IRB Authority, Membership and Responsibilities			
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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 and one Emergency IRB sub-committee to facilitate timely approval of applicable protocols. (See SOP 057 Emergency Use/Expanded Access.)
- 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.
- 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 through professional experience, expertise, and diversity, including considering race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes to ensure respect for its advice and counsel in safeguarding human subjects' rights and welfare.
- 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 appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members.
- 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 Technology Transfer 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:

Standard II-1, Elements II.1.A, B, C, D, & E