1 PURPOSE

This SOP defines WVU-affiliated and non-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 REFERENCES

WVU Policies:

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