4.1 Exempt Determination

To obtain an exemption determination, PIs must submit the following:

1. A completed Exemption application in the electronic system;
2. All recruitment materials (e.g., Cover Letter, recruitment script, flyer)
3. The materials used to obtain consent including electronic consent materials (provide a paper copy with the electronic materials, full description of the consent process (including remote consent. Refer to the eIC SOP and guidance on the WVU OHRP website.
4. All surveys, questionnaires, and data collection instruments
5. Letter(s) of Permission from each non-Organization site of performance
6. Verification of current human research protection training for all members of the research team, including the faculty advisor

The IRB Chair (or designee) reviews all requests for exemptions and determines whether the request meets the criteria for exempt research. The IRB Chair may designate an IRB member or qualified administrator to review requests for exemptions submitted to the IRB. The Chair selects designees who are qualified to review the submission based on their expertise of the protocol content and knowledge of regulations about research. If there is not a designated reviewer to consider requests for exemptions, the IRB Chair reviews the requests. Individuals involved in determining the exempt status of a proposed research project cannot be involved in the proposed research. Reviewers do not have any apparent conflict of interest.

To document the IRB reviewer’s determination of the request for exempt research, he/she acknowledges the Exemption. The IRB reviewer verifies on the application whether the submission meets the definition for “research.” If the request meets the definitions of both human subjects and research, the reviewer indicates whether the request for Exemption was granted or denied, and if granted, the rationale for the determination and category under which it was permitted.

PIs will be given feedback via the electronic system as to the qualification of the application for exempt status. Once the institutional review is completed, IRB staff will send an electronic acknowledgment to the PI of the results of the review.

Exempt studies are communicated to the IRB at the next convened meeting after approval of the Exemption.

All requests for an exemption must include a termination date. Exempt protocols must be reviewed every five years (New Common Rule) If the research extends beyond that date, then the researcher has to request another exemption or a renewal. The acknowledgment letter must include the specific categories justifying the Exemption.

4.1.1 Additional Protections in Exempt Research

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual make the determination of Exemption will
determine whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report.

If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose information, such as:

- Communicate that the activity involves research
- A description of the procedures
- State that participation is voluntary
- The name and contact information for the research

### 4.2 Expedited Review Procedures

Under an expedited review procedure, the review may be completed by the IRB Chair or by one or more IRB members designated by the Chair. IRB members who serve as designees to the IRB Chair for expedited review will be matched as closely as possible with their field of expertise to the project.

On an annual basis, the Chair will designate a list of IRB members eligible to conduct an expedited review. The designees should be experienced (having served on the IRB for at least one year) voting members of the IRB. The IRB Staff will select expedited reviewers from that list. Selected reviewers will have the qualifications, experience, and knowledge in the content of the protocol to be reviewed, as well as be knowledgeable of the requirements to approve research under expedited review. IRB members with a conflict of interest in the research will not be selected.

When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), should receive and review all documentation that would normally be submitted for a full-board review, including the complete protocol, a continuing review form summarizing the research since the previous review (including modifications and unanticipated problems), notes from the pre-screening conducted by the OHRP staff, and the current consent documentation.

The reviewer(s) conducting initial or continuing review complete the appropriate Reviewer Feedback Forms (RFFs) checklists to determine whether the research meets the criteria allowing review using the expedited procedure and if so, whether the research meets the regulatory criteria for approval. If the research does not meet the criteria for expedited review, then the reviewer will indicate that the research requires full review by the IRB and the protocol will be placed on the next agenda of the initial reviewer.

In reviewing the research, the reviewers will follow the Review Procedures in Section 3 and may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by the convened board.

Reviewers will indicate approval, required modifications or requirements for convened board review in the Online Review tab of the electronic system, and return to the OHRP. If modifications are required, the OHRP staff will inform the PI.
4.3 Convened IRB Meetings

Except when an expedited review procedure is used, the IRB will conduct initial and continuing reviews of all non-exempt research at convened meetings at which a quorum (see below) of the members present.

All members have laptop computers to access materials; handouts and projections contain the criteria for approval. Members can also teleconference and attend the meeting when they are not able to physically be at the meeting. The assigned IRB Administrator assigned keeps track of all proceedings and ensures that all required findings and questions are addressed. Meetings can be recorded as a tool to assist in the preparation of the written minutes. If meetings are recorded, the recording will be deleted within 72 hours of the meeting.

4.3.1 IRB Meeting Schedule

The IRB meets regularly throughout the year (usually once per month.) The schedule for the IRB may vary due to holidays or lack of quorum. The schedule for IRB meetings may be found on the WVU OHRP website for the benefit of all PIs, research coordinators, and other research staff when submitting protocol materials.

4.3.1.1 Special Meetings

Under exceptional circumstances, as determined by the Chair, a special meeting may be convened.

4.3.2 Preliminary Review

The IRB Administrators will perform a preliminary review of all protocol materials submitted to the WVU OHRP for determination of completeness and accuracy, including informed consent materials. Only complete submissions will be included on the IRB agenda.

The electronic system will inform the PI of missing materials and the deadline for receiving materials. In the case of a PI who is submitting a protocol for the first time or a PI who may not be well-versed in the protocol submission procedures, individualized IRB consultations can be scheduled by contacting WVU OHRP or submitting a request on the WVU OHRP website.

Specific questions about the IRB policies and procedures, determination of whether a particular protocol is human research or not and what particular forms are required for a particular project can be submitted to WVU OHRP by calling the phone number listed on the website or submitting a question using the form on the website.

4.3.3 Primary and Secondary Reviewers

When the IRB Administrator determines that the protocol submission is complete, the protocol is assigned according to the scientific discipline of the protocol, the potential reviewer’s area of expertise, and representation for vulnerable populations involved in the research. One reviewer will be assigned to each
protocol, and a reviewer may be assigned several protocols or other research items for review. Reviewers are assigned to all protocols requiring initial review, continuing review, and modifications. For protocols that may be outside of the knowledge base or representative capacity of IRB members, an outside consultant will be used. If the expertise required to review a protocol is not available in time for the intended meeting, the protocol will be added to the next available meeting when the appropriate expertise is available.

The primary and secondary reviewers are responsible for the following:

1. Having a thorough knowledge of all of the details of the proposed research.
2. Performing an in-depth review of the proposed research.
3. Leading the discussion of the proposed research at the convened meeting, presenting both the positive and negative aspects of the research.
4. Making suggestions for changes to the proposed research, where applicable.
5. Completing all applicable IRB reviewer forms.

If both the primary and secondary reviewers are absent from the meeting, a new reviewer may be assigned, providing the new reviewer has reviewed the materials before the meeting. Additionally, an absent reviewer can submit their written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting, who can serve as the primary reviewer.

NOTE: All of the IRB members receive and are expected to review all studies, not just the ones they are responsible for reviewing.

At least one primary reviewer must have accessible:

1. Any relevant grant applications
2. The sponsor’s protocol (if applicable)
3. The PI’s brochure (if applicable)
4. The DHHS-approved sample informed consent document (if applicable)
5. The complete DHHS-approved protocol (if applicable)

IRB members have access to materials provided to the primary and secondary reviewers. If an IRB member requires additional information to complete the review, they may contact the PI directly or the OHRP to request the need information from the PI. Protocol reviewers will use the WVU Reviewer Feedback Form as a guide to complete reviews.