WVU has established two on-site Institutional Review Boards (IRB) to ensure the protection of human subjects in human subjects research, conducted under the auspices of WVU. All non-exempt human subjects research conducted under the auspices of WVU must be reviewed and approved by a WVU IRB before the initiation of the research. In 2020, WVU created an Emergency IRB to facilitate timely review of protocols in emergencies.

All on-site WVU IRBs follow the same policies and procedures. Therefore, for this document, on-site IRBs will be referred to as the WVU IRB.

WVU has agreements in place with central IRBs and enters into IRB Authorization Agreements using written forms as well as single IRB platforms. When WVU is not the IRB of Record, this is referred to as using an external IRB. Procedures are found in Section 3.16.

The following describe the authority, role, and procedures of the on-site IRB.

### 2.1 IRB Authority

The IRB derives its authority from the WVU policy. Under Federal Regulations, the IRBs 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.

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 research if the WVU IRB has not approved it. 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 changes or modifications.

### 2.2 Number of IRBs

There are currently three on-site IRBs. The IO, the Director, and the Chairs of the IRBs will review the activity of the two IRBs on at least an annual basis, and make a determination as to the appropriate number of IRBs that are needed for the institution.
2.3 Roles and Responsibilities

2.3.1 Chair of the IRB

The WVU Institutional Official (IO), in consultation with the Director of OHRP, appoints a Chair and Vice-Chair of each IRB to serve for renewable three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

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. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chairs. The IRBs must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the HRPP.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions, e.g., the Vice-Chair and Director of the OHRP.

The IRB Chair advises the Institutional Official and the Director of the OHRP about IRB member performance and competence.

The performance of the IRB Chair will be reviewed on an annual basis by the Director of the OHRP, in consultation with the Institutional Official. Feedback from this evaluation will be provided to the Chair. If the Chair is not acting in accordance with the IRB's mission, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she may be removed.

2.3.2 Vice-Chair of the IRB

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

2.3.3 Subcommittees of the IRB

The IRB Chair, in consultation with the Director, may designate one or more IRB subcommittees to conduct investigations, review and interpret regulations to develop guides and operating procedures, etc. The IRB Chair, in consultation as needed with the Director, will appoint IRB members to serve on each IRB Subcommittee created under this Section. The number and composition of the IRB Subcommittee members shall depend on the authority delegated by the IRB Chair to such IRB Subcommittee (e.g., merely making recommendations versus decision-making authority).

Members of the IRB Subcommittee must be experienced in terms of seniority on the IRB and must be matched as closely as possible with their field of expertise to the study assigned to the IRB Subcommittee.

If the IRB Chair creates one or more IRB Subcommittees, he/she shall also indicate whether it is a standing or ad hoc IRB Subcommittee.
2.4 IRB Membership

IRB 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 amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at WVU. WVU has procedures (See Section 3) that specifically outline the requirements of protocol review by individuals with appropriate scientific or scholarly expertise.

Also, the IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in research conducted under the auspices of WVU.

No one from the WVU Office of Sponsored Programs or Office of Technology Transfer shall 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.

VA Research and Development administration officials, including, but not limited to, the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, are prohibited from serving as voting members of these boards.

The IRB must promote respect for its advice, counsel in safeguarding the rights and welfare of human subjects, and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

2.5 Composition of the IRB

1. The IRB will have at least five members with varying backgrounds to promote the complete and adequate review of research activities commonly conducted by WVU.

2. The IRB will be sufficiently qualified through the experience, expertise, and diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

3. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB ill therefore include persons knowledgeable in these areas.

4. If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, handicapped, or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in, working with these subjects. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about and experienced in working with these participants, either as a member of the IRB or as consultants (see Section 2.9).

5. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of
men or entirely of women, including the institutions consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.

6. The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

7. The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

8. The IRB includes at least one member who represents the general perspective of participants.

9. One member may satisfy more than one membership category.

10. The Director and administrators of the OHRP may be voting members of the IRB. On an annual basis, the IRB Chairs and the Director shall review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements. Required changes in IRB membership will be report to the OHRP.

2.6 Appointment of Members to the IRB

The IRB Chair, Vice-Chair, and/or the Director of the OHRP, identifies a need for a new, replacement, or alternate member. The IRB may nominate candidates and send the names of the nominees to the OHRP. Department Chairs and others may forward nominations to the Institutional Official, or the OHRP, or an IRB Chair.

The final decision in selecting a new member is made by the Institutional Official, in consultation with the IRB Chair and the Director of the OHRP.

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

On an annual basis, the IRB Chair and the Director of the OHRP review the membership and composition of the IR to determine if they continue to meet regulatory and institutional requirements.

2.7 Alternate Members

In general, the members of each IRB act as alternates for the other IRB. However, when there is a need for unique expertise, the appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.
2.8 IRB Member Conflict of Interest

No regular, alternate or ex officio member may participate in the review (initial, continuing, or modification at a convened meeting or by expedited review) of any research project in which the member has a conflict of interest (COI), including the review of unanticipated problems, allegations of non-compliance, except to provide information as requested. It is the responsibility of each IRB voting and non-voting member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and vote by leaving the room.

The Director of the OHRP will keep the WVU research community apprised of new information that may affect the Office of Research Integrity and Compliance, 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.

All voting, alternate, and ex officio members of the IRB complete a "WVU Conflict of Interest Research Disclosure Form" when first appointed and annually after that. If a member responds affirmatively to the existence of a potential conflict, the COIR Officer is notified. Institutional Conflict of Interest policies can be found on the WVU research compliance website.

Committee members may find themselves in any of the following conflicts of interest when reviewing research:

1. Where the member or consultant is involved in the design, conduct, and reporting of the research.
2. Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research.
3. Where the member holds significant financial interest related to the research being reviewed.
4. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

The IRB Chair will poll IRB members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds them that they should recuse themselves by leaving the room during the discussion and vote on the specific protocol. IRB members with a conflicting interest are excluded from being counted towards quorum. All recusals by members with COI are recorded in the minutes.

If the Conflict of Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or Director of WVU OHRP.

2.9 Use of Consultants

When necessary, the IRB Chair, designee, or Director of the OHRP may solicit individuals from the institution or community with competence in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. The need for an outside reviewer is determined in advance of the meeting by the IRB Chair, designee, or Director by reviewing the protocols scheduled to be reviewed at the convened meeting. The
OHRP will ensure that all relevant materials are provided to the outside reviewer before the convened meeting.

Written statements of consultants will be kept in IRB records. Essential information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the protocol.

The Director of the OHRP reviews the conflict of interest policy for IRB members (Section 2.8) with consultants; consultants must then verbally confirm to the Director of the OHRP that they do not have a conflict of interest before review. Individuals who have conflicting interests, or have spouses or family members with a conflicting interest in the sponsor of the research, will not be invited to provide consultation.

The consultant's findings will be presented to the full board for consideration, either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

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).

### 2.10 Duties of IRB Members

The agenda, submission materials, protocols, proposed informed consent forms, and other appropriate documents are distributed electronically to members before the convened meetings at which the research is scheduled to be discussed. Members review the materials at least one week before each meeting to participate fully in the review of each proposed project. IRB members will treat the research proposals, protocols, and supporting data confidentially.

### 2.11 Attendance Requirements

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, Vice-Chair, or an OHRP staff member. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the Director.

If an IRB member is to be absent for an extended period, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate, the alternate can serve during the primary member's absence, provided the IRB has been notified in advance.

### 2.12 Training and Ongoing Education of Chair and IRB Members

A vital component of a comprehensive Office of Research Integrity and Compliance is an education program for IRB Chair and the IRB members. WVU is committed to providing training and an on-going
educational process for IRB members and the staff of the OHRP related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

2.12.1 Orientation

New IRB members, including alternate members, will meet with the Director of the OHRP for an informal orientation session. New members will meet with the Senior Program Coordinator to become acquainted with the electronic review system. The IRB member will be given guidance on how to review protocols in the electronic system. Members will be directed where to find reference materials, such as:

- Belmont Report
- WVU Policies and Procedures for the Protection of Human Subjects
- Federal Regulations relevant to the IRB
- Reviewer guidance materials

New members are required to complete the Initial Education requirement for IRB members before they may serve as Primary Reviewer.

2.12.2 Initial Education

IRB members will complete the required modules in the CITI course in the Protection of Human Research Subjects.

2.12.3 Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB is consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB.

In addition to initial training requirements, IRB members and staff must also satisfy continuing education requirements on an annual basis. OHRP uses the following activities as a means for offering continuing education to IRB members and staff:

- In-service training at IRB meetings;
- Training workshops;
- Copies of appropriate publications, via hard copy or electronically;
- Identification and dissemination, by the Director, of new information that might have affected the Office of Research Integrity and Compliance, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;
- Unlimited access to the OHRP resource library

IRB members and staff are also required to complete CITI training every three years as part of WVU’s continuing education requirements.

Members and staff who are unable to attend education sessions will be provided with the opportunity to make up any training that 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.

The activities for continuing education vary yearly depending on the operating budget and areas of need, as determined by the 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 non-compliance will result in the individual not being renewed as an IRB member.

The Institutional Official (IO) will provide support to send as many members of the IRB as possible to attend the annual PRIM&R/ARENA conference or regional OHRP conferences on human research protections.

The HRPP Professional Staff is required to complete the entire CITI Course in the Protection of Human Research Subjects. Staff will be expected to attend OHRP training or some other resource at least annually. For members of the IRB staff who do not satisfy continuing education requirements, this will be evaluated as part of the individual's annual performance review.

2.13 Liability Coverage for IRB Members

The Organization's insurance coverage applies to employees and any other person authorized to act on behalf of the Organizations or acts of omissions within the scope of their employment or authorized activity.

2.14 Review of IRB Member Performance

The IRB Member's performance will be reviewed on an annual basis by the Director and IRB Chairs. IRB Members will received formal feedback on the results of this review. Members who are not acting per the IRB's mission or policies and procedures, or who have an undue number of absences, may be removed.

2.15 Reporting and Investigating Allegations of Undue Influence

If an IRB Chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the Institutional Official (IO), depending on the circumstances. The IO will appoint a team to conduct a thorough investigation. If the claim is substantiated, corrective action will be taken to prevent additional occurrences.