of the protocol application will not be granted until all deficiencies, if any, are corrected to the satisfaction of the IRB or IRB reviewer(s). The date of approval for expedited protocol applications is the date the conditions were determined to be met. This is considered the final date of initial approval. The date of approval for full board review for the protocol application is calculated based on the date of the last convened IRB meeting, and not on the final date of initial approval.

Failure to submit a response to IRB-stipulated changes or inquiries related to deferred protocol applications within 75 days of the IRB date of determination will result in the administrative closure of the IRB file. The PI will receive notification of the closure of the protocol application, including an explanation for this action. An extension beyond 75 days may be granted by the IRB if sufficient cause is provided by the PI.

3.1.4 **Disapproved:** If the protocol application fails to meet one or more IRB approval criteria, the IRB may disapprove the application. Disapproval cannot be given through the expedited review procedure. A protocol application may only be disapproved by a majority vote at a convened meeting of the IRB. If a designated expedited reviewer believes a protocol application should be disapproved, the reviewer documents the recommendation in the expedited reviewer feedback materials in the WVU electronic protocol system and contacts the OHRP staff. The OHRP staff then forward the protocol application to the next available agenda for discussion by the full IRB at a convened meeting.

Criteria for disapproval may include but is not limited to the following:

- The protocol application violates any laws or regulations of the United States, the state of West Virginia, or West Virginia University.
- Risks to participants outweigh the benefits to them or society.
- Unnecessary risks are created.
- Selection of participants is inequitable.
- Procedures for obtaining and documenting informed consent are inadequate.
- Payment or other offered inducements are likely to influence participants' judgment.
- The protocol is poorly or improperly designed such that meaningful conclusions cannot be derived.
- The protocol is promotional (seeding), and not scientific in nature.

4 REFERENCES

WVU Policies:
SOP 019: Full Board Protocols
SOP 018: Expedited Protocols

Federal Regulations:
45 CFR 46.118

AAHRPP:
Element II.5.B.

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

Approval in Principle			
Document	**Version #**	**Effective Date**	**Page**
SOP 009	1.0	09-24-2021	Page 1 of 1

1 PURPOSE

1.1 This SOP outlines the WVU IRB process for applications and proposals lacking definite plans for the involvement of human participants.

2 OVERVIEW

2.1 Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that human participants may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal.

2.2 These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human participants' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

2.3 Except for research waived under 45 CFR 46.101(i) or exempted under 45 CFR 46.104, no human participants may be involved in any research project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution (WVU OHRP or WVU PI), to the Federal department or agency component supporting the research.

3 REFERENCES

Federal Regulations:
45 CFR 46.118

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

1 PURPOSE

To describe the policies and procedures for ensuring the rights and welfare of research participants are protected when West Virginia University (WVU) Institutional Review Board (IRB) is sharing oversight of research with another organization.

2 PROCEDURES

2.1 When WVU serves as the IRB of Record

When a WVU principal investigator (PI) requests that the WVU IRB serve as the IRB of Record for a non-WVU research site, the PI submits a WVU specific protocol for review and approval prior to or concurrent with the addition of non-WVU sites. The WVU IRB determines on a case-by-case basis whether to review the site additions as separate protocols or as amendments to the previously approved research. If a site is added via amendment, the WVU IRB decides whether to handle such an amendment using expedited review procedures or the convened IRB for review.

Please note: WVU IRB will not initiate reliance agreements for exempt activities, activities deemed to meet WVU's Flex criteria, or activities deemed to be not human subject research. Exceptions may be made on a case-by-case basis for expedited/minimal risk activities that are not federally funded. (See SOPs 017: Exempt, 020: Flex, and 011: Human Subject Research Determination NHSR.) ***Under no circumstances, without prior written approval previous to IRB submission, will WVU serve as the IRB of Record on studies where WVU is not the prime award recipient and the WVU PI is not the primary PI on the award.***

The Relying Site Provides WVU IRB with the general information (e.g., FWA, Point of Contact/Institutional Official, Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation information, ancillary reviews, local consent language, local laws, investigator qualifications, local resources, recruitment materials, and communication plan, (as applicable). The WVU IRB considers this information when conducting its review.
The WVU IRB, with input from the relying site, determines whether an investigator/research staff conflict of interest management plan, if any, allows the research to be approved at WVU (See SOP 042: Conflicts of Interest.)

The WVU IRB reviews the following for all relying sites, and ensures reporting of such events in accord with the requirements specified in the reliance agreement and/or supporting documentation:

- Suspension or termination of IRB approval;
- All unanticipated problems involving risks to participants or others;
- Serious or continuing noncompliance; and
- Requests of audits of research protocols.

Note: The relying site researcher/research team should create a process for submitting the above events to the WVU IRB when WVU serves as IRB of Record. (See SOP 031: Research Related Event Reporting for more information.)

The WVU IRB will determine on a case-by-case basis whether it will serve as the privacy review board for organizations outside of WVU's covered entity. If WVU IRB determines it will not serve as the privacy review board for external organizations, each relying site must comply with its own institution's HIPAA policies and procedures.

The WVU IRB notifies the investigators (and, if applicable, the external organization) of its review decisions consistent with any reliance agreement.

The WVU IRB makes available relevant IRB records, including minutes, approved protocols, consent documents, and other records that document the IRB's determinations to the relying organization upon request.

The WVU OHRP website contains relevant IRB policies available to the relying organization, human research protection program (HRPP) staff, and investigators/research staff. The WVU investigator forwards applicable updates to collaborators at relying organizations. (See SOP 003: Investigator responsibilities, qualifications, and training.)

The WVU IRB provides contact information to investigators/research staff to use for answers to questions, to express concerns, and to convey suggestions regarding IRB review.

The WVU OHRP assigns one of its staff (when applicable) as a consultant to guide the WVU IRB in making determinations on amendment requests submitted by the WVU investigator that may affect consent forms, HIPAA authorization language, and/or other local language that could be considered applicable to ancillary administrative review.

2.2 When WVU serves as the Relying IRB

**Please note: When a WVU investigator is conducting research involving human subjects, the WVU IRB will review and oversee the conduct of the research with some exceptions.*

The WVU investigator submits a written request to cede/defer IRB review to another organization's IRB. A member of the WVU OHRP specifies which studies are eligible for review by another organization's IRB. The determination to defer review is made on a case-by-case basis. Determinations may be made by the WVU VPR, WVU OHRP Director, and/or a member of the WVU OHRP staff in consultation with WVU Legal Counsel and/or WVU IRB and OHRP Leadership.

Please note: WVU IRB will not initiate reliance agreements for exempt activities, activities deemed to meet WVU's Flex criteria, or activities deemed to be not human subject research. Exceptions may be made on a case-by-case basis for expedited/minimal risk activities that are not federally funded. (See SOPs 017: Exempt, 020: Flex, and 011: Human Subject Research Determination NHSR.)

A member of the WVU OHRP staff provides WVU investigators with information regarding:

- Which activities are eligible for review by another IRB;
- The requirements to obtain approval(s) from other WVU committees regarding local context such as Institutional Biosafety (IBC), Investigational Drug Service (IDS), Radiation Safety, and other committees as applicable prior to study activation at WVU;
- Local requirements or local research context issues relevant to the IRB of Record's determinations prior to study activation at WVU;
- The requirement to notify the IRB of Record when local policies that impact IRB review are updated; and
- The stipulation that university officials cannot approve any research subject to a reliance agreement if it has not been approved by the IRB of Record.

The WVU IRB reviews HIPAA authorization and/or waiver of authorization forms for WVU and may allow external IRB to review the WVU HIPAA authorization form if a mutually agreed between WVU and the IRB of Record.

The WVU investigator complies with the IRB of Record's policies and procedures for initial and continuing review, record keeping, and reporting requirements, and ensures that all information requested by the IRB of Record is provided in a timely manner. (See SOP 003: Investigator and Key Personnel Responsibilities, Qualifications and Training.)

The WVU investigator complies with the following local reporting requirements for studies where WVU cedes/defers IRB review and oversight to an external IRB:

- Unanticipated Problem Involving Risk to Subjects or Others when the event involves WVU subjects or researchers;
- Serious or Continuing Noncompliance determinations by the IRB of Record when the event involves WVU subjects or researchers; and
- Suspension or Termination by the IRB of Record to which WVU cedes/defers IRB review and oversight.

The WVU IRB and/or WVU OHRP staff may:

- Review local reports and request additional information (when applicable) for studies where WVU cedes/defers IRB review and oversight to an external IRB; and/or
- Conduct local audits/administrative assessments of protocols for studies where WVU cedes/defers IRB review and oversight to an external IRB.

(See SOP 041: WVU OHRP Quality Improvement Program.)

3 ORGANIZATIONAL RESPOSIBILITIES

The WVU IRB requires a written agreement to be completed between organizations involved in a reliance relationship. The written agreement describes which organization (reviewing and relying) is responsible for the following:

- Human subjects research education qualifications of investigators and research staff;
- Scientific review;
- Verifying concordance between any applicable grant and the IRB or Ethics Committee (EC) application;
- Review of potential noncompliance, including complaints, protocol deviations, and results of audits:
    - Identifying which organization is responsible for deciding whether each allegation of noncompliance has a basis in fact; and
    - Identifying which organization's process is used to decide whether each incident of noncompliance is serious or continuing;
- Management plans for investigators and research staff when a conflict of interest exists;
- Management of organizational conflict of interest related to the research; and
- Continued oversight of active studies until closure or a mutually agreed upon transfer of the studies to another IRB of Record, should a reliance agreement be terminated.

4 PROTOCOLS UNDER DHHS AND/OR FDA PURVIEW

The WVU IRB requires a written agreement to be completed between the organizations involved in a reliance relationship under HHS and/or FDA purview. The written agreement outlines which organization (reviewing or relying) is responsible for determining the following:

- Whether the relying organization applies its FWA to some or all research and ensures that the IRB review is consistent with the relying organization's FWA;
- When required, which organization is responsible for obtaining approvals from the US Department of Health and Human Services (HHS) when the research involves pregnant women, fetuses, and/or neonates; children; or prisoners; and
- Which organization is responsible for reporting serious or continuing noncompliance; unanticipated problems involving risks to subjects or others; and suspensions or terminations of IRB of EC approval.

The IRB Reliance Administrator (or designee) is responsible for managing all reliance and/or authorization written agreements falling under WVU IRB purview.

For any non-domestic (outside of the US) research under the purview of WVU IRB where single IRB criteria do not apply, WVU IRB will work with external IRBs and/or Ethics Committees to ensure that the research can commence in the location outside of the United States. IRB approval

should be obtained from an IRB and/or Ethics Committee familiar with the location outside of the United States where the research takes place.

WVU's IRB Reliance Administrator (or designee) will work to ensure the following when single IRB review applies:

- Communicate with the awardee organization to ensure applicable authorization agreements are in place and that documentation is maintained.
- Determine on a case-by-case basis which organization will be responsible for meeting additional certification requirements, such as Certificates of Confidentiality or NIH Genomic Data Sharing Policy.
- Communicate with participating institutions to document the rationale for not relying upon a Single IRB review in accordance with NIH policy on exceptions from single IRB review (also see below, Section 5).

5 PROTOCOLS UNDER THE NIH SINGLE IRB REVIEW POLICY

The NIH requirement for single IRB (sIRB) review applies to awardees and participating research sites within the United States. For non-exempt protocols under the purview of the NIH Single IRB Policy, the WVU IRB requires a written agreement to be completed between the organizations involved in the reliance relationship. The written agreement describes the responsibility for:

- Ensuring reliance agreements are in place and documentation supporting the agreements is maintained;
- Ensuring additional certification requirements are completed, such as the NIH Genomic Data Sharing Policy; and
- Determining whether the reliance on a single IRB is appropriate versus conducting local IRB review in accordance with NIH policy on exceptions from single IRB review.

6 PROTOCOLS UNDER THE REVISED COMMON RULE COOPERATIVE RESEARCH PROVISION

The Revised Common Rule's Cooperative Research Provision (45 CFR 46.114) applies to all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency. These institutions must rely on approval by a single IRB for the portion of the research conducted in the United States.
For Non-exempt protocols that fall under the Cooperative Research Provision, the WVU IRB requires a written agreement to be completed between the organizations involved in the reliance relationship. The written agreement describes the responsibility for:

- Ensuring reliance agreements are in place and documentation supporting the agreements is maintained;

- Ensuring additional certification requirements are completed, such as the NIH Genomic Data Sharing Policy, if applicable; and
- Determining whether the reliance on a single IRB is appropriate versus conducting local IRB review in accordance with the Revised Common Rule's Cooperative Research Provision on exceptions from single IRB review.

7 COLLABORATION WITH NON-AAHRPP ACCREDITED INSTITUTIONS

WVU may agree to cede/defer responsibility for IRB review to an institution not accredited by AAHRPP for research that is not greater than minimal risk. To defer responsibility, the non-WVU IRB must have an OHRP-approved FWA and OHRP-registered IRB. Under the terms of the FWA, an institution guarantees that it complies with the federal regulations governing human subjects research and follows a statement of ethical principles for protecting the rights and welfare of human subjects in research.

Assurance of compliance with the applicable laws and regulations is further documented through the completion of a written reliance agreement. WVU investigators comply with WVU's standard operating procedures (SOPs) as outlined above when relying on an external IRB.

WVU may request a response to the following questions from the non-WVU IRB before WVU determines whether to cede/defer IRB review to an institution not accredited by AAHRPP:

- Has the institution's HRPP/IRB been cited in the last three years by FDA or OHRP?
- Can the institution's HRPP/IRB leadership attest that it has completed its own quality review process, such as:
    - Use of AAHRPP's Evaluation Instrument for Accreditation to conduct a self-assessment;
    - Completion of the US FDA's self-evaluation checklist for IRBs or ECs; or
    - An equivalent process? (And, if so, to describe it.)

When appropriate, the non-WVU IRB is asked to submit its institution's HRPP/IRB policies and/or procedures regarding the following* to WVU OHRP staff:

- Initial Review;
- Continuing Review;
- Adverse Event/Unanticipated Problem/Protocol Violation Review; and
- Reporting of serious/continuing noncompliance, unanticipated problems involving risks to subjects or others, and suspension or termination of research.

*Please note: upon review, additional policies/procedures may be requested by WVU's OHRP staff.

8 OTHER HRPP REQUIREMENTS

Ancillary reviews such as biosafety, radiation safety, and COI review are conducted by the Relying Institution or another organization external to the IRB of Record. To ensure the IRB of

Record/HRPP is appropriately informed of these reviews, WVU requires the completion of a cIRB/Reliance Application. When WVU acts as the Relying Institution, the WVU cIRB/Reliance Application is made available to appropriate ancillary reviewers and the result of the review is communicated to the WVU investigator. The cIRB/Reliance Application also documents circumstances when the IRB of Record must consider additional regulatory requirements such as those of the Department of Defense (DOD) and/or the Department of Justice (DOJ). (See SOP 051: Ancillary Reviews.)

WVU investigators are informed of ancillary reviews and the requirements of communicating the outcomes to the IRB of Record in the Reliance Acknowledgement after submitting a Reliance Application in WVU's electronic IRB system. When appropriate, investigators receive education regarding the additional ancillary reviews and the importance of forwarding the reviews to the external IRB of Record. Reliance Applications receive a 10-year acknowledgement.

90-day PI Site-Specific Holds
Protocols overseen by an external IRB where it is discovered the WVU PI did not submit a reliance request and/or did not register and receive acknowledgement from WVU OHRP prior to initiating research activities will be subject to a 90-day PI site-specific hold. This site-specific hold will be communicated to the external IRB of Record and will be in effect until the PI submits the reliance application to WVU and receives acknowledgement to begin human subject research at WVU. Additional requirements, such as relying site investigator training/education, may be imposed on a case-by-case basis, at the discretion of the WVU OHRP staff.

Direct-Sponsor Submissions to Central IRBs
WVU site PIs and research teams must submit protocol materials received by the Sponsor to the Central IRB. Sponsors may not submit protocol materials to Central IRBs directly, on behalf of the WVU site PI and research team.

9 INDIVIDUAL INVESTIGATOR AGREEMENTS

A member of the WVU OHRP staff and/or the WVU IRB determines on a case-by-case basis whether Individual Investigator Agreements (IIAs) apply to studies where WVU serves as the IRB of Record.

10 REFERENCES

WVU Policies:
SOP 003: Investigator and Key Personnel Responsibilities, Qualifications, and Training
SOP 011: Human Subject Research Determination (NHSR)
SOP 017: Exempt
SOP 020: Flex

SOP 042: Conflicts of Interest
SOP 051: Ancillary Reviews

Federal Regulations:
21 CFR 50
21 CFR 56
46 CFR 46.114
NIH Single IRB Policy

AAHRPP:
AAHRPP Standard I-9

Guidance:
FDA Cooperative Research Guidance
FDA Non-Local IRB Review Guidance
OHRP Engagement Memo (2008)
OHRP Terms of the Federalwide Assurance of Protection for Human Subjects

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/21	New SOP
6/9/22	Minor language revision in 2.1 and 2.2: "Exceptions may be made on a case-by-case basis for expedited/minimal risk activities that are not federally funded"
8/8/22	Minor revisions to address AAHRPP Step 1 requirements

1 PURPOSE

This SOP describes applicable DHHS and FDA definitions, the scope of human subject research for which WVU's OHRP has responsibility, and the process by which determinations are made that an activity is research involving human subjects. This SOP also describes Not Human Subject Research (NHSR) submission procedures for any project that does not qualify as human subject research, but for which the individual would like to receive an acknowledgement from WVU's OHRP/IRB.

2 OVERVIEW

Federal regulations define when an activity is research involving human subjects. As described below, an activity is human subjects research (i.e., and subject to regulatory and institutional requirements) if it fits either the DHHS or FDA definitions. All research involving human subjects must be approved by an IRB before being performed unless the research has been determined to be exempt from the federal regulations in accordance with 45 CFR 46.104.

3 DEFINITION FOR FDA-REGULATED RESEARCH

Activities are considered human subjects research and are subject to FDA regulations when they meet the FDA definition of "clinical investigations" and involve a "subject" as defined in FDA regulations.

Under FDA regulations, activities are "clinical investigations" when they involve:

a. Use of a drug other than the use of an approved drug in the course of medical practice; OR
b. Use of a medical device other than the use of an approved medical device in the course of medical practice; OR
c. Gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for food, including a dietary supplement that bears a nutrient content claim or health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biologic product for human use, or an electronic product (in some cases).

NOTE: In the above criteria, "approved" means "approved by the FDA for marketing."

Under FDA regulations, individuals are considered "subjects" when they become a participant in research, either as a recipient of the test article or as a control. If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom **OR on whose specimen** an investigational device is used or as a control.

4 DEFINITION FOR DHHS-REGULATED RESEARCH

Activities are considered human subjects research and are subject to DHHS regulations when they meet the DHHS definition of "research" and involve a "subject" as defined in DHHS regulations.

DHHS defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under DHHS regulations, "subject" means a living individual about whom an investigator (whether professional or student) is conducting research:

a. obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR
b. obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator (or study personnel) and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

5 APPLICATION OF THIS POLICY

WVU defines research involving human subjects as any of the following:

- Human subjects research that is subject to the FDA regulation;
- Human subjects research that is subject to the DHHS regulation;
- Human subjects research that meets the DHHS definition of research, regardless of the source of funding.

WVU IRB will review all research conducted at the institution and its affiliates when it meets this definition.

WVU has agreed to a Federalwide Assurance (FWA) to apply to the Health and Human Services regulations and terms of the assurance to all federally funded research conducted at this institution. Generally, WVU IRB will apply the Health and Human Services regulations to all human subjects research conducted at the institution and its affiliates, regardless of the source of funding. Research that is not federally funded and that is outside of the FWA is subject to the same level of review except where otherwise described in WVU OHRP's policies.

Research that does not meet the definition of research involving human subjects must be determined by WVU OHRP, not an individual researcher (see exceptions below). Researchers should submit their inquiries to irb@mail.wvu.edu.

For the purposes of this policy, the following activities are not considered research; however, the PI may want to submit an NHSR application if he or she wishes to publish the research in the future or would like to obtain an WVU OHRP NHSR acknowledgement letter:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information that focus directly on specific individuals about whom the information is collected
- Public health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- Authorized optional activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions
- Research projects involving analysis of secondary data from pre-approved, publicly available datasets/repositories will not require prior WVU IRB approval.
- Quality Improvement/Quality Assurance/Evidence Based Practice
- Program Evaluations
- Case Reports/Case Studies with five cases or less (can be retrospective or prospective in nature)
- Classroom/Educational research involving data collection activities for training purposes with the sole intent to teach methods and not contribute to generalizable knowledge

6 NHSR DETERMINATION PROCEDURES

6.1 A researcher who wishes to conduct research activities, or activities which he or she feels does not meet the regulatory definition of human subjects research, should review WVU OHRP's online guidance to determine whether or not to submit an NHSR application to WVU's electronic IRB system.

6.2 The researcher may want to submit an NHSR application even if their activities do not appear to require WVU OHRP or IRB review and approval. For example, if the researcher wishes to publish the research in the future or would like to obtain an NHSR acknowledgement letter, he or she should submit an NHSR application. If a researcher is unsure whether to submit, they should e-mail WVU OHRP staff at irb@mail.wvu.edu for additional assistance.

6.3 Once an NHSR application is submitted via WVU's electronic IRB system, WVU OHRP staff will review all information submitted by the researcher. Additional information may be requested by the WVU OHRP staff, as needed.

6.4 If a determination of "non-human subject research" is made by the WVU OHRP staff or the IRB, the PI is notified via the WVU electronic IRB system, typically in the form of an acknowledgement letter.

6.5 If the WVU OHRP staff or the IRB determine the project meets the regulatory definition of human subjects research, WVU OHRP staff will communicate with the PI accordingly as to how he or she should proceed with the submission and review of the research.

7 REFERENCES

Federal Regulations:
21 CFR 46.102
21 CFR 56.102

AAHRPP:
Element I.1.A.

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

1 PURPOSE

This SOP describes the informed consent process, the required and additional elements of informed consent, waiver/alteration criteria, and regulatory and legal requirements required in obtaining informed consent from participants.

2 OVERVIEW

Investigators are required to obtain informed consent as a legal and ethical obligation. Informed consent is an essential part of ethical human subjects research. IRBs and investigators are responsible for ensuring that researchers provide informed consent to participants before research participation unless the requirement for informed consent is waived or altered by the IRB.

Please note: IRB-approved consent forms must be used when recruiting human subjects for research under the auspices of WVU. Upon review and approval, the electronic system will watermark each page of the PDF file uploaded as the consent documents. The watermark will contain the approval date and the expiration date, along with the protocol number.

3 GENERAL INFORMATION

3.1 The requirement to obtain the informed consent of individuals before involving them in research is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report. Respect for persons requires that individuals are treated as autonomous agents, the rights and welfare of persons with diminished autonomy are appropriately protected, and potential research participants are "given the opportunity to choose what shall or shall not happen to them" (Belmont Report).

3.2 The consent process involves more than a consent form. Informed consent has been described as an "interactive process that involves the researcher informing potential participants of the purposes and procedures of the research, the risks and benefits associated with the research, and how the data provided by the participant will be protected and stored" (AAA Statement on Ethnography and Institutional Review Boards). This discussion must be culturally and linguistically appropriate for the population under study.

3.3 In addition to the language and content of the consent process, the nature and circumstances of the process are also important aspects of informed consent. Circumstances such as, who will conduct the consent discussion, who will provide consent, and the timing of obtaining consent (including any waiting period between informing the participant and obtaining consent), are critical to facilitating the participant's understanding of what has been disclosed and promoting the voluntariness of the participant's decision about whether or not to participate in the research.

3.4 Informed consent is an ongoing process. Even in the absence of new information or changes to research procedures, periodic review or confirmation of a participant's

consent is often desirable (e.g., in studies that take place over a long period, particularly complex studies, or longitudinal studies involving progressive disorders or aging populations). Participants must be able to freely decide whether to withdraw or to continue participating in the research at all times.

3.5 Projects involving deception or incomplete disclosure of material aspects of the research must meet the criteria for a waiver or alteration of informed consent. When appropriate, participants should be given additional pertinent information (debriefed) after participating in the research. Debriefing procedures and materials must be submitted to the IRB. If investigators believe a debriefing is not an appropriate procedure for the proposed study or that debriefing could cause participants more harm than the deception/incomplete disclosure itself, appropriate justification must be provided to the IRB. The IRB will make the final determination about whether debriefing is necessary and whether the proposed process is sufficient.

4 CONSENT PROCESS REQUIREMENTS

The consent process must have all of the following attributes to comply with federal regulations for informed consent:

4.1 The circumstances of the consent process will provide the participant or legally authorized representative sufficient opportunity to consider whether to participate.

4.2 The circumstances of the consent process will minimize the possibility of coercion or undue influence.

4.3 The information provided during the consent process will be presented in language understandable to the participant or the participant's legally authorized representative. The consent discussion should not include complex, technical, or highly specialized language or medical jargon that would not be understandable to potential participants.

4.4 The information communicated during the consent process is free of exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or to release (or appear to release) the investigator, sponsor, or the university (or its agents) from liability for negligence.

5 INFORMED CONSENT COMPONENTS

5.1 Concise Summary

Lengthy and/or complex consent documents must begin with a concise and focused summary of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research and to encourage discussion about the pros and cons of research participation. The following items may be addressed in this summary:

- Purpose of the research;

- Expected duration of the research;
- Research procedures to be followed;
- The most critical risks or discomforts (i.e., highest frequency or greatest severity);
- Reasonably expected benefits;
- Appropriate alternative procedures or courses of treatment;

Other additional information may be needed based on the study design and the intended participant population. Information listed in the concise summary need not be repeated later in the consent form unless that information is necessary to help ensure the consent remains understandable to the participant.

5.2 **Required Elements**

The information provided during the consent process must be consistent with the federal requirements. Unless informed consent is waived or altered by the IRB (see "Waiver or Alteration of Informed Consent" below), the consent process must include the following basic elements:

- A statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any experimental procedures;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others that may reasonably be expected from the research;
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- Explanation of whom to contact for answers to pertinent questions about the research and the participant's rights and whom to contact in the event of a research-related injury to the participant; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the

information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

  - A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

- For research involving greater than minimal risk, an explanation about whether:
  - Medical treatments are available if injury occurs and, if so, what they will consist of or where future information can be obtained;
  - Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained.
- For research regulated by FDA:
  - A statement that informs the participant of the possibility that FDA may inspect the records;
  - For applicable clinical trials, the following statement notifying the participant that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by the U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

5.3 **Additional Elements**

One or more of the following elements will also be provided to potential participants during the consent process, when appropriate:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the investigator may terminate participation without regard to the participant's consent;
- Any additional costs to the participant that may result from participation in the research;
- Consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided;

- The approximate number of participants involved in the study;
- A statement that participants biospecimens (even if identifiers are removed) may be used for commercial profit and whether or not the participant will share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions;
- Whether the research will (if known) or might include whole genome sequencing for research involving bio-specimens.

Please note: Additional information beyond the basic and additional elements of consent (above) may also be required when the IRB determines that this information would meaningfully add to the protection of research participants.

6 SPECIAL CONSIDERATIONS IN INFORMED CONSENT

The circumstances of the consent process must provide potential participants or their legally authorized representatives sufficient opportunity to consider whether to participate and minimize the possibility of coercion or undue influence. Additional safeguards are required to provide the rights and welfare of participants when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., prisoners, children, students, employees, educationally or economically disadvantaged individuals, or individuals with impaired decision-making capacity). Additional requirements for obtaining informed consent (or assent) in specific populations are described in the following WVU OHRP policies:

- Pregnant women, fetuses, or neonates (SOP 048: Research Involving Pregnant Women, Neonates, and Fetuses)
- Prisoners (SOP 047: Research Involving Prisoners)
- Children (SOP 014: Research Involving Children)
- Students or Employees (SOP 013: Vulnerable Populations)
- Adults with impaired decision-making capacity (SOP 013: Vulnerable Populations)
- Economically or educationally disadvantaged individuals (SOP 013: Vulnerable Populations)
- Non-English-speaking individuals (See “Short Form Written Consent Document below”)

7 OBSERVATION OF THE CONSENT PROCESS

According to the federal regulations, the IRB has the authority to observe or have a third party observe the consent process. Observation of the consent process can provide additional protections to research participants (e.g., in studies involving adults with impaired decision-

making capacity or studies with complex interventions). Observation can be performed by members of the IRB, WVU OHRP staff, or other individuals designated by the IRB, investigator(s), or sponsor.

8 WAIVER OR ALTERATION OF INFORMED CONSENT

In the limited circumstances described below, the IRBs can approve a consent process that does not include, or alters some or all of the elements of informed consent.

8.1 Research on Public Benefit or Service Programs:

The IRB can waive or alter the requirements for informed consent for non-exempt research examining state or local public benefit or service programs or certain features of those programs if **all** of the following criteria are met:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs;
- The research could not practicably be carried out without the waiver or alteration; and
- The research is not FDA-regulated.

8.2 Minimal Risk Research:

The IRB can waive or alter the requirements for informed consent for non-exempt research that meets **all** of the following criteria:

- The research involves no more than minimal risk to participants;
- The waiver or alteration will not adversely affect the rights and welfare of participants;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
- Whenever appropriate, participants or legally authorized representatives will be provided with additional pertinent information after participation.

8.3 Research Designed to Study Conditions in Children

The IRB can waive or alter the parental or guardian permission requirements for certain non-exempt research involving children. For more information, please see SOP 015: Assent and Parental Permission.

8.4 **Planned Emergency Research**

The IRB can approve a waiver of the requirements for informed consent for non-exempt research in life-threatening situations when it is not possible to obtain informed consent from participants or their legally authorized representatives. For more information, see SOP 054: Planned Emergency Research.

8.5 **Emergency Use of Investigational Drugs, Biologics, or Devices**

For more information about exceptions to the requirements for informed consent in "emergency use" (life-threatening) situations in which it is not possible to obtain informed consent from patients before using an investigational drug, biologic, or device when no other standard acceptable treatment is available, please see SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices.

9 USE OF SHORT FORM WRITTEN CONSENT DOCUMENT

Federal regulations require that the informed consent process is conducted in "language understandable" to research participants, and, with certain exceptions, that informed consent is documented in writing by the use of a written consent form approved by the IRB and signed and dated by the individual or individual's legally authorized representative. In limited situations, the regulations permit the informed consent process to be conducted orally, with a written "short form" consent document. This process may be used to obtain the informed consent of non-English speaking participants or their legally authorized representatives, as described below.

The short form consent document may be used only in the following circumstances:

- The participant or legally authorized representative does not speak/understand English;
- The participant or legally authorized representative speaks only a language(s) that was not anticipated in the study population or location (i.e., unexpectedly encountered);
- The IRB has not approved an appropriately translated consent form in the participant's language; and
- There is not adequate time for preparation and IRB review and approval of a translated consent form.

When the study population or location includes people who speak a language other thanEnglish, or where the circumstances of participant enrollment provide sufficient time for preparation and IRB review and approval of translated documents, the short form should not be used.

9.1 **Short Form Procedures**

- The PI may request to use a short form written consent document stating that study personnel have presented the elements of informed consent (as required by 45 CFR 46.116) orally to the participant or their legally authorized representative.
- The IRB reviews the request and may approve the short form option for documentation only if the study meets all of the requirements outlined above and in 45 CFR 46.117(b), and as applicable, in 21 CFR 50.27(b).
- When the IRB approves use of the short form written consent:
    - The PI ensures there is a witness to the oral presentation. For participants who do not speak English, the PI ensures the witness is conversant in both English and the participant's language
    - The IRB approves a written summary of the oral consent presented to the participant or the participant's legally authorized representative, which embodies the basic and appropriate elements of disclosure;
    - The participant or participant's legally authorized representative signs the short form. For FDA-regulated research, the participant or the participant's legally authorized representative signs and dates the short form;
    - The witness signs both the short form and a copy of the summary;
    - The person obtaining consent signs a copy of the summary; and
    - The person obtaining consent gives a copy of the summary to the participant or the participant's legally authorized representative, in addition to a copy of the short form.

10 EXCEPTION TO INFORMED CONSENT REQUIREMENT

Information or biospecimens can be obtained for screening, recruiting, or determining eligibility of prospective participants without informed consent (and without the need for the IRB to waive informed consent) if **either** of the following conditions is met:

- The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative; or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored (existing) identifiable biospecimens.

11 POSTING OF CLINICAL TRIAL CONSENT FORMS

For clinical trials conducted or supported by a federal department or agency, the Final Rule (Revised Common Rule) requires that a copy of an unsigned, IRB-approved consent form be posted on a publicly available federal website (ClinicalTrials.gov). The funding awardee or federal department/agency is responsible for posting the form after recruitment is complete but no later than 60 days after the last participant visit. Proprietary or institutionally sensitive

information may be redacted; only one consent form per research project must be posted regardless of the number of participant groups or research project sites.

12 REFERENCES

WVU Policies:
SOP 013: Vulnerable Populations
SOP 014: Research Involving Children
SOP 015: Assent and Parental Permission
SOP 047: Research Involving Prisoners
SOP 048: Research Involving Pregnant Women, Neonates, and Fetuses
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices
SOP 054: Planned Emergency Research
SOP 055: Electronic Informed Consent

Federal Regulations:
21 CFR 50.20
21 CFR 50.25
21 CFR 56.109
21 CFR 56.111
45 CFR 46.111
45 CFR 46.116

AAHRPP:
Element II.3.F
Element III.1.F

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

1 PURPOSE

This SOP outlines additional protections that researchers and IRBs should consider when proposed research activities involve potentially vulnerable populations, including students, employees, and adults with impaired decision-making capacity.

2 OVERVIEW

The inclusion of certain groups of participants who may be vulnerable to undue influence or coercion may require additional protections. When reviewing research involving vulnerable populations, the IRB applies any additional federal regulations, state and local laws, and institutional policies as applicable. The IRB evaluates whether additional safeguards have been included project to protect the rights and welfare of participants who may be vulnerable to undue influence. The IRB requires at least one or more knowledgeable individuals or have experience in working with these populations to be part of the review process.

3 GENERAL INFORMATION

3.1 Federal regulations require additional protections for participants vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. These, and other individuals not specifically named in the regulations, may be vulnerable to coercion or undue influence because their autonomy is limited in some way, thereby affecting their ability to provide voluntary, informed consent. (See SOP 014: Research Involving Children and SOP 047: Research Involving Prisoners.)

3.2 Pressures to participate may be subtle, as when research is conducted in settings or institutions providing employment or services (e.g., medical care or education). Individuals may believe that choosing or refusing to participate will influence access to or the quality of employment opportunities or desired services. Research should be designed to address any such potential pressures to maintain an individual's right to decline participation. Researchers and IRB should consider participant selection, recruitment, and informed consent processes.

3.3 Observation of these consent processes (e.g., by IRB members or other WVU OHRP staff) or other similar protections should be considered when concerns exist about whether potential participants can exercise free choice regarding research participation. Examples include research involving individuals whose willingness to participate may be unduly influenced by the expectation of potential benefits for their disease or condition, or those who may be in a position to fear negative consequences (real or perceived) from a supervisor or other authority figure for refusing to participate.

4 STUDENTS AS RESEARCH PARTICIPANTS

4.1 Students, including WVU students (e.g., undergrads, graduate students, medical students, residents, fellows, doctoral students, etc.), can be recruited for research participation. A student must not be required to participate in research (without a comparable non-research alternative offered) as a course requirement. Individual students, nor groups of students, should not be selected solely based on convenience when they would not otherwise be appropriate for inclusion.

4.2 Recruitment of students as research participants must be designed to minimize the possibility of coercion or undue influence. In general, potential participants should be solicited from a broad pool of individuals meeting the conditions for the research rather than by personal solicitation of specific individuals. Strategies to minimize the potential influence of an investigator when recruiting their students include recruitment by general announcements, postings or sign-up sheets, or other methods that require a student interested in participation to initiate contact with the researcher(s).

4.3 Researchers and IRBs must consider strategies to ensure voluntary participation when the participants of research include students who receive instruction directly from the researcher(s). Young students may volunteer to participate in research to please a teacher or because they fear that failure to participate will negatively affect their relationship with the teacher-researcher or faculty in general. Students' cultural or religious backgrounds may also influence their choices. A student's decision about research participation must not affect (favorably or unfavorably) grades, potential letters of recommendation, or other opportunities or decisions made by teacher-researchers.

4.4 Except in unusual circumstances, researchers should not enroll students from their classes when the research involves greater than minimal risk without the prospect of direct benefit to individual participants. Such research should occur only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and it is determined that the research is of significant importance and cannot be conducted without the enrollment of these students.

4.5 Additional safeguards may be needed to protect the privacy interests of research participants when the participants are students. Classroom conditions may make it difficult for researchers to keep an individual's participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question in the project or when peer pressure is a component of the research). In such situations, consideration should be given to whether conducting the research off-site and/or outside of regular school hours may minimize potential risks.

4.6 Protecting the confidentiality of research participants' personal information when the participants are students may also present additional challenges. The extent to which personal information and/or research data may be accessible to parents, teachers, or others not directly involved in the research must be considered and disclosed to potential participants and their parents/guardians (as applicable) in the informed consent and assent processes (See SOP 012: Informed Consent Requirements, and SOP 015: Assent and Parental Permission.)

4.7 Certain additional protections for students and parents are provided by federal regulations. The proposed use of student education records for research must comply

with the requirements of the Family Educational and Rights Privacy Act (FERPA). Research involving surveys with students must comply with the Protection of Pupil Rights Amendment (PPRA).

See below for more detailed FERPA and PPRA policies and procedures WVU OHRP and WVU IRB must follow when a research project is supported or funded by Department of Education (ED), or in some instances, research not directly funded by the ED but conducted in a school that receives funding from the ED.

FERPA

4.8 WVU OHRP promotes compliance with FERPA via IRB review. If the IRB reviewer and/or convened committee is unable to appropriately assess FERPA and ensure compliance, WVU's General Legal Counsel and Ex Officio IRB member(s) will review the project as applicable to FERPA compliance. The IRB or WVU's General Legal Counsel and Ex Officio IRB member(s) may grant exceptions to parental/student consent to release student records for research, or they will identify an individual or committee with the authority to do so as needed.

4.9 An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- 4.9.1 Develop, validate, or administer predictive tests.
- 4.9.2 Administer student aid programs.
- 4.9.3 Improve instruction.

4.10 A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the organization or researcher conducting the research that specifies:

- 4.10.1 The determination of the exception.
- 4.10.2 The purpose, scope, and duration of the study.
- 4.10.3 The information to be disclosed.
- 4.10.4 That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
- 4.10.5 That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
- 4.10.6 That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- 4.10.7 The time period during which the organization must either destroy or return the information.

4.11 Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

- 4.11.1 Student's name and other direct personal identifiers, such as the student's social security number or student number.

4.11.2 Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.

4.11.3 Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

4.11.4 Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

PPRA

4.12 WVU OHRP promotes compliance with PPRA via IRB review. If the IRB reviewer and/or convened committee is unable to appropriately assess PPRA and ensure compliance, WVU's General Legal Counsel and Ex Officio IRB member(s) will review the project as applicable to PPRA compliance. The IRB or WVU's General Legal Counsel and Ex Officio IRB member(s) may grant exceptions to parental/student consent to release student records for research, or they will identify an individual or committee with the authority to do so as needed.

4.13 No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

4.13.1 Political affiliations.

4.13.2 Mental and psychological problems potentially embarrassing to the student or his or her family.

4.13.3 Sexual behavior and attitudes.

4.13.4 Illegal, anti-social, self-incriminating, and demeaning behavior.

4.13.5 Critical appraisals of other individuals with whom the student has close family relationships.

4.13.6 Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.

4.13.7 Religious practices, affiliations, or beliefs of the student or the student's parent.

4.13.8 Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

4.14 Prior consent means:

4.14.1 Prior consent of the student, if the student is an adult or emancipated minor; or

4.14.2 Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

4.15 For certain research not directly funded by the ED and conducted in a school that receives funding from the ED, the IRB verifies compliance with the ED regulations that

schools are required to develop and adopt policies in conjunction with parents regarding the following:

4.15.1 The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.

4.15.2 Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):

- Political affiliations or beliefs of the student or the student's parent.
- Mental or psychological problems of the student or the student's family.
- Sex behavior or attitudes.
- Illegal, anti-social, self-incriminating, or demeaning behavior.
- Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or the student's parent.
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

4.15.3 The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.

4.15.4 Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.

4.15.5 The administration of physical examinations or screenings that the school or agency may administer to a student.

4.15.6 The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

4.15.7 The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

4.15.8 Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

5 ACCESS TO INSTRUCTIONAL MATERIAL USED IN A RESEARCH OR EXPERIMENTATION PROGRAM

5.1 When a research project is supported or funded by Department of Education (ED), all instructional material (including teachers' manuals, films, takes, or other supplementary instructional material), which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.

5.2 Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

5.3 Children are persons enrolled in research not above the elementary or secondary education level, who have not reached age of majority as determined under state law.

6 STUDENT RESEARCH "POOLS" AND EXTRA CREDIT

6.1 WVU students are offered the opportunity to participate in research (as participants) in various ways. Examples include participation for credit as part of a course requirement, for extra credit in a course, or in exchange for payment. A student must not be required to participate in research for course credit unless a comparable non-research alternative is also offered.

6.2 To minimize the potential for coercion, alternatives to participating in research for course credit must be comparable in terms of time, effort, and fulfillment of course requirements. Examples include reading and/or writing research papers, attending research presentations offered by faculty, or observing the performance of research projects.

6.3 All research participants, including students, must be free to withdraw from participation at any point in a project without penalty. Students who withdraw from a research project for course credit must receive full course credit for participation. When payment is offered, credit for payment should accrue as the project progresses (as appropriate to the research) and should not be contingent upon the student completing the entire project.

6.4 Project-specific informed consent is required as described in SOP 012: Informed Consent Requirements and SOP 016: Documentation of Informed Consent Process. Parental permission and assent are required for any student who meets the legal definition of a child/minor (See SOP 014: Research Involving Children).

6.5 The policy and procedures for offering extra credit as an incentive to WVU students for voluntary participation in research are outlined below:

6.5.1 The department wishing to offer extra credit as an incentive to student research participation develops and submits an Extra Credit Policy Plan to WVU OHRP.

6.5.2 The WVU IRB Chair Committee reviews and approves the Extra Credit Policy Plan.

6.5.3 Upon approval, the department will receive an Extra Credit Policy Approval Letter.

6.5.4 After receiving the approval letter, researchers can submit research protocols providing extra credit opportunities to potential student participants.

6.5.5 When a protocol is submitted for review, the reviewer(s) and/or WVU OHRP staff should verify that an Extra Credit Policy Plan is on file for that department before approval of the protocol.

6.5.6 If an Extra Credit Policy Plan is not on file, the reviewer(s) and WVU OHRP staff should inform the PI so that an Extra Credit Policy Plan can be submitted for review, or the extra credit language should be removed from the protocol.

7 EMPLOYEES AS RESEARCH PARTICIPANTS

7.1 Employees, including university employees (e.g., full-time, part-time, temporary, visiting, student employee appointments, etc.) may be recruited for research participation. However, an employee must not be required to participate in research as a condition of employment. Individual students, nor groups of students, should not be selected solely based on convenience when they would not otherwise be appropriate for inclusion.

7.2 Recruitment of potential participants who are employees must be designed to minimize the possibility of coercion or undue influence. In general, potential participants should be solicited from a broad pool of individuals meeting the conditions for project, rather than from individuals who report directly to the researcher(s). Strategies to minimize the potential influence of a researcher when recruiting their employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the researcher(s).

7.3 Researchers and IRBs must consider strategies to ensure voluntary participation when the participants of research include employees who are directly supervised by the researcher(s). An employee's decision about research participation must not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.

7.4 Except in unusual circumstances, researchers should not enroll employees under their direct supervision when the research involves greater than minimal risk without the prospect of direct benefit to individual participants. Such research should proceed only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and it is determined that the research is of significant importance and cannot be conducted without the enrollment of these employees.

7.5 Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for researchers to keep an individual's participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question under project or when peer

pressure is a component of the research). In such situations, research should be conducted off-site and/or outside of regular work hours, when possible, to minimize potential risks.

7.6 Protecting the confidentiality of research participants' personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the research must be considered and disclosed to potential participants in the informed consent process (See SOP 012: Informed Consent Requirements).

7.7 In cases where regular workplace activities are also the research topic, researchers must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would occur even without the research. When access to individuals or the site's facility is needed for recruitment and/or research activities, a letter of support from someone authorized to speak on behalf of the employees/site may be required.

8 ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY

8.1 Impaired decision-making capacity comprises a broad range of conditions. Examples include healthy individuals in shock (temporary decisional impairment), those born with severe intellectual disabilities (permanent decisional impairment), individuals with age-related dementia (progressive decisional impairment,) individuals with mental illnesses such as schizophrenia (fluctuating capacity), and individuals under the influence of certain drugs (temporary and/or fluctuating capacity). Generally, all adults should be presumed capable of providing informed consent unless there is either specific evidence that an individual's condition/disability would impair reasoning or judgment or another indication that the individual is unable to understand and choose whether or not to participate in research.

8.2 Researchers and IRBs should consider the capacity of potential research participants to provide informed consent. Methods to assess capacity appropriate to the research should be included when necessary. Key factors in individuals' consideration of research participation include an appreciation of how the risks, benefits, and alternatives to participation apply to them personally. When the research involves greater than minimal risk, an independent assessment of the potential participant's capacity to consent should be performed (or confirmed), except in unusual circumstances where the IRB determines that the research is of critical importance and could not be conducted if the independent assessment were to be required. Methods to provide independent assessments include subjective assessments made by a qualified professional independent of the research team or use of a valid objective instrument(s) designed to evaluate capacity.

8.3 Federal regulations require additional safeguards to protect the rights and welfare of research participants who are likely to be vulnerable to coercion or undue influence. Among others, the regulations include children and individuals with impaired decision-making capacity in this category. When children are the and adults with impaired

decision-making capacity are included in the research and the ability to provide informed consent is in question, obtaining assent may be an appropriate safeguard (see "Assent of Adults" below). Additional protections for adults with impaired decision-making capacity should be proportional to the severity of the decisional impairment and level of risk.

8.4 Researchers and IRBs should consider the following in their decision to enroll adults with impaired decision-making capacity:

- The extent to which the research aims to improve the understanding, diagnosis, prevention, or treatment of the disorders or conditions that are the cause of the incapacity
- The study of related conditions, phenomena, or circumstances that uniquely affect the research participants may contribute in important ways to the current or future welfare of the population and therefore may also serve to justify their inclusion in research
- The inclusion of individuals who lack the capacity may be appropriate in research that offers therapeutic or other benefits to the individual participant when standard approaches are less effective, unproven, or satisfactory.

8.5 Researchers and IRBs should consider additional safeguards, balancing the need for protection with the individuals' right to autonomy. Examples of additional safeguards include (but are not limited to) the following:

- Securing an independent assessment of the participant's capacity to consent (or valid objective instrument(s) designed to evaluate capacity);
- Identification of a legally authorized representative who has the authority to consent to the adult's participation in research;
- Obtaining assent (if applicable) from the participant, in addition to surrogate consent;
- Regular assessment of the participant's capacity and provisions for reconfirming the consent of a participant who regains capacity during the course of the research;
- Involvement of family members familiar with the participant's personal values;
- Designation of an individual at the beginning of the project to serve as a legally authorized representative (only) if the participant's decision-making capacity becomes compromised during the project;
- Use of informational/educational techniques to enhance communication and understanding during the consent process (such as teach-back method);
- Including waiting periods in the consent process;
- Involvement of a research participant advocate;

- Limiting the risks to which an adult with impaired decision-making capacity is exposed when direct benefits are not anticipated;
- Use of an independent monitor, or data monitoring committee; or
- Observation of the informed consent process by a third party as designated by the IRB.

8.6 Regulations require that IRBs regularly review research involving vulnerable participants consider including one or more individuals who are knowledgeable about and experienced in working with these participants. When reviewing research involving adults with impaired decision-making capacity, WVU OHRP and WVU IRBs will include an individual with appropriate background, knowledge, and experience, and/or a representative of the relevant advocacy group as a member or consultant to the IRB.

8.7 For more information about the requirements for involving adults with impaired decision-making capacity in research in life-threatening situations, see SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices and SOP 054: Planned Emergency Research.

9 ASSENT OF ADULTS

9.1 An adult with impaired decision-making capacity or other adult cognitively unable to provide informed consent may participate in research only if a legally authorized representative for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB. If the participant regains (or develops) the capacity to consent, then their informed consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid.

9.2 An adult with impaired decision-making capacity may be able to assent to participation. The IRB is responsible for determining when the assent of some or all such adults is required in proposed research and the appropriate method for documenting the adult's assent (if any), as described below.

9.3 Assent to participate in research by an adult with impaired decision-making capacity (for whom a legally authorized representative will provide informed consent) is to be obtained when, in the judgment of the IRB, the adult is cognitively capable of providing assent. In determining whether proposed participants are capable of providing assent, the IRBs will take into account the condition and psychological/emotional states of the adults involved. The IRB's determination of the participant's capacity to assent may apply to all or only some of the adults to be involved in a proposed research activity.

9.4 Assent processes are to include the key elements of informed consent described in SOP 014: Informed Consent Requirements and are to be provided in language appropriate for an adult with impaired decision-making capacity, based on the nature of the research and the expected ability of the prospective participant(s) to understand the purpose and the procedures involved in the research.

9.5 The assent of adults with impaired decision-making capacity to participate in research is to be obtained, except in any of the following circumstances:

- The adults are not capable of providing assent based on condition or psychological/emotional state;
- The capability of some or all of the adults is so limited that they cannot reasonably be consented; or
- Assent can be waived using the criteria for waiver (or alteration) of informed consent, as described in SOP 014: Informed Consent Requirements.

9.6 The IRB may determine that assent of some or all of the adults is not required. If assent is not a requirement of some adults, the IRB will indicate which adults (e.g., individuals with severe dementia) are not required to assent.

9.7 When the assent of an adult with impaired decision-making capacity is required, the IRBs must determine the appropriate method of documenting assent (if any). This decision should be based on considerations such as the length and complexity of the research and the adult's condition and psychological/emotional state.

9.8 When documentation of assent is required, either of the two options below are considered adequate:

- An assent form, similar to the consent document signed by the legally authorized representative, is used for the adult assent and signature; or
- A signature line for assent is added to the consent document that the legally authorized representative and adult both sign.

Please note: The IRB can also approve assent forms or revised consent documents on a case-by-case basis in other formats to satisfy requirements for obtaining and documenting assent of adults with impaired decision-making capacity.

9.9 When assent is not documented by use of a form or method as described above, documentation of assent may be limited to verifying that assent took place using a witness or other method. The IRB may also decide that documentation of assent is not warranted. If verbal assent will be obtained, the IRB must review a written description of the information (i.e., script) that will be provided to participants during the assent process.

9.10 In some research, such as longitudinal projects involving progressive disorders or aging populations, participants may be able to provide informed consent at the beginning of their participation but may experience progressive or intermittent symptoms that lead to decisional impairment during participation in the project. In these situations, researchers should consider the need to discuss with prospective participants whether the participant should designate someone at the beginning of the project to serve as a legally authorized representative in the case that the participant's ability to assess their own needs/interests becomes compromised during the project.

9.11 For cases in which the authority of a legally authorized representative for an adult participant's participation in research is unclear, researchers and IRBs should consult with WVU's General Counsel for Research for guidance.

10 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 014: Research Involving Children
SOP 015: Assent and Parental Permission
SOP 016: Documentation of Informed Consent Process
SOP 047: Research Involving Prisoners
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices
SOP 054: Planned Emergency Research

Federal Regulations:
21 CFR 56.111
45 CFR 46.111

AAHRPP:
Standard II.4

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/21	New SOP
8/8/22	Minor revisions to address AAHRPP Step 1 Requirements

1 PURPOSE

This SOP outlines additional protections that WVU researchers and IRBs must provide to children involved in human subject research.

2 OVERVIEW

Federal regulations require additional protections for children involved in research. These requirements include IRB review for some research activities involving children that would be exempt if the participants were adults, use of parental permission and child assent instead of informed consent for participation, and conditions for IRB approval of proposed research depending on the level of risk.

3 GENERAL INFORMATION

3.1 To approve research involving children, the IRB must determine that the proposed research provides the special protections for children specified by federal regulations and this policy, in addition to meeting the criteria for approval of all human subject research described by SOP 007: IRB Approval Criteria.

3.2 One or both parents (or a legally appointed guardian) must provide and document permission for a child to participate in research unless those requirements are waived by the IRB. In most cases, children capable of assenting must express their willingness to participate. (SOP 015: Assent and Parental Permission.)

3.3 DHHS Exemption Category 2 (research involving survey or interview procedures or observation of public behavior) does not apply to research with children, except for research involving educational tests or observations of public behavior when the researcher does not participate in the activities being observed. (See SOP 017: Exempt Research.)

3.4 If the research involves incarcerated and/or pregnant children, the requirements for research involving prisoners and/or pregnant women, respectively and as applicable, must be met in addition to the requirements for research involving children. (See SOP 047: Research Involving Prisoners and SOP 048: Research Involving Pregnant Women, Fetuses, or Neonates.)

3.5 In special circumstances, children under 18 years of age may legally provide informed consent for some or all the activities involved in research. For more information, please see SOP 015: Assent and Parental Permission.

4 PERMISSIBLE CATEGORIES OF RESEARCH INVOLVING CHILDREN

4.1 Three categories of research involving children may be approved by the IRB. These categories differ according to the level of risk involved, the prospect of direct benefit to participants, and anticipated research findings. For all categories, the proposed research

must satisfy the requirements for parental or guardian permission and child assent as described in SOP 015: Assent and Parental Permission.

4.2 The following categories of research may involve children (as long as additional conditions are met):

1. Research involving only minimal risk (OMR);
2. Research involving more than minimal risk (MMR) but presenting the prospect of direct benefit;
    a. The risk is justified by the anticipated benefit to the child
    b. Comparison of the risk to the anticipated benefit is at least as favorable as that presented by available alternative approaches
3. Research involving greater than minimal risk without the prospect of direct benefit but likely to yield generalizable knowledge about the child's disorder or condition
    a. The risk presents no more than a minor increase over minimal risk
    b. The research involves experiences that are reasonably equivalent to those in the child's actual (or expected) medical, dental, psychological, social, or educational situations
    c. The research is likely to yield generalizable knowledge about the child's disorder or condition that is of critical importance for the understanding or improvement of the disorder/condition

4.3 Research that does not fall into one of the three categories above but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children requires additional review, as described below.

5 RESEARCH SUBJECT TO DHHS REGULATIONS REQUIRING ADDITIONAL REVIEW ("407 REVIEW")

5.1 Additional requirements apply for research involving children that is conducted or supported by DHHS, and that does not fall into one of the three categories of approval research described above. The research may be conducted only under **all** of the following conditions:

- The IRB finds and documents that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- The research is reviewed by OHRP (on behalf of DHHS), in consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law, etc.) and relevant child advocates;

- An opportunity is provided for public review and comment (including a public meeting announced in the *Federal Register*);
- The Assistant Secretary for Health (on behalf of the Secretary) will determine either:
  - The research satisfies the regulatory conditions for approval, or
  - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; will be conducted in accordance with sound ethical principles and that adequate provisions will be made for soliciting the assent of children and the permission of their parents or guardians;

5.2 Upon IRB approval, WVU OHRP staff will forward the "407 Review" request to OHRP (DHHS). The following information should be included:

- Institution name and WVU federal wide assurance (FWA) number
- IRB name and registration number
- Institutional contact's name, title, telephone, mailing address, and e-mail address
- IRB documentation that the proposed research does not meet the regulatory requirements for approval but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children
- Title of protocol and name of Principal Investigator (PI)
- The current version of the protocol reviewed and approved by the WVU IRB
- DHHS application number and name of the funding agency
- The ccurrent version of the parental permission and assent documents reviewed and approved by the WVU IRB
- Relevant IRB minutes and/or correspondence

5.3 For more information on the "407 Review" process, see OHRP Guidance on the DHHS 45 CFR 46.407 ("407") Review Process.

5.4 Informed Consent for the specific research project is required as described in SOP 012: Informed Consent Requirements and SOP 016: Documentation of Informed Consent Process. Parental permission and assent are required for any student who meets the legal definition of a child/minor (See SOP 014: Research Involving Children).

6 RESEARCH NOT SUBJECT TO DHHS REGULATIONS REQUIRING ADDITIONAL REVIEW

6.1 Research involving children that does not fall into one of the three categories of approval research described above (see "Permissible Categories of Research Involving Children")

and that is not subject to DHHS regulations may be conducted under all of the following conditions:

- The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- Consultation is obtained, as necessary, from expert(s) in pertinent disciplines (e.g., science, medicine, education, ethics, law, etc.) and relevant child advocates;
- An opportunity is provided for review and comment by the local community where research is to be conducted; and
- The WVU Institutional Official (IO), in consultation with the above groups, determines that the research is consistent with sound ethical principles and the requirements of WVU OHRP policy regarding assent and parental permission and may proceed.

The PI and any consultants assisting with the review may be invited to attend the IRB meeting at which the research is discussed.

7 WARDS

As described below, specific protections are required for children who are also wards of the state or any other agency, institution, or entity.

7.1 Children who are wards may be included in research involving more than minimal risk (MMR) without the prospect of direct benefit but likely to yield generalizable knowledge about the child's disorder or condition if the research is either:

- Related to their status as wards; or
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

7.2 When wards are included in the research described above, an advocate must be appointed for each child who is a ward to protect the child, to the extent possible, from exploitation, coercion, or undue influence. The following requirements apply to individuals serving as advocates:

- The advocate will serve in addition to any other individual acting on behalf of the child as a guardian or in loco parentis;
- An individual may serve as an advocate for more than one child;
- The advocate must be an individual who has the background/experience and agrees to act in the best interests of the child throughout the child's participation in the research;

- This includes helping to ensure that the child understands what will be required of them during the research, and if capable, that the child provides assent to participate; and
- Acting in the best interests of the child could also include evaluating the ongoing effect(s) of the research on the child.

- The advocate must not be associated in any way (except in the role as an advocate or IRB member) with the research, researcher(s), or guardian organization.

7.3 Examples of individuals who might serve as advocates are IRB members, patient advocates, caseworkers, social workers, or counselors knowledgeable about children's rights and welfare. An advocate's appointment should be made by a group or individual with no interest in or affiliation with the research being conducted. The IRB should review and approve the process for appointing advocates.

8 DOCUMENTATION

8.1 The IRB considers each of the specific findings related to additional protections required for research involving children. WVU OHRP staff document discussions of controverted issues at convened meetings in the meeting minutes.

8.2 Specific findings are either documented by WVU OHRP staff in the meeting minutes (i.e., for protocols reviewed by the convened board) or by exempt/flex/expedited reviewers in determinations in accord with applicable SOPs. The IRB does not reapply categories during subsequent reviews unless changes to the protocol warrant such review.

9 IRB SPECIFIC FINDINGS REGARDING RESEARCH INVOLVING CHILDREN

For any protocol involving children, the IRB must determine which of the four categories of research apply to the research project, if any.

1. Research involving only minimal risk to children
   - The research presents no greater than minimal risk to the children; and
   - Permission if one parent is sufficient (as outlined in 45 CFR 46.408).
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child participants involved in the research
   - The risk is justified by the anticipated benefits to the participants (children);
   - The relation of the anticipated benefit to the risk presented by the research;
   - the research is at least as favorable to participants as that provided by available alternative approaches; and
   - Permission of one parent is sufficient (as outlined in 45 CFR 46.408).
3. Research involving greater than minimal risk and no prospect of direct benefit to the individual child participants involved in the research but likely to yield generalizable knowledge about the participant's disorder or condition
   - The risk of the research represents a minor increase over minimal risk;

- The intervention or procedure presents experiences to the child participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition, which is of vital importance for understanding or amelioration of the disorder or condition; and
- Permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child (as outlined in 45 CFR 46.408).

4. Research that the IRB believes does not meet the conditions of the above research categories but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
    - For specifics related to this category, please see sections 6 and 7 above; and
    - Permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child (as outlined in 45 CFR 46.408).

10 REFERENCES

WVU Policies:
SOP 007: IRB Approval Criteria
SOP 012: Informed Consent Requirements
SOP 014: Research Involving Children
SOP 015: Assent and Parental Permission
SOP 016: Documentation of Informed Consent
SOP 017: Exempt Research
SOP 047: Research Involving Prisoners
SOP 048: Research Involving Pregnant Women, Fetuses, or Neonates

Federal Regulations:
45 CFR 46 Subpart D
21 CFR 50 Subpart D
34 CFR 97 Subpart D

AAHRPP:
Standard II.4

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

1 PURPOSE

This SOP describes the requirements for assent and parental (or guardian) permission for research involving children (and in some cases, adults with impaired consenting or decision-making capacity).

2 OVERVIEW

Assent and parental (or guardian) permission must be obtained as required by federal regulations and IRB determinations for research involving children. Assent is generally required for children based on their ages, maturity, condition, and the nature of the research, unless assent can appropriately be waived for some or all the children that are not capable of providing assent.

3 GENERAL INFORMATION

3.1 The requirements for obtaining the informed consent of research participants or their legally authorized representatives apply when children are the subjects of research, unless these requirements are waived by the IRB. A parent (one or both) or, in some cases, a guardian, must provide permission for their child to participate in research based on sufficient information and adequate opportunity to consider the child's voluntary participation. For more information about the requirements for informed consent processes, see SOP 012: Informed Consent Requirements.

3.2 The requirement for documenting informed consent by use of a written consent form (electronic or hard copy), approved by the IRB, and signed by the subject or the subject's legally authorized representative, applies when children are the subjects of research, unless this requirement is waived by the IRB. A parent (one or both) or, in some cases, a guardian, must document permission for their child to participate in research as described below and in SOP 016: Documentation of the Informed Consent Process.

3.3 Although according to federal regulations children cannot provide valid informed consent to participate in research, they may be able to assent to participation. In general, investigators should obtain the assent of children to participate in research whenever children are capable of assenting. The IRB is responsible for determining when assent of some or all children is required in proposed research and the appropriate method for documenting a child's assent (if any), as described below.

3.4 Assent may also be appropriate for adults with impaired decision-making capacity and other adults unable to consent for themselves, for whom a legally authorized representative will provide informed consent. For more information about assent in adults, see SOP 013: Vulnerable Populations.

4 ASSENT OF CHILDREN

For research involving children, the requirements for obtaining and documenting a child's assent, or the waiver of these requirements are described below. Additional requirements for research involving children are described in SOP 013: Vulnerable Populations.

4.1 **Assent Process**

4.1.1 In addition to the requirements for parental or guardian permission, adequate provisions for soliciting the assent of a child to participate in research are required when the child is capable of providing assent. In determining whether proposed participants are capable of assenting, investigators and IRBs will consider the ages, maturity, condition, and psychological/emotional states of the children involved. The IRB's determination of the children's capacity to assent may apply to some or all the children to be involved in a proposed research activity.

4.1.2 Assent processes are to include the key elements of informed consent as described in SOP 012: Informed Consent Requirements and are to be provided in language appropriate for children, based on the nature of the study and the expected capacity of the potential participant(s) to understand the purpose and procedures involved in the research.

4.1.3 For research activities involving older children or adolescents whose capacity to understand is similar to that of adults, the assent process will include information similar to what would be provided for informed consent by adults or for parental/guardian permission. For children whose age and/or maturity level limits their ability to fully understand the research but who are still capable of being consulted about participating, it may be appropriate to focus only on providing an accurate description of the experience itself (e.g., what will happen, how long it will take, whether it might involve any pain or discomfort, etc.).

4.1.4 The assent of children to participate in research is to be obtained except in the following circumstances:

- The children are not capable of providing assent based on age, maturity, or psychological state;
- The capability of some or all the children is so limited that they cannot reasonably be consulted;
- The intervention or procedure involved in the research holds out a prospect of direct benefit to the health or well-being of the children and is available only in the context of research; or
- Assent can be waived using the criteria for waiver (or alteration) of informed consent or parental/guardian permission, as described below (see "Waiver or Alteration of Parental Permission").

4.1.5 The IRB may determine that the assent of some or all children is not required. If assent is not a requirement of some children, the IRB should indicate which children (e.g., children less than 2 years old) are not required to assent.

4.2 **Documentation of Assent**

4.2.1 When a child's assent is required, investigators and the IRB must determine the appropriate method, if any, of documenting assent. This decision should be based on considerations such as the length and complexity of the research and the child's age, maturity, and degree of literacy.

4.2.2 If older children or adolescents will be involved in research for which a consent form would have been used if the participants were adults, a similar form to document the child's assent is generally appropriate. For younger children who are still unable to read or other children unlikely to be familiar with signing documents (e.g., through prior experience with testing or other procedures normally encountered in their everyday lives), documentation of assent may be limited to verifying that assent took place using a witness or other method. Alternatively, the IRB may decide that documentation of assent for children of any age is not warranted.

4.2.3 Assent form templates containing the basic elements of informed consent are available on the WVU OHRP website. When documentation of assent is required, use of the applicable assent template language is generally required. Alternatively, based on the age and literacy level of the children and nature of the research, for some studies investigators may add an assent signature line to the consent document that parents will sign. The IRBs can also approve assent forms on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting assent.

4.2.4 If verbal assent will be obtained, the IRB must review a written description of the information (i.e., a script) that will be provided to children during the assent process.

4.3 **Parental Permission**

4.3.1 For research involving children, the permission of a parent(s) or guardian must be obtained and documented for their child to participate in research, unless these requirements are waived by the IRB. The requirements for informed consent processes apply when children are the subjects of research, including disclosure (to parents or guardians) of the basic and additional elements of consent. For more information about the requirements of informed consent, see SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process.

4.3.2 Parental permission form templates (or consent documents) containing the basic elements of informed consent are available on the WVU OHRP website. To streamline IRB review and assure that regulatory requirements are met, use of the

applicable template language is generally required. The IRBs can also approve parental permission/consent documents on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting permission.

4.3.3 Based on the regulatory requirements, when children are involved in research, investigators and IRBs must determine whether the permission of both parents is required or if the permission of one parent is sufficient as described below.

4.3.4 For research that involves only minimal risk (OMR) or more than minimal risk (MMR) with the prospect of direct benefit to the individual child, the IRB may determine either of the following:

- Permission of **both** parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; **or**
- Permission of **one** parent is sufficient.

4.3.5 For research that involves MMR without the prospect of direct benefit to the individual child, the permission of **both** parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

4.3.6 For children who are wards of the state (or any other agency, institution, or entity), a guardian must provide permission for the ward to participate in research, in lieu of a child's biological or adoptive parents. When research involves MMR without the prospect of direct benefit to the individual child, an advocate who agrees to act in the best interests of the child throughout the duration of the child's participation, including ensuring that to the extent possible the child understands what will be required of them during the research, must also be appointed.

4.3.7 Additional requirements for research involving children, including children who are wards of the state, are described in SOP 013: Vulnerable Populations.

5 WAIVER OR ALTERATION OF PARENTAL PERMISSION

In the limited circumstances described below, the IRB can waive or alter the requirements for obtaining parental or guardian permission.

Note: "Passive consent" is sometimes used in research with children to describe a situation where the investigator assumes that the parent permits a child to participate (e.g., information about a study is mailed to the parent and if the parent does not want their child to participate, they must return a form "opting out"). This procedure is not consistent with the regulatory requirement to obtain parental permission. In these instances, the investigator can request the IRB to consider if the conditions for a waiver of parental permission can be met under 45 CFR 46.408(c) or 45 CFR 46.116(f)(3).

5.1 **Research on Public Benefit or Service Programs**

5.1.1 The IRB can waive or alter the requirements for parental permission for non-exempt research examining state or local public benefit or service programs or certain features of those programs if **all** of the following criteria are met:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs;
- The research could not be practicably carried out without the waiver or alteration; and
- The research is not FDA-regulated.

5.1.2 Minimal Risk Research

The IRB can waive or alter the requirements for parental permission for non-exempt research that meets **all** of the following criteria:

- The research involves no more than minimal risk to participants;
- The waiver or alteration will not adversely affect the rights and welfare of participants;
- The research could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format; and
- Whenever appropriate, subjects or their parent/guardian will be provided with additional pertinent information after participation.

5.1.3 Research Designed to Study Conditions in Children

A. The IRB can waive or alter the requirements for parental permission for non-exempt research designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children) when the following additional criteria are also met:
    i. An appropriate mechanism is in place to protect the children: and
    ii. The waiver is not inconsistent with federal, state, or local laws.

- Note: IRBs may waive the requirement for obtaining parental or guardian permission as described above even if the research involves more than minimal risk to the participants.

B. When determining an appropriate mechanism for protecting child participants (e.g., appointment of an advocate or assent monitor), investigators and IRBs will consider the nature of the research (including any potential risks and anticipated benefits) and the children's ages, maturity, condition, and psychological/emotional states.

5.1.4 Planned Emergency Research

The IRB can approve a waiver of the requirements for informed consent for non-exempt research in life-threatening situations in which it is not possible to obtain informed consent from subjects or their legally authorized representatives (i.e., parent or legal guardian), including studies in which children are the subjects of the research. For more information, see SOP 054: Planned Emergency Research.

5.2 **Special Circumstances**

5.2.1 A mother under 18 years of age (i.e., a parent that is legally still a child) can provide permission for her child to participate in research. However, for her own research participation, the permission of one or both of the mother's parents is required, unless the requirement for parental permission is waived by the IRB.

5.2.2 Under the Family Educational and Rights Privacy Act (FERPA), a child under 18 years of age who attends a school beyond the high school level (e.g., a college or university) can consent to release information from their educational records for use in research. However, to participate in research the child must also have the permission of one or both parents, unless the requirement for parental permission is waived by the IRB.

6 CHILDREN WHO REACH THE LEGAL AGE OF CONSENT WHILE ENROLLED IN A STUDY

Informed consent is an ongoing process throughout the duration of a research study. When a child who was enrolled in research with parental (or guardian) permission reaches the legal age of consent, the subject's participation is no longer regulated by the requirements regarding parental permission. Legally effective informed consent must be obtained (unless waived by the IRB) from the now-adult participant for any continued interactions, interventions, or other activities that meet the definition of "research involving human subjects," including analysis of individually identifiable data or specimens.

7 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 013: Vulnerable Populations
SOP 016: Documentation of Informed Consent Process
SOP 054: Planned Emergency Research

Federal Regulations:
21 CFR 50.3
21 CFR 50.20
21 CFR 50.25
21 CFR 50.51-55
21 CFR 56.109
21 CFR 56.111
45 CFR 46.111
45 CFR 46.116
45 CFR 46.402-408

AAHRPP:
Standard II.4

History of Revisions to SOP

Effective Date	Nature of Revision(s)
9/24/2021	New SOP

1 PURPOSE

This SOP describes the institutional and federal regulatory requirements related to the documentation of informed consent of participants who will participate in human subjects research at WVU.

2 OVERVIEW

Federal regulations require that informed consent is documented in most circumstances by using a written (paper or digital copy) consent form approved by the IRB and signed by the research participant or the participant's legally authorized representative. Consent materials used to recruit participants must include the required (and any applicable additional) elements of informed consent unless the IRB approves either an alteration of consent, use of a short form stating that the elements of consent have been presented, or a waiver of the requirements for written documentation of the consent process.

3 GENERAL INFORMATION

3.1 The informed consent document provides key information regarding research participation and serves as a reference for participants or a legally authorized representative. Although a signed consent form is usually required, the signed form alone does not constitute an adequate informed consent process. For more information on the informed consent process, see SOP 012: Informed Consent Requirements.

3.2 Unless waived or altered by the IRB, consent forms must include the basic elements of informed consent, and when appropriate, any additional elements as described below and by SOP 012: Informed Consent Requirements.

4 INFORMED CONSENT DOCUMENTS AND/OR MATERIALS

4.1 Required Elements

Consent form templates containing the basic elements of informed consent are available on the WVU OHRP website. Using the WVU IRB-approved templates is required to streamline the IRB's review and assure that regulatory and institutional legal requirements are met. The IRB can also approve the consent forms on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting informed consent. The federally required consent elements are described in SOP 012: Informed Consent Requirements.

4.2 Additional Elements

One or more additional elements of informed consent will also be provided to prospective participants during the consent process, when appropriate, or as required when the IRB determines that the information would meaningfully add to the protection of research participants. The additional elements are described in SOP 012: Informed Consent Requirements.

5 SHORT FORM CONSENT DOCUMENTS AND/OR MATERIALS

Use of short form consent documents in WVU research is limited to situations involving a prospective research participant/legally authorized representative who does not speak/understand English, and enrollment of participants speaking the specific language was not anticipated (e.g., a translated consent form in the participant's language has not been approved by the IRB). For more information on the use of the short form consent, including witness, signature, and follow-up translation requirements, see SOP 012: Informed Consent Requirements.

6 SIGNATURE AND RECORDKEEPING REQUIREMENTS

6.1 FDA regulations require that a participant or legally authorized representative date the consent form at the time it is signed. Although not required by DHHS regulations, DHHS OHRP recommends that consent forms are dated to document that a participant's informed consent was obtained before beginning research interventions or interactions. WVU's consent form templates include a line for adding the date the consent form is signed. A copy of the consent document is to be given to the person signing the form.

6.2 The practice of a participant/LAR returning a signed paper consent form to the researcher using a facsimile (fax) or e-mail must be approved by the IRB as an exception. WVU recommends the use of eConsent when a participant/LAR is not in the same physical location as the consenting researcher.

6.3 Electronic signatures may be used to document consent, in compliance with 45 CFR 46, 21 CFR 11, and applicable FDA guidance. A written copy (electronic or hard copy) must be given to the individual signing the consent form. Electronic versions of consent forms (when used to meet documentation requirements) must be available for review and retention by potential participants.

Complete signed consent forms should be stored confidentially in a secure location for at least three years after completion (or cancellation) of the research unless a longer retention period is required by other applicable university policy or contractual agreement. For more information on record retention, please see SOP 038: Research Data Retention.

6.4 The WVU IRB requires the consenting researcher to sign the returned consent form after participant/LAR signature for More Than Minimal Risk Research. WVU considers the consent to be "fully executed" when both the participant/LAR and the consenting researcher have signed the consent. A copy of the fully executed consent must be provided to the person who signed the consent.

6.5 For additional information on eConsent policies and procedures, please see SOP 052: E-Informed Consent.

7 RESEARCH PARTICIPANTS UNABLE TO SIGN A CONSENT DOCUMENT

7.1 A person who speaks and understands English but does not read and write can be enrolled in a study by "making their mark" on the consent document. An adult who is not involved in the research will witness the entire informed consent process and sign the consent document.

7.2 A person who understands English but is physically unable to talk or write can be enrolled in a research project if they are competent and able to indicate approval or disapproval by other means. The method used to communicate with the potential participant and the specific way the individual communicated agreement to participate in the research project is to be documented on the consent form. An adult not involved in the research will witness the entire informed consent process and sign the consent document as a witness on the witness signature line.

8 WAIVER OF DOCUMENTATION OF INFORMED CONSENT

In limited circumstances, the IRB can waive the requirement for the investigator to obtain a signed consent form for some or all research participants.

8.1 Risk of Breach of Confidentiality

The IRB can waive the requirement for written documentation of informed consent for non-exempt research if **all** of the following criteria are met:

- The only record linking the participant and the research would be the consent document;
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each participant will be asked whether the participant wants documentation linking them with the research, and the participant's wishes will govern; and

- The research is not FDA-regulated.

8.2 "Only Minimal Risk" (OMR) Research

The IRB can waive the requirement for written documentation of informed consent for non-exempt research if **both** of the following criteria are met:

- The research involves no more than minimal risk of harm to participants; and
- The research involves no procedures for which written consent is normally required outside of the research context.

8.3 Distinct Cultural Groups

The IRB may waive the requirement for a signed informed consent form if the participants are members of a distinct cultural group or community in which signing forms is not the norm for non-exempt research if **both** of the following criteria are met:

- The research meets the definition of only minimal risk; and
- There is an alternative method for documenting consent that was obtained.

8.4 Additional Requirements

8.4.1 When the requirement for written documentation of consent is waived, the IRB must review a written description of the information (i.e., a script) provided to participants (e.g., when consent is obtained by telephone or online). This information must include the basic elements of informed consent and any applicable additional elements as described above and in SOP 012: Informed Consent Requirements, unless the IRB has also approved an alteration of consent.

8.4.2 When the requirement for written documentation of consent is waived, the IRB may also require that an investigator provide participants with a written statement regarding the research. Examples include approved consent forms (without signature line), cards containing researcher and/or third-party contact information, and informational documents outlining the research procedures.

9 POSTING OF CLINICAL TRIAL CONSENT FORMS

For clinical trials conducted or supported by a federal department or agency, the Final Rule (Revised Common Rule) requires that a copy of an unsigned, IRB-approved consent form be posted on a publicly available federal website (ClinicalTrials.gov). The funding awardee or federal department/agency is responsible for posting the form after recruitment is complete but no later than 60 days after the last visit. Proprietary or institutionally sensitive information may be redacted; only one consent form per research project must be posted regardless of the number of participant classes or research project sites.

10 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 055: Electronic Informed Consent

Federal Regulations:
21 CFR 50.20
21 CFR 50.25
21 CFR 50.27
21 CFR 56.109
21 CFR 56.111
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP

1 PURPOSE

This SOP describes the process for the review and approval of protocols exempt from IRB review and approval.

2 OVERVIEW

Federally funded research activities that meet all applicable criteria set forth by the regulations (45 CFR 46.104) and involve no greater than "minimal risk" may qualify for exemption from IRB review. Additionally, non-federally funded research activities that meet all applicable criteria set forth by the WVU IRB may qualify for exemption from IRB review. An exemption must be determined by the IRB, (or designee), not an individual investigator. The exemption categories are described below. The IRB (or designee) may rule a proposal as exempt if it fits into one (or more) of the exemption categories and is no greater than minimal risk. However, the WVU IRB may determine that there are research protocols that may pose ethical concerns and are reviewed as with any other new protocol application.

The IRB Chair may designate an IRB member(s) or qualified WVU OHRP Administrator to review Exempt submissions. Reviewers are selected based on their expertise in the application content and knowledge of applicable regulations. If a designated reviewer is not available, the IRB Chair will review the submission.

All exempt reviews conducted by WVU IRB designated members meet the requirements of a limited IRB review by ensuring that when appropriate, the research plan includes adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data.

WVU retains the authority to suspend or terminate IRB approval of research approved with a limited review.

WVU IRB does not utilize broad consent. Exemption categories intended for research using broad consent are not applied at WVU.

Exempt protocols are communicated to the IRB at the next convened meeting after approval of the project.

3 PROCEDURES

3.1.1 Pre-Submission

The PI should determine if the research project qualifies for Exempt submission by reviewing Section 4 (Scope of this Policy) of this SOP.

- The PI should complete the required training.

- The PI should determine the regulatory requirements for the project and the data that will be collected or used during the project. Locate and complete the required forms and guidance on the WVU OHRP website, such as HIPAA Waivers, Data Intake Forms, and Consent documents.
- The PI should review the required provisions for vulnerable or disadvantaged populations, as directed in Section 5 (Vulnerable Populations).
- The PI should create the Informational Cover Letter (if applicable) on the WVU OHRP website.

3.1.2 Submission

The PI should submit the completed Exemption application using the WVU electronic IRB system, and upload the following documents as applicable:

- Recruitment materials (cover letter, recruitment script, flyer, etc.)
- Informational Cover Letter (if applicable)
- Surveys, questionnaires, and data collection instruments
- Letter(s) of permission from each non-WVU site
- Verification of current human subject protection training for all members of the research team, including the faculty advisor
- Research Data Use and Protection Certification

3.1.3 **WVU IRB Review**: A WVU IRB Chair (or designee) reviews all requests for research submitted under the Exempt submission type and determines whether the application meets the criteria for inclusion.

3.1.4 **WVU IRB Determinations**: The reviewer may require additional protections for participants or require that the application be submitted or reviewed using an alternative submission type. Determinations made by the reviewer will be communicated with the Principal Investigator via the WVU electronic IRB system.

3.1.5 **WVU IRB Acknowledgement**: The acknowledgement of the Exempt application serves as formal documentation of the reviewer's determination. Exempt protocols are granted a five (5) year approval period.

3.1.6 **Amendments to Exempt Protocols:** Amendments must be submitted as new application if the researcher discovers the following:

- Modifications that increase risk to participants - modifications that increase risk to participants must be submitted for review and approval before implementing the change.
- Funding Changes - federal funding awarded, or funding from WVCTSI.

- If an amendment causes the protocol to be ineligible for Exemption, the amendment must be submitted as a new application in WVU+kc. Additional Human Subjects Protection (HSP) Training may be required. Please refer to the WVU OHRP website for guidance on additional training based on the type of protocol submitted in WVU+kc.

3.1.7 **Continuing Review**: Acknowledged Exempt protocols are granted a five (5) year approval period. To extend the approval period beyond the initial five (5) year period, a new initial application must be submitted for review and acknowledgement by the WVU IRB.

3.1.8 **Reporting Requirements**: Approved protocol applications must follow the reporting requirements outlined in SOP 031: Research Related Event Reporting.

4 SCOPE

4.1.1 Exemption for research involving survey or interview procedures does not apply to research in children. Research involving observations of public behavior in children when the investigator does not interact with the children being observed, is considered exempt.

4.1.2 Exemption for research does not apply to prisoners as research participants. IRB review is required (See SOPs 013: Vulnerable Populations, 018: Expedited Review, and 019: Full Review).

4.1.3 Research activities not regulated by the FDA in which the only involvement of human participants will be one or more of the following categories are exempt from IRB review, but require institutional review:

4.1.4 Research conducted in established or commonly (standard practice) accepted educational settings, involving normal educational practices, such as:

- Research on regular and special education instructional strategies; or
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

4.1.5 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior if AT LEAST ONE of the following criteria are met:

- Information obtained is NOT recorded in such a manner that human participants can be readily ascertained (identified), directly or through identifiers linked to the participants;
- Any disclosure of the human participants' responses outside the research would NOT reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through

identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by 46.117(a)(7).

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4.1.6 Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4.1.7 Research involving the collection or study of secondary data, documents, records, pathological specimens, or diagnostic specimens, if at least one of the criteria below are met (please note, this includes retrospective and prospective collection of secondary data):

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the researcher's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b) [Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from specimens)]; or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and incompliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501

[Note: This category is unlikely to be used. If you believe that it is applicable, please contact WVU OHRP for assistance.]

Note: This category does not apply to FDA regulated research.

4.1.8 Research protocols involving the collection of data from medical records may qualify as exempt from review under the secondary collection category (4.1.7 above) provided that the following criteria are met:

- While this category involves secondary research for which consent is not required, the IRB could request the researcher to obtain informed consent or request a waiver of informed consent for prospectively collected data under sub-category (iii). Informed consent would not apply to category (i) publicly available data, or (ii) researcher agrees not to record identifiers or re-identify/re-contact subject. However, the IRB may ask the researcher to justify why informed consent is not practicable for prospective collections

4.1.7 Research involving the collection or study of secondary data, documents, records, pathological specimens, or diagnostic specimens, if at least one of the criteria below are met (please note, this includes retrospective and prospective collection of secondary data):

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the researcher's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b) [Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from specimens)]; or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and incompliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501

[Note: This category is unlikely to be used. If you believe that it is applicable, please contact WVU OHRP for assistance.]

Note: This category does not apply to FDA regulated research.

4.1.8 Research protocols involving the collection of data from medical records may qualify as exempt from review under the secondary collection category (4.1.7 above) provided that the following criteria are met:

- While this category involves secondary research for which consent is not required, the IRB could request the researcher to obtain informed consent or request a waiver of informed consent for prospectively collected data under sub-category (iii). Informed consent would not apply to category (i) publicly available data, or (ii) researcher agrees not to record identifiers or re-identify/re-contact subject. However, the IRB may ask the researcher to justify why informed consent is not practicable for prospective collections

under category (iii). A HIPAA Waiver of Authorization should be submitted for both review types (exempt and expedited). Waiver of Informed Consent will need to be submitted for medical records research not qualifying for exempt category four (see 4.1.7 above).

4.1.9 Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service program;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs.
- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services provided under the Older American Act).
- The research demonstration project must be conducted pursuant to the specific federal statutory authority, there must be no statutory requirements of IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of participants, and the exemption must be invoked only with authorization or concurrence by the funding agency.

4.1.10 Taste and food quality evaluation and consumer acceptance protocols:

- If wholesome foods without additives are consumed; or
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental containment at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4.1.11 The following categories of clinical investigations are exempt from the requirements of IRB review:

- Emergency use of a test article provided that such emergency use is reported to the IRB within five (5) working days. Any subsequent use of the test article at the institution is subject to IRB review. [21 CFR 56.104(c)]
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5 REFERENCES

WVU Policies:
SOP 013: Vulnerable Populations
SOP 018: Expedited Review
SOP 019: Full Review

SOP 031: Research Related Event Reporting

Federal Regulations:
21 CFR 56.104 (c) (d)
45 CFR 46.104

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP
10/16/2024	Removed information pertaining to old common rule; removed duplicate information; formatting and grammar updates

1 PURPOSE

This SOP describes the process for protocols requiring expedited IRB review and approval. The categories for research that the IRB may review through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register (FR) Volume 63, No. 216, and (3) the research is not classified. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB. (See SOP 007: Criteria for Approval.)

2 OVERVIEW

Unless the IRB determines otherwise, continuing review of research (following approval period of 5 years) is not required for research eligible for expedited review if:

- The protocol was approved on or after the implementation of the Final Rule (January 21, 2019).
- The protocol was transitioned to the Final Rule.

The IRB chair may designate an IRB member(s) to review Expedited submissions. Reviewers are selected based on their expertise in the application content and knowledge of applicable regulations. If a designated reviewer is not available, the IRB Chair will review the submission.

The IRB Chair or designee may use the expedited review procedure to review minor modifications to previously approved research during the period for which approval is authorized if the following conditions are met:

- The proposed modifications are administrative changes or similar minor changes; or
- The research was previously determined to be eligible for expedited review under Federal Regulation categories 1-7 and/or 9 (see below), and the proposed modifications do not change the protocol's expedited determination

The full IRB must review any modification that possibly entails more than minimal risk to the participants at a convened meeting.

Expedited studies are communicated to the IRB at the next convened meeting after approval of the project.

*Please note: Some expedited review categories described below could qualify for WVU's Flex Review mechanism. Please see SOP 020: Flex Review for additional information on Flex review.

3 EXPEDITED REVIEW CATEGORIES

3.1 Clinical studies of drugs and medical devices, only when condition (a) or (b) is met:

a) Research on drugs for which an investigational new drug application (21 CFR 312) is not required.
b) Research on medical devices for which:
    i. An investigational device exemption application (21 CFR 812) is not required; or
    ii. The medical device is cleared/approved for marketing, and the device is being used in accordance with its cleared/approved labeling.

3.2 Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an eight (8) week period, and collection may not occur more-frequently than two (2) times per week; or

b) From other adults and children[i], considering the age, weight, and health of the participants, the collection procedure, amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml, or 3 ml per kilogram in an eight (8) week period, and collection may not occur more than two (2) times per week.

    i. Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. [45 CFR 46.402(a)]

3.3 Prospective collection of biological specimens for research purposes by noninvasive means. Examples include the following:

a) Hair and nail clippings in a non-disfiguring manner
b) Deciduous or permanent teeth at the time of extraction or if routine patient care indicates a need for extraction
c) Excreta and external secretions, including sweat
d) Uncannulated saliva, collected either in an unstimulated fashion or stimulated by chewing gum base, wax, or applying a dilute citric solution to the tongue
e) Placenta removed at delivery
f) Amniotic fluid obtained at the time of rupture of the membrane before, or during labor
g) Supra- and sub-lingual dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques
h) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
i) Sputum collected after saline mist nebulization

3.4 Data collection through noninvasive procedures (not involving general anesthesia or sedation) is routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples include the following:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the participant or an invasion of the participant's privacy
b) Weighing or testing sensory acuity
c) Magnetic resonance imaging (MRI) and Functional MRI (fMRI)
d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

3.5 Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

3.6 Data collected from voice, video, digital, or image recordings made for research purposes.

3.7 Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, or cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

3.8 Continuing review of research previously approved by the convened IRB as follows:

a) The research is permanently closed to the enrollment of new participants for longer than a year;
b) All participants have completed all research-related interventions; AND
    i. The research remains active only for long-term follow-up; OR
    ii. No participants have been enrolled, and no additional risks have been identified; OR
    iii. The remaining research activities are limited to data analysis.

This category (Category 8) identifies three situations in which research that is greater than minimal risk and was initially reviewed by a convened IRB, may undergo subsequent continuing review by the expedited review procedure. For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site when the conditions of this category are satisfied for that site. However, with respect to category 8(b), while the criterion that "no participants have been enrolled" is interpreted to mean that no participants have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

3.9 Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.

4 PROCEDURES

4.1 The IO and WVU OHRP Director authorize WVU OHRP staff to complete a preliminary review of the submitted protocol materials to determine completeness and accuracy. WVU OHRP staff assign protocols to IRB members (primary reviewers) for review paying close attention to the protocol's scientific discipline, the potential reviewer's area of expertise, and representation for vulnerable populations involved in the research.

4.2 The IRB Chair or designee is assigned as an expedited reviewer. The assigned expedited reviewers perform an in-depth review of pertinent documentation and materials submitted by the investigator and WVU OHRP staff.

4.2.1 For new protocol submissions and continuing review applications, the assigned expedited reviewer and WVU OHPR staff ensure that it is documented within the WVU electronic IRB system application that the research meets the criteria for expedited review and approval. The WVU OHRP staff and IRB reviewer ensure that the applicable expedited category (or categories) is selected.

4.2.2 For amendment applications, the assigned expedited reviewer and WVU OHRP staff ensure that it is documented within the WVU electronic IRB system whether the amendment to the previously approved research is eligible for expedited review and the modification involves no more than minimal risk to participants.

4.3 If the expedited reviewer determines the application does not qualify for an expedited review, the reviewer notifies the WVU OHRP staff, who will assign the protocol submission for the next available convened IRB meeting.

4.4 If the expedited reviewer recommends that the protocol submission be tabled or disapproved, the reviewer notifies the WVU OHRP staff, who will move the item to the agenda for discussion at a convened IRB meeting. In accordance with SOP 008: IRB Determinations, the research may only be tabled or disapproved by the convened IRB.

4.5 If the expedited reviewer determines that the criteria for approval of the application have been met, the reviewer may approve the application.

5 REFERENCES

WVU Policies:
SOP 008: IRB Determinations
SOP 017: Exempt Review
SOP 019: Full Review

SOP 020: Flex Review

Federal Regulations:
21 CFR 312
21 CFR 812
45 CFR 46.402(a)

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP

1 PURPOSE

This SOP describes the process for the review of protocols requiring Full Board IRB review and approval.

2 OVERVIEW

A thorough evaluation of all research proposals submitted for review is conducted by IRB members allowing the IRB to determine if the protocol application meets the minimum criteria for initial approval (see SOP 007: Criteria for IRB Approval) and for continuing approval (See SOP 030: Continuing Review of Approved Research). IRB members review changes in approved research during the period for which approval has already been given to determine if the protocol application meets the minimum criteria for ongoing review (See SOP 028: Post-Approval Submissions).

At a minimum, all members of a convened board are expected to be familiar with all IRB applications scheduled for review in advance of a convened board meeting, and are expected to be familiar with the agenda and items for the meeting they will attend.

Additionally, the IRB relies upon an assigned reviewer system (as described in SOP 006: IRB Meeting Conduct). A primary reviewer is (typically, and whenever possible) assigned to each application or item on the agenda to be reviewed by the convened board. A secondary reviewer may be assigned to protocols reviewed at the convened meeting.

Assigned IRB reviewers perform an in-depth review of all documentation and materials submitted by the PI and screened by WVU OHRP staff. Assigned reviewers may be required to review additional material requested by the IRB for the purpose of protocol approval.

Comments are not limited to the assigned reviewer(s). All members of the convened committee have access to the submitted documents and may provide comments regarding any proposed research. Any board member or WVU OHRP staff member, at their discretion, can request (but are not limited to) the following:

- Ad hoc and/or ex officio consultant review;
- Any additional necessary information beyond what has been provided by the investigator; and
- Third-party verification of information submitted by the investigator.

3 PROCEDURES FOR FULL IRB REVIEW

3.1 WVU OHRP staff are authorized by the IO and WVU OHRP Director to complete a preliminary review of submitted protocol materials to determine completeness and accuracy. OHRP staff assign protocols to IRB members (primary reviewers) for review

paying close attention to the protocol's scientific discipline, the potential reviewer's area of expertise, and representation for vulnerable populations involved in the research.

3.2 Primary reviewers are required to perform an in-depth review of all submitted documents in advance of convened meetings to be familiar with, and prepared to discuss, the protocol. Primary reviewers are most often responsible for presenting their findings, providing an assessment of the merits and safety of the protocol, reviewing the consent process, and recommending specific actions to the IRB. If the primary reviewer cannot attend the meeting, they must provide detailed comments to the IRB Chair or Vice Chair to present on their behalf. If present, the primary reviewer should lead the discussion of the protocol at the convened meeting.

3.3 Secondary reviewers, if assigned, are expected to review all submitted documents in advance of the meeting, are responsible for reviewing the consent process outlined by the protocol, and should add to the discussion as necessary.

3.4 Each assigned reviewer's findings are documented either in the meeting minutes or within the WVU electronic protocol submission system via completion of applicable reviewer forms. After discussion and review of the primary (and if needed, secondary) reviewer's findings, the IRB determines whether the protocol application meets the minimum criteria for initial approval, the minimum criteria for continuing approval, or the minimum criteria for ongoing review. Additional checklists may be required when a protocol application necessitates additional considerations (e.g., the research involves a vulnerable group, use of a medical device, use of an investigational drug, or funding that requires specific findings beyond minimum criteria for approval).

3.5 Notification of IRB Review: The WVU OHRP staff notifies the investigator of the IRB's determination within seven (7) business days of the convened board meeting. Written notification includes the IRB's decision with requested revisions or requested clarification, when applicable.

3.6 Review of Requested Revisions: Based on the terms of approval at the time of initial review, the IRB will review the investigator's response to requested revisions as outlined in SOP 008: IRB Determinations. Final approval will not be granted until all of the IRB's recommendations and requests are appropriately and adequately addressed. Final approval will be granted by a vote of IRB members present at the meeting.

4 REFERENCES

WVU Policies:
SOP 007: IRB Approval Criteria
SOP 008: IRB Determinations
SOP 028: Post-Approval Submissions

SOP 030: Continuing Review of Approved Research

Federal Regulations:
21 CFR 56.109
45 CFR 46.109

AAHRPP:
Element II.2.E
Element II.5.B

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

The purpose of this SOP is to outline a flexible "Flex" IRB review process for minimal risk research that is not subject to federal regulations governing human subjects research and is not conducted or supported by any US federal agency. The flexible review process reduces administrative and regulatory burdens for minimal risk research that is not under federal purview while maintaining core ethical principles that protect the rights and welfare of research participants. For minimal risk research that is not conducted or supported by a US federal agency, WVU has the flexibility to apply IRB review standards that differ from federal regulations, provided research participants are afforded equivalent protections. Please Note: WVU OHRP cautions that although research that is not federally funded is not required to meet federal regulations, the research is not exempt from the ethical guidelines of the Belmont Report and thus requires review and approval by WVU OHRP and the IRB.

2 OVERVIEW

The WVU OHRP provides a flexible IRB review option for minimal risk research projects that meet the required criteria specified below. While this policy allows for greater flexibility in the review process, it ensures equivalent protections for research participants. All research reviewed at WVU, regardless of research type, will be guided by the core ethical principles of respect for persons, beneficence, and justice. Equivalent protections include IRB review, human subject protection training, financial disclosures from research teams, agreement by participants for research involving direct interactions, provisions for confidentiality and security if data are identifiable, HIPAA protections when applicable, and the reporting of unanticipated problems.

The IRB Chair may designate an IRB member(s) or qualified WVU OHRP Administrator to review Flex protocol submissions. Reviewers are selected based on their expertise in the application content and knowledge of applicable regulations. If a designated reviewer is not available, the IRB Chair will review the submission.

Flex protocol submission numbers and outcomes are communicated to the IRB at the next convened meeting after approval of the project.

3 PROCEDURES

3.1 Pre-Submission

3.1.1 The PI should determine if the research project qualifies for Flex submission by reviewing Section 4 (Scope of this Policy) of this SOP.

3.1.2 The PI should complete the required training.

- The abbreviated CITI Program Biomedical Research Investigator or Social and Behavioral Research Investigator course satisfies the training requirements for Flex.

- WVU OHRP requires the full Biomedical or Social and Behavioral Research Investigator training course. **If the protocol application is disqualified for Flex during the review, there could be delays in approval if the required training is not completed.**

The PI should determine the regulatory requirements for the project and the data that will be collected or used during the project, complete the required forms and review the applicable guidance on the WVU OHRP website (e.g., HIPAA Waivers (if applicable), Data Protection Form, and Informational Cover letter and permission question with standard approved language).

3.1.3 The PI should review the required provisions for vulnerable or disadvantaged populations, as directed in Section 5 (Vulnerable Populations).

3.1.4 The PI should create the Informational cover letter using the Flex template/guidance.

3.2 Submission

3.2.1 The PI should submit the completed Flex protocol application using the WVU electronic protocol submission system, and attach the following documents as applicable:

- Recruitment materials
- Informational Cover Letter
- Surveys, questionnaires, and data collection instruments – including the standard question to obtain voluntary permission to participate.
- Letter(s) of permission from each non-WVU site
- Research Data Protection Certification

3.3 WVU IRB Review

WVU OHRP staff are authorized by the IO and WVU OHRP Director to complete a preliminary review of the submitted protocol materials to determine completeness and accuracy. WVU OHRP staff assign protocols to IRB members (primary reviewers) for review paying close attention to the protocol's scientific discipline, the potential reviewer's area of expertise, and representation for vulnerable populations involved in the research.

A WVU IRB Chair (or designee) reviews all requests for research submitted under the Flex submission type and determines whether the application meets the criteria for inclusion.

3.4

3.5 WVU IRB Determinations

The reviewer may require additional protections for participants or require that the application be submitted or reviewed using an alternative submission type.

Determinations made by the reviewer will be communicated with the Principal Investigator via the WVU electronic protocol submission system.

3.6 WVU IRB Approval

The approval of the Flex protocol application serves as formal documentation of the reviewer's determination. Approved Flex protocols are granted a five (5) year approval period.

3.7 New protocol submissions are required for the following situations regarding Flex project changes:

- Amendments are not allowable for Flex protocols.
- Changes to current Flex projects that increase risk to participants require the Flex protocol to be submitted for review and approval as a new project before implementing the change.
- Changes in scope of the project (e.g., new or changed goals/hypothesis) or alterations in research procedures that significantly change the scope of the project (e.g., retrospective review adding a prospective component, adding a vulnerable population, etc.) require the Flex protocol to be submitted for review and approval as a new project before implementing the change.
- Any federal funding awarded or funding from WVU CTSI require the Flex protocol to be submitted for review and approval as a new project before implementing the change.

Additional Human Subjects Protection (HSP) training may be required. Please refer to the WVU OHRP website for guidance on additional training.

3.8 Continuing Review

Approved Flex protocols are granted a five (5) year approval period. To extend the approval period beyond the initial five (5) year period, a new initial protocol application must be submitted for review and approval by the WVU IRB.

3.9 Reporting Requirements

Approved protocol applications must follow the reporting requirements outlined in SOP 031: Research Related Event Reporting.

4 SCOPE

4.1 The Flex submission type applies to:

- Research that is NOT federally funded or supported
    - Federally funded or supported is defined at WVU as any of the following:
        - Funded by a direct grant

- Funded through a sub-award or pilot grant associated with federal funds
- Includes personnel on a federally funded training grant
- Research conducted under a no-cost extension
- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves an FDA-regulated product or dietary supplement
- Involves data collection about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule
- Involves any services that could be billed to a federal program

- Research that is Only Minimal Risk (OMR)
  - Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

4.2 EXCLUDED

4.2.1 Research that cannot be submitted using the Flex submission type

- Expedited Category Four (4)
  - Research with federal funding - Per 45 CFR 46.101(a), research that receives federal funding is regulated by the Common Rule.
  - Research supported, in full or in part by programs that are supported by federal funding: WV Clinical & Translational Science Institute (CTSI), WV IDeA Network of Biomedical Research Excellence (WV-INBRE), Center of Biomedical Research Excellence (CoBRE), or other programs supported by federal funding.
  - Research involving the Food and Drug Administration (FDA) regulated elements.
  - Research approvable under Expedited Category 1 (45 CFR 46.110) including:
    - Research related to drugs for which an Investigational New Drug application is not required.
    - Research on medical devices for which an Investigational Device Exemption is not required or the medical device is approved for marketing and used following its approved label.
    - Research requiring an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application(s).

Sensitive topics in research:

- Research related to alcohol and drug treatment
- Research related to suicide or suicide ideation
- Research related to sexual behavior or practices
- Research related to illegal activities or ethically questionable behaviors
- Research related to racism, ageism, classism, discrimination, and sexism
- Research involving experiences of grief and loss, trauma, or violence
- Research related to job performance of competency
- Research involving other stigmatizing or controversial topics, as determined by WVU OHRP/IRB

- Certificate of Confidentiality awarded by the NIH:
  - Applying for or obtaining an NIH Certificate of Confidentiality implies a risk to participants should their identity be disclosed outside of the research.
- Prisoner Populations
  - Research targeting prisoner populations. Persons in transitional custody whose liberty is restricted, such as halfway houses, electronic monitoring, probation, or house arrest, are not considered by WVU human research protections program to meet the federal definition of a prisoner. For those individuals, the criteria at 45 CFR 46.111 offers sufficient protection for their level of vulnerability.
- Flex - Other Protected Populations
  - Research targeting tribal members, military personnel, wards of the state, or cognitively impaired individuals are not permitted under the Flex Model.
- International research
- Research involving genetic testing
- Flex collaborative research
  Research requiring an IRB Authorization Agreement (IAA)
  Some research involving minors
  Clinical trials

4.3 INCLUDED

4.3.1 Research that can be submitted using the Flex submission type

- Collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings, saliva, urine, or cheek swabs.
- Research involving tissues and samples collected under Standard of Care procedures:

- Collection of blood samples from healthy, non-pregnant adults who weigh at least 110 pounds may not exceed 550ml in 8 weeks, and collection may not occur more frequently than twice per week.
- Collection of blood samples from other adults and children may not exceed the lesser of 50ml or 3ml/kg in 8 weeks and collection may not occur more frequently than twice per week.
- Tissue or sample extraction or collection would be conducted regardless of the research (as the Standard of Care). Only identifiable samples collected for this Standard of Care procedure are permitted to be used. An example of this would be a Standard of Care tooth extraction. **If an additional sample or volume is needed in addition to the Standard of Care, the research cannot be submitted using Flex.**
- Review of data that have been collected, or will be collected, solely for non-research purposes.

- Research permitted and approved under Expedited Categories 2 and 3 (45 CFR 46.110).
- Research permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110).
- The recording/collection of Personally Identifiable Information (PII) and Protected Health Information (PHI).
  - Application for Waiver of HIPAA requirements must be attached with the Flex application and, if appropriate, approved by the IRB Chair or designee.
- Retrospective or Prospective research
  - Prospective research - the participant should be consented or meet the conditions to waive informed consent, as applicable.
- Deception
  - Deception is research in which participants are intentionally deceived as to the purpose of the research must have an adequate de-briefing and opt-out plan.
- Research involving minimal risk intervention (Expedited Categories 6 & 7)
  - Participants are asked to complete minimal risk behavioral interventions that are brief, harmless, painless, and not physically and/or emotionally invasive or offensive (i.e., asking subjects to play an online game or solve puzzles under varying noise conditions). The information obtained and recorded should not risk damaging the subject criminally, financially, their employability, educational advancement, or reputation.

5 VULNERABLE POPULATIONS

5.1 Flex submissions related to research involving protected populations including, but not limited to the list below must include sensitivity considerations and provisions:

- Collection of blood samples from healthy, non-pregnant adults who weigh at least 110 pounds may not exceed 550ml in 8 weeks, and collection may not occur more frequently than twice per week.
- Collection of blood samples from other adults and children may not exceed the lesser of 50ml or 3ml/kg in 8 weeks and collection may not occur more frequently than twice per week.
- Tissue or sample extraction or collection would be conducted regardless of the research (as the Standard of Care). Only identifiable samples collected for this Standard of Care procedure are permitted to be used. An example of this would be a Standard of Care tooth extraction. **If an additional sample or volume is needed in addition to the Standard of Care, the research cannot be submitted using Flex.**
- Review of data that have been collected, or will be collected, solely for non-research purposes.

- Research permitted and approved under Expedited Categories 2 and 3 (45 CFR 46.110).
- Research permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110).
- The recording/collection of Personally Identifiable Information (PII) and Protected Health Information (PHI).
  - Application for Waiver of HIPAA requirements must be attached with the Flex application and, if appropriate, approved by the IRB Chair or designee.
- Retrospective or Prospective research
  - Prospective research - the participant should be consented or meet the conditions to waive informed consent, as applicable.
- Deception
  - Deception is research in which participants are intentionally deceived as to the purpose of the research must have an adequate de-briefing and opt-out plan.
- Research involving minimal risk intervention (Expedited Categories 6 & 7)
  - Participants are asked to complete minimal risk behavioral interventions that are brief, harmless, painless, and not physically and/or emotionally invasive or offensive (i.e., asking subjects to play an online game or solve puzzles under varying noise conditions). The information obtained and recorded should not risk damaging the subject criminally, financially, their employability, educational advancement, or reputation.

5 VULNERABLE POPULATIONS

5.1 Flex submissions related to research involving protected populations including, but not limited to the list below must include sensitivity considerations and provisions:

Protected Populations and Requirements

- Pregnancy

  Pregnant adult women may be included. However, the research should not expose the fetus or mother to more than minimal risk.

  Consent must be sought and obtained from the participant, using an Informational Cover letter and (when applicable) permission question with standard approved language.

- Children

  Participants under the age of 18 years old may be included. The research should not involve more than minimal risk, and tasks should be limited to benign interventions.

  Unless waived, parental consent and child assent must be sought and obtained, using the Informational Cover letter and (when applicable) permission question with standard approved language.

6 INFORMED CONSENT

6.1 A Waiver of Documentation of Informed Consent will automatically be applied to all qualified Flex Applications; however, reviewers retain the right to require signatures from participants and the PI conducting the consent process.

6.2 PIs should customize the Informational Cover letter and (when applicable) permission question with standard approved language for the research project. The form should be presented to the participant, either physically or via electronic communications (i.e., online survey) before the participant begins research-related activities. Participants should indicate their willingness to participate in the study after reading the cover letter.

6.3 Parental Permission is required for approved research that targets children under 18 years of age.

7 REFERENCES

WVU Policies:
SOP 007 IRB Approval Criteria
SOP 008 IRB Determinations
SOP 031 Research Reporting Requirements
SOP 036 Research Data Use and Protection

Federal Regulations:
21 CFR 56.104 (c) and (d)
45 CFR 46.101, 301, 401

AAHRPP:
Standard II.2

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/16/2024	Updated expectations for resubmission; added categories of research not permissible under Flex model.

1 PURPOSE

This SOP describes the process for the approval period and determinations of expiration for human subject research within the auspices of the WVU IRB.

2 OVERVIEW

Continuing review must occur at intervals appropriate to the degree of risk. The determination of the length of the approval period is made by the IRB considering the degree of risk, and according to the standards outlined in SOP 030: Continuing Review of Approved Research.

The determination of the length of the approval period, if applicable, is documented by the reviewer within the WVU electronic protocol submission system, and if reviewed by the convened board, in the meeting minutes. The expiration date is the last day of approval and the date by which continuing review must occur.

Review of a change in a protocol (i.e., modification or amendment) does not alter the date by which continuing review must because continuing review is review of the full protocol, not simply a change to it.

3 PROCEDURES FOR ASSIGNMENT OF DETERMINED EXPIRATION DATE

3.1 The approval period of a protocol, whether during initial or continuing review, is determined by the IRB. The assignment of the expiration date is based on the type of review and the determination of approval period.

3.1.1 For research reviewed by a convened board, WVU's electronic protocol submission system automatically assigns the expiration date as one day earlier in the following year than the date the convened board approves the research. The OHRP staff is responsible for verifying the correct expiration date. If the IRB determines the study requires continuing review more or less frequently than annually, the OHRP staff enters the expiration date manually in the WVU electronic protocol submission system according to the IRB determination.

3.1.2 For protocols approved for five years (if eligible), the WVU electronic protocol submission system automatically assigns the expiration date as one day earlier than five years from the date the IRB approves the research. The OHRP staff is responsible for verifying the correct expiration date.

3.1.3 For research that is expired and is reviewed after the expiration date, the investigator must submit a new protocol for review and the new expiration date will be set as described above. The WVU electronic protocol submission system

automatically closes the expired protocol, and the investigator submits a new protocol for review and approval.

3.1.4 For research that is approved with changes by the convened IRB, the expiration date will be set as described above. The approval period does not begin until the changes are accepted by the IRB Chair (or designee) and the approval letter is sent.

4 EXPIRATION OF APPROVED STUDIES

4.1 The IRB sends the investigator/research team multiple automatic notifications from the WVU electronic protocol submission system regarding the need to apply for continuing review prior to the expiration date. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted.

4.2 A continuing review submission must be completed and submitted within the WVU electronic protocol submission system to be reviewed by the IRB even if the continuing review cannot be conducted before the expiration date. If the investigator/research team fails to apply for re-approval within the allotted time based on the review type of their research (45 days for Full Review, and 30 days for Expedited Review, per SOP 030: Continuing Review of Approved Research), the protocol will be automatically closed. Once the protocol is closed, the Principal Investigator (PI) must submit a new protocol application for initial review and approval before he or she can continue with the research.

4.3 Once IRB approval for a protocol expires, an expiration notice is automatically generated and sent from the WVU electronic protocol submission system. The expiration notice informs the PI the research is expired. No research activity may continue until the new study application is reviewed and approved by the IRB. The notice also informs the PI that no new participants may be enrolled until the new protocolapplication is reviewed and approved by the IRB.

4.4 Conducting any protocol-related procedures after IRB approval expires must be requested in writing to the IRB Chair for review and approval. If the IRB Chair determines that participants s enrolled in the project with an expired protocol would suffer a hardship because research procedures/medication must be discontinued, appropriate research procedures may continue beyond the expiration date for a reasonable amount of time. The IRB Chair will address on a case-by-case basis those rare instances where failure to enroll new participantss would seriously jeopardize the safety or well-being of an individual. Prospective research data cannot be collected until a new protocol application or other progress report is reviewed and approved. The IRB Chair will notify the PI of the decision by way of written documentation (e-mail is appropriate) and this documentation will be attached permanently to the new study application in the WVU electronic protocol submission system, accessible by all IRB members and OHRP staff.

4.5 Expiration of IRB approval does not require a report according to SOP 034: Reporting to External Agencies.

5 REFERENCES

WVU Policies:
SOP 030: Continuing Review of Approved Research
SOP 034: Reporting to External Agencies

Federal Regulations:
21 CFR 56.109
45 CFR 46.109

AAHRPP:
Element II.2.E

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

This SOP describes the requirements for research involving investigational drugs or biologics, including the responsibilities of Principal Investigators (PIs), IRBs, and sponsors.

2 OVERVIEW

PIs and IRBs must ensure that research (i.e., clinical investigation) involving investigational drugs or biologics is conducted in accordance with applicable federal regulations. These regulations describe, among other things, requirements for Investigational New Drug Applications (INDs), drug accountability and record retention, and responsibilities of PIs, IRBs, and sponsors when research is conducted with investigational drugs.

3 GENERAL INFORMATION

3.1 When human subjects research involves the use of drugs or biological products, FDA regulations apply. Investigators must provide sufficient information about the drug or biologic for the IRB to evaluate its associated risks and benefits, including the FDA approval status of the product (i.e., approved for marketing or investigational).

3.2 An Investigational New Drug Application (IND) must be filed with FDA to test the safety and efficacy of a new (i.e., investigational) drug for marketing approval. Studies involving the "investigational/research use" of an approved drug also require an IND if the intent of the research is to generate data that will lead to a new clinical indication, formulation, or advertising claim, or the research includes a new dose, population, or other factor that significantly increases risk (or decreases acceptability of the risk).

3.3 As described above, an IND is required for some research uses of a marketed drug or biologic; however, certain exemptions apply to the FDA requirements. For information about FDA exemptions from the requirements for an IND for studies involving marketed drugs, see Addendum A.

3.4 When an IND is required for the proposed use of a marketed drug or biologic in research, investigators must submit an application (Form FDA 1571) to FDA. An IND number will be assigned by FDA upon receipt of the application. Unless earlier notification is received, studies may be initiated 30 days after FDA's receipt of the application. For more information about obtaining an IND and forms and instructions, see 21 CFR 312 Subpart B – Investigational New Drug Application and Information for Sponsor-Investigators Submitting Investigational New Drug Applications (INDs). Final IRB approval will not be given until a valid IND number is provided.

3.5 An investigator obtaining an IND for the proposed use of a drug or biologic in research becomes a "sponsor-investigator" and additional institutional resources are available to assist investigators in complying with applicable FDA regulations.

3.6 The "off-label" use of an FDA-approved, marketed drug (i.e., a use other than the indication(s) approved by FDA) by a physician for treatment purposes does not require an IND or IRB approval. When such uses meet the regulatory definitions of research or clinical investigation, IRB approval is required. An IND may also be required, unless the conditions for exemption (described in Addendum A) are met.

3.7 In certain non-emergency situations, an investigational drug intended to treat a serious or immediately life-threatening condition may be used outside of a clinical investigation, as part of an "expanded access" program. Such "treatment use" of an investigational drug requires an IND and IRB review and approval. For more information, see the Expanded Access section below.

3.8 Additional requirements apply to the emergency use of an investigational drug or biologic and planned emergency research involving investigational drugs or biologics subject to FDA regulations. (See SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices and SOP 054: Planned Emergency Research.)

4 SUBMISSION AND PRE-REVIEW PROCEDURES

4.1 To describe proposed uses of drugs or biologics in human subject research, PIs will indicate in their WVU electronic protocol submission that they will be using drugs or biologics (including dietary supplements/ingredients) in their proposed research.

4.2 During the pre-review process, WVU OHRP staff are responsible for making an initial determination about whether a PI's proposed use of a drug or biologic involves the use of a marketed drug in the course of medical practice, requires an IND, or meets one of the FDA exemptions from the IND requirements. The IRB committee will make the final determination. *Note: For assistance in determining whether an IND is required in a specific situation, FDA may be contacted directly.* (For contact information, see FDA guidance "Off-label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices.)

4.3 When the research involves a drug or biologic with an IND, WVU OHRP staff will verify that the IND number provided by the PI is valid. Protocol-specific confirmation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) will be obtained. The investigator's drug brochure is NOT a protocol-specific document and cannot be used to validate an IND number.

5 IRB REVIEW

5.1 The convened IRB committees will review proposed research involving investigational drugs or biologics considering the criteria for approval as described in SOP 007: IRB Approval Criteria. *Note: Research involving a drug for which an IND is required is not eligible for expedited review.*

5.2 When research involves the use of an investigational drug or biologic, to approve the research the IRBs committees will also require the following:

- Available clinical and non-clinical information on the investigational product that is adequate to support the proposed research.
- Documentation of a valid IND unless the proposed use of the drug or biologic represents the use of a marketed product in the course of medical practice or meets one of the FDA exemptions from the IND requirements.
- An adequate plan for monitoring data to ensure the safety of subjects and for reporting adverse events and unanticipated problems involving risks to subjects or others.
- A plan for control, accountability, and storage of the investigational drug or biologic that ensures that the product will be used only in the approved research under the direction of the approved investigator(s); and
- For sponsor-investigators, that they are knowledgeable about and will comply with additional FDA requirements associated with conducting research for which an IND has been obtained.

6 EXPANDED ACCESS

6.1 Expanded access, sometimes called “compassionate use,” is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by the FDA). Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials. Except for emergency expanded access use when there is not sufficient time to secure prospective IRB review, an investigator treating a patient with an investigational drug under expanded access is responsible for obtaining IRB review and approval before treatment with the investigational drug may begin.

6.2 Under FDA's current regulations for investigational drugs and biologics, there are three areas of expanded access:

- Expanded access for individual patients, including for emergency use.
- Expanded access for intermediate-size patient populations (generally smaller than those typical of a treatment IND or treatment protocol – a treatment protocol is submitted as a protocol to an existing IND by the sponsor of the existing IND); and
- Expanded access for widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations).

6.3 For more information, see FDA guidance Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers and Charging for Investigational Drugs under an IND – Questions and Answers, or contact WVU OHRP at irb@mail.wvu.edu.

7 INVESTIATIONAL DRUG CONTROL, ACCOUNTABILITY, AND RECORD RETENTION

7.1 Investigational drugs used at WVU must be appropriately controlled, administered, and stored in compliance with the IRB and FDA requirements, and applicable university policies. Such requirements include processes to ensure that investigational products are manufactured, handled, and stored in compliance with applicable good manufacturing practices; inventory and accountability records are maintained for investigational drug receipt, dispensing, and disposition; and investigational drugs are used only in accordance with available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information and the approved protocol.

7.2 Investigators may delegate accountability, storage, and recordkeeping responsibilities to the WVU Hospitals Department of Pharmaceutical Services, who have a Pharmacy Coordinated Investigational Drug Service. For more information, please contact the WVUH Department of Pharmaceutical Services. Alternatively, an investigator may provide a plan to ensure that the investigational drug or biologic will be used according to the IRB-approved protocol, under the direction of the approved investigator(s), and in compliance with FDA and university requirements.

8 ADDITIONAL RESPONSIBILITIES OF SPONSOR-INVESTIGATORS

8.1 Investigators obtaining an IND to initiate and conduct research must also fulfill the federal requirements of sponsors. These requirements include (but are not limited to) additional FDA reporting (e.g., annual progress reports), data monitoring, and

recordkeeping obligations. Additional institutional assistance may be available when a WVU investigator wishes to obtain an IND to perform human subjects research. Sponsor-investigators may be referred to any number of institutional groups who can assist with IND requirements related to being a sponsor-investigator.

8.2 In addition to FDA regulations for the protection of human subjects, (21 CFR Parts 50 and 56), and the use of investigational drugs (21 CFR 312), additional regulations may apply to sponsor-investigators, depending on the nature of the research. It is the responsibility of the investigator to become familiar with these regulations and requirements if he or she becomes a sponsor-investigator for FDA-regulated research. These regulations could include:

- Electronic Records/Signatures (21 CFR 11).
- Financial Disclosure by Clinical Investigators (21 CFR 54).
- Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs (21 CFR 210).
- Applications for FDA approval to Market a New Drug (21 CFR 314).
- Bioavailability and Bioequivalence Requirements (21 CFR 320).
- Over-the-counter Human Drugs which are Generally Recognized as Safe and Effective and Not Misbranded (21 CFR 330); or
- Applications for FDA Approval of a Biologic License (21 CFR 601).

8.3 Additional Human Subject Protection (HSP) training (see WVU's CITI training page) for first-time sponsor-investigators may be required prior to protocol approval and activation of the FDA-regulated research.

8.4 For more information describing the FDA requirements for sponsor-investigators when research is initiated and conducted with investigational drugs or biologics, see FDA's Investigational New Drug Application (21 CFR 312) Subpart D – Responsibilities of Investigators and Sponsors. Additional guidance describing the international standards for good clinical practices in human subjects research (ICH/GCP) is available at ICH E6(R2): Good Clinical Practice Industry Guidance.

9 REFERENCES

WVU Policies:
SOP 007: IRB Approval Criteria
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices
SOP 054: Planned Emergency Research

Federal Regulations:
21 CFR 50
21 CFR 56
21 CFR 312
21 CFR 600

AAHRPP:
Standard I.7

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

ADDENDUM A: IND Subpart A (21 CFR 312)

Applicability

Except as provided in this section, this part applies to all clinical investigations of products that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to the licensing provisions of the Public Health Service Act (58 Stat. 632, as amended (42 U.S.C. 201et seq.)).

Exemptions

1. The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if **all of the following apply**:

i. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
ii. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
iii. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
iv. The investigation is conducted in compliance with the requirements for institutional review set forth in 21 CFR 56 and with the requirements for informed consent set forth in 21 CFR 50; and
v. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

2. (i) A clinical investigation involving an in vitro diagnostic biological product listed in paragraph (ii) of this section is exempt from the requirements of this part if:
   a) It is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and
   b) It is shipped in compliance with 312.160.

   (ii) In accordance with paragraph (i) of this section, the following products are exempt from the requirements of this part:

      a) Blood grouping serum;

b) Reagent red blood cells; and
c) Anti-human globulin.

3. A drug intended solely for tests in vitro or in laboratory research animals is exempt from the requirements of this part if shipped in accordance with 312.160.

4. FDA will not accept an application for an investigation that is exempt under the provisions of paragraph (1) of this section.

5. A clinical investigation involving the use of a placebo is exempt from the requirements of this part if the investigation does not otherwise require the submission of an IND.

6. A clinical investigation involving an exception from informed consent under 21 CFR 50.24 of this chapter is not exempt from the requirements of this part.

1 PURPOSE

This SOP describes the requirements for research involving medical devices, including the responsibilities of Principal Investigators (PIs), IRBs, and sponsors.

2 OVERVIEW

PIs and IRBs must ensure that research (i.e., clinical investigation) involving medical devices is conducted in accordance with applicable federal regulations. These regulations describe, among other things, requirements for Investigational Device Exemptions (IDEs), use of custom devices and accountability and record retention, and responsibilities of PIs, IRBs, and sponsors when research is conducted with medical devices.

3 GENERAL INFORMATION

3.1 When human subjects research involves the use of medical devices, FDA regulations apply. Investigators must provide sufficient information about the device for the IRB to evaluate its associated risks and benefits, including the FDA approval status of the product (i.e., approved for marketing or investigational).

3.2 Medical devices can receive FDA approval or clearance for marketing in several different ways. Examples include pre-market approval, which is given following clinical trials to determine the safety and efficacy of a new device, and marketing clearance (510(k) pre-market notification), granted by FDA when a device is determined to be "substantially equivalent" to a device already on the market. Investigational devices include medical devices under clinical investigation to test their safety and efficacy, as well as investigation of certain modifications, or new intended uses of already marketed devices.

3.3 The FDA requirements for studies involving investigational devices are proportional to the potential risk level (see "Significant and Non-Significant Risk Device Studies" below). Studies presenting a significant risk to subjects must be conducted under an IDE. Non-significant risk studies do not require an IDE but must meet the abbreviated IDE requirements described in Addendum A. Certain investigational device studies are exempt from the IDE requirements. For more information about the FDA exemptions for IDE requirements, see Addendum A.

3.4 When an IDE is required for the proposed use of an investigational device in research, investigators must submit an application to FDA. An IDE number will be assigned by FDA upon receipt of the application. Unless earlier notification is received, studies may be initiated 30 days after FDA's receipt of the application. Final IRB approval will not be given until a valid IDE number is provided. For more information about obtaining an IDE, see 21 CFR 812 Subpart B – Application and Administrative Action and Device Advice: IDE Application.

3.5 An investigator obtaining an IDE for the proposed use of an investigational device in research becomes a "sponsor-investigator" and additional institutional resources are available to assist investigators in complying with applicable FDA regulations (see Additional Responsibilities of Sponsor-Investigators" below).

3.6 FDA regulations allow sponsors to charge for an investigational device. The charge should not exceed an amount "necessary to recover the costs of manufacture, research, development, and handling of the investigational device." Proposed charges are included in the IDE application. The IRBs should ensure that charges for investigational devices appear appropriate and equitable and that any additional costs to subjects are disclosed during the consent process.

3.7 The "off-label" use of a marketed device (i.e., a use other than the indication(s) approved by FDA) by a physician for treatment purposes does not require an IDE or IRB approval. When such uses meet the regulatory definitions of research or clinical investigation, IRB approval is required. An IDE may also be required, unless the research meets the conditions for an abbreviated IDE (described in Addendum B) or exemption (described in Addendum A).

3.8 In certain non-emergency situations, an investigational device intended to treat a serious or immediately life-threatening condition may be used under a Treatment IDE. Such "treatment use" of an investigational device requires IRB review and approval. For more information, see 21 CFR 812.36 – Treatment Use of an Investigational Device, Device Advice: IDE Early/Expanded Access, or contact WVU OHRP at irb@mail.wvu.edu.

3.9 The "compassionate use" of an investigational device allows access for a patient (or small group of patients), who does not meet the requirements for inclusion in a research protocol for the device, but for whom a physician believes the device may provide benefit in treating and/or diagnosing the disease or condition. Such use of an investigational device is considered a protocol "deviation" for which prior FDA approval and reporting to the IRB is required. For more information, see FDA guidance Device Advice: IDE Early/Expanded Access and SOP 031: Research Related Event Reporting.

3.10 Additional requirements apply to the emergency use of an investigational device or biologic and planned emergency research involving investigational devices subject to FDA regulations. (See SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices and SOP 054: Planned Emergency Research.)

3.11 Although custom devices and humanitarian use devices are not investigational, additional FDA requirements apply to their use, including IRB notification or review as described below (see "Custom Devices" and "Humanitarian Use Devices").

4 SUBMISSION AND PRE-REVIEW PROCEDURES

4.1 To describe proposed uses of medical devices in human subject research, PIs will indicate in their WVU electronic protocol submission that they will be using devices in their proposed research.

4.2 During the pre-review process, WVU OHRP staff are responsible for making an initial determination about the FDA requirements applicable to the device's use. For investigational devices, **one** of the following determinations must be made:

- The device requires an IDE (i.e., significant risk (SR) device research);
- The device fulfills the requirements for an abbreviated IDE (i.e., non-significant risk (NSR) device research); or
- The device meets one of the FDA exemptions from the IDE requirements.

The IRBs will make the final determination. *Note: For assistance in determining whether an IDE is required in a specific situation, FDA may be contacted directly.*

4.3 When the research involves a device with an IDE, WVU OHRP staff will verify that the IDE number provided by the PI is valid. Protocol-specific confirmation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) will be obtained.

5 IRB REVIEW

5.1 The convened IRBs will review proposed research involving investigational devices considering the criteria for approval as described in SOP 007: IRB Approval Criteria. *Note: Research involving a device for which an IDE (including an abbreviated IDE) is required is not eligible for expedited review.*

5.2 When research involves the use of a device, to approve the research the IRBs will also require the following:

- Available clinical and non-clinical information on the investigational product that is adequate to support the proposed research and to make the SR/NSR determination (when applicable).
- Documentation of a valid IDE, unless the proposed use of the device fulfills the requirements for an abbreviated IDE (NSR device) or meets one of the FDA exemptions from IDE requirements.
- An adequate plan for monitoring data to ensure the safety of subjects and for reporting adverse events and unanticipated problems involving risks to subjects or others.

- A plan for control, accountability, and storage of the investigational device that ensures that the product will be used only in the approved research under the direction of the approved investigator(s); and

- For sponsor-investigators, that they are knowledgeable about and will comply with additional FDA requirements associated with conducting research for which an IDE has been obtained.

6 SIGNIFICANT AND NON-SIGNIFICANT RISK DEVICE STUDIES

6.1 Significant risk (SR) device studies pose the potential for serious risk to the health, safety, and/or welfare of research subjects. Examples include studies involving surgical sutures, cardiac pacemakers, intravascular stents, and orthopedic implants. An IDE is required for SR device studies.

6.2 Non-significant risk (NSR) device studies do not present potential serious risks to subjects. Examples include studies involving most daily-wear contact lenses and lens solutions, ultrasonic dental scalers, and foley catheters. NSR studies do not require an IDE but must follow the abbreviated IDE requirements (see Addendum B).

6.3 Sponsors are responsible for making the initial risk determination for a proposed investigational device research project. The IRB must review the sponsor's SR or NSR assessment and may modify the determination if the IRB disagrees. If the FDA has made the SR or NSR determination prior to IRB review, the IRB is not required to make this determination (FDA's determination is final).

Note: FDA makes SR/NSR determinations when an IDE is submitted, or if asked by a sponsor, investigator, or IRB, and will provide documentation of its decision upon request. Upon receipt of an IDE application, sponsors are notified via email of the date that FDA received the original application and the IDE number assigned. An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. In cases of disapproval, a sponsor has the opportunity to respond to the deficiencies and/or to request a regulatory hearing under 21 CFR Part 16.

6.4 The IRB will make the SR or NSR determination for a protocol by convened review. A description of the device, reports of prior studies conducted with the device, proposed investigational plan, risk assessment, and subject selection criteria should be considered. The sponsor's rationale for its SR or NSR determination (unless already determined by FDA) should also be reviewed. The SR/NSR determination must be documented in the IRB minutes, including a description of the reason(s) for the IRB's decision.

6.5 The IRB is not required to make a SR/NSR determination for studies involving devices that meet the criteria for exemption from the IDE regulations.

6.6 For examples of SR and NSR devices, see FDA guidance Significant Risk and Nonsignificant Risk Medical Device Studies. *Note: Because the device's proposed use in a protocol must be reviewed, inclusion of a device on either list should not be the only consideration used by the IRB in making the SR/NSR determination.*

7 EXPANDED ACCESS

7.1 Expanded access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by the FDA). Expanded access refers to the use of a medical device when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the device that is generally derived from clinical trials. Except for emergency expanded access use, when there is not sufficient time to secure prospective IRB review, an investigator treating a patient with an investigational device under expanded access is responsible for obtaining IRB review and approval before treatment with the investigational device may begin.

7.2 Under FDA's current regulations, there are three categories of expanded access:

a) Expanded access for individual patients, including for emergency use.

b) Expanded access for intermediate-size patient populations (smaller than those typical of a treatment IDE or treatment protocol – a treatment protocol is submitted as a protocol to an existing IDE by the sponsor of the existing IDE); and

c) Expanded access for widespread treatment use through a treatment IDE or treatment protocol (designed for use in larger patient populations).

For more information, see FDA guidance Expanded Access for Medical Devices or contact the WVU OHRP at irb@mail.wvu.edu.

8 INVESTIGATIONAL DEVICE CONTROL, ACCOUNTABILITY, AND RECORD RETENTION

8.1 Investigational devices used in WVU research must be appropriately controlled and stored in compliance with IRB and FDA requirements and applicable university policies. Such requirements include processes to ensure that investigational products are manufactured, handled, and stored in compliance with applicable good manufacturing practices; inventory and accountability records are maintained for investigational device receipt, dispensing, and disposition; and investigational devices are used only in

accordance with available information regarding their design, physical and chemical composition, performance, safety, biocompatibility, labeling, and the approved protocol.

8.2 Investigators must provide a plan to ensure that investigational devices will be used according to the IRB-approved protocol, under the direction of the approved investigator(s), and in compliance with FDA and the university requirements.

9 ADDITIONAL RESPONSIBILITIES OF SPONSOR-INVESTIGATORS

9.1 Investigators obtaining an IDE to initiate and conduct research must also fulfill the federal requirements of sponsors. These requirements include (but are not limited to) additional FDA reporting (e.g., annual progress reports, data monitoring, and recordkeeping obligations). Additional institutional assistance may be available when a WVU investigator wishes to obtain an IDE to perform human subjects research. Sponsor-investigators may be referred to any number of institutional groups who can assist with IDE requirements related to being a sponsor-investigator.

9.2 In addition to FDA regulations for the protection of human subjects, (21 CFR Parts 50 and 56), additional regulations may apply to sponsor-investigators, depending on the nature of the research. It is the responsibility of the investigator to become familiar with these regulations and requirements if they become a sponsor-investigator for FDA-regulated research. These regulations could include:

- Electronic Records/Signatures (21 CFR 11).
- Financial Disclosure by Clinical Investigators (21 CFR 54).
- Medical Device Reporting (21 CFR 803).
- Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807).
- In Vitro Diagnostic Products for Human Use (21 CFR 809).
- Pre-market Approval of Medical Devices (21 CFR 814).
- Medical Devices: Quality System Regulation (21 CFR 820).
- Medical Device Classification Procedures (21 CFR 860); or
- Laboratory Requirements (42 CFR 493).

9.3 Additional Human Subject Protection training (CITI GCP Course for Clinical Trials Involving Investigational Devices or GCP Course for Clinical Trials with Investigational Drugs or Biologics) for first-time sponsor-investigators will be required prior to protocol approval and activation of the FDA-regulated research.

9.4 For more information describing the FDA requirements for sponsor-investigators when research is initiated and conducted with investigational devices, see FDA's Investigational New Drug Application (21 CFR 312) Subpart D – Responsibilities of Investigators and Sponsors. Additional guidance describing the international standards for good clinical practices in human subjects research (ICH/GCP) is available at ICH E6(R2): Good Clinical Practice Industry Guidance.

10 IN VITRO DIAGNOSTICS (IVD)

10.1 Leftover specimens are frequently used in feasibility studies and studies to characterize the performance of new in vitro diagnostic devices. Routine clinical care testing can provide information about the laboratory characteristics of the specimen that allow investigators to quickly ascertain whether the specimen will meet the research protocol inclusion criteria. The remnants of these specimens therefore become valuable to the research at a point when they are of no value to the patient and are ready to be discarded. It is possible, in certain circumstances, for IVD devices to be conducted using leftover specimens obtained without informed consent while protecting the human subjects who are the sources of such specimens. FDA can exercise enforcement discretion as to the informed consent requirements if the following are true:

- The research protocol meets IDE exemption criteria.
- The research protocol uses leftover specimens;
- The specimens are not individually identifiable.
- The clinical information accompanying the specimens does not make the specimen identifiable.
- The individuals caring for the patients are different from, and do not share information about, the patient with those conducting the research;
- The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information; and
- The research protocol has been approved by an IRB.

11 HUMANITARIAN USE DEVICES

11.1 An approved humanitarian device exemption (HDE), containing sufficient information for FDA to determine that the probable benefits outweigh the risks of a device's use, is required for marketing a humanitarian use device. *Note: Results from*

scientifically valid clinical investigations demonstrating efficacy are not required for HDEs. For a list of approved HDEs, see Approved HDE Summaries of Safety and Possible Benefit.

11.2 Humanitarian use devices (HUDs) are *marketed* products; therefore, their use does not constitute research when used according to the approved labeling. However, IRB approval is required before the HUD is initially used at an institution. FDA regulations require that initial IRB review and approval of the HUD occur at a convened meeting. Continuing review must be performed at least annually but may be conducted by expedited review procedures.

11.3 IRB review of HUDs should consider the criteria for approval (as applicable) described by regulations and WVU OHRP Policy (SOP 019: Full Board Review). The following materials should be reviewed:

- HDE approval order.
- Description of the device.
- Product labeling.
- Patient information packet.
- Consent form; and
- Summary of the proposed use of the device, including a description of any screening procedures, HUD procedure, and any follow-up visits, tests, or procedures for patients.

Patient information packets are available for most HUDs and contain a description of the potential risks and benefits of the HUD and any procedures associated with its use. The HDE approval order, product labeling, and patient information packet for a HUD can be obtained from the FDA website; see Approved HDE Summaries of Safety and Possible Benefit.

11.4 Informed consent should be obtained orally or in writing before HUD use. Minimally, the consent process should contain a discussion of the potential risks and benefits of the HUD, description of the procedures associated with its use, and a statement that the device is a "humanitarian use device" that has not undergone clinical testing for effectiveness. Use of the HUD should not be referred to as "research" or a "clinical investigation." The IRBs will approve the consent process, its content, and any associated documents (i.e., consent form, information packet, etc.) that will be distributed to recipients of the HUD. HIPAA research authorization is not required unless the HUD is used as part of a research protocol.

11.5 FDA regulations require the institution and/or device manufacturer to report to FDA, and the IRB, deaths or serious injuries that may have been caused by a HUD or malfunctions that would, "be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

11.6 Investigational use of a HUD (i.e., for broader or different indication than approved by FDA) requires an approved IDE in addition to IRB approval when the HUD is a significant risk device. For more information on HUDs, including investigational and emergency uses, see FDA Guidance on HDE Program.

12 CUSTOM DEVICES

12.1 FDA regulations do not require IRB review and approval for custom device use. However, to ensure adequate patient protections, the requirements for the emergency use of devices, including prior notification, informed consent, and five-day reporting, should be followed when custom devices are used. For more information on these requirements, see SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices.

13 REFERENCES

WVU Policies:
SOP 007: IRB Review Criteria
SOP 019: Full Board Review
SOP 031: Research Related Event Reporting
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices
SOP 054: Planned Emergency Research

Federal Regulations:
21 CFR 50
21 CFR 56
21 CFR 812
21 CFR 814

AAHRPP:
Standard I-7

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

ADDENDUM A: Investigational Device Exemptions (21 CFR 812) Subpart A – General Provisions

Applicability

No IDE is required if the researchmeets one of the exemption categories in [812.2(c) Exempted Investigations] that apply to human subjects research. All criteria in each category must be true in order to meet the exemption category. IRB review and informed consent are still required.

Exempted Investigations

1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

2. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of part 807 in determining substantial equivalence.

3. A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:

    a) Is noninvasive;
    b) Does not require an invasive sampling procedure that presents significant risk;
    c) Does not by design or intention introduce energy into a subject; and
    d) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

4. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

5. A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

ADDENDUM B: Investigational Device Exemptions (21 CFR 812) Subpart A – General Provisions – Abbreviated IDE Requirements for Non-Significant Risk (NSR) Device

Applicability

No IDE is required if the research meets one of the exemption categories in [812.2(c) Exempted Investigations] that apply to human subjects research. All criteria in each category must be true in order to meet the exemption category. IRB review and informed consent are still required.

Please note: The following categories of investigations are considered to have approved applications for IDEs, unless FDA has notified a sponsor under 812.20(a) that approval of an IDE application is required. If a device risk level is considered Non-Significant Risk (NSR), it is subject to IDE Abbreviated Requirements. In this case, the IRB acts as a surrogate to FDA. For significant risk (SR) devices, formal IDE submission to FDA is still required.

Abbreviated Requirements

1. An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:
    a. Labels the device in accordance with 812.5;
    b. Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk (SR) device, and maintains such approval by the IRB;
    c. Ensures that each investigator participating in an investigation of the device obtains informed consent from each subject under 21CFR 50 and documents it, unless documentation is waived by an IRB under 56 CFR 109(c);
    d. Complies with requirements of 812.46 with respect to monitoring investigations;
    e. Maintains the records required under 812.140(b)(4-5) and makes the reports required under 812.150(b)(1-3) and (5-10);
    f. Ensures that participating investigators maintain records required by 812.140(a)(3)(i) and make the reports required under 812.150 (a) (1), (2), (5), and (7); **AND**
    g. Complies with the prohibitions in 812.7 against promotion and other practices.

1 PURPOSE

This SOP describes the process WVU OHRP follows to ensure uniformity in the review and approval of genetic research across all WVU sites.

2 OVERVIEW

Studies falling into this class of research must be approved by the IRB. Genetic research on human participants must have a legally enforceable informed consent including all federally required and additional elements, and additional requirements which may be imposed by the WVU OHRP for safety reasons. Genetics informed consent documents must include a statement concerning the ownership of any derived property as a result of research done on the genetic material. Transfer of ownership, by way of research, will generally go to West Virginia University and not the investigator/PI conducting the research. This may change through special dispensation by WVU and its officers. Studies concerning sensitive topics such as autism, race or ethnicity, and how genetics relates to everyday life may be a special concern to the IRB. To properly protect participants in the populations described above, the IRB may impose special guidelines, regulations, or requirements, as necessary.

3 PROCEDURES

3.1 For informed consent to be legally enforceable, it must comply with 45 CFR 46.116. For additional information on informed consent, please see SOP 012: Informed Consent Requirements and SOP 014: Documentation of Informed Consent Process.

3.2 The following are additional elements that must be included in the informed consent for genetic research:

- Statement about whether test results will be returned
- Whether mistaken paternity will be reported
- Whether adoption or undisclosed maternity will be reported
- Whether participants have the option to find out the results
- A list of sources of genetic material
- Statement that participant must be informed of their rights through Genetic Information Nondiscrimination Act (GINA)
- HIPAA Authorization if PHI will be attached to the genetic material
- Statement about what it means for participants to relinquish ownership of their genetic material (i.e., DNA)
- Multiple options for consenting (if applicable)

3.3 The following are additional elements that must be included in the informed consent for genetic research in which the genetic material will become part of a bank:

- Statement as to where DNA will be stored
- Statement of who will have access to the DNA

- Whether PHI will be attached to the DNA
- Whether the participant can opt out of banking and remain a part of the research
- Whether participants will be contacted later to consent to future studies

3.4 The following are additional elements that must be included in the informed consent for genetic research concerning ownership of the genetic material/DNA:

- Statement that the genetic material is a gift
- Non-exhaustive list of what the genetic material could be used for
- Statement that relinquishing property rights is permanent
- Statement that the genetic material provided and all research therefrom can be patented by the genetic material owner and/or research proprietor

3.5 WVU researchers must include a statement in the informed consent that tells the participant the genetic material obtained (if the participant agrees to genetic testing of their sample) will be owned by WVU and can be used for any purpose at the discretion of WVU officials.

3.6 During the approval process, the IRB will take into consideration any outcomes from the research that may have a net negative (greater risk than benefit) effect on society. In these instances, the IRB may use normal processes in attempts to remediate the effects during the course of the research.

4 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 014: Documentation of Informed Consent Process

Federal Guidance:
Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) – Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases, issued April 13, 2018.

AAHRPP:
Element I.1.G

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

This SOP describes the process the WVU IRB follows in reviewing payment arrangements to research participants to ensure an equitable selection of participants.

2 OVERVIEW

The IRB only approves payment methods that are not coercive and do not present undue influence. The description of payment arrangements is also part of the consent process. Therefore, the IRB must review statements regarding payment arrangements in the consent document(s) to prevent any statements that may be misleading, inaccurate, or otherwise violate the regulatory requirements of consent.

Payment to research participants for participation in research is not considered a benefit. Payments for participation are provided to reimburse participants for their time, effort, or other expenses. The WVU IRB uses the term "compensation" for payments to participants.

3 PROCEDURES

3.1 The PI (or research team) should provide the total compensation and the schedule of payments to participants if any. The information should be provided in the application and the consent document(s) during the initial review.

3.2 The IRB reviews both the amount of payment and the proposed method and timing of disbursement to ensure that compensation is appropriate. The IRB reviews the consent document(s) to ensure that an accurate description of compensation is presented.

4 REFERENCES

Federal Regulations:
45 CFR 46.116

AAHRPP:
Element II.3.C.1

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP

Screening, Recruiting, and Advertising for Participant Enrollment			
Document	**Version #**	**Effective Date**	**Page**
SOP 027	1.0	10-15-2021	Page 1 of 3

1 PURPOSE

This SOP describes the process a WVU investigator must follow when screening and recruiting participants in human subject research and when advertising for their research projects.

2 OVERVIEW

2.1 WVU IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the participant or the participant's legally authorized representative if either of the following conditions are met:

a. The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative; or
b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Investigators must abide by the HIPAA Privacy Rule, when applicable. (See SOP 036: Research Data Protection / Data and Safety Monitoring.)

2.2 The IRB will evaluate recruitment processes (including advertisements) to ensure an equitable selection of participants. Additionally, the IRB considers advertising or soliciting for participants to be the start of the informed consent process. Therefore, the IRB reviews proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent. Advertisements should be included as part of the initial protocol application.

2.3 The investigator must obtain IRB approval before the use of all television, radio, print advertisements, e-mail solicitations, letters, websites, social media, and other recruitment methods and materials intended for the recruitment of prospective research participants.

2.4 When advertisements are to be taped for broadcast, the IRB must review the final audio or video advertisement before approval. The IRB may review and approve the script of an advertisement before taping to preclude re-taping because of inappropriate wording. The review of the final recorded message prepared from the IRB-approved script may be conducted via expedited procedures (for protocols that required initial approval from the convened IRB).

2.5 When advertisements or recruitment materials are to be delivered electronically, a link to the electronic materials and a printable file containing the final materials must be submitted with the protocol application for review. This includes websites, and text for social media, email messages, etc.

2.6 Recruitment and advertisements sent using email must follow the University Email policy and consider if the electronic method can lead to identification of a prospective participant and if identification is a risk to the prospective participant related to the research protocol.

2.7 The IRB reviews "direct advertising for research participants" which is defined as advertising that is intended to be seen or heard by prospective participants to solicit their participation in the research. This includes any sponsor-provided advertisements or Investigator-drafted advertisements.

2.8 Advertisements must be submitted to the IRB in their final form to receive IRB final approval for use.

3 PROCEDURES

3.1 Investigators should describe the plan for screening, recruiting, or determining eligibility in the initial research proposal.

3.2 Any advertising materials should be attached in the initial protocol application. Any advertising materials developed after IRB approval should be submitted as a modification to the approved protocol.

3.3 IRB review and approval for additional advertisements or changes in currently approved screening, recruiting, or advertising must be submitted in the form of an amendment to the IRB for approval prior to implementation (for expedited or full board studies only).

3.4 The IRB Chair or designee may review changes to approved screening, recruiting, or advertising by expedited means. However, the Chair or designee may refer the advertisement to the full, convened IRB if the IRB reviewer has doubts or other complicated issues are involved.

4 REFERENCES

Federal Regulations:
21 CFR 50.20
21 CFR 56.111(a)(3)
21 CFR 56.111(b)
45 CFR 46.116(g)

AAHRPP:
Element II.3.C.1

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP

1 PURPOSE

This SOP describes the process for the review and approval of post-approval protocol submissions (amendments, deviations, and closures) to a previously approved protocol for research conducted under the auspices of the WVU IRBs.

2 OVERVIEW

Changes to approved Full Board and Expedited protocols cannot be made or conducted on human subjects without approval from WVU IRB in the form of an amendment, , except where necessary to eliminate apparent immediate hazards to human subjects.

3 PROCEDURES FOR AMENDMENT SUBMISSIONS

3.1 Researchers must submit requests for proposed changes to the IRB in the form of an amendment request (not applicable for NHSR, Flex, and Exempt) or "notify the IRB" request (not applicable for NHSR) in the WVU electronic protocol submission system. Amendment submissions should be submitted no later than 30 days after receiving changes from sponsors, collaborators, etc.

3.2 During amendment review, the IRB determines whether the research with the proposed changes meets the regulatory criteria for approval and any other applicable requirements are met.

3.3 Amendments **cannot be** submitted for NHSR, Exempt, or Flex protocol types. Changes to these protocol types which increase the level of risk to participants OR in which federal funding is added would require the protocol to be resubmitted as a new project.

3.4 If a researcher makes necessary changes to eliminate apparent immediate hazards, a protocol deviation outlining the circumstances and any documents used must be submitted to the IRB.

4 PROCEDURES FOR DEVIATION SUBMISSIONS

4.1 Researchers are required to report deviations that meet one or more of the following criteria:

- Intended to eliminate an apparent immediate hazard to a research participant; or

- Caused possible harm to participants or others, or placed them at increased risk of harm – including physical, psychological, economic, or social harm; or
- Possible serious or continuing non-compliance.

4.2 Any report of a deviation to the IRB should be made in a timely fashion but no later than 10 working days of its occurrence or identification. If a deviation report is not submitted within 10 working days of its occurrence or identification, the IRB should make a serious/continuing noncompliance determination (see SOP 049: Non-Compliance and Research Misconduct).

4.3 The PI or research staff report(s) deviations by completing a "Notify IRB" submission request in WVU's electronic protocol submission system.

4.4 WVU OHRP staff perform a thorough review and evaluation of the deviation. Requests for clarifications, corrections, or revisions to the report from the PI are made if further information is needed to evaluate the deviation.

4.5 The deviation is evaluated to determine if it had a significant effect on the participants' rights, safety, or welfare or corrupted the integrity of the resultant scientific data. The IRB Chair may be consulted at any time during this process for assistance.

4.6 Any corrective actions taken should be described in the PI's proposed preventive, corrective action plan and should include the active process for addressing the causal elements to ensure that the reviewer can conclude that the PI has a viable plan in place for assuring the safety of the research participants and the oversight of data integrity.

4.7 After the review and evaluation of the incident, the following actions may be taken:

- The IRB acknowledges the deviation with no further actions indicated.
- The deviation is returned to the PI to be submitted as an adverse event and/or unanticipated problem involving risks to participants or others. Please see SOP 031: Research Related Event Reporting.
- If the OHRP staff determines that the deviation possibly meets the definition of serious or continuing non-compliance according to SOP 049: Non-Compliance and Research Misconduct, the deviation is handled according to the procedures outlined in that SOP.

5 PROCEDURES FOR PROTOCOL CLOSURE SUBMISSIONS

5.1 The completion or termination of the research project is considered a change in activity to the protocol and must be reported to the IRB. The PI submits a final project (or closure) report to notify the IRB of the completion or termination of a project, including protocols determined to be exempt. A final project/closure report provides information to the IRB regarding the final status of the project and allows the IRB to close the protocol within the WVU electronic protocol submission system.

5.2 If the PI fails to apply for continuing review or fails to submit a final project report, the IRB may administratively close the protocol. When the IRB acknowledges closure reports, the protocol file is closed, and no further activity related to the protocol may be conducted. Protocol files are retained as described in SOP 039: IRB Records and Data and Information Management.

5.3 **Submission of Final Project/Closure Reports:**

5.3.1 Final project reports should be submitted within 30 days after the completion or termination of the protocol.

5.3.2 The following documentation is required for IRB review:

5.3.2.1 Final project/closure report application submitted via the WVU electronic protocol submission system.
5.3.2.2 Preliminary or final results, if available.
5.3.2.3 Sponsor documentation of research project completion or termination, if it exists.
5.3.2.4 Closure information and/or documentation from IRB of Record for Central and Single IRB protocols.

5.4 **IRB Review of Final Project/Closure Reports:**

5.4.1 A designated member of the IRB reviews all final project/closure reports and, if needed, requests further information from the PI to clarify any questions that may arise.

5.4.2 Once the IRB has determined that sufficient information is provided, the PI will receive acknowledgment of the final project report and closure of the protocol from the electronic protocol submission system.

5.5 **IRB Administrative Closure:**

5.5.1 If a protocol expired and a protocol application review or a final project/closure report has not been submitted, the protocol will be administratively closed by the IRB. Refer to SOP 021: Approval Period and Determination of Expiration for procedures regarding expired protocols.

6 REFERENCES

WVU Policies:
SOP 021: Approval Period and Determination of Expiration
SOP 031: Research Related Event Reporting
SOP 039: IRB Records and Data and Information Management
SOP 049: Non-Compliance and Research Misconduct

Federal Regulations:

45 CFR 46.109
45 CFR 46.110

AAHRPP:
Element III.2.D

History of Revisions to SOP

Effective Date	Nature of Revision(s)

1 PURPOSE

This SOP describes the WVU IRB authority and process to suspend or terminate approval of research that is not being conducted in accordance with WVU IRB and/or institutional policy, is not in compliance with Federal Regulations, or that has been associated with unexpected serious harm to participants. Suspensions and terminations will be reported to HHS OHRP, the FDA, and appropriate institutional officials when applicable as listed in SOP 034: Reporting to External Agencies.

A PI may also place a voluntary administrative hold on previously approved research when in the judgment of the PI, an administrative hold is appropriate to protect the rights or welfare of participants.

In this policy, an IRB designee refers to the following: The IRB Chair, IRB Vice Chair, WVU OHRP Director, Institutional Official, or a person designated in writing to assume the role of one of these persons temporarily.

2 PROCEDURES FOR ADMINISTRATIVE HOLDS

2.1 A PI, institutional official, or sponsor may place a research project on administrative hold. Some or all research activities may be placed on hold until additional information can be obtained to determine if a change in the risk/benefit assessment of the research has occurred or if potential areas of non-compliance exist in a currently approved research protocol.

2.2 In consultation with the PI, institutional official, or sponsor, the IRB or IRB designee determines whether any additional procedures need to be followed to protect the rights and welfare of current participants.

2.3 In consultation with the PI, the IRB or IRB designee determines how and when currently enrolled participants will be notified of the administrative hold.

2.4 The appropriate party must:

- Notify the IRB in writing (email is sufficient) that the PI, institutional official, or sponsor is voluntarily placing the research on administrative hold.
- Provide a description of the research activities that will be stopped. Research activities may include but are not limited to recruitment, screening/enrollment, research intervention/interaction, follow-up, or all research activities.
- Provide a list of all currently enrolled participants' status within the study and the proposed actions to be taken (if needed) to protect the rights and welfare of current participants during the administrative hold action.
- Provide a written description of actions that will be taken before IRB approval of proposed changes to eliminate apparent immediate harm

2.5 After written notification from the appropriate party has been received, WVU OHRP staff is notified by the IRB Chair or designee of the research project on administrative hold and the required actions.

2.6 WVU OHRP staff initiate an inquiry process and consider if the additional information gathered during the inquiry stage of an investigation determines that no change to the risk/benefit ratio has occurred, the rights or welfare of participants have not been compromised, and issues of non-compliance have been ruled out. The inquiry may necessitate a for-cause audit according to SOP 041: WVU OHRP's Quality Improvement Program, to obtain needed information.

2.7 WVU OHRP staff write a report of the findings. The IRB Chair or designee notifies the PI and other appropriate parties in writing of these findings and the required corrective actions, if any, and allows the research to return to active status. Determinations of unanticipated problems involving risks to participants or others, or non-compliance that are a result of these findings will be reported according to SOP 031: Research Related Event Reporting and SOP 049: Non-Compliance and Research Misconduct.

3 PROCEDURES FOR SUSPENSION OR TERMINATION OF IRB APPROVED RESEARCH BY THE CONVENED IRB OR IRB DESIGNEE FOR CAUSE

3.1 If the research is not being conducted in accordance with the policies, requirements, and determinations of the IRB, or federal rules or regulations, or has been associated with unexpected serious harm to participants, the convened IRB or designee (i.e., IRB Chair) may suspend or terminate some or all research activity to protect the rights or welfare of participants.

3.2 The IRB designee considers whether any actions need to be implemented to protect the rights and welfare of current participants and orders any actions that need to be taken during the investigation process.

3.3 The IRB designee notifies WVU OHRP staff of the suspension and actions ordered.

3.4 The IRB Chair or designee notifies the PI of the suspension in writing that there are reasonable concerns, that infractions have occurred and that an investigation has been initiated. This letter is drafted according to the procedures for communication of terminations and suspensions provided below.

3.5 WVU OHRP staff initiate an investigation process and consider if the additional information gathered during the inquiry stage of an investigation determines that no change to the risk/benefit ratio has occurred, the rights or welfare of participants have not been compromised, and issues of non-compliance have been ruled out. The investigation may necessitate a for-cause audit according to SOP 041: WVU OHRP's Quality Improvement Program to obtain needed information.

3.6 WVU OHRP staff create a written report detailing the findings of the investigation as well as appropriate corrective actions to address problems or deficiencies. The written report is sent to the convened IRB, IRB Chair, OHRP Director, and other institutional officials and other units within the university or the covered entity as appropriate.

3.7 The convened IRB considers the written report and whether any required actions need to be implemented to protect the rights and welfare of current participants. The convened IRB votes on the actions to be taken. Possible actions the convened IRB may consider include, but are not limited to:

- Continuing the interventions that are currently being administered to enrolled participants under the research protocol, at least temporarily, when the interventions could be of direct benefit to the participants or when withholding the interventions poses increased risk to the participants.
- Transferring currently enrolled participants to another institution engaged in the research so that participation of the participants may continue.
- Transitioning currently enrolled participants to medical management outside of the research context.

Note: Determinations of unanticipated problems involving risks to participants or others, or non-compliance that are a result of the findings, will be made according to SOP 031: Research Related Event Reporting and SOP 049: Non-Compliance and Research Misconduct.

3.8 The convened IRB votes to lift the suspension, continue or modify the suspension, or terminate the research.

3.9 WVU OHRP staff document in the IRB minutes the reasons for the suspension or termination, and if applicable, any required actions.

3.10 WVU OHRP staff communicate with the PI following Procedures for Communications of Terminations and Suspensions below.

4 PROCEDURES FOR COMMUNICATION OF TERMINATIONS AND SUSPENSIONS TO INVESTIGATORS

4.1 WVU OHRP staff will draft a letter to the PI. The IRB Chair reviews and signs the letter (electronic signature is acceptable). Copies are to be provided to the Institutional Official, WVU OHRP Director, IRB members, and the immediate supervisor or department chair of the PI. The letter should include:

- The activities to be stopped;
- The required actions to be taken by the PI;
- An explanation of the reasons for the decision; and
- A request to immediately notify the IRB chair with a list of names of participants who might be harmed by stopping research and a rationale as to why they might be harmed.

4.2 The PI may appeal or respond to the convened IRB in writing.

4.3 WVU OHRP staff will follow SOP 034: Reporting to External Agencies on reporting the suspension or termination of approved research by the IRB to appropriate organizational officials, sponsors, coordinating centers, and regulatory agencies.

5 REFERENCES

WVU Policies:
SOP 031: Research Related Event Reporting
SOP 034: Reporting to External Agencies
SOP 041: WVU OHRP's Quality Improvement Program
SOP 049: Non-Compliance and Research Misconduct

Federal Regulations:
45 CFR 46.113
21 CFR 56.113

AAHRPP:
Element I.5.D.
Element II.2.H.

History of Revisions to SOP

Effective Date	Nature of Revision(s)
10/15/2021	New SOP

1 PURPOSE

This SOP describes the process for the continuing review of research under the auspices of WVU IRB that has been previously approved and is ongoing.

2 OVERVIEW

The IRB must conduct a continuing review of an approved protocol for the purposes of renewal of the IRB approval period. Continuing review is **NOT** required for the following: non-FDA Expedited protocols, protocols determined to be Exempt, those protocols that are approved under Flex Review, and NHSR projects.

When considering whether to renew a study, the IRB uses the same criteria used to grant initial approval. The IRB will not approve protocols submitted for continuing review if, because of interim changes in IRB policies and procedures, the IRB would not approve that same protocol as a new proposal.

During continuing review, the IRB determines whether the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. Additionally, the IRB may need to impose new precautions or revise those it had previously imposed on the research protocol. The IRB will re-assess the approval period for each continuing review application. Determinations are made using the applicable reviewer forms in addition to the reviewer feedback form (as a guide) within the WVU electronic submission system.

Investigators are required to submit a continuing review application to the WVU electronic IRB system at least 45 calendar days prior to the expiration of the study for Full Board protocols, and at least 30 calendar days prior to the expiration of the study for Expedited protocols.

The IRB will conduct a continuing review of ongoing research at intervals that are appropriate to the level of risk for each research protocol. Documentation of the determination of length of the approval period is made in the applicable reviewer forms and, if applicable, the minutes of the convened board meeting.

The determination of the length of approval period is made by the IRB considering the degree of risk, and according to the following standards:

3 CONTINUING REVIEW FOR RESEARCH SUBJECT TO FDA REGULATION OR GRANDFATHERED STUDIES

3.1 For studies that are subject to FDA or pre-2018 Common Rule requirements, the following standards of continuing review apply:

3.1.1 For studies reviewed at a convened meeting, continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research protocol.

3.1.2 For studies approved using expedited review procedures, continuing review must occur within one (1) year from the date the IRB Chair or designated expedited reviewer gave final approval to the research protocol.

4 CONTINUING REVIEW FOR RESEARCH SUBJECT TO THE REVISED COMMON RULE

4.1 For studies conducted under the WVU's Federal Wide Assurance (FWA) within the U.S. Department of Health and Human Services (HHS) and subject to the Final Rule, the following standards of continuing review apply:

4.1.1 For studies reviewed at a convened meeting, the continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research protocol.

4.1.2 Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review (See SOPs 018: Expedited Review and 020: Flex Review). Expedited Studies that fall under FDA Expedited Category 1 will still require annual continuing review.

4.1.3 Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

5 CONTINUING REVIEW FOR STUDIES CONDUCTED OUTSIDE OF WVU'S FWA

5.1 For studies conducted outside of WVU's FWA, the following standards of continuing review apply:

5.1.1 For studies reviewed at a convened meeting, continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research protocol.

5.1.2 Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review (See SOPs 018: Expedited Review and 020: Flex Review). Expedited Studies that fall under FDA Expedited Category 1 will still require annual continuing review.

5.1.3 Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

6 REFERENCES

WVU Policies:
SOP 018: Expedited Review
SOP 020: Flex Review

Federal Regulations:
21 CFR 56.109
45 CFR 46.109
45 CFR 46.101(l)(4)(i)(A)(3)

AAHRPP:
Standard I-9
Element II.2.E.2

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

This SOP describes the process to identify and report possible research-related events (Deviations, Violations, Exceptions, Adverse Events/Serious Adverse Events (AE/SAE), and Unanticipated Problems involving Risks to Subjects or Others (UPIRTSO) to the WVU IRB. Researchers are required to submit the report as soon as possible after the site investigator learns of the event, and in call cases, within 10 days. This policy applies to all research occurring under the auspices of WVU IRB.

2 EVENTS REQUIRING REPORTING

2.1 Researchers and research staff are responsible for reporting unanticipated problems involving risks to subjects or others to the IRB. Such reports may include adverse events, subject complaints, protocol deviations, and other untoward events involving risk. Reports may also include events that are not categorized as adverse events and are not directly related to an individual subject's participation in a study but represent risk to others. Events that do not cause detectable harm or adverse effects to subjects or others may still represent unanticipated problems.

2.2 Events that occur in WVU research that may represent unanticipated problems involving risks to subjects or others should be promptly reported. For the timeframe for such reporting, see section 2.3 below. The following events may represent unanticipated problems involving risks to subjects or others:

- Adverse device effects that are serious, unanticipated, and related;
- Adverse events or injuries that are serious, unexpected, and related;
- Breaches of confidentiality involving potential risks;
- Data and Safety monitoring board (DSMB) reports, interim analyses, or other oversight committee/monitoring reports altering the risk/benefit profile;
- Events requiring reporting according to the protocol, sponsor, or funding agency;
- New information indicating an unexpected change in risks or potential benefits (e.g., literature/scientific reports or other published findings);
- Protocol deviations, violations, or other accidental or unintentional changes to the protocol or procedures possibly involving risks or with the potential to recur, even if no harm has actually occurred;
- Subject complaints indicating an unanticipated risk, or complaints that cannot be resolved by the research staff (see SOP 032: Complaints and Concerns);
- Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject;
- Audit findings, inquiry, or written report by a federal agency (e.g., FDA Form 483);
- Suspension by the sponsor, investigator, or institutional entity; or
- Other problems or findings (e.g., loss of study data or forms, a subject becomes a prisoner while participating in the research, etc.) that a researcher or research staff member believes could influence the safe conduct of the research.

2.3 Timeframes for Reporting

A. The events described above should be promptly reported to the IRB using the Event Report submission in WVU's electronic IRB system within 10 days of the PI, researchers, or research staff members learning of the event.
B. Events resulting in temporary or permanent interruption of study activities by the researcher, sponsor, or DSMB to avoid potential harm to subjects should be reported within 48 hours.
C. Events resulting in the incarceration of a study subject should be reported within 72 hours (3 days) of the PI, researchers, or research staff members learning of the incarceration.
D. Events that may represent unanticipated problems involving risks to subjects or others should be reported (as described above), regardless of whether they occur during or after the study or involve a subject who has withdrawn from or completed study participation. If changes to the research or consent process are proposed as a result of the event, or if additional information will be provided to current and/or past participants, an amendment request must also be submitted for IRB review.
E. Additional sponsor reporting requirements may exist and are not outlined in this policy.

2.4 Events that may be reasonably anticipated (or expected) should be described in the informed consent process/form and do not require prompt reporting to the IRB by researchers and/or research staff.

2.5 The following are examples of events that do not require reporting (unless outlined in 2.6 for studies with annual review):

- Adverse device effects that are non-serious, anticipated, or unrelated;
- Adverse events or injuries that are non-serious, expected, or unrelated;
- Deaths not attributed to the research (e.g., from natural causes, accidents, or underlying disease) and the researcher(s) have ruled out any connection between the study procedures and the participant's death;
- IND safety reports from external sites not involving WVU research;
- Subject complaints that were resolved or complaints not involving risks;
- Protocol deviations or violations unlikely to recur or not involving the possibility of risks to subjects (to others);
- Subject complaints that were resolved or complaints not involving risks;
- Problems or findings not involving risk (unless the investigator or research staff member believes the information could affect participants' willingness to continue in the research).

2.6 The following are examples of events should be reported at the next continuing annual review/renewal if the protocol type requires annual review:

- DSMB reports, interim analyses, or other reports, findings, or new information not altering the risk/benefit ratio of the research;
- Brochure updates not involving safety information;
- Protocol deviations or violations unlikely to recur or not involving the possibility of risks to subjects (or others);
- Problems or findings not involving risk (unless the investigator or research staff member believes the information could affect participants' willingness to continue in the research).

3 PROCEDURES FOR REPORTING RESEARCH RELATED EVENTS

3.1 The PI reports the problem under this policy by completing and electronically submitting the information via the Notify IRB function within the WVU electronic IRB system. The PI attaches the Research Event Report Form (can be found on WVU OHRP's website within the Forms page) to the submission in the electronic system.

3.2 The submission is assigned by WVU OHRP staff through the WVU electronic IRB system to an IRB reviewer for review and evaluation. The IRB reviewer may request clarifications, corrections, or revisions to the report from the PI if further information is needed to evaluate the event.

3.3 If the IRB reviewer determines that the event is not an unanticipated problem involving risks to participants or others as defined in this policy, the reviewer indicates such in the electronic IRB system. The PI is notified via the electronic IRB system, and no further action is taken.

3.4 If the IRB reviewer determines the problem might be, or likely is, an unanticipated problem involving risks to participants or others as defined by this policy, the event is referred to the convened IRB for review. All applicable materials are forwarded to the convened IRB at 5 business days prior to the convened meeting.

3.5 Based on the nature of the event and the expertise required to assess it, the IRB Chair or designee acts as the primary reviewer and presents his or her findings to the convened IRB. The convened IRB evaluates the event by considering whether the problem is an unanticipated problem involving risks to participants or others as defined by this policy. The convened IRB votes on whether the report is an unanticipated problem involving risks to participants or others. IRB staff records the discussion and rationale for any action and vote in the minutes.

3.6 If the convened IRB determines that the problem is not an unanticipated problem involving risks to participants or others as defined by this policy, the convened IRB acknowledges the event as submitted, indicating the event is not considered to be an unanticipated event involving risks to participants or others. The PI is notified via the electronic IRB system, and no further action is taken.

3.7 If the convened IRB determines that the problem is an unanticipated problem involving risks to participants or others as defined by this policy, the convened IRB may consider any of the following actions, but is not limited to:

- modification of the protocol;
- modification of the information disclosed during the consent process provided by the investigator;
- providing additional information to current participants (this must be done whenever the information may relate to the participant's willingness to continue participation); providing additional information to past participants;
- requiring current participants to re-consent to participation;
- alteration of the frequency of continuing review;

- observation of the research or the consent process;
- requiring additional training of the investigator;
- notification of investigator(s) at other site(s);
- obtaining additional information; or
- administrative hold, termination, or suspension of the research (see SOP 029: Suspension, Termination, and Investigator Hold, Early Termination).

3.8 If the IRB determines that the event was an unanticipated problem involving risks to participants or others, the matter is referred to the OHRP staff to handle according to SOP 034: Reporting to External Agencies.

4 REFERENCES

Federal Regulations:
21 CFR 50.25(b)(5)
21 CFR 56.108(b)(1)
21 CFR 812.150(a)(1)
45 CFR 46.103(b)(5)(i)
45 CFR 46.116(b)(5)

AAHRPP:
Element II.2.G
Element III.2.D

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/21	New SOP
11/17/23	Clarification for section 2.5 (reporting requirements for protocols with annual review)

1 PURPOSE

1.1 This SOP describes the process followed when research participants or other individuals express concerns or complaints regarding involvement in or the conduct of WVU research involving human participants.

2 OVERVIEW

2.1 The WVU IRB is committed to the protection of research participants. As such, research participants are encouraged to express any concerns or complaints regarding a WVU research project.

2.2 Consent documents must include the investigator's contact information (email address and phone number) for any questions, complaints, and/or concerns the participant or the legal representative may have about the research or related matters. Consent documents must also include contact information for the WVU OHRP. This contact information is made available for submitting questions, complaints, and/or concerns. Concerns and complaints may be submitted anonymously if preferred. Information about how to report complaints is also provided on the WVU OHRP website (https://human.research.wvu.edu/about/participants) (LINK TO THIS). This link includes the option to submit a concern or complaint with complete anonymity.

2.3 The WVU IRB will investigate all complaints or concerns received regarding human subject research conducted under its jurisdiction. All complaints and/or concerns will be handled confidentially, including the reporting of alleged violations of investigator compliance.

3 PROCEDURES

3.1 Complaints received by an investigator or members of the research staff must be reported to the IRB following the guidelines of the WVU OHRP policy regarding research-related events. (See SOP 031: Reporting Research-Related Events.)

3.2 Complaints directly reported to the IRB will be documented following the Reporting Research-Related Events policy (SOP 031).

3.3 The OHRP Director or designee will attempt to find a suitable resolution and respond to the complaint or concern in a timely manner. As necessary, complaints may be brought to the WVU IRB Chairs for discussion and recommendation.

3.4 If the concern or complaint involves possible noncompliance or research misconduct, the complaint will be handled according to WVU OHRP's Noncompliance and Research Misconduct Policy (SOP 034).

4 REFERENCES

WVU Policies:
SOP 031: Reporting Research-Related Events
SOP 034: Noncompliance

Federal Regulations:
21 CFR 56.108(b)(1)

AAHRPP:
Standard I-4
Element III.1.G

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

This SOP outlines WVU OHRP and WVU IRB procedures for guiding researchers when research is conducted involving coded private information or biospecimens.

2 OVERVIEW

WVU OHRP procedures are based on the federal OHRP guidance document entitled, "Coded Private Information or Specimens Use in Research, Guidance" (October 15, 2008, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html).

3 GENERAL INFORMATION

3.1 For the purposes of this SOP, coded is defined as (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain that has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

3.2 Under the definition of human subject at 45 CFR 46.102(f), obtaining identifiable information or identifiable specimens for research purposes constitutes human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

- Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and
- Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in possession of the investigator.

3.3 In general, private information or specimens are considered individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

3.4 Conversely, private information or specimens are not individually identifiable when they cannot be linked to specific individuals by the investigator(s) directly or indirectly through coding systems. For example, research involving only coded private information or specimens does not involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are met:

- The private information or specimens were not collected specifically for the current proposed research project through an interaction or intervention with living individuals; and
- The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    - The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (i.e., note that HHS regulations do not require the IRB review and approve this agreement);
    - There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances until the individuals are deceased; or
    - Other legal requirements . prohibit the release of the key to the investigators until the individuals are deceased.

3.5 In some cases, an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited above may:

- Unexpectedly learn the identity of one or more living individuals, or
- For previously unforeseen reasons now believe that it is important to identify the individual(s).

If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity would now involve human subjects under the HHS regulations. Unless this human subjects research is determined to be exempt (See SOP 017: Exempt Review), IRB review of the research would be required. Informed Consent of the subjects also would be required unless the IRB approved a waiver of informed consent (See SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process).

4 WHO SHOULD DETERMINE WHETHER CODED PRIVATE INFORMATION OR SPECIMENS CONSTITUTES HUMAN SUBJECTS RESEARCH

4.1 The researcher (PI), in consultation with the WVU OHRP staff, will determine if the research involving coded information or specimens requires IRB review. If the request is verbal (by phone or in person) or by email, it is the researcher's responsibility to maintain

documentation of the decision. If the researcher submits a formal submission, the request must include sufficient documentation of the activity to support the determination. Formal requests for determinations will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file (either in the form of paper, email, or other electronic/automated system records).

5 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 016: Documentation of Informed Consent Process
SOP 017: Exempt Review

Federal Regulations:
45 CFR 46.102(f)

AAHRPP:
Element I.1.A

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

This SOP describes the process WVU follows to comply with all applicable local, state, and federal regulations in the conduct of research and to communicate certain actions to entities that may have an interest in the status of the research being conducted. The IRB will notify institutional officials, funding sources, regulatory agencies as appropriate. When the IRB determines: that an event represents an unanticipated problem involving risks to participants or others, that an event meets serious or continuing non-compliance criteria, or suspends or terminates approval of research.

2 AAHRPP REPORTING REQUIREMENTS

The IRB must report to the Association for Accreditation of Human Research Protection Programs (AAHRPP) within 48 hours after West Virginia University officials or any researchers (if the researcher is notified rather than WVU) becomes aware of:

- Any negative actions taken by a government oversight office, including, but not limited to, federal OHRP determination letters, FDA warning letters, FDA 483 inspection reports with official action indicated, FDA restrictions placed on IRBs or researchers.
- Any litigation, arbitration, or settlements initiated related to human research protections.
- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the WVU human research protections program.

The IRB Director, IRB Chair, or Vice Chair will report allegations of research misconduct to the WVU Institutional Official, who will coordinate the inquiry, investigation, and hearing phases as needed. All investigations and reporting to appropriate officials will be conducted according to WVU's Policy for Research Misconduct. (See SOP 049: Non-Compliance and Research Misconduct.)

3 PROCEDURES

After the IRB makes a determination necessitating reporting to external agencies (See SOP 031: Research Related Event Reporting), a WVU OHRP administrator or designee prepares a letter containing the following information:

- The nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research);
- Name of the institution conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem, including the findings of the organization and the reasons for the IRB's decision;
- Corrective actions and/or sanctions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants, etc.);

- Plans, if any, to send a follow-up or final report by a specific date or when an investigation has been completed, or a corrective action plan has been implemented;
- For suspensions or terminations of IRB approval of FDA-regulated research, the letter will also include:
    - The name of the drug, biologic, or device;
    - The IND number, or IDE number/non-significant risk (NSR) status of the device;
    - The address(es) of the clinical investigator(s)

3.1 The IRB Chair, Vice Chair, or designee reviews the letter and modifies the letter as needed.

3.2 The IRB Chair, Vice Chair, or designee electronically approves (and, if possible, electronically signs) the letter.

3.3 The IRB administrator or designee sends a copy of the report to the following as applicable. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.

- Principal investigator;
- Sponsor, if the research is sponsored;
- The Institutional Official at WVU and, when appropriate, Officials of the institutions that have a Memorandum of Understanding (MOU) with the WVU IRB;
- Chairman or supervisor of the principal investigator and/or offending investigator;
- The IRB, by providing the determination letter;
- The Institutional Representative(s) identified in a relevant reliance agreement if the WVU IRB is responsible for review and oversight of the research;
- The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually identifiable patient information from that covered entity;
- The Information Security Officer of an organization if the event involved violations of information security requirements of that organization;
- WVU Office of Risk Management (if applicable);
- The federal OHRP, if the research is subject to DHHS regulations or subject to a DHHS Federal Wide Assurance;
- Other federal agencies when those agencies oversee the research, if they require reporting separate from that to the federal OHRP;
- FDA, if the research is subject to FDA regulations;
- The Department of Defense, if the research is conducted under the terms of the Department of Defense Addendum Federal Wide Assurance;
- The WVU OHRP administrator or designee can provide copies to others as deemed appropriate by the WVU OHRP Director, Institutional Official, IRB Chair, or designee.

3.4 TheWVU OHRP administrator or designee will ensure that all steps of this policy will be completed within 30 days of the IRB's final determination necessitating reporting. For more serious actions, the WVU OHRP administrator or designee may expedite reporting.

4 REFERENCES

WVU Policies:

SOP 031: Research Related Event Reporting

SOP 049: Non-Compliance and Research Misconduct

Federal Regulations:

21 CFR 56.108

45 CFR 46.108

AAHRPP:

Standard I-9

Element II.2.G

Element II.2.H

Element II.2.I

History of Revisions to SOP

Effective Date	Nature of Revision(s)
11/8/21	New SOP

1 PURPOSE

The policy and procedures for creating or using a WVU-approved data or tissue repository utilizing clinical health information or authorized tissue specimens for purposes of human subject research are outlined in this SOP. All research conducted on stored human tissue at WVU must be obtained from a WVU IRB-approved tissue repository.

For purposes of this document, **tissue** includes any cell tissue, fluid, or excreta from which measures of normal or pathologic human physiologic function can be obtained.

Tissue includes, but is not limited to pathological specimens, diagnostic specimens, hair and nail clippings, deciduous and permanent teeth, dental plaque and calculus, sweat, uncannulated saliva, placenta removed at delivery, amniotic fluid, cerebrospinal fluid, genetic material, urine, blood, and other bodily fluids.

This policy applies to:

- Tissue collected as part of an approved protocol, standard operating room procedure, or from a non-university affiliated institution that will be stored in a tissue repository for future research at WVU or its affiliates.
- First-trimester fetal tissue may be subject to additional requirements. (See SOP 048: Research Involving Pregnant Women, Fetuses, or Neonates).
- Clinical health information or authorized tissue specimens from decedents

This policy does not apply to:

- Tissue repositories that exist for purposes other than research, such as for quality improvement or State reporting.
- Research conducted using human tissue under established guidelines for IRB review if the tissue collected is used for the approved protocol or discarded.

2 OVERVIEW

Repositories housing human tissue and data about human subjects are used to collect, store, and distribute these materials for research purposes. Researchers wishing to create repositories are responsible for registration and adherence to institutional policies and procedures and applicable regulatory requirements. The WVU IRBs are responsible for the suspension/termination of research related to a registered tissue or data repository that does not comply with this policy. The WVU IRBs have the authority to suspend or terminate any or all research conducted using a tissue or data repository that is not in compliance with the guidelines set forth in this policy, and/or within the IRB approved protocol collecting, managing, or using the repository specimens or data.

3 PROCEDURES FOR CREATING A DATA OR BIOSPECIMEN REPOSITORY:

3.1 The researcher completes the HSC Onsite Data or Biospecimen Repository electronic form which initially goes to CTSI for review. The researcher then obtains the required approvals (see below). The following is a list of general steps taken to initiate the Onsite Tissue and Database Repository process:

- Submit HSC Onsite Data or Biospecimen Repository electronic form, which will include:

  - Obtaining a Statistical Waiver Certification as per 45 CFR 164.514(b)(1) and signature
  - Providing the names of those acting as Honest Brokers (if applicable)
  - Obtaining Departmental Chair approval
- Submit IRB protocol with complete plan for repository creation (if the repository or bank is being created prospectively for research purposes and informed consent will be obtained from potential donors)
- Obtain IRB approval
- Obtain IBC approval (if applicable)
- Obtain CTSI Director approval (submit IRB approval letter for approval)
- CTSI facilitates the final approval of the HSC Onsite Data or Biospecimen Repository and communicates approval to the researcher.

All WVU tissue repositories must have biosafety approval from the Institutional Biosafety Committee (IBC) before the WVU IRB can provide approval. The researcher ensures that the required Informed Consent is obtained and submitted with the Onsite Tissue and Database Repository electronic form. Deposits of specimens into the tissue repository must conform to the IRB-approved guidelines for conducting research on human tissue. (See SOP 011: Human Subject Research Determination (NHSR)).

All specimens stored in a tissue repository must be accompanied by a copy of the consent agreement signed by the donor. The table below outlines when additional prospective informed consent is required in order to store specimens in a tissue repository:

Type	Consent Requirements
Decedents	Informed consent must be obtained from appropriate family members and submitted with the registration application.
Donor Consent	Human tissue, accompanied by a copy of an IRB approved consent agreement signed by the donor (see below for Approved IRB Protocols), can be placed into an approved tissue bank for unspecified research purposes.
Approved IRB Protocols	Human tissue can be deposited as part of an IRB approved protocol for the following: (1) Following standard operating or delivery room procedures. (2) Following standard diagnostic and treatment procedures (e.g., dental extraction, collection of bodily fluids). (3) From a non-affiliated institution that conforms to comparable standards for the protection of human subjects.
Surgical Consent	If human tissue obtained through standard operating or delivery room (non-research) procedures is to be placed into a tissue bank for potential research purposes, a separate consent form signed by the donor must be obtained in addition to the standard operating room consent form.
Type	**Consent Requirements**
Non-Surgical Consent	If tissue obtained for purposes of standard medical or dental diagnostic and treatment (non-research) procedures is to be placed into a tissue bank for potential research purposes, a separate consent form must be approved by the IRB for this purpose.

	For example, if a blood sample is obtained for standard clinical diagnostic purposes and then discarded without identifiers, no consent is required, unless the blood is analyzed as part of a research project prior to being discarded, in which case a signed IRB approved consent form is required. If the remaining blood or components of blood from a standard clinical diagnostic test are banked for potential research use, a signed IRB approved consent form is required.
Tissue Acquired from a Non-affiliated Institution	If identifiable human tissue is acquired from an institution, laboratory, or company not affiliated with West Virginia University for the purpose of tissue banking for research, the tissue must be accompanied by an approved consent agreement signed by the tissue donor. The approved consent agreement must contain comparable language to the approved WVU tissue banking language, providing assurance that the tissue can be used without additional consent as long as donor confidentiality is maintained, that the tissue can be used with subject identification with additional consent, and that the financial considerations regarding the cost and potential financial advantage to institutions are enumerated.
CORE (Center for Organ Recovery and Education)	The CORE consent form may be substituted for the WVU form.

3.2 The researcher submits the form electronically via an automated submission system, where it is received by the CTSI Director of Research Analytics or their approved designee.

3.3 Upon review, the CTSI Director asks for additional information and as necessary, collaborates with WVU OHRP/IRB to ensure the form meets criteria for approval without IRB review or approval.

3.4 If an IRB approved protocol is needed prior to creating a new repository for research purposes, the researcher is informed that they must first submit a protocol application to the IRB prior to initiation of the repository.

4 MAINTAINING A DATA OR BIOSPECIMEN REPOSITORY

Storage of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined within the IBC Guidelines. Disposal of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined through the IBC Guidelines. Information provided by the Institutional Biosafety Committee and Biosafety unit of Environmental Health and Safety at West Virginia University may be found on the WVU Biosafety website. Identification numbers assigned by the tissue bank will be the only method of linking the specimen. The Specimen Record, the Donor Record. Donor Record, and the Specimen Record will be stored in separate files. The Specimen Record - Include demographic and medical information from the patient's medical or

research record which does not identify the patient. Variables like age (< 90), medical diagnosis, and laboratory values can be included in the Specimen Record. The Donor Record - Include information identifying the donor, such as a copy of the approved consent agreement signed by the donor. All files containing Protected Health Information (PHI) must be stored according to HSC ITS guidelines in an approved storage location, such as the HSC Secure Network Drive or Virtual Desktop Infrastructure.

5 TYPES OF IRB APPROVAL FOR SECONDARY RESEARCH ON EXISTING DATA OR BIOSPECIMENS THAT HAVE BEEN STORED IN AN APPROVED ON-SITE REPOSITORY

Protocol Type	Description
NHSR	If human tissue is de-identified (stripped of all 18 Protected Health Information Identifiers) so that the researcher cannot trace the tissue back to the donor, then the project is considered to be not human subjects' research (NHSR).
Exempt	If identifiable human tissue is removed from a bank for research purposes, but the researcher records the data without identifiers, the project is considered Exempt research."
Expedited or Full Board Review	If identifiable human tissue is removed from a tissue bank for research purposes and information is provided to the PI in a manner that human subjects can be or are identified, and the researcher uses the identifiers, the project must follow the procedures for Expedited Review or Full Board Review
Tissue Sent to a Non-affiliated Institution	If identifiable human tissue is removed from an approved tissue bank at West Virginia University and sent to an institution, laboratory, or company not affiliated with West Virginia University for purposes of research, the PI must conform to the IRB Guidelines for the Protection of Human Subjects by obtaining approval through an approved protocol from their institution. A Data Use Agreement for Limited Data Sets form must be submitted following approval.

6 CONDUCTING SECONDARY RESEARCH USING EXISTING DATA OR BIOSPECIMENS THAT HAVE BEEN STORED IN AN APPROVED ON-SITE REPOSITORY

Removal of human tissue from a repository for research purposes: All researchers must apply for an IRB approval for each individual research project utilizing tissue from a tissue bank.
Tissue deposited and/or removed from a tissue bank must be logged using a Tissue Bank Log which will include date and time of deposit or removal, specimen number, the approved IRB protocol number, name(s) of investigators making the deposit or removal, and name of the tissue bank personnel responsible for completing the transaction.

Pre-Existing Specimens: The WVU IRB acknowledges that there may be specimens that were collected prior to the development and enforcement of the approved policy for conducting research on human tissue, and that records accompanying these specimens may not be in compliance with current WVU IRB policy. Whenever possible, it is the duty of the tissue bank to bring records from pre- existing specimens into compliance with current IRB policy (e.g., obtaining copies of consent forms to accompany specimens, separating the Specimen Record from the Donor Record, completing a Tissue Bank Development Application to register an on-site Tissue Bank).

Grandfather Clause: All tissue deposited or removed from a tissue bank after 1 January 2011 must conform to this policy. Any tissue banked after 1 January 2011 must conform to this policy. As it may be impractical to obtain consent for many specimens deposited before 1 January 2011, the tissue bank will not be required to demonstrate evidence of informed consent for specimens collected prior to this date.

7 REFERENCES

WVU Policies:
SOP 011: Human Subject Research Determination (NHSR)
SOP 048: Research Involving Pregnant Women, Fetuses, or Neonates
WVU HSC and WVU Medicine Information Security Policies
IBC Guidelines

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/21	New SOP

1 PURPOSE

The policy and procedures for protecting research data and ensuring compliance with regulations such as HIPAA are outlined in this SOP.

2 SCOPE

This policy applies to all protocol submissions to the WVU OHRP and requests for Data Use Agreements related to human subject research conducted under the auspices of WVU.

3 BACKGROUND

WVU uses an automated form with workflows to manage compliance, track, and approve researcher requests to use and store secondary data and to approve the storage for primary data. Based on the responses to questions on the form, the request and storage plan is reviewed by the appropriate ITS departments, and HIPAA requirements are determined based on the WVU HIPAA Hybrid policy. Additionally, notifications are sent to departments such as Export Control and Office of Sponsored Programs for advanced notice of research that may impact the departments.

4 RESPONSIBILITY

- The PI is responsible for completing the process outlined in the Procedures section as the first step in a research project. (This process must be completed before submitting a protocol and before requesting a data agreement.)
- The PI is responsible for understanding the data requirements, institutional policies, and regulatory requirements for the research project. For example, the type of data (PHI, PII, anonymous, de-identified), the risk related to the data, and the process for transmitting data into or outside the institution.
- The WVU Information Technology Services departments are responsible for providing appropriate storage options and requirements and approvals for the research data and approving data protection as appropriate for the risk and regulatory requirements, including HIPAA.
- The WV CTSI is responsible for reviewing requests for institutional medical and dental records and biospecimen/data repository data, including a review for HIPAA compliance.
- The WVU Office of Sponsored Programs is responsible for ensuring regulatory and institutional compliance related to Data Agreements.
- The WVU IRBs are responsible for ensuring the WVU Research Data Protection process has been completed for each protocol submission. WVU IRB determinations regarding the Research Data Protection process are only applicable to federal regulations governing human subject research, HIPAA requirements, and institutional policies affecting the human subject research.

5 PROCEDURES

- The PI completes the electronic WVU Research Data Protection submission form and obtains the required approvals. A Data Protection Certificate is sent to the PI upon approval. The Data Protection Certificate provides the PI with information related to the data, such as:
    a. Risk related to the data and the type of data
    b. Storage requirements and next steps

c. Additional compliance steps that may be required, such as a HIPAA Waiver of Authorization.
d. A summary of the information the PI provided when completing the form for the research project records.
e. Instructions for next steps if other approvals are needed for new software, hardware or participant payment systems.
f. A formal record of PI attestation of the following:
    i. The information submitted regarding the data is accurate
    ii. Compliance with the storage requirements
    iii. Agreement to complete a new Data Protection form if a change in the data requirements occurs that will impact the risk assigned to the data or the data type. For example, the data will be transmitted outside of the institution; identifiers will be included, etc.

- The PI attaches the Data Protection Certificate to the protocol submission using the automated protocol submission system.
- The completed form is stored in a WVU electronic system and can be referenced by the number automatically assigned and printed on the Data Protection Certificate.
- The WVU OHRP IRB staff reviews the submission to ensure that the Data Protection Certificate is attached and if the Data Protection Certificate indicates other agreements or forms are needed, the WVU OHRP staff ensures that the materials are received before the protocol can be acknowledged or approved by the WVU IRB.
- The WVU IRB (the HIPAA Privacy Board for WVU) reviews and considers the information within the Data Protection Certificate submitted as part of the research protocol. WVU IRB ensures that privacy and confidentiality of the data being collected, utilized, and/or shared as part of the research is consistent with federal regulations governing human subject research, HIPAA requirements, and institutional policies affecting the research, as applicable.
- The Data Protection Certificate and other required agreements and forms such as the HIPAA Waiver of Authorization, are stored in the automated protocol submission system.

6 REFERENCES

WVU Policies:
WVU HIPAA Hybrid Entity Designation
WVU Information Privacy Policy
WVU Sensitive Data Policy
WVU Data Retention and Destruction Policy

Federal Regulations:
HIPAA Safe Harbor
HHS Health Insurance and Accountability Act (HIPAA) of 1996
HHS HIPAA Privacy Rule (2000)
HHS HIPAA Security Rule (2003)

AAHRPP:
Element II.3.E

Element II.3.F

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/21	New SOP

1 PURPOSE

This SOP lays out the process and responsibilities for the WVU IRB to assure that research participants have knowledge of compensation and treatment availability for injury that may occur as a result of participating in research activities. This policy does not apply to remuneration or other compensation for research participation. For commercially sponsored studies, compensation, or payment of immediate necessary care for injury related to participation in research activities shall be provided according to the Informed Consent Document.

2 PROCEDURES

2.1 The researcher will insert language into the Informed Consent Document regarding immediate necessary care in the event of a research-related injury.

2.2 For commercially sponsored studies, the investigator will include language regarding compensation or payment of immediate necessary care for injury related to participation in research activities. The contractual agreement between the sponsor and the West Virginia University made through the Office of Sponsored Programs will have a general statement which explains the description of who will be responsible for medical care costs stemming from research-related injuries is found in the Informed Consent Document.

2.3 The IRB will review and approve the proposed compensation and injury language as a part of the new study submission.

2.4 The IRB will render its determination for approval of compensation or medical treatment for medical injury by: verifying that the template language for injury is contained in the Informed Consent Document; and reviewing the injury language to assure readability and understandability, and non-exculpation in relation to the proposed target study population.

2.5 In the event the sponsor requests conflicting language in the contract during the negotiation with the Office of Sponsored Programs, the contract may not be finalized until the Informed Consent Document is verified to be congruent with the sponsor's contract language. The Office of Sponsored Programs and the WVU OHRP staff will work together to ensure the accuracy of the language. If any changes are made to the approved Informed Consent Document, they must be approved by the IRB.

2.6 Contracts or other funding agreements require the sponsor to promptly (no longer than within 30 days) report to WVU any findings that could:

- Affect the safety of participants.
- Influence the conduct of the study or alter the IRB's approval to continue the study.

2.7 Contracts or other funding agreements require the sponsor to send data and safety monitoring plans and reports to WVU. Contracts or other funding agreements specify the time frame for providing

routine and urgent data and safety monitoring reports to WVU as indicated in the data and safety monitoring plan approved by the IRB.

2.8 The researcher or contract research organization provides an attestation or other written statement that contracts obligate the Sponsor to notify the researcher or organization conducting the research of any study results after the study has ended that could directly affect participant safety. A time frame of notification must be specified. This time frame is based on the appropriate time frame for each individual study. Researchers or the organization conducting the research are required to forward this information to the WVU IRB.

3 REFERENCES

AAHRPP:
Standard I-8

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/21	New SOP
8/8/22	Minor revisions to address AAHRPP Step 1 requirements (2.6-2.8 added)

1 PURPOSE

This SOP describes the guidelines that WVU researchers should follow regarding research data retention and destruction when closing a research project.

2 OVERVIEW

Researchers should retain signed documents and other information required by the sponsor, the federal agency regulating the research (i.e., DHHS OHRP, FDA, etc.), and the institution as required by regulatory requirements and institutional policy.

Records must be accessible for inspection and/or copying by authorized WVU OHRP and IRB representatives, other assigned WVU authorized officials, officials of federal and state regulatory agencies, HHS Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies.

This policy applies to both paper and electronic files. The WVU electronic protocol submission system, and other research systems provided such as *REDCap* retains and archives protocol and research information according to WVU policy. The PI should ensure retention requirements if other non-WVU electronic systems are used to conduct the research. For additional information on WVU's Record Keeping and Destruction Retention Policies, see the WVU Record Retention & Policy Schedule in the References section of this document.

3 RETENTION AND DESTRUCTION PROCEDURES

3.1 The researcher maintains signed documents (e.g., signed consents/assents) and records related to the research project for at least three (3) years after the project is closed, taking measures to prevent accidental or premature destruction of these documents. The researcher maintains any HIPAA-regulated documentation as outlined by HIPAA and WVU policies (typically up to 6 (six) years). Researchers store records consistent with the plan approved by the IRB and the institution in a secured manner to prevent breaches of confidentiality.

3.2 For research under the authority of FDA or other regulatory agencies, the researcher retains signed documents and records related to the research project for the period specified in the applicable regulations if the requirements are longer than three (3) years after closing the research project. For multi-site research projects, the researcher consults the sponsor regarding retention requirements but must maintain records for a minimum of six years after the research project closes.

3.3 The researcher ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.

4 REFERENCES

WVU Policies:
WVU Policy G1- Record Retention & Policy Schedule

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/21	New SOP

1 PURPOSE

This SOP describes the policies and procedures for WVU OHRP and IRB record keeping.

2 OVERVIEW

WVU OHRP and IRB maintain files in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, and other reporting documents. All records regarding a submitted proposal are retained as required by regulatory requirements and institutional policy. Records are kept regardless of whether the submitted proposal is approved. These records indicate clearly the documents that the IRB has approved.

Records are accessible for inspection and copying by authorized WVU OHRP and IRB representatives, Vice President for Research, officials of federal and state regulatory agencies, HHS Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies.

This policy applies to both paper and electronic files.

3 STORAGE OF AND ACCESS TO RECORDS

3.1 WVU OHRP staff may grant access to individuals outside of those listed above on an as-needed basis for official WVU business. Investigators or their authorized project personnel have reasonable access to files related to their research activities. WVU OHRP staff limit all other access to IRB records to those who have a legitimate need for them, as determined by the OHRP Director (or designee), and/or WVU legal counsel when submitted through state open records statutes.

3.2 Administrative requests for access must be submitted through WVU OHRP's electronic Information Access Request Form. This form requires the requestor's name, job title, department, and department head. Additionally, this form requires the requestor to justify the need to access the requested information, requirements for sharing the data, data fields or access requested, requested start date, and requested end date (which cannot exceed 90 days).

3.3 Once submitted electronically, the request is sent to the WVU OHRP Director (or designee) for a determination as to whether the request to access can be granted. The requestor receives the access request determination via e-mail after the determination is made.

3.4 In addition to protocol files, WVU OHRP maintains the following information and records. WVU OHRP staff organize and store records in files, binders, or electronically, as appropriate. Such records include but are not limited to:

- Standard operating procedures
- IRB membership rosters
- Meeting minutes, which include documentation of convened IRB meetings

- Federal Wide Assurance (FWA)
- Computerized research protocol tracking system
- Other IRB correspondence (as necessary)
- Agendas for IRB meetings, which include items to be reviewed and documentation of expedited and exempt/flex reviews
- Alleged non-compliance case records
- Mandated reports
- Resumes of currently active IRB members
- Electronic records documenting completion of mandatory training for project personnel, IRB members, and WVU OHRP staff

3.5 IRB membership rosters (see above) should include (but are not limited to) the following:

- Name
- Earned degrees
- Representative capacity
- Indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations
- Any employment or other relationship between each member and the institution (e.g., part-time employee, governing panel or board member, paid or unpaid consultant, etc.)

3.6 WVU OHRP staff maintain records that are not part of specific protocol files such as meeting minutes, agendas, standard operating procedures, and membership rosters, and periodically destroy them as appropriate and determined by the WVU OHRP Director (or designee).

3.7 WVU OHRP .also maintains communications to and from the IRB in the office and keep any relevant communication to a specific research protocol in the protocol record/file.

4 PROTOCOL RELATED DOCUMENTATION AND RECORD RETENTION

4.1 WVU OHRP maintains protocol records for a minimum of 7 years (as determined by the WVU OHRP Director or designee) after a research protocol is closed. This storage requirement applies even if the project never enrolled a participant. These protocol records may be stored indefinitely, at the discretion of the WVU OHRP Director and/or WVU Institutional Official.

4.2 Adequate documentation of each IRB's activities will be prepared, maintained, and retained in a secure location. Retained documents include but are not limited to:

- Copies or electronic files of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by PIs, and other reporting documents submitted by PIs
- Copies or electronic files of all submitted monitoring reports, site visit reports, progress reports, and other continuing review activities
- Copies or electronic files of all protocol review-related correspondence between the IRB and the PIs

5 REFERENCES

Federal Regulations:
45 CFR 46.115
21 CFR 56.115

AAHRPP:
Element II.5.A

History of Revisions to SOP

Effective Date	Nature of Revision(s)
12/20/2021	New SOP

1 PURPOSE

This SOP outlines the considerations and requirements for community-based participatory research (CBPR) under the auspices of WVU IRB.

2 OVERVIEW

Community-based participatory research (CBPR) is research that is conducted as an equal partnership between academic researchers and members of a community. In CBPR projects, the community participates fully in all aspects of the research process. Community is often self-defined, but general categories of community include geographic community, community of individuals with a common problem or issue, or a community of individuals with a common interest or goal.

When research is being conducted in communities researchers are encouraged to involve members of the community in the research process, including the design and implementation of research and dissemination of results when appropriate. WVU OHRP and/or the IRB will assist researchers in developing such arrangements.

3 GENERAL INFORMATION

3.1 The following are some questions that researchers should ask themselves/consider as they develop CBPR. These are also questions and topics the IRB should consider when reviewing CBPR:

- **Background, Purpose, and Objectives:**
  - How was the community involved or consulted in defining the need?
  - Who came up with the research objectives, and how?
  - Is this research justified with respect to community concerns?
  - Are there concrete action outcomes?
  - Who benefits, and how?
- **Research Methodology:**
  - How will the community be involved in the research? At what levels?
  - What training or capacity-building opportunities will be built in?
- **Procedures:**
  - Are the methods used sensitive and appropriate to various communities (consider literacy issues, language barriers, cultural sensitivities, etc.)?
  - How will scientific rigor and accessibility be balanced?
- **Participants:**

- Are the appropriate people included to get the questions answered (e.g., service providers, community members, leaders, etc.)?
- How will the research team protect vulnerable groups?
- Will the research process include or engage marginalized or disenfranchised community members? How?
- Is there a reason to exclude some people? Why?

- **Recruitment:**
  - What provisions have been put in place to ensure culturally relevant and appropriate recruitment strategies and materials?
  - Have "power" relationships been considered in the recruitment strategies to minimize coercion?
  - Who approaches people about the study and how?
- **Risks and Benefits:**
  - What are the risks and benefits of the research for communities? For individuals?
  - Are the risks (including risks to the communities) being presented honestly?
  - How will risks be minimized?
- **Privacy and Confidentiality:**
  - Where will data be stored?
  - Who will have access to the data? How?
  - What processes will be put in place to be inclusive about data analysis and maintain participants' privacy?
  - What will be the rules for working with transcripts or surveys with identifying information?
  - How will boundaries between multiple roles (e.g., researcher, counselor, peer) be maintained?
- **Compensation:**
  - How will people be reimbursed for their time and their efforts honored without it becoming coercive?
  - How will compensation be approached?
  - What provisions have been made for minimizing barriers to participation (e.g., providing for food, travel, childcare)?
  - Who is managing the budget? How are these decisions negotiated?

- **Conflicts of Interest:**
    - What happens when the researchers'/staff's roles are dual in nature (they are also friends, peers, service providers, doctors, nurses, social workers, educators, funders, etc., of participants)?
    - How will power differentials be appropriately acknowledged and negotiated?
- **Informed Consent Process:**
    - What does informed consent mean for "vulnerable" populations (e.g., children, individuals with impaired mental capacities, etc.)?
    - What processes are in place for gathering individual consent?
    - Where written informed consent is not being obtained, explain why.
    - What processes are in place for gathering community consent?
    - Where minors are to be included as participants, how will assent be obtained?
    - Are the consent processes culturally sensitive and appropriate for the populations being included?
- **Outcome and Results:**
    - How will the research be disseminated to academic audiences?
    - How will the research be disseminated to community audiences?
    - What new ways will this research be acted upon to ensure community/policy/social change?
- **Ongoing Reflection and Partnership Development:**
    - Is there a partnership agreement or memorandum of understanding to be signed by all partners that describes how they will work together?
    - What internal process evaluation mechanisms are in place?
    - When plans change to accommodate community concerns (as they invariably do in CBPR), how will this be communicated to the IRB?

4 IRB REVIEW OF CBPR

When CBPR studies are proposed, the above information will be included in the submission materials. When the IRB reviews CBPR studies, it will include, either as members or consultants, individuals with expertise in community-based participatory research.

5 REFERENCES

AAHRPP:
Element I.4.C

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP describes the policies and procedures regarding WVU OHRP's Quality Improvement Program and the activities within the scope of that program.

2 OVERVIEW

WVU OHRP supports a quality improvement (QI) program which promotes and maintains ethical research conduct and compliance with state and federal regulations, federal guidance, institutional policies, and best practices for human subject protections within the scope of research. WVU OHRP QI Program strives to evaluate and improve human research protections and activities through education, training, and monitoring.

3 EDUCATION AND TRAINING GOALS

3.1 The purpose of the WVU OHRP QI Program is to promote the following via education, training, and outreach mechanisms:

- Protection of the rights, welfare, and safety of human subjects participating in WVU research
- Compliance with federal, state, and institutional requirements governing human subject research
- The integrity of university research and WVU OHRP activities
- Education and training of research stakeholders, including university faculty and administrators, researchers, research staff, IRB members, WVU OHRP staff, and students involved in human subjects research
- Evaluation and follow-up of QI initiatives, corrective actions, and implementation of new quality improvement activities.

4 MONITORING

4.1 The objective of a routine IRB review (i.e., audit) is to ensure proper documentation, recordkeeping, data analysis, and adherence to applicable Federal regulations and IRB policy to monitor, measure, and improve the effectiveness of WVU's Human Research Protections Program. The review assesses the study conduct procedures, identifies errors and omissions, and is a means to provide the researcher with recommendations for corrections and improvements to protect the rights and welfare of research participants.

4.2 As part of WVU OHRP's QI Program initiatives, the following types of monitoring will take place as necessary:

- Internal Compliance Reviews will be performed based on WVU OHRP needs and staff availability.

- Routine reviews and monitoring activities will be performed based on WVU OHRP needs and staff availability. Routine reviews and monitoring may include PI self-assessments.

- Directed reviews of specific research and/or researchers at the request of the IRBs, WVU OHRP Leadership, or Institutional Official will also be performed as necessary to support IRB review, ensure human subject protections, and meet WVU OHRP QI program goals.

5 INTERNAL COMPLIANCE REVIEW

5.1 Internal directed audits and random internal compliance reviews will be conducted. The results may impact current practices and may require additional educational activities, and will be reported to the Director. The internal compliance auditor (WVU OHRP Assistant Director or designee) will:

- Review the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for the protection of vulnerable populations, as well as other risk/benefit ratio and consent issues that are included in the criteria for approval.
- Assess IRB minutes to assure quorum was met and maintained.
- Assess current adverse event reporting process.
- Ensure that privacy provisions, according to HIPAA, have been adequately reviewed, discussed, and documented in the IRB minutes.
- Evaluate the continuing review discussions to assure they are substantive and meaningful, and that no lapse has occurred since the previous IRB review.
- Observe IRB meetings or other related activities.
- Review IRB files to ensure retention of appropriate documentation and consistent organization of the IRB file(s) according to current policies and procedures.
- Review IRB database/electronic submission system to ensure accurate completion.
- Verify IRB approvals and reliance documentation for collaborating institutions or external performance sites.
- Review the appropriate metrics (e.g., time from submission to first review) to evaluate the quality, efficacy, and effectiveness of the IRB review process.
- Review the workload of IRB staff to evaluate appropriate staffing levels.
- Conduct other monitoring or auditing activities deemed appropriate by the IRB.

5.2 The Director or designated staff will review the results of internal compliance reviews with the IRB Chairs and Institutional Official (as needed). If any deficiencies are noted in the review, a corrective action plan will be developed by the Director and approved by the Institutional Official. The Director will have responsibility for implementing the corrective action plan, the results of which will be evaluated by the Institutional Official.

6 PROCEDURE FOR INITIATING A ROUTINE REVIEW

6.1 The WVU OHRP staff or designee selects a researcher or a research protocol for a routine review based on criteria that may include, but is not limited to one or more of the following:

- Research protocols involving procedures that are greater than minimal risk to participants
- Research protocols involving vulnerable populations
- Investigator-initiated drug and/or device studies
- Investigators conducting a large number of research projects
- Research protocols approved using expedited procedures that are not subject to continuing review

6.2 The WVU OHRP staff or designee contacts the researcher and establishes a time and place for the review. The WVU OHRP staff informs the researcher which documents are necessary for the review. The researcher must make such documents available at the time of the audit. Any other materials the WVU OHRP staff or designee deem necessary to accurately understand the research process under investigation shall be made available by the researcher upon request.

7 PROCEDURE FOR INITIATING A DIRECTED REVIEW

7.1 The convened IRB, IRB Chair, Subcommittee, or WVU OHRP Director may direct the WVU OHRP staff or designee to conduct a directed review (i.e., audit) in response to a particular concern. Concerns that may prompt a directed review include, but are not limited to, the following:

- Complaints or concerns made by a research participant, family member of the research participant, research staff member, or an employee of WVU or the covered entity
- Reports of audits or monitoring conducted by other committees affiliated with WVU OHRP/IRB, federal agencies, data and safety monitoring committees, or other agencies involved in the conduct of the research
- Issues of non-compliance

7.2 The WVU OHRP staff or designee contacts the researcher and establishes a time and place for the directed review. The WVU OHRP staff or designee informs the investigator

which documents are necessary for the directed review. The researcher must make such documents available at the time of the review. Any other materials the WVU OHRP staff or designee deem necessary to accurately understand the research process under investigation shall be made available by the researcher upon request.

8 PROCEDURE FOR CONDUCTING A REVIEW

8.1 Using the WVU IRB auditing documents and the researcher self-assessment checklist (if completed/available), WVU OHRP staff or designee reviews some or all aspects of the research records. These checklists become part of the final written report.

9 PROCEDURES FOR COMPLETING A REVIEW

9.1 After a review, the researcher is informed of the result of the review in a written report from the WVU OHRP office. The written report is also sent to the IRB Chair, WVU OHRP Director, and other Institutional Officials and other units within WVU or the covered entity, as deemed appropriate. A closeout visit may also be scheduled, either virtually or in-person.

9.2 If the review does not identify any problems, no action is taken.

9.3 If the review identifies problems or deficiencies, the WVU OHRP staff or designee includes appropriate corrective actions in a time frame determined by the WVU OHRP staff member or designee. WVU OHRP staff is responsible for reviewing these corrective actions and follows up with the researcher to ensure the corrective actions are completed. WVU OHRP staff may accept confirmation of completion for the corrective actions through a statement from the researcher, other documentation from the researcher, or a follow-up review.

9.4 If the corrective actions are not completed, WVU OHRP staff or designee may recommend to the convened IRB that a suspension be considered for the research project that was reviewed or for the research projects that a researcher is conducting, according to the procedures in SOP 029: Suspension, PI Administrative Hold, and Early Termination.

9.5 If the review identifies non-compliance, such as lack of oversight, deliberate falsification or omission, failure to comply with the requirements and determinations of the IRB, significant protocol violations, or deviations or frequent occurrences of such, the IRB follows SOP 049: Non-Compliance and Research Misconduct. The IRB may request additional corrective actions as per this policy.

9.6 If the review identifies a problem that might be an unanticipated problem involving risks to participants or others, the IRB follows SOP 031: Research-Related Event Reporting. The IRB may request additional corrective actions as per this policy.

10 REFERENCES

WVU Policies:
SOP 029: Suspension, PI Administrative Hold, and Early Termination.
SOP 031: Research-Related Event Reporting
SOP 049: Non-Compliance and Research Misconduct

AAHRPP:
Standard I-5

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP describes the process to identify, evaluate, manage, and minimize or eliminate the organization's proprietary interests, financial investments or holdings, and the personal financial interests of key organizational leaders when such interests could conflict with the organization's obligations to protect research participants, maintain the integrity of research, and ensure the credibility of the human research protections program.

2 PROCEDURES FOR IDENTIFYING AND REPORTING POTENTIAL ORGANIZATIONAL CONFLICTS

2.1 The initial review of human subjects research applications require that investigators disclose whether any WVU principal or co-investigator, has a financial interest that would reasonably appear to be affected by the research. Such financial interests involving key organizational leaders, or other potential organizational conflicts of interest, are forwarded to the WVU Conflict of Interest Office for review and approval. The Conflict of Interest website guides researchers in disclosing the above referenced potential conflicts of interest during a research project's initial review and approval process.

2.2 Principal investigators and co-investigators must submit a Conflict of Interest in Research Disclosure regardless of whether they have a Significant Financial Interest for Research to report. Disclosure requirements, review of conflict of interest in research, and COI-specific policies can be found in the Conflict of Interest Office's Governance, Ethics, Conflicts of Interest, and Outside Consulting Arrangements Policy. Principal investigators and Co-investigators complete the COI process within the electronic IRB submission system.

3 REFERENCES

WVU Policies:

Conflict of Interest Office's Governance, Ethics, Conflicts of Interest, and Outside Consulting Arrangements Policy

Federal Regulations:

42 CFR 50, Subpart F
45 CFR 94

AAHRPP

Standard I-6
Element III.1.B

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP lays out the process and responsibilities for training WVU OHRP staff and IRB members.

2 PROCEDURES

2.1 WVU OHRP Staff Training

2.1.1 WVU OHRP staff complete training in the protection of human research subjects. WVU OHRP staff may complete any training options offered for researchers approved by the West Virginia University IRB and/or WVU OHRP Director.

2.1.2 WVU OHRP staff receive initial and ongoing training in the areas related to their responsibilities, including all SOPs.

2.1.3 WVU OHRP staff are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research. The WVU OHRP Director supports such activities to the extent possible and as appropriate for staff responsibilities.

2.1.4 WVU OHRP staff unable to attend education sessions will be provided with the opportunity to make up any training they missed. If a make-up session is not possible (e.g., webinar or conference), then an equivalent educational opportunity will be offered at the discretion of the Director.

2.2 IRB Member Training

2.2.1 Initial Education: IRB members complete the required modules in the CITI course in the Protection of Human Research Subjects, including IRB Member CITI Training. This initial IRB Member CITI training is a one-time requirement unless otherwise specified by the WVU OHRP Director.

2.2.2 Continuing Education: IRB members participate in ongoing training in areas related to their responsibilities.

2.2.3 IRB Chair(s) and Vice Chair(s) receive additional training in areas related to their responsibilities.

2.2.4 IRB members are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subjects research. The WVU OHRP Director will support such activities to the extent possible and as appropriate for member responsibilities.

2.2.5 WVU OHRP uses the following activities (including, but not limited to the list below) as a means for offering continuing education to IRB members:

- In-service training at IRB meetings;
- Internal and External training workshops;
- Copies of appropriate publications, via hard copy or electronically;
- Identification and dissemination, by the Director or designee, of new information that might have affected the WVU OHRP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;

2.2.6 Members unable to attend education sessions will be provided with the opportunity to make up any training they missed. If a make-up session is not possible (e.g., webinar or

conference), then an equivalent educational opportunity will be offered at the discretion of the Director.

2.2.7 The activities for continuing education vary every year depending on the operating budget and areas of need, as determined by the WVU OHRP Director. The Director determines which continuing education activities are mandatory for IRB members and staff in a given year and tracks whether each individual has satisfied the requirements. IRB members who have not fulfilled their continuing education requirements will not be allowed to attend IRB meetings until they are fulfilled. Continuing noncompliance will result in the individual not being renewed as an IRB member.

3 REFERENCES

AAHRPP:
Standard I.1

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

WVU OHRP Digital and Electronic Signatures			
Document	**Version #**	**Effective Date**	**Page**
SOP 046	1.0	04-06-2020	Page 1 of 3

1 PURPOSE

1.1 To increase the efficiency of internal and external transactions that require authorization, the West Virginia University Office of Human Research Protections (WVU OHRP) may require that the WVU research community and research administration use electronic and digital signatures to conduct certain transactions that previously required handwritten or "wet" signatures and approvals on paper documents. This procedure establishes the scope by which WVU OHRP differentiates transactions for which digital and electronic signatures are required and recognized.

1.2 Digital Signature - Legally-binding digital signature delivered by a software solution that includes the following attributes: digital certificate, signing algorithm, identity-based confirmation, auditable attributes (name, date), validation of the certificate delivered by a digital signature solution.

1.3 Electronic Signature – A typed name or other representation of a signature not delivered by a digital signature solution with the capabilities listed above (i.e., cut\pasted signatures such as a cut\pasted signature or picture of a signature). For most internal authorizations, electronic signatures provide a suitable means of acknowledgment but cannot ensure that the individual is who they say they are. WVU and its affiliates provide policies regarding employee guidelines and associated discipline in the event of fraud, misrepresentation, or misuse of institutional resources.

1.4 The WVU+kc Protocol Management system is an acceptable form of electronic signature for Principal Investigators and other authorized staff who submit human subjects research-related forms and information to WVU OHRP for review and approval.

2 SCOPE

- This procedure applies to the internal\external documents listed below and can apply to other internal and external documents as determined by institutional management or the IRB Chairs.
- This procedure does not apply to Consent and Assent forms used during the conduct of research requiring research participant or legal, authorized representative signatures. Refer to WVU Informed Consent policies for more information.

3 RESPONSIBILITY

3.1 WVU staff engaging in the oversight or conduct of human subjects research conducted under the auspices of WVU are responsible for ensuring appropriate authorization of documents according to regulatory and institutional policy.

3.2 WVU OHRP is responsible for ensuring that documents related to the human research protections program are authorized appropriately and according to regulatory and institutional policy.

3.3 WVU staff are required to report suspect or fraudulent activity related to document signatures immediately to the WVU OHRP Director.

4 PROCEDURES

To the fullest extent permitted by law, WVU OHRP accepts digital and electronic signatures as legally binding and equivalent to handwritten or "wet" signatures to signify an agreement or authorization when the procedures listed below are followed:

4.1 INTERNAL DOCUMENTS:

The electronic signature methodology applied to documents for internal authorization for online forms:

- The following items are included in WVU OHRP internal online forms and are accepted as the document preparers signature:

  - A checkbox with the associated text: *By checking this box, I agree that I understand the contents of the document, and I am aware of the consequences of executing this document. I agree to the terms and conditions presented in this document.*
  - The typed name of the authorized employee with the date (If the software permits, a signature can be inserted in the place of the typed name).
  - The following text will be included at the end of the document: *Notice: WVU Office of Human Research Protections accepts this acknowledgment and the typed name of the individual as an authorized electronic signature under the WVU Human Research Protections SOP 046 –Digital and Electronic Signatures.*

4.2 INTERNAL DOCUMENTS that do not permit a typed name in the signature box (paper forms), forms that must be routed for multiple approvals, and in situations where a written or "wet" signature cannot be obtained:

- Complete the form, type your name, and the date in the signature box.
- Email the attached form to IRB@mail.wvu.edu or the appropriate WVU OHRP staff member.
- Include the following text in the email: "I authorize the contents of the attached form," and type your name.

4.2.1 Internal documents within the scope of this procedure:

- IRB Meeting Confidentiality Form
- CITI Program Admin Confidentiality Form
- WVU OHRP Information Access Request Form

4.3 EXTERNAL DOCUMENTS:

- A WVU OHRP approved digital signature solution will be used to obtain authorization for the external forms listed below and other documents as directed by institutional management or the IRB Chairs.

4.3.1 External documents within the scope of this procedure:

- Approval in Principle Letter
- IAA Non-WVU IRB of Record
- IAA WVU IRB of Record
- Collaborative Research Letter of Permission Form

4.4 It is a violation of this procedure for an individual to sign on behalf of another individual unless authority was explicitly granted by that individual and notice was sent to WVU OHRP via email from the individual granting permission.

5 REFERENCES

WVU Policies:
WVU Human Research Protection Policy Letter dated February 13, 2019

Federal Regulations:
Electronic Signature in Global and National Commerce Act (ESIGN)

West Virginia Laws:
Uniform Electronic Transactions Act (UETA) State Law

History of Revisions to SOP

Effective Date	Nature of Revision(s)
4/6/2020	New SOP

1 PURPOSE

This SOP outlines additional protections that researchers and the WVU IRBs must provide to prisoners involved in human subject research. The requirements described below apply to research involving prisoners and individuals who later become prisoners during their research participation.

2 OVERVIEW

Federal regulations require additional protections for prisoners involved in research. These requirements include that research involving prisoners (except for emergency use) may not be exempt from IRB review (i.e., Exempt or Flex review mechanisms at WVU), the IRB reviewing prisoner research must include a prisoner representative, and the proposed research must fall into one of the permissible categories described in the recommendations.

3 GENERAL INFORMATION

3.1 Prisoners may be convicted felons or untried individuals who are detained pending judicial action. The following are examples of individuals who are considered prisoners under these regulations:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or as an alternative to incarceration
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration
- Parolees who are detained in a treatment center as a condition of parole.

3.2 The following are examples of individuals who are not considered prisoners under these regulations:

- Individuals who are receiving non-residential, court-ordered substance abuse treatment and are residing in the community
- Individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others
- Persons living in the community and sentenced to community-supervised monitoring, including parolees
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, the specific circumstances of the planned participant population should be carefully considered

3.3 Researchers are “engaged” in research involving prisoners when (for purposes of the research) they obtain data through intervention or interaction, or obtain identifiable

private information about the prisoners. The following are examples of activities that constitute engagement in research involving prisoners:

- Seeking the informed consent of prisoners for research participation
- Using or studying identifiable private information about prisoners for research purposes
- Using or analyzing identifiable specimens obtained from prisoners for research purposes
- Surveying prisoners for a research study

3.4 In addition to the "standard" regulatory requirements for IRB composition (see SOP 006: IRB Meeting Conduct), when reviewing research involving prisoners the following requirements also apply:

- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in this capacity
    - The prisoner representative should have a close working knowledge and understanding of prison conditions from the prisoner's perspective
    - The prisoner representative should have the ability to express views independent of the prison administration
    - If the research is reviewed by more than one IRB, only one IRB must satisfy this requirement
- A majority of IRB members (other than the prisoner representative) has no association with the prison(s) involved.

Note: The IRB must meet these composition requirements for all types of review by the convened IRB, including initial review, continuing review, and review of amendments.

3.5 Expedited review of research involving prisoners must include a prisoner representative who meets the requirements to perform expedited review, as described in SOP 018: Expedited Review.

3.6 The DHHS exemption categories do not apply to research involving prisoners except when the exempt research examines a broader population that only incidentally involves prisoners. *Note: this exception for incidental prisoner inclusion will be made by the WVU IRB on a case-by-case basis.*

3.7 Prisoners may be involved in the emergency use of an investigational drug, biologic, or unapproved medical device. (See SOP 53: Emergency Use of an Investigational Drug, Biologic, or Device.)

4 PERMISSIBLE CATEGORIES OF RESEARCH INVOLVING PRISONERS

4.1 The following categories of research may involve prisoners:

1. Research on the possible causes, effects, and processes of incarceration and criminal behavior, provided that the study presents no more than minimal risk for prisoners and no more than an inconvenience to the participants.
2. Research on prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk for prisoners and no more than an inconvenience to participants.
3. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis, which is more prevalent in prisons than elsewhere, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assault).

   Note: Research in this category conducted or sponsored by DHHS may proceed only after the Secretary (DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice in the Federal Register of their intent to approve the research.
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the participant.

   Note: For research conducted or sponsored by DHHS that require the assignment (in a manner consistent with protocols approved by the IRB) of prisoners to control groups that may not benefit from the research, the research may proceed only after the Secretary (DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of their intent to approve the research.

4.2 Epidemiologic studies (e.g., related to chronic diseases, injuries, and environmental health) that do not meet the criteria above can also involve prisoners under **all** of the following conditions:

- The research presents no more than minimal risk for prisoners (e.g., interviews, collection of biological specimens, etc.) and no more than inconvenience to the prisoner-participants.
- Prisoners are not a particular focus of the research.
- The sole purpose of the research is **either one** of the following:
  - To describe the prevalence or incidence of a disease by identifying all cases.
  - To study potential risk factor associations for a disease.

5 REQUIRED IRB FINDINGS FOR RESEARCH INVOLVING PRISONERS

To approve research involving prisoners, along with determining that the regulatory criteria for approval are satisfied for non-prisoner participants (see SOP 007: IRB Approval Criteria), the IRB must make **all** of the following specific findings:

- The research represents one of the permissible categories (as noted above)
- Any possible advantages to the prisoner as a result of their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against such advantages in the "limited-choice" prison environment is impaired
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner participants
- Procedures for the selection of participants within the prison are fair to all prisoners and free from arbitrary intervention by prison authorities or prisoners
    - Unless the researcher provides the IRB with written justification for following some other procedures, control participants must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research
- The information is presented in language that is understandable to the participant population
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole
- Where the IRB finds there may be a need for follow-up exams or care of participants at the end of their participation, adequate provision has been made for this examination of care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

6 DOCUMENTATION AND CERTIFICATION

6.1 Protocol-specific findings related to the additional protections required for research involving prisoners will be documented in the IRB meeting minutes (or IRB records/electronic system for expedited review).

6.2 For prisoner research conducted or supported by DHHS, certification that the IRB reviewed the research and made the findings required by the regulations must be provided to the Secretary (DHHS) through the Office for Human Research Protections (OHRP). Upon IRB approval, WVU OHRP staff will forward the certification request to DHHS OHRP following the updated guidance on How to Prepare a Prisoner Certification Letter to OHRP.

6.3 Following its review of the prisoner certification request, if DHHS OHRP determines that the study involves one of the permissible categories of research, WVU will be notified by a letter authorizing the involvement of prisoners in the proposed research. The research may proceed only after receipt of the DHHS OHRP authorization letter. If multiple institutions are engaged in the same prisoner research, each institution must request certification from DHHS OHRP unless an institution relied on the review of another IRB.

6.4 Studies for which DHHS OHRP previously authorized prisoner involvement do not require "recertification" if amended unless the change to the research alters the applicability of the approved category of permissible prisoner research.

7 WHEN A PARTICIPANT BECOMES A PRISONER

7.1 When an enrolled participant becomes a prisoner in a study that was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners (listed above):

- The PI must notify the IRB as described by SOP 031: Research Related Event Reporting.
- All research activities with the now prisoner-participant must cease until the IRB can re-review the study (as applicable) to ensure that the requirements listed above have been satisfied.
    - If the participant is enrolled in a study that does not fall into one of the categories of permitted research, the participant cannot continue in the study.
    - In special circumstances in which the researcher asserts that it is in the best interests of the participant to remain in the study while incarcerated, the IRB Chair may determine that the participant may continue to participate until the re-review requirements are completed.

7.2 Upon receipt of notification that a previously enrolled research participant has become a prisoner and the researcher requests that the research is approved for prisoner participants, the IRB will promptly re-review the research in accordance with the review requirements. In these circumstances, some of the required findings may not be applicable (e.g., regarding the selection of participants within the prison if the participant was recruited outside of an incarcerated context). Any "non-applicable" findings should be documented along with the required specific findings.

7.3 If a researcher anticipates that some of the participants in a proposed study population are likely to be prisoners or become prisoners during the course of the study, the IRB may review the research prospectively for prisoner involvement. In this case, some of the required specific findings may not apply. The IRB should use discretion in deciding whether sufficient information is available at the time of review to make the required findings or to wait until more specific information is available (e.g., the specific institution where participants will be prisoners may be needed to evaluate the local research context).

8 DOCUMENTATION

8.1 The IRB considers each of the specific findings related to additional protections required for research involving prisoners. WVU OHRP staff document discussions of controverted issues at convened meetings in the meeting minutes.

8.2 Specific findings are either documented by WVU OHRP staff in the meeting minutes (i.e., for protocols reviewed by the convened board) or by expedited reviewers in determinations in accord with applicable SOPs. The IRB does not reapply categories during subsequent reviews unless changes to the protocol warrant such review.

9 WHEN FOLLOWING DEPARTMENT OF JUSTICE (DOJ) REQUIREMENTS:

9.1 **For National Institute of Justice (NIJ) funded research**:

9.1.1 All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer. (*See also*: Section 9.2.10)

9.1.2 All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

9.1.3 The consent document must disclose the name(s) of the funding agency(ies).

9.2 **For research conducted within the Bureau of Prisons**:

9.2.1 Implementation of Bureau programmatic or operational initiatives made through pilot projects is **not** considered research.

9.2.2 WVU, the IRBs, and researchers/research staff must follow the requirements of 28 CFR 512, including:

- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design must be compatible with both the operation of prison facilities and protection of human participants. The researcher must observe the rules of the institution or office in which the research is conducted.

- Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.

9.2.3 The selection of participants within any one organization must be equitable.

9.2.4 Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.

9.2.5 Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:

- No longer in Bureau of Prisons custody, AND
- Participating in authorized research being conducted by Bureau employees or contractors.

9.2.6 A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as statistical research or reporting record is provided to the agency.

9.2.7 Except as noted in the consent statement to the participant, the researcher must not provide research information that identifies a participant to any person without that participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertains.

9.2.8 Except for some computerized data records maintained at the official DoJ site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced to, an electronic retrieval system.

9.2.9 If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

9.2.10 Required elements of disclosure include:

- The identify of the researchers.
- Anticipated uses of the results of the research.
- The extent to which confidentiality of records identifying the participant will be maintained. For studies sponsored by NIJ, the participant should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size

or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research. (*See also*: Section 9.1.1)

- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

10 REFERENCES

WVU Policies:
SOP 006: IRB Meeting Conduct
SOP 007: IRB Approval Criteria
SOP 018: Expedited Review
SOP 031: Research Related Event Reporting
SOP 53: Emergency Use of an Investigational Drug, Biologic, or Device

Federal Regulations:
45 CFR 46 Subpart C
45 CFR 46.303
45 CFR 46.305
45 CFR 46.306

AAHRPP:
Standard II-4

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/22	New SOP
8/8/22	Minor revisions to address AAHRPP Step 1 requirements (Section 9 added)

1 PURPOSE

This SOP outlines additional protections that WVU researchers and IRBs must provide to pregnant women, fetuses, or neonates involved in human subject research. The requirements described below apply to research involving pregnant women, fetuses, or neonates.

2 OVERVIEW

Federal regulations require additional protections for pregnant women, fetuses, or neonates involved in research. The requirements include that research involving more than minimal risk is conducted only when benefits are anticipated for the mother and/or fetus, preclinical and clinical research has been conducted (where scientifically appropriate) that provide data for assessing potential risks, and informed consent processes describe the reasonably foreseeable risks to the fetus or neonate.

3 GENERAL INFORMATION

3.1 To approve research involving pregnant women, fetuses, or neonates, the IRB must determine that the research provides the additional protections described in 45 CFR 46 Subpart B (see "Additional Protections" section below) in addition to meeting regulatory criteria for approval of research involving non-pregnant participants (See SOP 012: Informed Consent Requirements).

3.2 In general, the risk to the fetus from research procedures (e.g., ultrasound, changes in maternal diet, etc.) must not be greater than minimal (i.e., only minimal risk). When the risk is considered to be more than minimal, the risk must be justified

3.3 "Viable" neonates may be included in research that provides the additional protections for children involved as participants in the research described by federal regulations and SOP 014: Research Involving Children.

4 ADDITIONAL PROTECTIONS FOR PREGNANT WOMEN AND FETUSES

4.1 Pregnant women or fetuses may be involved in research only if **all** of the following conditions are met (the IRB must determine these specific findings):

1. *Where scientifically appropriate* (e.g., research involving investigational drugs or medical devices), preclinical and clinical research (including research on non-pregnant women) has been conducted and provides data for assessing potential risks to pregnant women and fetuses.

2. Regarding the risk(s) of the research, any risk is the least possible for achieving the objectives of the research, and either of the following applies:
    a. The risk to the fetus is caused solely by interventions or procedures that offer the prospect of direct benefit for the woman or the fetus
    b. If there is no expectation of benefit(s), the risk to the fetus is not greater than minimal (i.e., only minimal risk), and the purpose of the research is the development of important knowledge that cannot be obtained by other means.
3. Consent of the pregnant woman is obtained and documented as described by SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process. Consent is obtained in any of the following circumstances:
    a. The research offers the prospect of direct benefit to the pregnant woman
    b. The research offers the prospect of direct benefit to both the pregnant woman and the fetus
    c. The research does not offer the prospect of benefit for either the woman or the fetus, but the risk to the fetus is not greater than minimal (i.e., only minimal risk) and the purpose of the research is the development of important knowledge that cannot be obtained by any other means.
4. The consent of *both* parents must be obtained and documented as described by SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process for research that holds out the prospect of direct benefit solely to the fetus, with the following exceptions:
    a. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity
    b. The father's consent need not be obtained if the pregnancy resulted from rape or incest.
5. Each individual providing consent is fully informed regarding the reasonably foreseeable influence of the research on the fetus or the neonate
6. No inducements (monetary or otherwise) will be offered to terminate the pregnancy
7. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
8. Individuals engaged in the research will have no part in determining the viability of a neonate.

5 ADDITIONAL PROTECTIONS FOR CERTAIN NEONATES

Nonviable neonates and neonates of uncertain viability may be involved in research as described below:

A. Nonviable neonates may be involved in research only if all of the following conditions are met (the IRB must determine these specific findings):
    1. *Where scientifically appropriate*, preclinical and clinical research has been conducted and provides data for assessing potential risks to neonates
    2. Vital functions of the neonate will not be artificially maintained
    3. The research will not terminate the heartbeat or respiration of the neonate
    4. There will be no added risk to the neonate resulting from the research
    5. The purpose of the research is the development of important knowledge that cannot be obtained by other means
    6. The consent of *both* parents must be obtained and documented as described by SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process, with the following exceptions:
        i. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent is sufficient
            1. The consent of a legally authorized representative (for either or both of the parents of a nonviable neonate) is not sufficient
            2. Provisions for waiver or alteration of the consent process are not applicable
        ii. The father's consent need not be obtained if the pregnancy resulted from rape or incest.
    7. Each individual providing consent is fully informed regarding the reasonably foreseeable influence of the research on the neonate
    8. Individuals engaged in the research will have no part in determining the viability of the neonate.

B. Neonates of uncertain viability may be involved in research (until a physician has determined whether or not the neonate is viable) only if all of the following conditions are met:
    1. *Where scientifically appropriate*, preclinical and clinical research has been conducted and provides data for assessing potential risks to neonates
    2. Regarding the risk(s) of the research, one of the following applies:

i. The research offers the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective

ii. If the research does not offer the prospect of enhancing the probability of survival, the purpose of the research is the development of important knowledge that cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research.

3. The consent of *either* parent is obtained and documented as described by SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process, with the following exceptions:

   i. If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of either parent's legally authorized representative is obtained

   ii. The consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

4. Each individual providing consent is fully informed regarding the reasonably foreseeable influence of the research on the neonate

5. Individuals engaged in the research will have no part in determining the viability of the neonate.

6 RESEARCH SUBJECT TO DHHS REGULATIONS

For research involving pregnant women, fetuses, or neonates that is subject to DHHS regulations, the below additional requirements apply:

6.1 Pregnant women and/or fetuses may be involved in more than minimal risk research without the prospect of direct benefit for the pregnant woman or the fetus if the applicable conditions described above (see "Additional Protections for Women and Fetuses") are met, with the following additional requirement:

- The purpose of the research is the development of important *biomedical* knowledge that cannot be obtained by any other means.

6.2 Nonviable neonates may be involved in research if the applicable conditions described above (see "Additional Protections for Certain Neonates") are met, with the following additional requirement:

- The purpose of the research is the development of important *biomedical* knowledge that cannot be obtained by any other means.

6.3 Neonates of uncertain viability may be involved in research that does not offer the prospect of enhancing the probability of the neonate's survival (to the point of viability)

when there is no added risk to the neonate resulting from the research if the applicable conditions described above (see "Additional Protections for Certain Neonates") are met, with the following additional requirement:

- The purpose of the research is the development of important *biomedical* knowledge that cannot be obtained by any other means.

6.4 Research involving pregnant women, fetuses, or neonates that does not meet the conditions for approval described by federal regulations and this policy may be conducted only if **all** of the following conditions are met:

- The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates
- The Secretary (DHHS), after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, ethics, law, etc.) and following opportunity for public review and comment (including a public meeting announced in the *Federal Register*), has determined either of the following:
    - The research satisfies the regulatory conditions for approval
    - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; the research will be conducted consistent with sound ethical principles; and informed consent will be obtained in accordance with the regulatory requirements pertaining to pregnant women, fetuses, or neonates.

7 RESEARCH INVOLVING WOMEN WHO MAY BECOME PREGNANT

For cases in which pregnancy is incidental to participant selection for research participation, the additional protections described by federal regulations and this policy do not specifically apply. However, researchers and the IRB will consider additional protections when an individual's participation could pose any risk to a potential fetus. In some research, participants should be advised to avoid pregnancy during or following the research, and to notify the researcher(s) immediately if pregnancy occurs. Exclusion of all women who could become pregnant may be justified in research involving potential serious risk(s) to a fetus.

8 DOCUMENTATION

8.1 The IRB considers each of the specific findings related to additional protections required for research involving pregnant women, fetuses, or neonates. WVU OHRP staff document discussions of controverted issues at convened meetings in the meeting minutes.

8.2 Specific findings are either documented by WVU OHRP staff in the meeting minutes (i.e., for protocols reviewed by the convened board) or by expedited reviewers in determinations in accord with applicable SOPs. The IRB does not reapply categories during subsequent reviews unless changes to the protocol warrant such review.

9 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 014: Research Involving Children
SOP 016: Documentation of the Informed Consent Process

Federal Regulations:
45 CFR 46.204
45 CFR 46.205
45 CFR 46.206
45 CFR 46.207
45 CFR 46.402

AAHRPP:
Standard II-4

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP describes the process WVU follows to address both allegations and confirmed reports of any non-compliance in accordance with 45 CFR Part 46 and 21 CFR Part 50. This policy applies to the research investigative team (for research misconduct allegations), the IRB, and WVU OHRP staff. WVU encourages members of the research community to report apparent non-compliance to the IRB. The determination that non-compliance is serious or continuing rests with the IRB.

2 PROCEDURES FOR ADDRESSING ALLEGATIONS OF NON-COMPLIANCE:

2.1 Allegations of non-compliance are investigated by the WVU OHRP Director (or designee), the IRB Chair, or a designated IRB Vice Chair.

2.2 The WVU OHRP Director (or designee) conducts a pre-inquiry review for preliminary informal checking of the facts to determine if there is a reasonable basis for the allegation and if the allegation can be supported or provided by evidence.

- If the allegation of non-compliance is determined by the WVU OHRP Director (or designee) not to be a credible confirmed report of non-compliance, in fact by definition, the inquiry stops, and no further action is taken.
- If the allegation of non-compliance is determined by the WVU OHRP Director (or designee) to be a credible, confirmed report of non-compliance, in fact by definition, the inquiry proceeds as outlined in this policy. The allegation of non-compliance is considered a confirmed report of non-compliance by definition.

3 PROCEDURES FOR ADDRESSING CONFIRMED REPORTS OF NON-COMPLIANCE

3.1 The WVU OHRP Director (or designee) forwards the confirmed report of non-compliance to the IRB Chair or IRB Vice Chair for review. The IRB Chair or Vice Chair determines whether the confirmed report of non-compliance either does not represent serious or continuing non-compliance or might represent serious or continuing non-compliance as defined in this policy.

3.1.1 If the IRB Chair or IRB Vice Chair determines that the confirmed report of non-compliance is neither serious nor continuing non-compliance, as defined by this policy, IRB Chair, or IRB Vice Chair consider but are not limited to the following actions:

- Acknowledgement of the problems, requiring no sanctions but with instructions regarding the necessity to establish procedures and policies to avoid further infractions.
- Require additional education and training applicable to human research participant protections of the investigator and/or staff.
- Request a corrective action plan from the investigator.
- No further action.

3.1.2 If the IRB Chair or IRB Vice Chair determines that the confirmed report of non-compliance might represent either serious or continuing non-compliance, as defined by this policy, the WVU OHRP Director, IRB Chair, or IRB Vice Chair will refer the confirmed report of non-compliance to the convened IRB with his or her evaluation.

3.2 When issues of non-compliance are reviewed by the convened IRB, the WVU OHRP Staff prepares the documents listed below, if they apply, and makes them available to all members of the convened IRB for review at least one week before the convened meeting. All members are expected to review the information and be prepared to discuss it at the meeting.

- The current IRB application;
- The informed consent document;
- The Investigator Brochure;
- The confirmed report of non-compliance;
- The audit report (investigation report) including a list of witnesses and documents reviewed;
- Previous reports of non-compliance and the past record of the investigator and his/her study team;
- All additional pertinent documents or portions thereof (e.g., primary data)

3.3 A WVU OHRP staff member assigns a primary reviewer based on scientific expertise to perform an in-depth review of the documents. The primary reviewer will present his/her findings at the convened meeting. The primary reviewer and the IRB Chair or IRB Vice Chair will lead the discussion during the meeting.

3.4 The convened IRB votes on whether the confirmed report of non-compliance represents serious non-compliance and/or continuing non-compliance as defined by this policy. WVU OHRP staff record the discussion and rationale for any action and vote in the minutes.

3.5 If the convened IRB votes on whether the confirmed report of non-compliance represents serious non-compliance and/or continuing non-compliance as defined by this policy. The IRB considers but is not limited to the following actions:

- Acknowledgement of the problems, requiring no sanctions but with instructions regarding the necessity to establish procedures and policies to avoid further infractions.
- Require additional education and training applicable to human research participant protections of the investigator and/or staff.
- Request a corrective action plan from the investigator.
- No further action.

3.6 If the convened IRB determines the confirmed report of non-compliance represents serious non-compliance or continuing non-compliance, as defined by this policy, the IRB considers but is not limited to the following actions:

- Verification that participant selection is appropriate.

- Observation of the research and the informed consent process by a WVU OHRP administrator or IRB member.
- Modifications of the protocol.
- Request an increase in monitoring of the research activity via an independent data safety monitor or board.
- Safety intervention as necessary such as visits to the activity site and continuing evaluation of the site by a WVU OHRP administrator or IRB member.
- Request audit and progress reports from the sponsor monitor or CRO.
- Request a directed audit of targeted areas of concern by a WVU OHRP administrator and/or IRB member.
- Request a status report after each participant receives intervention from the investigator.
- Modify the frequency of the continuing review cycle.
- Request additional PI and research project team education focused on human research protections from appropriate available sources (e.g., GCP Training, OHRP conferences, NIH tutorials, human research protections seminars).
- Notify current subjects if the information about the non-compliance might affect their willingness to continue participation.
- Provide additional information to past participants.
- Suspend IRB approval of the respective research protocol pending a written plan for the correction and/or prevention of the non-compliance.
- Remove the Principal Investigator of the research project.
- Suspend or terminate some or all of the research protocol and possibly other research being conducted by the Principal Investigator as well. (See SOP 029: Suspension, Administrative Hold, Early Termination and SOP 034: Reporting to External Agencies.)

3.7 If the IRB determines that the confirmed report of non-compliance was either serious non-compliance or continuing non-compliance, as defined by this policy, the matter is referred to the WVU OHRP staff to handle according to SOP 034: Reporting to External Agencies.

4 REFERENCES

WVU Policies:
SOP 029: Suspension, Administrative Hold, Early Termination
SOP 034: Reporting to External Agencies

Federal Regulations:
45 CFR 46.103 (a)
45 CFR 46.103 (b)
21 CFR 56.108 (b)

AAHRPP:
Element I.5.D

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP describes the process WVU's OHRP and IRB follow when a principal investigator (PI) decides to appeal an IRB determination or decision.

2 OVERVIEW

The WVU IRB has the authority to approve research activity, specify modifications required to secure IRB approval of the research activity, or disapprove any research activity overseen and/or conducted by WVU. The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB policies, and is not in compliance with applicable federal regulations, or that is associated with unexpected serious harm to participants (See SOP 029: Suspension, Administrative Hold, Early Termination).

Research approved by the IRB may be subject to further review by WVU officials as part of the human research protection program, as appropriate. The institutional official (IO) may override the IRB's decision to approve research; however, they may not approve the research if it has not been approved by the IRB, nor can they overrule other decisions made by the IRB (See SOP 004: IRB Authority, Membership, and Responsibilities).

Investigators may appeal:

- Revisions required by the IRB;
- IRB determinations of non-compliance, serious non-compliance, continuing non-compliance, or an unanticipated problem involving risks to participants or others;
- IRB disapproval of research; or
- Termination of an approved protocol by the IRB.

If the appeal is denied, the investigator's institution cannot override the IRB decision. Documentation of appeal, including all correspondence relating to the appeal, is retained within the research protocol in the WVU electronic IRB system.

3 PROCEDURES FOR APPEALING REVISIONS REQUIRED BY THE IRB

3.1 If a PI disagrees with a revision requested by the IRB, the PI may submit a written appeal to the WVU OHRP staff responsible for issuing the request. The PI should include information supporting any arguments made in the appeal.

3.2 For research reviewed using the expedited review procedure, the appeal is reviewed by the expedited reviewer who requested the revisions. The expedited reviewer may either (a) make a decision on the appeal, or (b) refer the appeal to the convened board. If the PI disputes the decision of the expedited reviewer, the appeal is then referred to the convened board for resolution.

3.3 For research reviewed by the convened IRB, the appeal is reviewed by the convened IRB. The PI may be invited to a convened meeting to provide clarification or additional information to the IRB.

The PI may also request to be in attendance at a convened meeting to provide clarification or additional information to the IRB. The PI may not be present for the vote on the appeal.

3.4 The expedited reviewer or convened IRB may accept the appeal, request different revisions, or deny the appeal. The investigator is notified in writing of the decision. If the appeal is accepted the investigator is not required to submit the requested revisions that applied to the appeal process. If different revisions are requested, the investigator must submit the different revisions. If the appeal is denied, the IRB decision is final, and the revisions must be made prior to approval.

4 PROCEDURES FOR APPEALING DETERMINATIONS MADE BY THE IRB

4.1 For the purposes of this policy, the term "IRB determination" means a determination of non-compliance, serious non-compliance, continuing non-compliance, or an unanticipated problem involving risks to participants or others.

4.2 If a PI disagrees with an IRB determination, the PI may submit the appeal and any information supporting the appeal in the form of "Notify the IRB" within the WVU electronic IRB system within 60 days of being notified of the determination.

4.3 For IRB determinations made through administrative review (review conducted by an IRB Chair, WVOHRP Director, or designee), the appeal is reviewed by the individual who made the determination. The administrative reviewer makes a decision on the appeal. If the PI disputes the decision of the administrative reviewer, the appeal is then referred to the convened board for resolution.

4.4 For IRB determinations made by the convened IRB, the appeal is reviewed by the convened IRB. The PI may be invited to a convened meeting to provide clarification or additional information to the convened IRB. The PI may also request to be in attendance at a convened meeting to provide clarification or additional information to the IRB. The PI may not be present for the vote on the appeal.

4.5 The administrative reviewer may accept the appeal or deny the appeal. The PI is notified in writing of the decision. If the appeal is accepted, a new determination is made using the information provided in the "Notify the IRB" report on which the appeal was submitted. If the appeal is denied, the IRB decision is final, and the original determination stands.

5 PROCEDURES FOR APPEALING THE IRB DECISION TO DISAPPROVE OR TERMINATE A STUDY

5.1 If a PI disagrees with the IRB decision to disapprove or terminate a study, the PI may submit a written appeal of the decision to disapprove or terminate to the IRB Chair and WVU OHRP Director within 60 days of being notified of the decision. The appeal should address the specific concerns of the IRB and the IRB basis for disapproval or termination.

5.2 The appeal is reviewed by the convened IRB. The PI may be invited to the convened meeting to provide clarification or additional information to the IRB. The PI may also request to be in attendance at a convened meeting to provide clarification or additional information to the IRB. The PI may not be present for the vote on the appeal.

5.3 The convened IRB votes to accept or deny the appeal. The PI is notified in writing of the decision.

5.3.1 If the appeal to the decision to disapprove a study is accepted, the PI is invited to submit a new study application to the IRB for review and approval, according to the conditions set forth by the IRB in accepting the appeal.

5.3.2 If the appeal to the decision to terminate a study is accepted, the PI may resume research activities after any conditions set forth by the IRB are met. In some cases, the IRB may require the PI to submit a new study application for review and approval prior to resuming research activities.

5.3.3 If the appeal is denied, the IRB decision is final, and the study may not be approved or resume.

6 REFERENCES

WVU Policies:

SOP 004: IRB Authority, Membership, and Responsibilities

SOP 029: Suspension, Administrative Hold, Early Termination

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP outlines additional requirements for ancillary committee and institutional reviews. The WVU OHRP communicates between various offices within WVU's human research protection program and may rely upon oversight and input by these groups for research that is within WVU IRB purview and research that is within an external IRB's purview but is occurring at a WVU-owned site.

2 OVERVIEW

Ancillary reviews assist the IRB and the institution with matters related to research feasibility, risk, regulatory requirements, and research compliance. Not all studies require ancillary review. If ancillary review is required, documentation of WVU IRB approval (or reliance acknowledgement, for studies under external IRB review) cannot be released until all ancillary reviews are completed.

Some ancillary reviews are automatically routed to appropriate offices and/or groups within WVU's human research protection program, while others are routed manually by the IRB and/or WVU OHRP staff to obtain the appropriate ancillary review. Although listed below are the most common ancillary reviews assigned to human subject research protocols at WVU, this list is not finite, nor is it all-inclusive. Other ancillary reviews will be utilized on an as-needed basis, and those groups may not be listed within this policy.

3 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The IBC is responsible for ensuring that recombinant DNA activities comply with the NIH guidelines. Projects involving human gene therapy or other DNA-related activities must be reviewed by the IBC, although the review may occur concurrently with IRB review. The IRB and the IBC communicate regarding committee deliberations and required revisions.

4 RADIATION SAFETY COMMITTEE

If a study requires radiation outside of the amount encountered within standard clinical care settings at WVU, the Radiation Safety Committee must review the study prior to final IRB approval (or reliance acknowledgement, for studies under external IRB review). This committee reviews any research that involves the use of X-rays, radioisotopes, lasers, etc. The committee provides expertise with regards to accepted radiation protection practices and regulations,and provides input on acceptable consent documentation language regarding risks involving radiation exposure in research.

5 INVESTIGATIONAL DRUG SERVICE (IDS)

If a study involves an investigational drug, the appropriate administrator within the WVU Investigational Pharmacy is notified and able to review the protocol. The appropriate IDS administrator communicates with the PI and/or the WVU OHRP/IRB if any changes are needed prior to use of an investigational drug for research purposes.

6 HIPAA PRIVACY REVIEW

If a study involves access to, use of, or sharing of an individual's protected health information for the conduct of research (e.g., medical chart reviews), a member of the HIPAA Privacy Board reviews and provides comments regarding the acceptability of HIPAA Authorizations, HIPAA Waivers of Authorization, HIPAA De-identification Forms, Limited Data Sets, etc., used within the course of research. WVU's HIPAA Privacy Board must ensure the research meets all federal and institutional requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prior to final IRB approval.

7 REFERENCES

Federal Regulations:
Health Insurance Portability and Accountability Act of 1996 (HIPAA)

AAHRPP:
Standard I-9

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP outlines the requirements for international research involving human participants when the research falls under the auspices of WVU IRB.

2 OVERVIEW

Approval of international research is permitted if "the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46." All policies and procedures applied to research conducted domestically should be applied to research conducted in other countries, as appropriate. The WVU IRB must receive and review the foreign institution or site's IRB review and approval of each project before the commencement of the research at the foreign institution or site. For federally funded research, approval of research for foreign institutions or sites "engaged" in research is only permitted if the foreign institution or site holds a Federalwide Assurance with OHRP and local IRB review and approval is obtained.

3 GENERAL INFORMATION

3.1 Approval of research for foreign institutions or sites "not engaged" in research is only permitted if one or more of the following circumstances exist:

- When the foreign institution or site has an established IRB/IEC, the researcher must obtain approval to conduct the research at the "not engaged" site from the site's IRB/IEC or provide documentation that the site's IRB/IEC has determined that approval is not necessary for the researcher to conduct the proposed research at the site.
- When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials permit the research to be conducted at the performance site.
- IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site's IRB/IEC determination, or letter of cooperation, as applicable.
- It is the responsibility of the WVU researcher and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.
- It is the responsibility of the WVU researcher and the foreign institution or site to confirm the qualifications of the researchers and research staff for conducting research in that country(ies).
- It is the responsibility of the WVU researcher and the foreign institution or site to ensure that the following activities will occur:

- Initial review, continuing review, and review of amendments
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to participants or others

The IRB will not rely on a local ethics committee that does not have the policies and procedures in place for the activities listed above.

- It is the responsibility of the WVU researcher and the foreign institution or site to notify the IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., previously "non-engaged" performance site begins consenting research participants, etc.).
- The WVU IRB will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted, including knowledge of local laws and cultural context.
- In the case where there is no local IRB review, the IRB may require an expert consultant, either from the local country where the research is conducted or from an international organization, with the expertise or knowledge required to adequately evaluate the research in light of local context.
- The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document, which must be provided by the researcher, with the credentials of the translator, detailed in the IRB application or amendment form. Verification of the back translation should be made available in the protocol files for IRB review. (See SOP 012: Informed Consent Requirements and SOP 016: Documentation of the Informed Consent Process.)

4 MONITORING OF APPROVED INTERNATIONAL RESEARCH

4.1 The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations.

4.2 When the IRB and local ethics committee will both be involved in the review of research, there is a plan for coordination and communication with the local ECs.

4.3 The IRB will require documentation of regular correspondence between the WVU researcher and the foreign institution or site and may require verification from sources other than the WVU researcher that there have been no substantial changes in the research since its last review.

5 REFERENCES

WVU Policies:
SOP 012: Informed Consent Requirements
SOP 016: Documentation of the Informed Consent Process

AAHRPP:
Standard I-3

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP outlines the requirements for emergency uses of investigational drugs or biologics, emergency uses of unapproved medical devices, and exceptions to the requirements for informed consent in emergency situations.

2 OVERVIEW

The emergency use provision in FDA regulations is an exemption from the requirements for prior review and approval of research by the IRB. The exemption, which must meet the specific conditions described in the regulations, allows for one emergency use of an investigational drug or biologic or unapproved medical device in a life-threatening situation for which no standard acceptable treatment is available and when there is not sufficient time to obtain IRB approval.

3 GENERAL INFORMATION

3.1 The emergency use of an investigational drug or biologic or unapproved medical device in research involving human subjects as defined by FDA regulations. All emergency uses are subject to the requirements of the WVU OHRP, except as described by this policy. *Note: The emergency use of a drug, biologic, or device does not meet the DHHS definition of research involving human subjects. For more information on activities that are defined by FDA and DHHS regulations as "research involving human subjects," please see SOP 011: Human Subject Research Determination.*

3.2 The use of a marketed drug, biologic, or medical device for an indication that is not listed in the FDA-approved product labeling (i.e., "off label" use) for an individual in a life-threatening situation does not constitute an emergency use as defined by FDA regulations and WVU OHRP policy. Regulations and university policy do not limit the authority of physicians to provide such emergency "medical care" to patients in life-threatening situations; however, physicians and other healthcare providers are responsible for complying with applicable state laws and institutional requirements regarding all uses of drugs, biologics, and medical devices.

3.3 FDA requirements for emergency uses of investigational drugs and biologics differ slightly from the requirements for emergency uses of unapproved medical devices, as described below. For more information on research involving investigational drugs and medical devices, please see SOP 022: Research Involving Investigational Drugs and SOP 023: Research Involving Investigational Devices.

4 CRITERIA FOR EMERGENCY USE

4.1 According to FDA regulations, the emergency use exemption may be used if **all** of the following conditions are met:

1. The use involves an investigational drug or biologic, unapproved medical device, or other "test article" as defined by FDA
    a. A test article is any drug, biologic, or medical device for human use, or human food additive, color additive, electronic product, or any other article subject to FDA regulations
2. The individual for whom the test article is intended is in a life-threatening situation
    a. To meet the criteria for life-threatening a condition does not have to be immediately life-threatening or immediately resulting in death
    b. Life-threatening also includes "severely debilitating"
    c. Severely debilitating does not include "pre-existing" (e.g., chronic) diseases or conditions with major morbidity
3. No standard acceptable treatment is available
    a. Also, the individual for whom the test article is intended does not meet the enrollment criteria for an existing IRB-approved study or an approved study does not exist
4. There is not sufficient time to obtain IRB approval
    a. An intervention is needed before review at a convened meeting of the IRB is feasible.

5 PRIOR NOTIFICATION OF EMERGENCY USE

5.1 The IRB Chair (or physician designee) of the appropriate IRB, will be notified of a physician/researcher's intent to use an investigational drug or biologic or unapproved medical device for emergency use. Notification may be made in person, electronically, or in writing. Researchers will provide the following information to allow the IRB Chair (or physician designee) to determine that FDA requirements for emergency use are met:

- Explanation of life-threatening situation necessitating the emergency use
- Description of standard treatment(s) previously used and/or why available options are not acceptable
- Investigational drug or biologic or unapproved medical device to be used
- If available, IND or IDE number of the drug, biologic, or device. Note: It is important to distinguish between emergency use INDs or IDEs and other types of expanded

access that do require IRB review and approval (e.g., expanded access, compassionate use, humanitarian use devices, etc.)

5.2 An IRB Chair's acknowledgement of the emergency use does not constitute an IRB approval of the clinical investigation. The researcher's notification is used by the IRB and the WVU OHRP to confirm that the proposed use meets FDA requirements and to assist the researcher with filing the required report within the five-day timeframe required by FDA regulations.

5.3 If the IRB Chair (or physician designee) determines there is adequate time to schedule an IRB sub-committee for the prospective IRB concurrence of the emergency use of an investigational drug, biologic, or unapproved medical device, a meeting is scheduled as soon as possible so that the emergency use is not unnecessarily delayed. *Note: In this instance, the physician/researcher is still required (per the Reporting Requirements section below) to notify the IRB in the form of a written report within five working days after the emergency use of the investigational drug, biologic, or unapproved medical device.*

5.4 If the IRB Chair (or physician designee) determines there is not adequate time to schedule an IRB sub-committee for the prospective IRB concurrence of the emergency use of an investigational drug, biologic, or unapproved medical device, the IRB Chair (or physician designee) acknowledges the emergency use based on FDA's definition of criteria for emergency use (see Section 5), and the required report (see Reporting Requirements section) will be forwarded to the next available convened meeting for review and concurrence of the IRB Chair's (or physician designee's) acknowledgement of the emergency use.

5.5 Emergency uses of investigational drugs and biologics and unapproved medical devices in all WVU affiliate healthcare sites under purview of the WVU IRB must also comply with applicable policies (Investigational Drug Service [IDS] policies). The IDS will be notified (as applicable) of the intended emergency use of an investigational drug or biologic to arrange for the product's shipment and proper storage, dispensing, and accountability.

6 INFORMED CONSENT REQUIREMENTS

6.1 Physicians/researchers are required to obtain the informed consent of the patient/participant or the subject's legally authorized representative in an emergency use situation. Consent form templates containing the basic elements of informed consent are available on the WVU OHRP website. Alternatively, the product manufacturer or sponsor may provide a consent form for emergency use. All of the basic elements of informed consent should be provided, unless the situation meets the conditions for exception, as described below.

7 EXCEPTION TO THE REQUIREMENTS FOR INFORMED CONSENT

7.1 When informed consent cannot be obtained, both the physician/researcher and a physician who is not otherwise involved in the emergency use must confirm, in writing, that all of the following conditions apply:

- The subject is confronted by a life-threatening situation necessitating the use of the investigational drug or biologic or unapproved medical device.
- Informed consent cannot be obtained because of an inability to communicate with or obtain informed consent from the patient/participant.
- Time is not sufficient to obtain informed consent from the patient/participant's legally authorized representative.
- No alternative method of approved or "generally recognized therapy" is available that provides an equal or greater likelihood of saving the subject's life.

7.2 If time is not sufficient to obtain an independent physician's determination that the criteria for an exception to the requirements for informed consent (described above) are met, and in the physician/researcher's opinion the immediate use of the investigational product is required to preserve the subject's life, the physician/researcher must do both of the following:

- Verify in writing that the four conditions for an exception to the requirements for informed consent apply
- Obtain an independent review and evaluation of the physician/researcher's determination in writing within five working days by a physician who is not otherwise involved in the emergency use.

7.3 The IRB must be notified of the exception within five working days after the emergency use, as described below (see Reporting Requirements section).

8 IND REQUIREMENTS FOR EMERGENCY USES OF DRUGS AND BIOLOGICS

8.1 The emergency use of an investigational drug or biologic requires an IND. To obtain an emergency use IND, a physician/researcher should contact the product manufacturer or sponsor to determine if the investigational drug or biologic can be made available for the emergency use under the company's IND.

8.2 Alternatively, if the manufacturer/sponsor will not provide the investigational product under its IND, a physician/researcher may contact FDA directly to obtain authorization for the company to ship the drug or biologic for the specific emergency situation in advance of an IND submission. For more information, please see FDA Contacts for Obtaining an Emergency IND.

8.3 Some manufacturers or sponsors will agree to the emergency use of an investigational drug or biologic, but require an "IRB approval letter" before shipping the product. When necessary, following the IRB Chair's review and acknowledgement of the emergency use as described above in "Prior Notification of Emergency Use," WVU OHRP staff will provide the physician/researcher with documentation acknowledging that the IRB is aware of the intended emergency use and considers the use to meet FDA requirements.

9 ADDITIONAL REQUIREMENTS FOR EMERGENCY USES OF UNAPPROVED DEVICES

9.1 FDA approval prior to emergency use or shipment of an unapproved medical device is not required. The emergency use may involve a device that does not have an existing IDE, a device used in a way that is not approved under an existing IDE, or a physician who is not named as an investigator to the IDE. Whenever possible, authorization should be obtained from the sponsor (if an IDE exists for the device) before the emergency use.

9.2 In addition to determining that the criteria for emergency use are met, physicians/researchers are required by FDA to assess the potential for benefit from the use of an unapproved device and to have "substantial reason" to believe that benefits will occur. Whenever possible, an independent assessment of the circumstances prior to emergency use should also be obtained from a physician who is not otherwise involved in the emergency use.

9.3 If the device has an existing IDE and the physician/researcher could not obtain authorization from the sponsor prior to the emergency use, the physician/researcher is responsible for reporting to the sponsor within five working days. The emergency use of an unapproved device must be reported to FDA by the sponsor (if an IDE exists for the device) within five working days of the time the sponsor learns of the use. If no IDE exists, the physician/researcher is responsible for reporting the emergency use directly to FDA. The physician/researcher's follow-up report should contain the information described below.

10 REPORTING REQUIREMENTS

10.1 Physicians/researchers are responsible for notifying the IRB in writing within five working days after the emergency use of an investigational drug or biologic or unapproved medical device. Reports should be sent to the WVU OHRP with the following information:

- Investigational drug or biologic or unapproved medical device used
- IND number of the drug or biologic or IDE number (if one exists) of the device

- Date(s) of administration of the investigational product
- Explanation of the life-threatening situations necessitating the emergency use
- Demographic information of the patient/participant (e.g., age, gender, etc.) without personally identifiable information
- Outcome(s) of the emergency use
- An unsigned copy of the consent document that was used
    - Alternatively, if consent was not obtained, either of the following as described above ("Exception to the Requirements for Informed Consent"):
        - The physician/researcher's and independent physician's verification prior to the emergency use that the conditions were met for the exception to the requirements for informed consent
        - The physician/researcher's verification that the conditions for exception were met and independent physician's review and evaluation (within 5 working days of the emergency use) of the physician/researcher's determination.

10.2 WVU OHRP staff will schedule the review of emergency use reports on the next available convened IRB agenda (within 30 calendar days) to determine that the circumstances met FDA requirements. If the convened IRB determines that the use failed to meet regulatory requirements, the convened IRB will determine if noncompliance occurred as described in SOP 049: Noncompliance and Research Misconduct. Physicians/researchers will be notified by WVU OHRP staff of the outcome of the convened IRB's review and determinations within 14 calendar days of the review.

10.3 Physicians/researchers are also responsible for reporting the circumstances of the emergency use to the product manufacturer or sponsor of the investigational drug or biologic or unapproved medical device when the emergency use was performed under the manufacturer's/sponsor's IND or IDE. Otherwise, the emergency use is reported directly to the FDA. The follow-up report should contain the following information:

- Summary of the conditions constituting the emergency
- Acknowledgement by the IRB Chair or IRB sub-committee of prior notification of the emergency use
- Whether informed consent was obtained or the conditions were met for the exception to the requirements for informed consent
- Independent assessment by a physician not otherwise involved in the emergency use (when applicable)
- Outcome(s) of the emergency use
- Other information as required by the product manufacturer or sponsor.

10.4 Physicians/researchers and IRBs are responsible for reporting and review of any adverse events, unanticipated problems involving risks to subjects or others, or other events associated with the emergency use, as described by SOP 031: Research Related Event Reporting and SOP 034: Reporting to External Agencies.

10.5 Physicians/researchers who obtain an IND or IDE for the emergency use or subsequent use of the investigational drug or biologic or unapproved medical device are responsible for complying with FDA requirements for the use of investigational drugs and devices, including providing progress and/or final reports. See FDA's website for regulations on Investigational New Drug Application and Investigational Device Exemptions guidelines.

11 LIMITATIONS OF EMERGENCY USE

11.1 The emergency use exemption allows for a single use or single "course of treatment" (e.g., multiple doses of an antibiotic) of an investigational drug or biologic or unapproved medical device without prior IRB review. FDA regulations require that any subsequent use of the investigational product at the same institution receive IRB review and approval before the product is used again.

11.2 FDA guidance acknowledges that it would be inappropriate to deny emergency treatment to a second individual "if the only obstacle is that the IRB has not had sufficient time to convene a meeting" to review the request. Physicians/researchers are encouraged to evaluate the likelihood of a similar need occurring again, and if future use is likely, immediately initiate efforts to obtain IRB review and approval of a protocol to permit further use of the investigational drug, biologic, or device.

11.3 Emergency use of an investigational drug or biologic or unapproved medical device must be differentiated from "Planned Emergency Research" in life-threatening situations. Planned emergency research is research conducted in emergency settings with subjects who cannot provide informed consent because of their life-threatening medical conditions (e.g., comparisons of methods for treating acute ischemic strokes) and who do not have an available legally authorized representative. Unlike emergency uses, planned emergency research must be approved in advance by FDA (or DHHS) and the IRB and publicly disclosed to the community in which the research will be conducted. For more information about the requirements for planned emergency research, please see SOP 054: Planned Emergency Research.

12 REFERENCES

WVU Policies:
SOP 011: Human Subject Research Determination
SOP 022: Research Involving Investigational Drugs
SOP 023: Research Involving Investigational Devices
SOP 031: Research Related Event Reporting
SOP 034: Reporting to External Agencies
SOP 049: Noncompliance and Research Misconduct

Federal Regulations:
21 CFR 56.104
21 CFR 56.109 (c)
21 CFR 56.109 (e)

AAHRPP:
Element I.7.C
Element III.2.D

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

1 PURPOSE

This SOP outlines the additional protections required by federal regulations for planned emergency research when the requirements of informed consent are waived.

2 OVERVIEW

The IRB may approve an exception to the requirements for informed consent for research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent from research participants or their legally authorized representatives.

3 GENERAL INFORMATION

3.1 Persons with life-threatening conditions who cannot provide informed consent or refuse research participation are considered a vulnerable population. The lack of participant autonomy and inability of prospective participants to provide informed consent requires additional protections to be provided in the review, approval, and conduct of this research.

3.2 Previous and continuing IRB reviews are required for planned emergency research. The IRB must approve both the research and the exception to the requirements for informed consent (i.e., waiver) by finding and documenting that the regulatory criteria described below are met.

3.3 To approve a waiver of informed consent for research conducted in emergencies, a licensed physician who is a member (or consultant) of the IRB and who is not otherwise participating in the research must agree with the IRB's determination that the criteria for consent waiver are met. Documentation of the physician's concurrence is also required for approval; therefore, IRB meeting minutes should record the physician's vote when the planned emergency research is reviewed.

3.4 The requirements for planned emergency research subject to FDA regulations differ slightly from the requirements for research subject to DHHS regulations, as described below. For information on activities defined by FDA and DHHS regulations as "research involving human subjects," see SOP 011: Human Subject Research Determination. All planned emergency research at WVU must meet the requirements described below in "Exceptions to the Requirements for Informed Consent."

3.5 Planned emergency research conducted in life-threatening situations must be differentiated from the "emergency use" of an investigational drug or biologic or unapproved medical device. The emergency use provision in FDA regulations allows for a single use of an investigational drug or biologic or unapproved medical device for a human subject in a life-threatening situation for which no standard acceptable treatment is available and when there is insufficient time to obtain IRB approval. For more

information about the requirements for emergency uses, see SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices.

4 EXCEPTIONS TO THE REQUIREMENTS FOR INFORMED CONSENT

4.1 The IRB may approve emergency research without requiring that informed consent is obtained from participants or their legally authorized representatives only if the IRB finds and documents that each of the following requirements has been met:

1. The participants are in a life-threatening situation
    a. Intervention is required before consent from legally authorized representatives is feasible
2. Available treatments are unproven or unsatisfactory
    a. The relative risks and benefits of the proposed intervention are unknown or thought to be equivalent (or better) compared to standard therapy
3. The collection of valid scientific evidence (including evidence from randomized, placebo-controlled studies) is necessary to determine the safety and efficacy of the intervention
4. Obtaining informed consent is not feasible because of all of the following:
    a. The participants will not be able to give their informed consent as a result of their medical condition(s)
    b. The intervention under investigation must be administered before obtaining consent from the participants' legally authorized representatives is feasible
    c. There is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the research
5. Participation in the research presents the prospect of direct benefit to the subjects because of all of the following:
    a. Participants are facing a life-threatening situation that necessitates intervention
    b. Appropriate animal and other preclinical research has been conducted, and the information derived from the research (and related evidence) supports the potential for the intervention to provide a direct benefit to the participants
    c. Risks associated with the research are reasonable to known information about the medical condition of the potential class of participants, the risks

and benefits of standard therapy, and the known information about the risks and benefits of the proposed intervention or activity

6. The research could not be practicably carried out without the IRB approval of a waiver of informed consent
    a. Recruitment of participants providing informed consent could bias the science, the science is less rigorous as a result of restricting the research to subjects who can provide consent, or the research would be unreasonably delayed by restricting it to consenting subjects
7. The protocol defines the length of the potential therapeutic window based on scientific evidence, and the researcher has committed to attempting to contact a legally authorized representative for each participant within that window of time and, if feasible, to asking the legally authorized representative for consent rather than proceeding without consent
    a. Researchers will summarize efforts made to contact legally authorized representatives and provide this information to the IRB at the time of continuing review
8. The IRB has reviewed and approved an informed consent process and consent document meeting all the requirements described in regulations and policies outlined in SOP 012: Informed Consent Requirements and SOP 016: Documentation of Informed Consent Process.
    a. The approved informed consent procedures and consent document are to be used with participants or their legally authorized representatives when feasible
    b. The IRB has approved procedures and information to be used when providing an opportunity for a family member to object to the participant's participation (as described below)
9. Additional protections of the rights and welfare of participants will be provided, including at least:
    a. Consultation (including consultation carried out by the IRB, where appropriate) with representatives of the communities in which the research will be conducted and from which the participants will be drawn
        i. Examples: holding a public meeting in the community from which participants will be recruited to discuss the research, conducting a telephone poll, establishing a separate panel of community members, including community consultants to the IRB, and adding unaffiliated members to the IRB who are representative of the community
        ii. The IRB will consider community input when reviewing the research

b. Before initiation of the research, public disclosure of plans for the research and its risks and expected benefits to the communities in which the research will be conducted and from which the participants will be recruited

c. Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population and its results

d. Establishment of an independent data monitoring committee to provide oversight of the research

e. If obtaining informed consent is not feasible (and a legally authorized representative is not reasonably available), the researcher has committed to attempting to contact within the therapeutic window the participant's family member who is not a legally authorized representative, if feasible, and asking whether they object to the subject's participation in the research

   i. Only one family member must be consulted and agree (or object) to the subject's participation in the research

   ii. If more than one family member is present and family members disagree, the family members must work out the disagreement to enroll the potential participant

   iii. Researchers will summarize efforts made to contact family members and provide this information to the IRB at the time of continuing review

Note: If a participant is enrolled in the study with waived consent and the participant dies before a legally authorized representative, or family member can be contacted, information about the study (as described below) is to be provided to the participant's legally authorized representative or family member, if feasible.

4.2 The IRB will approve procedures to inform the participant, the participant's legally authorized representative (if the participant remains incapacitated), or a family member (if the legally authorized representative is not reasonably available) of the following at the earliest feasible opportunity:

- That the participant was included in the research
- Details of the research and other information contained in the informed consent document
- The subject's participation may be discontinued at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Note: If it is a legally authorized representative or family member that is told about the research and the participant's condition improves, the participant is also to be informed as soon as feasible.

5 RESEARCH SUBJECT TO FDA REGULATIONS

For planned emergency research subject to FDA regulations, other specific requirements also apply, as described below.

5.1 The IRB will confirm and document that a separate IND or IDE is obtained for the use of the investigational drug, biologic, or device to be studied in the research that identifies the protocol as one that may include participants who are unable to consent. *Note: A separate IND or IDE is required even if an IND for the same drug or an IDE for the same devices as the one to be studied already exists.*

5.2 If the IRB cannot approve the research either because the criteria described above are not met, or because of relevant ethical concerns, documentation of the IRB's findings will be provided in writing to the researcher and sponsor within 14 calendar days.

- The sponsor must promptly disclose this information to FDA and to researchers who have been asked to participate in the research or a "substantially equivalent clinical investigation" and to other IRBs that have been or are asked to review this or a substantially equivalent investigation by that sponsor.

6 RESEARCH SUBJECT TO DHHS REGULATIONS

6.1 The IRB may approve research subject to DHHS regulations involving an "emergency research consent waiver" under **either** of the following two conditions:

- The IRB finds and documents all of the following:
    - The research is subject to FDA regulations
    - The research will be performed under a separate IND or IDE (see "Research Subject to FDA Regulations" above)
    - The FDA requirements for exception from informed consent for emergency research have been met (see "Exception to the Requirements for Informed Consent" above)
- The IRB finds, documents, and reports to OHRP all of the following:
    - The research is not subject to FDA regulations
    - The DHHS requirements for waiver of informed consent for emergency research have been met (see "Exception to the Requirements for Informed Consent" above).

6.2 Because of the regulatory limitations relating to research involving prisoners, fetuses, pregnant women, and human in vitro fertilization, a waiver of informed consent cannot be approved for emergency research involving these populations. *Note: these limitations do not apply to research subject only to FDA regulations.*

7 REFERENCES

WVU Policies:
SOP 011: Human Subject Research Determination
SOP 012: Informed Consent Requirements
SOP 016: Documentation of Informed Consent Process
SOP 053: Emergency Use of Investigational Drugs, Biologics, or Devices

Federal Regulations:
21 CFR 50.24
21 CFR 50.25
21 CFR 50.27
45 CFR 46.116
45 CFR 46.117

AAHRPP:
Element II.4.C

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP

Electronic Informed Consent (eIC)/HIPAA Authorizations			
Document	**Version #**	**Effective Date**	**Page**
SOP 055	1.0	01-21-2022	Page 1 of 7

1 PURPOSE

This SOP describes the policy for protocol submissions requesting to use electronic systems to obtain informed consent and electronic HIPAA Authorizations (when applicable).

2 SCOPE

- Research conducted under the auspices of West Virginia University.
- Research protocols for which WVU **IS** the IRB of Record.
- Federally funded and non-federally funded research.
- Research protocols requiring Informed Consent from prospective participants (Full Board and Expedited)
- Electronic Informed Consent completed in person or remote (where the consenting researcher and the prospective participant are not in the same location)
- Research protocols requiring a signed HIPAA Authorization from prospective participants.

The scope does not include:

- The electronic processes and materials used for the recruitment of prospective participants.
- Research protocols for which WVU **IS NOT** the IRB of Record.

3 RESPONSIBILITY

The PI is responsible for:

- Ensuring compliance with SOP 012: Informed Consent Requirements
- Ensuring that approved software and transmission methods are used for electronic delivery of consent materials and surveys.
- Determining if electronic Informed Consent (eIC) or electronic delivery of surveys is appropriate for the targeted population.
- Ensuring that prospective participants can use the electronic systems and providing paper-based consent if required.
- Submitting the required materials for paper-based, in-person, and remote informed consent to the IRB for review and approval.
- Designing the consent process to include adequate time for the prospective participant/legally authorized representative review of consent materials before asking for a signature.
- More than Minimal Risk (MMR) Research - Verifying the identity of the person who will sign the consent form and obtaining the signature of the authorized person on the research team who consented the participant.

4 OVERVIEW

Participant Considerations:

1. The participants should be informed of approximately how long the process will take and what information will be presented to them to ensure that the eIC is presented appropriately and that participants will have enough time to dedicate to the eIC process.
2. Electronic materials should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage participants to access all consent materials before documenting their consent.
3. Electronic informed consent may either supplement or replace paper-based informed consent processes to best address the participant's needs throughout the study. For example, some participants may prefer one method over another. Other participants may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. In such cases, the eIC process may not be appropriate for these participants. Therefore, participants should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.
4. Paper-based consent must be hand delivered or sent to the participant/legally authorized representative (LAR) using postal mail. Emailing the materials is not permitted.
5. In some circumstances, it may be appropriate for PIs or research personnel to assist participants in using the eIC technology. For example, research personnel may help the participant/LAR navigate the consent by clicking on links for the participant.

Remote/Onsite

1. The PI cannot delegate authority to the electronic system to obtain informed consent to the electronic system to complete the informed consent process. Whether part or all of the eIC process takes place onsite or remotely, the responsibility for obtaining informed consent remains with the PI and the research personnel, to which responsibility has been appropriately delegated.
2. The consent process may occur at the study site when both the PI and participant are at the same location, or it may occur remotely (e.g., at the participant's home or another convenient venue) where the participant reviews the consent document in the participant's home absence of the PI. The eIC materials may be provided for both onsite and remote access.
3. If the entire process takes place at the study site, the study personnel can personally verify the participant's identification, review the eIC content, answer questions about the material, have follow-up discussions, and witness the signing of the eIC.
4. FDA: If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the participant who will be participating in the research study or is the participant's LAR (see 21 CFR 11.100(b)). Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods.

5. Whether the eIC is obtained from the participant onsite or remotely, the eIC process must provide sufficient opportunity for the participant to consider whether to participate (see 45 CFR 46.116 and 21 CFR 50.20). The PI should have methods in place to ensure that the eIC process allows participants the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with study personnel or through a combination of telephone calls or video conferencing with a remotely located PI or study personnel.

Ensuring Participant Understanding

1. When telephone calls and video conferencing are used during the eIC process, PIs and research personnel should remind participants to conduct the eIC discussion in a private location to help ensure privacy and confidentiality.
2. To assist the participant in understanding the material, the eIC may use interactive electronic-based technology, including diagrams, images, graphics, videos, and narration. The eIC should be appropriate for the intended audience, considering the participant's age, language, and comprehension level. The eIC may contain various methods to help a PI assess the participant's understanding of the information presented during the eIC process. For example, the eIC may include optional questions at any time during the eIC discussion that can be used to help educate the participant about the information presented, as well as assess the participant's understanding of the informed consent materials. Such optional questions and other methods may be used to gauge participant comprehension of key study elements and highlight areas where the participant might need further explanation and discussion before signing the informed consent to enter the study.
3. WVU maintains an approved list of technology for interacting with participants/LARs. Use of personal devices is not permitted, and texting messaging and chat are not approved unless the capability is available within the approved technology.

Electronic Signatures

1. The procedure for eIC may include an electronic method to capture the signature of the participant or the participant's LAR. Federal OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required. Federal OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.
2. WVU General Counsel has approved the electronic signature capability for the approved electronic consent systems.

Verification of Identity

1. Compliance with the requirements in Part 11 is meant in part to prevent fraudulent use. Therefore, the regulations found at 21 CFR part 11 require that an organization verify an individual's identity before it establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature or any element of such electronic signature (see 21 CFR 11.100(b)). FDA regulations do not specify any particular method for verifying an individual's identity and accepts many different methods. For example, verifying someone's identity can be done by using information from some

form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, the use of security questions to confirm an individual's identity can also be considered.

2. Only the approved electronic systems may be used for eIC at WVU. The approved system includes the capability for security questions for the participant to answer and enter before accessing the informed consent form.

Assent

1. The eIC process can be used to obtain assent from pediatric participants (when required) and parental permission from their parent(s) or guardian. The general requirements for informed consent, found in 45 CFR 46.116 and 46.117 and 21 CFR 50.20, 50.25, and 50.27, (see also SOP 016: Documentation of the Informed Consent Process) apply to parental permission, in addition to the requirements for permission by parents or guardians and for assent by children found at 45 CFR 46.408 and 21 CFR 50.55.13 (see also SOP 015: Assent and Parental Permission). Therefore, parental permission may be obtained and documented using the same eIC procedures as would be used for informed consent.

2. When approving an eIC assent process, an IRB should consider whether the capability of a child to assent may be affected by the method used to obtain and/or document child assent. For example, if assent would otherwise be required, the method used to obtain eIC assent should not impede the child's capability to provide assent. The language and presentation of information must be understandable to the child. In addition, when the IRB determines that assent is required, it must also determine whether and how assent must be documented (see 45 CFR 46.408(e) and 21 CFR 50.55(g)). (See SOP 015: Assent and Parental Permission.)

3. Depending on the method of identity verification used to satisfy the regulations in 21 CFR part 11 for electronic signatures in FDA-regulated clinical investigations, a child may lack the documentation necessary to verify their identity to prevent fraudulent use of electronic signatures (e.g., driver's license) (see Q7). Depending on the clinical investigation, it may be reasonable for the parent to initially document the child's assent, which can then be verified when the PI first sees the child.

Providing a Copy of the Consent Document

1. HHS and FDA regulations require that the person signing the informed consent (i.e., the participant or the participant's LAR or the parents or guardians of participants who are children) be given a copy of the written informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)) unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)). Although FDA regulations do not require that the participant's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the participant. The copy provided to

the participant can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained, and information should be accessible until study completion. Note that if the eIC uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in any printed paper copy, if one is provided.

2. The approved electronic consent systems at WVU provide the capability for the participant to receive a copy of the consent form electronically. Depending on the system used, the copy will be a participant downloaded PDF copy of the consent form and a separate downloaded PDF of the electronic signature (participant/LAR only) or a securely emailed copy of the consent form and signatures (participant/LAR and consenting researcher) in one PDF file.
3. When using eIC onsite (participant/LAR and researcher are in the same location), consideration should be given to how the copy will be provided. If the system requires a download and an institutional device is used, the PI should make arrangements for paper copies to be provided after eConsent is completed.

Safeguarding Participant Information

1. For FDA-regulated clinical research, the electronic system that supports the eIC must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure the participant's identity, participation, and personal information are secure and protected after informed consent has been obtained.
2. If the entity holding the participant's personal information is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law No. 104-191)15 or acting as a business associate of a HIPAA-covered entity, the requirements in the HIPAA Privacy, Security, and Breach Notification Rules apply (see 45 CFR parts 160 and 164). For example, the participant's information within an electronic system must be encrypted unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable and appropriate equivalent measure.
3. The electronic systems in use for informed consent are HIPAA compliant, and one system is compliant with FDA access requirements and HIPAA requirements.
4. WVU requires participants/LARs to agree to the use of email for the transmission of the consent information from within the approved systems.

Transmission of eConsent Materials

1. The transmission of all eConsent materials must occur using the approved systems. The PDF of the approved Informed Consent document is uploaded into a WVU IRB approved eTemplate and transmitted to the participant/LAR or the contents of the document can be entered into the electronic system as text. Approval to waive the watermark from the WVU IRB is required.
2. WVU does not permit consent information to be transmitted using employee or personal email accounts. Transmission may only occur from within the approved systems.

Electronic HIPAA Authorizations

1. HIPAA authorizations may be obtained electronically, provided that the participant's signature (or the participant's personal representative) is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (ESign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a participant (or a participant's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.
2. WVU General Counsel has approved the electronic signature capability for the approved electronic consent systems.
3. WVU provides the capability to send HIPAA Authorizations as standalone document or within an Informed Consent Document

Protocol Submission

1. The PI should submit copies and links of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the participant will receive and view during the eIC process with the protocol application.
2. The PI must obtain IRB approval for any subsequent modifications to the information, whether electronic or in hard copy.
3. It is recommended that the PI discuss plans for using unapproved products and methods for eIC with WVU OHRP before finalizing development of the eIC to ensure that the IRB agrees that such a format may be used for the applicable research for obtaining informed consent.
4. eIC Worksheets are required to provide the IRB with adequate information regarding the proposed eConsent process.

5 REFERENCES

WVU Policies:

SOP 012: Informed Consent
WV CTSI COE SOP #110-00 Informed Consent Process
WVU #1.11.3.3 Sensitive Data Policy
WVU #1.11.3.6 HIPAA Hybrid Entity Designation Policy
Informed Consent Form Templates (Word)
REDCap eTemplates (REDCap Library)
Qualtrics eTemplates

Federal Regulations:
21 CFR Part 11
45 CFR 46.116, 46.117
45 CFR Part 160, Part 164 (subparts A and C) – Electronic HIPAA Authorizations
21 CFR 50.25
HIPAA Security Rule
E-Sign Act (Public Law 106-229) – Electronic HIPAA Authorizations
UETA – Electronic HIPAA Authorizations

AAHRPP:
Element II.3.F
Element II.3.G

History of Revisions to SOP

Effective Date	Nature of Revision(s)
1/21/2022	New SOP