The West Virginia University OHRP will prepare and maintain adequate documentation of the IRB’s activities. All records must be accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities.

### 8.1 IRB Records

The IRB records include, but are not limited to:

1. Written operating procedures.
2. IRB membership rosters.
3. Training records for researchers, staff, and IRB members.
   - IRB Administrators have access to an external database that maintains accurate records of the completed human participant research training(s). Electronic copies of the documents are accessible by the IRB Administrators.
4. IRB correspondence letters.
5. IRB project files.
6. Documentation of Emergency Exemption from Prospective IRB Approval. (21 CFR 56.104(c))
7. Documentation of Exceptions from Informed Consent Requirements for Emergency Use of a Test Article. (21 CFR 50.23)
8. Documentation of exemptions.
9. Documentation of convened IRB meeting minutes.
10. Documentation of review by an external, when appropriate.
13. Protocol violations were submitted to the IRB.
14. Quality Improvement Program (QIP) reviews.

### 8.2 IRB Project Files

Information will be maintained for each research application (protocol) submitted for review in the electronic system. Each protocol will be assigned a unique identification number by the electronic system for tracking purposes. The information maintained for each protocol includes, but is not limited to:

1. Protocol and all other documents submitted as part of a new protocol application (i.e. sponsor documents, PI brochure, sample consent, and forms).
2. Protocol and all other documents submitted as part of a request for continuing
review/termination of research application. This also includes progress reports, statements of significant new findings provided to participants, reports of injuries to patients.

3. Documents submitted and reviewed after the project has been approved, including reports of modifications to research/amendments and adverse event reports.

4. Copy of IRB-approved consent form

5. IRB reviewer forms (when expedited review procedures are used) and scientific reviewer forms (where applicable).

6. Documentation of type of IRB review.

7. For expedited review, documentation of any determinations required by the regulations and protocol-specific findings supporting those determinations, including waiver or alteration of the consent process, research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children.

8. Documentation of all IRB review actions.

9. Notification of expiration of IRB approval to the PI, and instructions for submitting relevant continuing review materials.

10. Notification of suspension of research.

11. Correspondence about appeals.

12. Copies of approval letters and forms that describe what Principle PI must have before beginning the project.

13. IRB correspondence to and from research PIs.

14. All other IRB correspondence related to the research.

15. For devices, a report of prior investigations.

16. Reports of unanticipated problems involving risk to participants or others and adverse events.

Documentation of audits, investigations, and reports of external site visits

8.3 The IRB Minutes

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date or within three weeks of the meeting date, whichever comes first. Once approved by the members at a subsequent IRB meeting, the minutes must not be altered by anyone, including a higher institutional authority.

A copy of IRB-approved minutes for each IRB meeting will be distributed to the IO and, for VA research, the R&D Committee. Minutes of IRB meetings must contain sufficient detail to show:

1. Attendance
   a. Names of members present.
b. Names of members or alternate members who are participating through videoconference or teleconference and documentation that those attending using these methods received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

c. Names of alternates attending in place of specified absent member(s).
   i. Alternates may substitute for specific absent members only as designated on the official IRB membership roster

d. Name of consultant(s) present.

e. Name of PI(s) present.

f. Name of guest(s) present.

NOTE: The initial attendance list shall include those members present at the beginning of the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote number, on each action, will reflect the number of members present for the vote on that item. Members who recuse themselves because of conflict of interest are listed by name.

2. The presence of quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.

3. Business items discussed.


5. Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB.

6. Votes on these actions (Total Number Voting; Number voting for; Number voting against; Number abstaining; Number of those excused, Number of those recused)

7. Basis or justification for these actions, including required changes in research.

8. Summary of controverted issues and their resolution.

9. The approval period for initial and continuing approved protocols, including identification of research that warrants review more often than annually and the basis for that determination.

10. The risk level of initial and continuing review protocols approved at the meeting.

11. Review and Board determination of reports, e.g., unanticipated problems or safety reports; report of violation/deviations; serious or continuing non-compliance; suspensions/terminations, etc.

12. Review of Data and Safety Monitoring Board (DSMB) summary (if applicable).


14. Justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

15. Protocol-specific documentation that the research meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or
all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent.

16. Protocol-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived.

17. When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the Minutes will document the IRB’s justifications and findings regarding the determinations stated in the Subparts of the IRB’s agreement with the protocol-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived.

18. Justification is provided by the PI on IRB forms, as applicable.

19. Special protections warranted for other groups of participants who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons, or economically or educationally disadvantaged persons, regardless of the source of support for the research.

20. The rationale for significant risk/non-significant risk device determinations.


22. Identification of any research for which there is a need for verification from sources other than the PI that no material changes are made in the research.

23. A list of research protocols approved since the last meeting utilizing exempt and expedited review procedures. This list includes the full board protocols that received designated member approval via expedited subcommittee. A list of research protocols that expired or was closed administratively since the last meeting will also be provided to the board. Acknowledgment of these lists will be documented in the minutes.

24. An indication that, when an IRB member has a conflicting interest (see Section 2.8) with the research under review, the IRB member was not present during the voting on the protocol, and that quorum was maintained.

25. Key information provided by consultants will be documented in the minutes or a report provided by the consultant.

### 8.4 IRB Membership Roster

A membership list of IRB members must be maintained; it must identify members sufficiently to describe each member’s chief anticipated contributions to IRB deliberations. The list should contain the following information about members:

1. Name
2. Earned Degrees
3. Affiliated or non-affiliated status (neither the member nor an immediate family member of the member may be affiliated with the Organization)
4. Status as a scientist (physician-scientist, other scientist, non-scientist, or social, behavioral scientist). For purposes of this roster, IRB members with research experience are designated
as scientists. Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students being trained in research fields will be designated as scientists.

5. Indications of experience, such as board certifications or licenses sufficient to describe each member’s chief anticipated contributions to IRB deliberations.

6. Representative capacities of each IRB member: which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations locally involved in the research.

7. Role on the IRB (Chair, Vice-Chair, etc.)

8. Voting status (voting members and non-voting members)

9. For alternate members, the primary member or scientist status for whom the member could substitute

The OHRP must keep the IRB membership list current. The Director of the OHRP must promptly report changes in IRB membership to the Office for Human Research Protections, Department of Health and Human Services.

8.5 Access to IRB Records

The IRB has policies and procedures to protect the confidentiality of research information:

1. IRB records are kept in a protected electronic system. Doors to the OHRP are closed and locked when the rooms are unattended.

2. Ordinarily, access to all IRB records is limited to the Director, IRB Chair, IRB members, IRB Administrator, IRB staff, authorized institutional officials, and officials of Federal and state regulatory agencies (OHRP, FDA). Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining the security of IRB records. All other access to IRB records is limited to those who have a justified need, as determined by the IO and WVU OHRP Director.

3. Records are accessible for inspection and copying by authorized representatives of Federal regulatory agencies.

4. Records may not be removed from the OHRP; however, the IRB staff will provide copies of records for authorized personnel, if requested.

5. All other access to IRB project files is prohibited.

8.6 Record Retention

IRB records (as described in Section 8) are retained for at least three (3) years after completion of the research. All other records are retained for at least five (5) years.
Non-protocol records are stored in a secure electronic system and can only be accessed by the Office of Research Integrity and Compliance staff. Records will be backed up and stored off-site, according to security and storage policies of West Virginia University Information Technology Office.