4 Documentation and Records

CMU shall 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 at reasonable times and in a reasonable manner.

4.1 IRB Records

IRB records include but are not limited to:

1. Written operating procedures.
2. IRB membership rosters [See Section 4.5].
3. Training records. The IRB Administrator maintains accurate records listing research investigators, IRB members, and IRB staff who have fulfilled the facility's human subject training requirements. Electronic copies of documentation are maintained in the official IRB records located in the IRB Office.
4. IRB correspondence (other than protocol related).
5. IRB Study Files
6. Documentation of exemptions].
7. Documentation of convened IRB meetings minutes [See Section 4. 4 for information included in the minutes].
8. Documentation of review by another institution's IRB when appropriate.
9. Documentation of cooperative review agreements, e.g. Memoranda of Understanding (MOUs).
10. Federal Wide Assurances.
11. Protocol violations submitted to the IRB.
12. Quality assurance reviews.

Documentation for off-site IRBs include:

1. On-line access to all applicable protocol documents.
2. MOU/Agreements of IRB Services.
3. Workflow/SOPs.
4. Notes/documents pertaining to administrative reviews.

4.2 IRB Study Files

The IRB will maintain a separate IRB study file for each research application (protocol) that it receives for review. Protocols will be assigned a unique identification number by the IRB document management system and entered into the IRB tracking system.

Accurate records are maintained of all communications to and from the IRB. Copies are filed in the PI's project file. The CMU IRB maintains a separate file for each research protocol that includes, but is not limited to:

1. Protocol and all other documents submitted as part of a new protocol application.
2. Investigator brochure, if any.
3. Scientific evaluations when provided by an entity other than the IRB.
4. All other documents submitted as part of an application for continuing review/termination of research application.
5. Documents submitted and reviewed after the study has been approved, including reports of modifications to research/amendments and Adverse Event reports.
6. Copy of IRB-approved Consent Form.
7. DHHS-approved sample consent form document and protocol, when they exist.
8. IRB reviewer forms.
9. Documentation of type of IRB review.
10. 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.
11. Documentation of all IRB review actions.
12. Notification of expiration of IRB approval to the PI, and instructions for submitting relevant continuing review materials.
13. Notification of suspension or termination of research.
14. Correspondence pertaining to appeals.
15. Copies of approval letters and forms that describe what the PI must do before beginning the study.
16. IRB correspondence with research investigators and IRB correspondence relevant to the research
17. For devices, a report of prior investigations.
18. Reports of unanticipated problems involving risk to subjects or others and adverse events.
19. Documentation of audits, investigations, reports of external site visits.

4.3 Documentation of Expedited Reviews

IRB records for initial and continuing review by the expedited procedure must include the specific permissible category; that the activity described by the investigator satisfies all of the criteria for approval under expedited review; the approval period and any determinations required by the regulations including protocol-specific findings supporting those determinations.

Additionally, records must include:

1. The rationale for conducting continuing review of research that otherwise would not require continuing review.
2. The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk.

4.4 IRB Minutes

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. Once accepted 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 made available to the IO.

Minutes of IRB meetings must contain sufficient detail to show:

1. Attendance
2. Names of members present.
3. Names of members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions.
4. Names of alternates attending in place of specified (named) absent members. (Alternates may substitute for specific absent members only as designated on the official IRB membership roster.)
   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 on each action will reflect those members present for the vote on that item. Members who recuse themselves because of conflict of interest are listed by name and their reasons are documented.
5. Names of consultants, investigators, and guests present.
6. Announcements made by the Chair regarding member conflict oif interest and confidentiality of discussion at meetings.
7. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.
8. Business items discussed.
9. Continuing education.
10. Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB.
11. Votes on these actions (total number voting, number voting for, number voting against, number abstaining; number of those excused, number of those recused).
12. Basis or justification for these actions including required changes in research.
13. Summary of controverted issues discussed and their resolution.
14. 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.
15. Risk level of initial and continuing approved protocols.
16. Review of interim reports, e.g. unanticipated problems or safety reports, amendments, report of violation/deviations, serious or continuing non-compliance, suspensions/terminations, etc.

17. Review of Plans for Data and Safety Monitoring and Review of Data Safety Monitoring Board (DSMB) summary if applicable.
18. Justification for deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
19. 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 the required elements of informed consent or when waiving the requirement to obtain an informed consent.
20. Protocol-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived.
21. 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 or the IRB's agreement with the findings and justifications as presented by the investigator on IRB forms.
22. Special protections warranted for other groups of subjects who are likely to be vulnerable to coercion or undue influence, such as cognitively impaired persons or economically or educationally disadvantaged persons, regardless of source of support for the research.
23. The rationale for significant risk/non-significant risk device determinations.
24. Determinations of conflict of interest.
25. Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research.
26. A list of research approved since the last meeting utilizing expedited review procedures.
27. 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 deliberations or voting on the proposal and that the quorum was maintained.
28. Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

4.5 IRB Membership Roster

A current 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 must contain the following information about members:

1. Name.
2. Earned degrees.
3. Affiliated or non-affiliated status(described in Section 1.3)
4. Status as scientist or nonscientist
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 research.
7. Role on the IRB (Chair, Vice-Chair, etc.).

8. Voting status.
9. For alternate members, the primary member or class of members for whom the member could substitute.

The DRC is an *ex officio* member of the IRB and may participate in discussions and render opinion about interpretation of regulations, but does not participate in voting.

The HRPP office must keep IRB membership list current. The DRC must promptly report changes in IRB membership to the Office for Human Research Protections, Departments of Health and Human Services.

4.6 Access to IRB Records

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

1. Electronic records are kept on secure servers maintained by contractors with whom CMU has entered into licensing agreements.
   Doors to the IRB Offices are closed and locked when the rooms are unattended.
2. Ordinarily, access to all IRB records is limited to the DRC, IRB Chair, IRB members, IRB staff, authorized institutional officials, and officials of federal and state regulatory agencies (eg, OHRP, FDA). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining security of IRB records. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO and DRC.
3. Records are accessible for inspection and copying by authorized representatives of f regulatory agencies during regular business hours.
4. Records may not be removed from the IRB Office; however, the IRB staff will provide copies of records for authorized personnel if requested.
5. All other access to IRB study files is prohibited.

4.7 Record Retention

IRB minutes are retained indefinitely.

IRB records of protocol reviews must be retained by the facility for at least three (3) years after completion of the research.