6.1 Meeting Preparation

All required materials need to be submitted (in full) 5 business days before the convened meeting for inclusion on the next agenda. The meeting agenda will be prepared by the WVU OHRP staff and distributed to the IRB members before the meeting. The materials include: the agenda, previous month’s meeting minutes, applicable business items and audits, continuing education materials, and protocol review materials electronically no later than five business days before the scheduled meeting to allow sufficient time for the review process.

6.1.1 Materials Received by the IRB Members

Each IRB member receives and reviews the following documentation, as applicable, for all protocols on the agenda:

1. Complete protocol application
2. Proposed consent, parental permission, and/or assent form(s)
3. Recruitment materials and subject information
4. Data collection instruments (including all surveys and questionnaires)

6.2 Quorum

A quorum consists of a simple majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. At least one of the LAJVAMC VA members of the Board must be present during the review of VA research.

A quorum must be established and maintained for the deliberation and vote on all matters requiring a vote. The IRB Chair, with the assistance of the WVU OHRP staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair, with the assistance of the WVU OHRP staff, will be responsible for ensuring that the meeting remains appropriately convened. If a quorum is not maintained (including the loss of required members such as the non-scientific member), votes cannot be taken until the quorum is restored, even if half of the members are still present. If a quorum is not maintained, the pending action item must be deferred, or the meeting terminated. The WVU OHRP staff will document the time of arrival and departure for all IRB members and notify the IRB Chair if a quorum is not present.

It is generally expected that at least one unaffiliated member and at least one member who represents the general perspective of participants (the same individual can serve in both capacities) will be present at all IRB meetings. Although the IRB may, on occasion, meet without this representation, individuals serving in this capacity must be present for at least 80% of the IRB meetings.

IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means (e.g., teleconferencing or video conferencing) that permits them to listen to and speak during IRB deliberations and voting. When
not physically present, the IRB member must have received all pertinent materials before the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, voicemail, text messaging, facsimile, or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

### 6.3 Meeting Procedures

The IRB Chair, or Vice-Chair if the IRB Chair is absent, will call the meeting to order, once it has been determined that a quorum is in place. The Chair or Vice-Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room when there is a conflict. The IRB will review and discuss the minutes from the previous meeting and determine if there are any revisions/corrections to be made. If there are no changes to be made, the Minutes will be accepted as presented and considered final.

If it is determined that revisions/corrections are necessary, the Minutes will be amended and presented at the following IRB meeting.

The IRB reviews all submissions for initial and continuing review, as well as requests for modifications. The Primary and Secondary Reviewer present an overview of the research and lead the IRB through the completion of the regulatory criteria for approval in the Reviewer Feedback Form checklists. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest (see below). For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

It is the responsibility of the assigned WVU OHRP staff member to record the proceedings of the session. WVU OHRP staff are responsible for taking Minutes at each IRB meeting.

### 6.4 Guests

The Principal Investigator may be invited to the IRB meeting to answer questions about their proposed or ongoing research. The Principal Investigator may not be present for the discussion or vote on their research.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and/or the Director. Guests may not speak unless requested by the IRB. Guests must sign a confidentiality agreement.