West Virginia University (WVU) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for or participating in, research conducted by or under the auspices of WVU. In the review and conduct of research, actions by WVU will be guided by the principles (i.e., respect for persons, beneficence, and justice) outlined in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report). The actions of WVU will also conform to all applicable federal, state, and local laws and regulations. To fulfill this policy, WVU has established a Human Research Protections Program (HRPP) within the Office of Human Research Protections (OHRP).

### 1.1 Mission Statement

The mission of the WVU HRPP is to:

1. To safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;
2. To provide timely and high-quality education, review, and monitoring of human research projects; and
3. To facilitate excellence in human subjects research.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate, and continually improve the protection of human research participants.
- Dedicate resources sufficient to do so.
- Exercise oversight of research protection.
- Educate investigators and research staff about their ethical responsibility to protect research participants.
- When appropriate, intervene in research and respond directly to concerns of research participants and research personnel.

### 1.2 Institutional Authority

The WVU Human Research Protection Program operates under the authority of the Organization policy "Human Research Protection Program" adopted on August 17, 2010. The policy letter states that the operating procedures in this document "serve as the governing procedures for the conduct and review of all human research conducted under the auspices of the OHRP." The HRPP Policy and these operating procedures are made available to all WVU investigators and research staff and are posted on the OHRP website (http://ohrp.research.wvu.edu).

### 1.3 Regulatory Compliance

The OHRPP is responsible for ensuring compliance with federal regulations, state law, and institutional policies. All human subjects' research at WVU is conducted following the policy and regulations found in the Common Rule and 21 CFR 50 and 56. Where federal agencies have additional requirements, see the
following guidance documents found on the FDA website:

- DOD
- DEd
- DNRC
- DoJ
- EPA

The actions of WVU will also conform to all other applicable federal, state, and local laws and regulations.

WVU voluntarily applies the International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Guidelines (sometimes referred to as "ICH-GCP" or "E6") to certain types of human subjects research conducted under its HRPP. In general, WVU applies the ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. When a sponsor requires institutional ICH-GCP compliance, the IRB will conduct a review following ICH-GCP requirements. See the document *International Conference on Harmonization (ICH) Good Clinical Practices (GCP), Applicability to Human Subjects Research* for guidance on the applicability of the ICH-GCP requirements.

### 1.4 Federalwide Assurance (FWA)

The HRPP operates under the authority of its current Federalwide Assurance (FWA-A00005078) and has designated two IRBs (registered as 00000314 and 00002568) to review all human research protocols. In its FWA, HRPP has opted to limit the application of the FWA to research funded by DHHS or federal agencies that have adopted the Common Rule. WVU operates a third IRB for emergency purposes (FWA 00012546).

### 1.6 Written Policies and Procedures

The WVU *Human Research Protections Policy and the HRPP Standard Operating Procedure (SOP)* detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the WVU IRBs. The SOPs are not static documents. The policies and procedures are annually reviewed and revised by the Director of the Office of Human Research Protections Program (OHRP), the Institutional Review Board, and WVU Research Corporation (R.C.) General Counsel, or as need dictates. The Vice President for Research will approve all revisions of the policies and procedures.

The Director of the OHRP will keep the WVU research community apprised of new information that may affect the Office of Human Research Protections, including laws, regulations, policies, procedures, and emerging ethical and scientific issues via its websites and through campus electronic mailing lists. The policies and procedures will be available on the WVU IRB website, and electronic copies will be available upon request.

### 1.7 HRPP Organization

The HRPP is a comprehensive system to ensure the protection of human subjects' participating in
research. It consists of various individuals and committees such as the Institutional Official, the Director of the OHRP, the IRB, other committees or subcommittees addressing human subject's protection, investigators, IRB staff, research staff, health and safety staff (i.e., Biosafety Officer, Radiation Safety Officer) and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

The following officials, administrative units, and individuals have primary responsibilities for implementing the HRPP.

1.7.1 Institutional Official

The ultimate responsibility for the WVU HRPP resides with the WVU Vice President for Research (VPR), who serves as the Institutional Official (IO) of the program. The I.O. is responsible for ensuring the WVU HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects' research. The I.O. is legally authorized to represent OHRP. They are the signatory of the FWA and assume the obligations of the FWA. The I.O. also holds the ultimate responsibility for:

1. Oversight of the Institutional Review Boards (IRB), including the appointment and delegation of authority to the IRB Chairs and members.
2. Oversight of the conduct of research conducted by all WVU investigators
3. Assuring the IRB members are appropriately knowledgeable to review research following ethical standards and applicable regulations
4. Ensuring that all investigators are adequately knowledgeable to conduct research in accordance with ethical standards and applicable regulations
5. The development and implementation of an educational plan for IRB members, staff, and investigators

1.7.2 Director of the Office of Human Research Protections (OHRP)

The Director of the OHRP (Director) is selected by and reports to the Institutional Official (IO) and is responsible for:

1. Developing, managing, and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. Responsibilities include monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program.
2. Advising the VPR (I.O.) on key matters regarding research at the University.
   - Implementing the institutions' HRPP policy.
   - Submitting, implementing, and maintaining an approved FWA through the VPR and the Department of Health and Human Services Office of Human Research Protection (OHRP).
3. Managing the finances of the WVU HRPP.
4. Assisting investigator in their efforts to carry out WVU’s research mission.

5. Developing and implementing needed improvements, and ensuring follow-up of actions, as appropriate, to manage risk in the research program.

6. Developing training requirements as required, and as appropriate, for investigators, subcommittee members, and research staff. The Director will also ensure that training is completed on a timely basis.

7. Serving as the primary contact at WVU Medicine for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.

8. Day-to-day responsibility for the operation of the OHRP, including supervision of the HRPP staff.

9. Responding to faculty, student, and staff questions.

10. Working closely with the Chairs of the IRBs on the development of policy and procedures, as well as organizing and documenting the review process.

1.7.3 Institutional Review Board (IRB)

WVU HRPP operates three IRBs, appointed by the Institutional Official (IO). The IRBs prospectively review and make decisions concerning all human research conducted at WVU facilities, by its employees or agents, or under its auspices. The IRB is responsible for the protection of the rights and welfare of human research subjects at WVU. It discharges this duty by complying with the requirements of the Common Rule, state regulations; the FWA; and institutional policies. (See Section 2 for a detailed discussion of the IRB)
1.7.4 General Counsel's Office

The WVU HRPP relies on the WVU General Counsel and the WVU Research Corporation General Counsel for the interpretations and applications of West Virginia law and the laws of any other jurisdiction where research is conducted as they apply to human subject research. When there are any conflicts between federal, state, or local law and other applicable laws, the General Counsel will determine the appropriate resolution. General Counsel will also advise the IRB about other legal issues such as who is a child, and who can serve as a legally authorized representative or guardian.

1.7.5 Department Chairs

Department Chairs, in general, are responsible for ensuring that the Principal Investigator (PI) is qualified by training and experience to conduct the proposed research. Also, department chairs are responsible for ensuring that the P.I. has sufficient resources and facilities to conduct the proposed research. For each protocol submitted to the WVU IRB for approval, the department chair must certify that s/he accepts responsibility for assuring adherence to the federal and state regulations and institutional policies governing the protection of human subjects of research, including applicable institutional credentialing requirements.

Department chairs are required to review all protocols before they are submitted to the IRB for review. The signature of the Department Chair indicates that the study is found to be scientifically sound and can be expected to answer the proposed question reasonably.

Department chairs are responsible for assuring that investigators have the resources required to conduct the research in a way that will protect the right and welfare of participants. Such resources include, but are not necessarily limited to, personnel, space, equipment, and time.

1.7.6 Principal Investigator

The principal investigator is the ultimate protector of the human subjects who participate in research. The investigator is expected to abide by the highest ethical standards and for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research following the approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. All subjects must give informed consent as required, and the investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility.

In addition to complying with all the policies and standards of the governing regulatory bodies, the investigator must comply with institutional and administrative requirements for conducting research. The investigator is responsible for ensuring that all research staff completes appropriate training and must obtain all required approvals before initiating research. When investigational drugs or devices are used, the investigator is responsible for providing written procedures for their storage, security, dispensing, and disposal.
1.7.7 Other Related Units

1.7.7.1 WVU Office of Sponsored Programs

Sponsored Programs staff members review all research agreements with federal, foundation, or non-profit sponsors. This institutional review ensures that all terms of the award comply with institutional policies. Only designated senior individuals within Sponsored Programs Administration has the authority to approve research proposals and to execute research agreements on behalf of the institution. As a further control, internal documents retained by Sponsored Programs as part of the application process for extramural funding include verification from the IRB whether a Data Safety Monitoring Plan (DSMP) is in place and the timelines associated with that DSMP will be given to the OSP. When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of WVU, a subcontract is executed between WVU and the collaborating institution. The subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval by submission of an executed Form 310 (as applicable). The collaborating institution must also ensure that key personnel involved in human subjects' research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of the education of key personnel to WVU.

1.7.7.2 WVU Pharmacy - board

A pharmacist from the WVU Department of Pharmaceuticals Services and/or the WVU School of Pharmacy serves on each of WVU's IRBs, allowing the Pharmacy to have complete information about all IRB approved research that takes place at WVU, WVU Medicine and under its jurisdiction. The Pharmacist member assures that information about all studies involving drugs used in research is shared with the Pharmacy Staff as appropriate and that the WVU Medicine Pharmacy and Therapeutics Committee is made aware of IRB research involving drugs.

The WVU Medicine Pharmacy typically does engage in the ordering/providing, dispensing, or compounding of drugs for human studies, according to a study-specific and patient-specific medication order developed by the Pharmacy in collaboration with the Researcher. The manufacturing/compounding of drug products not commercially available is coordinated by the WVU Medicine Pharmacy with outside Pharmacy vendors. Insofar as inpatient drug studies and/or those outpatient drug studies that have subjects who become inpatients at WVUH, the Pharmacy coordinates the use of the study drug while the subject is an inpatient, and all such inpatient study drugs must be provided through the Pharmacy.

The Pharmacy is available to provide guidance to investigators in relation to the management of the study drugs.

1.7.8 Relationship between Components

The IRBs function independently of, but in coordination with, other institutional regulatory committees. The IRBs, however, make their independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRBs have review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to

Page 6
regulation by any federal department or agency that has adopted the human subjects regulations.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve human research that has not been approved by the IRB.

1.8 HRPP Operations

In addition to the leadership structure described above, other support staff members for the HRPP include four staff members.

1.8.1 WVU Office of Human Research Protections (OHRP)

The WVU HRPP reports to the Director of the WVU OHRP who has day-to-day responsibilities for its operations.

Additionally, the office is staffed by a Senior Program Coordinator, Senior Administrative Assistant, three Administrative Associates, and a Continuous Improvement Manager. The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis.

1.8.1.1 Senior Program Coordinator (SPC) and Senior Administrative Assistant (SAA)

The Senior Program Coordinator (SPC) and Senior Administrative Assistant (SAA) are responsible for all aspects of the IRB throughout the review process of a research proposal involving human subjects. This responsibility includes the initial review of documents and screening of research protocols before its review by the IRB, as well as serving as the liaison between the investigators and the IRB. The SPC and SAA review the IRB minutes for accuracy and ensures proper documentation of discussions, including controverted issues and actions taken by the IRB during its convened meetings.

1.8.1.2 Administrative Assistants/Associates (AA)

The Administrative Assistants/Associates (AA) are responsible for providing administrative and clerical support to the IRB Chair and SPC and SAA as well as scheduling and coordinating all IRB functions. The IRB AAs are also responsible for IRB record retention. The AAs are responsible for maintaining complete IRB files, records of all research protocols, IRB correspondence (including e-mails).

1.8.2 Selection, Supervision, and Evaluation of Staff

The Director selects all HRPP staff who support the IRB and OHRP under WVU Human Resources policies and procedures. Depending on the position to be filled, qualifications to be considered in the selection of HRPP staff include prior experience in IRB administration or another position within an HRPP (e.g., study coordinator), or at the assistant or clerical levels, a desire to learn and be an active participant in the regulatory, ethical, and procedural aspects that support an HRPP. HRPP staff are supervised by the OHRP Director and evaluated on an annual basis, according to WVU Human Resources policies and procedures.
1.9 HRPP Resources

The OHRP is located in offices at 886 Chestnut Ridge Road and is equipped with all the necessary office, meeting, storage space, and equipment to perform the functions required by the HRPP. The adequacy of personnel and non-personnel resources of the HRPP program is assessed on an annual basis by the Director with the HRPP staff and are reviewed and approved by the I.O.

The WVU Institutional Official provides resources to the IRB and OHRP, including adequate meeting and office space, and staff for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources provided for the IRB and OHRP, including resources for the HRPP education program, legal counsel, conflict of interest, the quality improvement plan, and community outreach, will be reviewed during the annual budget review process.

COVID-19 – As of March 2020, the WVU OHRP operates remotely. Adequate resources have been provided to continue seamless remote operation. Staff and IRB Members conduct the required HRPP activities using the internet and institutional standards for secure meetings, file storage, and communication.

1.10 Conduct of Quality Assurance (Quality Improvement) Activities

The objective of the WVU HRPP's Quality Assurance (Quality Improvement) Plan is to measure and improve human research protection effectiveness, quality, and compliance with organizational policies and procedures, as well as applicable federal, state, and local laws. The Quality Assurance (Quality Improvement) Plan will be managed and implemented by an individual in a compliance role.

1.10.1 Investigator Audits and Compliance Reviews

Directed ("for cause") audits and periodic (not "for cause") compliance reviews will be conducted to assess investigator compliance with federal, state, and local law, and institutional policies, and to identify areas for improvement, and suggest recommendations based on existing policies and procedures. Directed audits of IRB-approved research studies are in response to identified concerns. Periodic compliance reviews are conducted using a systematic method to review IRB-approved research regularly. The results will be reported to the Director and all IRB members. Activities of auditors during directed audits and periodic compliance reviews may include:

- Requesting progress reports from researchers.
- Examining investigator-held research records.
- Contacting research subjects.
- Observing research sites where research involving human subjects and/or informed consent processes are being conducted.
- Auditing advertisements and other recruiting materials as deemed appropriate by the IRB.
- Reviewing projects to verify from sources, other than the Researcher, that no unapproved changes have occurred since the previous review.
• Reviewing conflict of interest concerns to assure the consent documents include the appropriate information and disclosures.
• Reviewing HIPAA authorizations.
• Conducting other monitoring or auditing activities, as deemed appropriate by the IRBs.

Annually, the Director defines at least one targeted measure of compliance within the HRPP. This document is used to define and measure compliance with these annual goals. To evaluate whether the defined goals are being achieved, the compliance officer collects and records compliance data stemming from the activities listed above each quarter. The data is then logged into the Goal Tracking Form for tracking purposes. At the end of each fiscal year, the Director evaluates whether the respective goals were achieved and adjusts the affected processes to correct any deficiencies.

1.10.2 Reporting and Disposition

The results of all quality assurance activities are reported to the Director and the IRB Members. Any non-compliance will be addressed according to the procedures in Section 10 of the Standard Operating Procedures.

If an audit or review finds that subjects in a research project have been exposed to unexpected serious harm, the reviewer will promptly report such findings to the Director and the IRB Chairs for immediate action.

1.10.3 Internal Compliance Reviews

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 IRB Auditor 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 the IRB minutes to assure that quorum was met and maintained.
• Assess the 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 assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures.
• Review the IRB database to ensure all fields are completed accurately.
• Verification of IRB approvals for collaborating institutions or external performance sites.
• Review the appropriate metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process.
• Review the workload of IRB staff to evaluate appropriate staffing level.
• Other monitoring or auditing activities deemed appropriate by the IRB.

The Director or designated staff will review the results of internal compliance reviews with the IRB Chairs and the Institutional Official. 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 implementing the corrective action plan, the results of which will be evaluated by the Institutional Official.

1.10.4 Quality Improvement

All quality assurance reports, both research-related and HRPP-related, will be reviewed by the Director and the Institutional Official in order to determine if systemic changes are required in the HRPP to prevent re-occurrence. If so, a corrective action plan will be developed, implemented and evaluated by the Director and Institutional Official (IO).

1.11 Collaborative Research Projects

In the conduct of cooperative research projects, WVU acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. When a cooperative agreement exists, WVU may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. A formal relationship must be established between WVU and the other institution through either a Cooperative Agreement or a Memorandum of Understanding. This relationship must be formalized before WVU will accept any human research protocols from the other institution or rely on the review of the other institution.

It is the policy of WVU to assure that all facilities participating in a human subjects study receive adequate documentation about the study in order to protect the interests of study participants. Before a study can begin, it must be acknowledged by the IRBs of record for each participating facility and, where appropriate, the IRB of record for the coordinating facility.

For collaborative research, the P.I. must identify all institutions participating in the research, the responsible IRB(s), and the procedures for dissemination of protocol information (IRB initial and continuing approvals, relevant reports of unanticipated problems, protocol modifications, and interim reports) between all participating institutions.

When WVU relies on another IRB, the Director of OHRP will review the policies and procedures of the IRB to ensure that they meet WVU standards. If the other IRB is part of an accredited organization,
then it will be assumed that the WVU standards are being met.

When WVU reviews research conducted at another institution, the particular characteristics of each institution’s local research context must be considered, either:

i. Through knowledge of its local research context by a WVU IRB; or

ii. Through subsequent review by appropriate designated institutional officials, such as a Chairperson and/or other IRB members.

If WVU is the coordinating facility, the Principal Investigator must document how human subject protection information will be communicated to the other participating facilities engaged in the research study. The investigator is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures.

The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IRB of record and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the coordinating facility and at the participating facilities (e.g. V.A. Research and Development Committee approval) prior to enrollment of participants.

The P.I. must follow these procedures when WVU is the coordinating facility:

1. The investigator submits the following information in their IRB application materials:
   a. Whether research activities at participating institutions are defined as engagement.
   b. Name of each participating facility.
   c. Confirmation that each participating facility has an FWA (including the FWA number).
   d. Contact name and information for the lead investigator at each participating facility.
   e. Contact name and information for the IRB of record at each participating facility.
   f. Method for assuring all participating facilities have the most current version of the protocol.
   g. Method for confirming that all amendments and modifications in the protocol have been communicated to participating sites.
   h. Method for communicating with participating facilities and serious adverse events and unanticipated problems involving risks to subjects or others.
   i. Method of communicating regularly with participating sites about study events.

2. The investigator submits approval letters from the IRB of record for all participating sites.

3. The investigator maintains documentation of all correspondence between participating sites and their IRB of record.
UPDATE HISTORY

December 2017  S. Stutler Miscellaneous Updates
August  2020  Organizational Name Change, Minor Updates