4.0 Documentation and Records

4.1 Policy

Pennington Biomedical Research Center shall prepare and maintain adequate documentation of IRB 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.

4.2 Definitions

Research records: consists of records prepared, created, gathered, or maintained by an investigator or research staff for research at the institution.

4.3 IRB Records

IRB records include, but are not limited to:

- Written operating procedures
- IRB membership rosters (See Section 4.5).
- IRB member training records. The IRB maintains accurate records listing IRB members and IRB staff that have fulfilled the institution's human subject training requirements. All Pennington Biomedical employees' (investigators, administration and support staff) human research protections training are coordinated by the Director of Legal and Regulatory Compliance. Outside investigators involved in research are required to show proof of human subjects training to the IRB before study approval
- IRB correspondence (other than protocol related)
- IRB study files (See Section 4.4 for information included in study files)
- Documentation of exemptions (See Section 4.7)
- Documentation of convened IRB meetings minutes (see Section 4.6 for information included in the minutes)
- Documentation of review by another institution's IRB when appropriate
- Documentation of cooperative review agreements
- Federal wide assurances
- Quality assurance reviews
- Workflow/SOPs

Regulations & Guidance: DHHS 45 CFR §46.115(a)-(b); FDA 21 CFR §56.115(a)-(b)

4.4 IRB Study Files

The IRB office will maintain a study file for each IRB study submission that is submitted for review. Once a study submission is confirmed to include appropriate submission materials and signature of investigator(s), it is assigned a unique IRB number by the IRB staff.

All communications to and from the IRB are maintained. Depending on the type of communication, maintenance may be via e-mail or paper. IRB study files include, but are not limited to:

1. Protocol and all other documents submitted as part of an initial IRB application
2. Protocol and all other documents submitted as part of a request for continuing review/closure report. This also includes progress reports, statements of significant new findings provided to subjects, reports of injuries to patients
3. Documents submitted and reviewed after the study has been approved, including reports of modifications to research and unanticipated problem reports
4. Copy of the IRB-approved consents/assents
5. Sponsor-approved sample consent form document and protocol, when they exist
6. IRB member reviewer forms
7. Documentation of type of IRB review
8. 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, neonates, and research involving children
9. Documentation of all IRB review actions
10. Notification of suspension of research, if applicable
11. Correspondence pertaining to appeals/grievances, if applicable
12. Copies of approval letters and forms that describe what investigators must have before beginning the study
13. IRB correspondence to and from investigators
14. All other IRB correspondence related to the research
15. Reports of unanticipated problems
16. Documentation of audits, investigations, reports of external site visits
17. Scientific evaluations

18. DHHS-approved sample consent document and protocol, when they exist
19. Protocol Deviations/Violations/Exceptions
20. Documentation of non-compliance
21. Investigator Brochure, if any
22. Recruitment materials
23. Data and safety monitoring reports, if any

Regulations & Guidance: FDA 21 CFR §56.115(a)

4.5 IRB Membership Roster

A membership list of IRB members must be maintained for each IRB committee. It must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about IRB 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 institution)
4. Employment or other relationship between each IRB member and Pennington Biomedical Research Center
5. Status as 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.
6. Indications of experience, such as board certifications or licenses sufficient to describe each member's principal anticipated contributions to IRB deliberations
7. Representative capacities of each IRB member; 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
8. Role on the IRB (e.g., IRB Chair, etc.)
9. Voting status. Note that all IRB members are, by definition, entitled to vote. Guests and non-voting member’s guests do not have a right to vote or be counted toward a quorum

10. Alternate member status, including the IRB member for whom they alternate with

The IRB office must keep the IRB membership list current. IRB records including a curriculum vitae and human subjects' protection training of each IRB member. The IRB staff must promptly report changes in IRB membership to OHRP.

Regulations & Guidance: FDA 21 CFR §56.115(a).

4.6 IRB Minutes

Actions by duly convened IRB proceedings must be reduced to writing and available for review within 3 weeks of the recorded meeting date. Once approved by the IRB at a subsequent IRB meeting, the minutes must not be altered by anyone including a higher institutional authority. It should be noted that errors or corrections to approved IRB minutes, as approved by a majority of the convened IRB, will be included in the next meeting minutes.

A copy of IRB approved minutes for each IRB meeting is distributed to the designated institutional official.

Minutes of IRB meetings must contain sufficient detail to show:

1. Names of IRB members present
2. Names of IRB members or IRB alternate members who are participating through videoconference, teleconference or other electronic means, and documentation that those not physically present have received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions
3. Names of absent IRB members
4. Names of alternates attending in lieu of specified (named) absent IRB members. Alternates may substitute for specific absent members only as designated on the official IRB membership roster
5. Names of consultants present, if applicable
6. Name of investigators or research staff present
7. Names of guests present
8. The attendance list shall include those members present at 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;
9. The presence of a quorum initially and throughout the IRB meeting, including the presence of one member whose primary concern is in a non-scientific area;

10. Business items discussed;
11. Continuing education conducted;
12. Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB;
13. Votes on these actions (total number voting; number voting for; number voting against; number abstaining; number of those excused, number of those recused);
14. Basis or justification for all IRB actions and/or decisions including required changes in research or disapproval;
15. Summary of controverted issues and their resolution;
16. Approval period for initial and continuing review protocols, including identification of research that warrants review more often than annually and the basis for that determination;
17. Risk level of initial and continuing review approved protocols;
18. Review of interim reports (e.g. adverse events or safety reports; amendments; report of violations or deviations, etc.);
19. Review of DSMB summaries;
20. Review of DSMB plans;
21. Applications that have met or not met the stipulations;
22. Justification of deletion or modifications of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document;
23. 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;
24. Protocol-specific documentation that the research meets the required criteria [45 CFR §46.117(c)] when the requirements for documentation of consent are waived;
25. When approving research that involves populations covered by subparts B or D of 45 CFR §46, the minutes will document the IRB justifications and findings regarding IRB determinations stated in the Subparts or the IRB agreement with the findings and justifications as presented by the investigator on IRB forms;
26. The rationale for significant risk device/non-significant device determinations;
27. COI determinations;

28. 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 (e.g., cooperative studies, or other collaborative research);

29. Special protections warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, cognitively-disabled persons, or economically or educationally disadvantaged persons, regardless of source of support for the research;

30. A list of research approved since the last meeting utilizing expedited review procedures and the specific citation for the category of expedited review of the individual protocol;

31. Documentation of approval by the IRB Chair (or designee) of research contingent on specific minor conditions in the minutes of the first IRB meeting that takes place after the date of the approval;

32. An indication that, when an IRB member has a COI (see section 2.5 – IRB Member Conflict of Interest) 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. The name of the IRB member will be captured in the minutes as well as the reason for their departure; and

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

IRB minutes are audited every quarter to ensure all items are included.Regulations & Guidance: 45 CFR §46.116(c)-(d); 45 CFR §46.117(c); 45 CFR §46.204; 45 CFR §46.205; 45 CFR §46.206; 45 CFR §46.207; 45 CFR §46.305; 45 CFR §46.306; 45 CFR§46.404; 45 CFR §46.405; 45 CFR §46.406; 45 CFR §46.407; 45 CFR §46.408; 42 USC 498 A(b)(1); 42 USC 498 A(b)(2); 42 USC 498 A(c); FDA 21 CFR §50.51; 21 CFR §50.52; 21 CFR §50.53; 21 CFR §50.54; 21 CFR §50.55; 21 CFR §50.56; 21 CFR §56.109(c); 21 CFR §56.115(a)

4.7 Documentation of Exempt Review Findings

Documentation of exempt review consists of the reviewer's citation of a specific exemption category and written concurrence by the IRB of the activity.

4.8 Documentation of Expedited Reviews

IRB records for initial and continuing review by the expedited procedure must include:

1. The specific permissible category;

2. A description of action taken by the reviewer;

3. The approval period; and

4. Any determinations required by the regulations including protocol-specific findings supporting those determinations.

4.9 Access to IRB Records

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

1. All paper IRB records are kept secure in filing cabinets or locked storage rooms. The IRB office is closed and locked when unattended.

2. Access to IRB records, whether paper or electronic, is limited to the IRB Chair, IRB members, IRB staff, authorized institutional officials, and officials of federal and state regulatory agencies (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 institutional official.

3. Records are accessible for inspection and copied by authorized representatives of federal regulatory agencies during regular business hours.

4. Paper 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, paper or electronic, is prohibited.

4.10 Record Retention

IRB records (as described in Section 4.3) pertaining to research, which is conducted, must be stored securely. Paper records are stored in the IRB office.

IRB records must be retained for at least three (3) years after completion of the research. IRB records not associated with research or for protocols cancelled without subject enrollment will be retained at the facility for at least 3 years after closure of the IRB file.

IRB records retained beyond their retention date will be shredded or otherwise destroyed unless prohibited by institutional policy.

See Section 4.12 for record retention requirements for studies involving investigational drugs and investigational devices.

Regulations & Guidance: DHHS 45 CFR §46.115(b); FDA 21 CFR §56.115(b); 21 CFR §56.312.62(c)

4.11 Investigator Records

Investigators are required to maintain accurate, current and complete records of their human subject research activities. In general, investigators should establish and maintain a file for each study that has been reviewed by the IRB. These files should closely resemble the IRB's file structure on the study.

Within each study, investigators also should maintain a file for each subject who signs a consent document agreeing to participate in the study. These subject-specific files should include the original signed consent document and copies of case report forms, and any other correspondence between the investigator and the subject.

Research records should be maintained as appropriate to the type of study. For example, when a study is sponsored externally, these records should be kept for at least 3 years after the study has been completed and the sponsor has indicated that the records are no longer required.

4.12 Records for FDA-Regulated Studies

4.12.1 Investigational Drugs

Investigators are expected to maintain accurate, complete and current records with respect to studies involving investigational drugs consistent with FDA requirements found at 21 CFR §312.62(a)(b)(c). This includes the following:

1. Disposition of drug: an investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.

2. Case histories: an investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual that administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including (e.g., signed and dated consent forms), and medical records (e.g., physician progress notes, the individual's hospital chart(s), and the nurses' notes). The case history for each individual shall document that informed consent was obtained prior to participation in the study.

3. Record retention: A investigator shall retain records involving investigational drugs involved in an FDA-regulated study for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

Regulations & Guidance: FDA 21 CFR §312.62.

4.12.2 Investigational Devices

Investigators must maintain accurate, complete and current records involving investigational devices involved in an FDA-regulated study consistent with FDA requirements found at 21 CFR §812.140(a)(d). This includes the following:

1. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports;

2. Records of receipt, use or disposition of a device that relate to:

    a. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.

    b. The names of all persons who received, used, or disposed of each device.

    c. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

3. Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data (e.g., signed and dated consent forms) and medical records (e.g., physician progress notes, copies of individual's hospital chart(s), and the nurses' notes). Such records shall include:

    a. Documents, evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

    b. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the

investigation, including information about relevant previous medical history and the results of all diagnostic tests.

c. A record of the exposure of each subject to the investigational device, including, the date and time of each use, and any other therapy.

4. The protocol with documents showing the dates of and reasons for each deviation from the protocol.

5. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.