Chapter 8

IRB Record Keeping and Documentation Requirements

DHHS regulation at 45 CFR 46.108(3-4) require that Prism Health implement written policies and procedures to govern the operations and direct the activities of the Prisma Health IRB (45 CFR 46 .108(3-4)).

IRB records will include documentation of all IRB findings and determinations as required under DHHS and FDA human subject protection regulations and as recommended by official (i.e., written) OHPR and FDA guidance.

1.IRB COMMUNICATIONS

All communications related to review and approval of submitted research protocols is managed through the Prisma Health protocol management system.

2.IRB RECORDS DEFINED

At a minimum, Prisma Health IRB records must include all information required under DHHS and FDA regulations at 45 CFR 46.115 and 21 CFR 56.115, respectively and as recommended by official OHRP and FDA guidance.

IRB files will be organized such that the following information may be accessed:

a) Written IRB Operating Procedures
b) Current and Past IRB Membership Rosters
c) Training Records
d) All Correspondence to and from the IRB
e) IRB Research (Protocol) files
f) Research (Protocol) Tracking System
g) Documentation of Exemptions from DHHS regulations
h) Documentation of Exemptions and Exceptions from FDA regulations
i) Documentation of Expedited Reviews
j) Documentation of IRB Findings and Review Category for the involvement in Research of Pregnant Women, Fetuses, Neonates, Prisoners, and Children
k) Documentation of IRB findings and justifications for waiver of informed consent and waiver of documentation for informed consent
l) Information for all approved research addressing each of the eight Criteria for Approval under DHHS regulations at 21 CFR 56.111 and 46 CFR 46.111.
m) Documentation of convened IRB meetings, minutes.
n) Records pertaining to initial and continuing review, if applicable, or the research reviewed by expedited procedure will include documentation of actions taken by the reviewer, including any findings required by laws, regulations, codes, and guidance.
o) Documentation of review by another institution's IRB
p) Adverse event reports
q) Reports of unanticipated problems involving risks to subjects or others
r) Documentation of non – compliance

3.Record Retention and Access

1. In accordance with Federal regulations at 21 CFR 56.115(b) and 45 CFR 46.115(b), Prisma Health records will be retained for no less than three years; research records will be retained for no less than three years; research records will be retained by Prisma Health

for no less than three years after the completion of the research. This includes research protocols reviewed by the IRB but for which no participants were enrolled.

2. All Prisma Health IRB records will be maintained in a permission-restricted electronic database. IRB access to IRB records is limited to IRB Chairs, IRB committee members, IRB staff, the Institutional Official, Compliance officer and Compliance analyst, officials of Federal and State regulatory agencies including OHRP and FDA.
3. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IRB Chair or the HRPP Directors.

4. IRB Membership Rosters

All Prisma Health IRB membership rosters will include at least the following information:

a. Names of IRB members.
b. Names of alternate members and the corresponding regular member(s) for who each alternate may serve.
c. Earned degrees and specialties of each member and alternate, if applicable, sufficient to describe each member's anticipated contribution to IRB deliberations.
d. The representation capacity of each member or alternate.
e. Status as a scientist or non-scientist.
f. Any employment or other relationship with Prisma Health or its components.
g. The IRB rosters are not publicly available.
h. Education and Training Records.

5. Research Investigator Training

At a minimum, all research investigators must complete Human Subjects Protection Training (HSP) and if required by the research being conducted, Good Clinical Practice Training (GCP) available through the Collaborative IRB Training Initiative (CITI) education program, or equivalent, if approved by the IRB Chair or HRPP Director. Re-certification is required every three years and is accomplished by completing the CITI Continuing Education or "Refresher" course or equivalent if approved by the IRB Chair or HRPP Director.

It is the investigator's responsibility to ensure that all key research personnel have completed the required training. Failure to comply with this educational requirement will result in the delay or approval or removal of the study of those who are not compliant with this requirement.

6. IRB Member Education

On receiving an appointment to the IRB, new members will receive reference materials (including this manual) necessary to review research from the ethical and regulatory perspective. All IRB members must also complete the initial Human Subject Protection Training (e.g., CITI educational program). Re-certification is required every three years and can be accomplished by completing the CITI Continuing Education or "Refresher" course or other human subject protections training approved as equivalent by the IRB Chair or HRPP Director.

New members will be required to attend three meetings to observe committee deliberations and gain an understanding of member expectations and the deliberation process. Once the observations are completed, an appointment letter will be issued by the Committee Chair.

Committee member education will be provided at scheduled committee meetings on pre-determined topics and "just in time" if needs are identified based on unique protocols to be reviewed, changes in regulation or policy, or committee member or chair request.

Additional continuing education requirements may be established as deemed necessary by the Institutional Official and/or the HRPP Director.

7. IRB Research Protocol Files

The IRB will maintain a separate electronic file for reach research protocol that it receives for review. ***Such electronic files will be kept for a period not less than three years after study completion.***

Each IRB file will contain at least the following materials:

a) The protocol application form
b) Copies of all research related activities reviewed (e.g., determinations of other ancillary committees)
c) The IRB-approved informed consent document
d) Investigator Brochure(s) if any
e) Sponsor or cooperative group protocols and sample informed consent documents if any
f) Advertising or recruitment materials
g) For FDA-regulated research where the Prisma Health PI holds the IND or IDE, copies of FDA correspondence containing the IND/IDE number.
h) Applications for protocol amendments and modifications
i) Continuing review progress reports and related information
j) Reports of unanticipated problems involving risks to participants or others
k) Report of injuries to participants and adverse events occurring within institutions that have designated the Prisma Health IRB to review the research, and reported to any regulatory agency
l) Reports of external adverse events and/or safety reports received from sponsors or cooperative groups
m) Data and Safety Monitoring Board (DSMB) reports or Data Safety Monitoring Committee (DSMC) reports if any
n) Results of internal quality control and monitoring activities if any
o) All IRB correspondence to and from research investigators, government agencies, data monitoring boards, or sponsors
p) All other IRB correspondence related to the research, including documentation of non-compliance
q) Documentation of all IRB review and approval actions, including initial and continuing convened (full) or expedited IRB review
r) Documentation of type of IRB review (e.g., full, expedited, exempt, NHSR)
s) Documentation of project closure (It is the policy of the Prisma Health IRB to administratively close and return any new research application when additional information requested by the IRB is not submitted within a 90-day period)
t) Documentation of significant new findings provided to participants

8. Protocol Management System

Prisma Health IRB records are maintained in a centralized protocol management system.

The protocol management system will include at a minimum the following information:

a) Title of the Research (protocol)
b) Name of Principal investigator
c) Name of Sub-Investigators
d) Participating Prisma Health Institutions/sites
e) Funding Source (if any)
f) Date of initial approval
g) Date of most recent continuing approval
h) End of current approval period
i) Type of review (expedited, convened review or determination of exemption)
j) Involvement of children or vulnerable population
k) Current Status (in Review, approved, suspended, closed)

Documentation of Exemptions and Exceptions

Determination that research activities are exempt from human subjects regulation is made by the IRB Chair, a qualified member of the IRB, the HRPP Director or IRB coordinators with expertise to make this determination.

In reviewing exemption requests, the reviewer must receive sufficient information from the investigators to determine is the exemption determination applies. Research for which there is a statutory requirement of funding agency requirement for IRB review, or for which there are proposed clinical interventions, or potential breach of privacy interest of the participant or for which ethical concerns are raised, cannot be determined to meet exemption requirements.

Documentation of verified exemptions consists of the reviewer's written concurrence in the IRB protocol file that the activity described in the Investigator's application for the exemption from the human subjects regulations satisfies the conditions of the cited exemption category.

The categories of exempt research are stipulated by in the Federal Regulations (Common Rule) and in DHHS regulations at 45 CFR 46 .104(d)(1-8).

The exemptions categories (1), (4), (5), (7), and (8) may be applied to research involving children if the conditions of the exemption are met.

Determinations of exemptions and exceptions will be communicated in writing by the IRB on behalf of the reviewer.

9. Exceptions from Informed consent Requirement for Emergency Use of a Test Article

FDA regulations at 21 CFR 50.23 permit the use of a test article with the informed consent of the subject (or the subject's legally authorized representative) where the clinical investigator and a physician, not

otherwise involved in the research, certify in writing that (i) the subject is confronted with a life-threatening emergency; (ii) informed consent cannot be obtained because of an inability to communicate; (iii) time is not sufficient to obtain consent from the subject's legally authorized representative; and there is no alternative approve or generally recognized representative; and (iv) there is no alternative approved or generally recognized therapy that provides equal or greater likelihood of saving the life of the subject. This written certification must be submitted to the Prisma Health IRB within 5 working days of the use of the test article.

Reporting does not constitute IRB approval for the emergency use. The IRB staff will maintain document of this report.

Emergency use of investigational drugs requires that the patient become a subject in a research protocol. (21CFR50,23(g)).

10. Exemption from IRB Review Requirement for Emergency Use of a Test Article

FDA regulations at 21 CFR 56.104© permit the emergency use of a test article without IRB review. Emergency use is defined as use of a test article on human subject in a life- threatening situation in which no standard acceptable treatment is available, and in which there is no sufficient time to obtain IRB approval (21CFR56.102(d)). All the following conditions must be met for this type of emergency use:

- an individual is in a life-threatening situation,
- no standard acceptable standard treatment is available,
- there is insufficient time to obtain IRB approval; and
- the emergency use must be reported in writing within five working days.
- Reporting does not constitute approval for the emergency use by the IRB.
- The clinical investigator must notify the IRB Chairperson prior to emergency use where at all possible.
- Emergency use of test articles is discussed in greater detail in Section 12.

11. **Documentation of Expedited Review**

Expedited IRB review procedures may be employed for (i) minor changes in previously approved research during the specified approval period; and (ii) research activities that fall within the FDA/DHHS specified categories (45 CFR 46.110 and 21 CFR 56.110) and involve no more than minimal risk to subjects. Documentation for expedited reviews will be maintained in the Prisma Health IRB record and will include the actions taken by the reviewer including the category and circumstances that justify using expedited procedures. Documentation of concurrence with expedited processes is provided in reviewer notes. Expedited review may be conducted by IRB Chair, IRB committee members, or IRB coordinators with demonstrated knowledge of the expedited categories.

12. Documentation of IRB Meetings – Minutes of IRB Meetings

a) HRPP staff will compile minutes of the Prisma Health IRB committee meetings. The documented minutes will be provided to committee members with the agenda packet prior to next convened meeting of the committee for review and approval.

b) Protocol approvals and other IRB actions will be processed, implemented, and communicated immediately following the IRB meeting at which the action took place. It is not required to wait for approval of minutes for these actions to be implemented.

c) Any errors in finalized minutes will be rectified as they are identified by committee members prior to or during the committee meeting. After the minutes are corrected, they will be saved as a new "Revised" version and approved by a convened committee.

d) The IRB Coordinator is responsible for documenting committee meeting minutes, recording attendance, and monitoring quorum requirements as the IRB discusses, deliberates, and votes and each agenda item.

e) **Attendance at Prisma Health IRB Meetings. The minutes will list attendance as follows:**
   - Names of members present.
   - Names of alternates attending in lieu of specified (named) absent members. Alternates may substitute for specific absent members only as designated on the official IRB membership roster.
   - Names of consultants present.
   - Name of investigators present.
   - Names of guests present.

f) **Quorum Requirements and Voting at Prisma Health IRB Meetings.** IRB minutes will include a statement of Quorum Requirements based on the following standards.
   - A majority of the IRB members (or their designated alternates), including at least one member whose primary concerns are in non-scientific areas, must be present in order to conduct a convened meeting. For research to be approved, it must receive the approval of a majority of those members present at the meeting.
   - Members may be present in person, through virtual media, or audio. Members present via virtual media will be noted as such in the minutes [notation only required if only specific individuals are not present in person; if meeting is scheduled as virtual for members, this will be noted in the minutes].
   - All members will receive all pertinent information prior to the meeting and are able to participate in all discussions actively and equally.
   - Member who arrives to the meeting late, leave early, or called away from the meeting for a period, will not be counted as present or counted among those voting or abstaining for those actions before their arrival or after their departure. The minutes will identify these individuals as not present for each application action as required.
   - Prisma Health IRB minutes will include documentation of quorum

and votes for each IRB action by recording votes as follows: total number voting; number voting for; number voting against; number abstaining; and names of recused members.
- Members absenting themselves due to conflicting interest may not be counted toward quorum requirements. These members will be counted and identified by names as "recused"; and
- No individual who is not listed on the official Prisma Health IRB membership roster may vote at a convened meeting or review protocols through expedited processes.

13. Actions Taken by the Convened Prisma Health IRB

a) IRB minutes will include all actions taken by the Prisma Health IRB related to
   i. Initial and continuing review of applicable research.
   ii. Review of protocol or informed consent modifications or amendments.
   iii. Unanticipated problems involving risks to subjects or others.
   iv. Adverse event reports.
   v. Reports from sponsors and cooperative groups.
   vi. DSMBs or DSMCs.
   vii. Reports of continuing non-compliance with the human subject regulations.
   viii. Suspensions or terminations of research.
   ix. Other actions as required.

b) These determinations will also be provided in writing to investigators in the form of a letter from the IRB which includes, at a minimum, the following information (where appropriate)
   i. Investigators name,
   ii. Title of Study,
   iii. IRB Record Number,
   iv. Approval date,
   v. Continuing review interval,
   vi. Changes to the materials submitted to secure final approval.

c) IRB action for initial or continuing review of research include those listed below.
   i. **Approved** as submitted with no changes. The research may proceed once the protocol has final institutional approval.
   ii. **Modifications Required** with Specific Changes. The IRB Committee will determine if changes are:
      - **Substantive:** meaningful or considerable and will need to be re-reviewed once changes are made by fully convened committee.
      - **Non-substantive:** minor and/or editorial changes required for clarity of content and understandability and can be reviewed through expedited processes when changes completed and re- submitted.

iii. **Deferred.** No vote or action pending receipt of additional substantive information. If the Prisma Health IRB determines that it lacks sufficient information about the research to proceed with its review, the research protocol may not proceed until the convened IRB has approved a revised protocol application incorporating all necessary information.

iv. **Not Approved.** The IRB has determined that the research cannot or should not be conducted at Prisma Health.

d) **Separate votes are required for all IRB actions.**

e) **The Basis for Requiring Modifications to or Disapproving Research**

The minutes of the IRB meetings will include the basis for requiring changes or in disapproving research, including the basis for any deletion or substantive modification of information concerning risks or alternative procedures. This information will be provided in writing to the investigator, who will be given an opportunity to respond in person or in writing.

f) **Summary of Controverted Issues at Convened Meetings**

The minutes of IRB meeting will include a summary of the discussion of all controverted issues and their resolution.

g) **Required IRB Findings and Determinations**

The following specific IRB findings and determinations will be documented in IRB meeting minutes, including protocol-specific information justifying each finding or determination.

i. The level of risk of the research. When not stated in the minutes, the IRB has determined that the protocol, is greater than minimal risk.

ii. The approval period for the research, including identification of research that warrants review more often than annually.

iii. Justification for waiver or alteration of informed consent, addressing each of the four criteria at 45 CFR 46.116(f)(3). Briefly, the criteria that the IRB must find, and document:

1. The research involved no more than minimal risk to subjects
2. The waiver or alteration will not adversely affect the rights and welfare of subjects
3. The research could not practicably be carried out without the waiver or alteration
4. If the research involves using identifiable private information or identifiable biospecimens in an identifiable format; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. When not stated in the minutes, the IRB has

concurred with the criteria information provided in the new protocol application.

iv. Justification for waiver of the requirements for written documentation of consent in accordance with criteria.

v. For DHHS supported research, justification for approval of research involving pregnant women, human fetuses, and neonates, addressing each of the criteria specified under Subpart B of the DHHS human subject regulations.

vi. For DHHS supported research, justification for approval for research involving prisoners, addressing each of the categories and criteria specified under Subpart C of the DHHS human subject regulations. The Prisma Health IRB does not review research that involves prisoners. However, Prisma Health research may participate in research under Subpart C, in collaborative partnerships. These are reviewed through external review process with appropriate reliance agreements in place by IRBs that are certified for such review and the Prisma Health IRB will assure all appropriate protocol specific operating procedures and local policies are in place and approved by the reviewing IRB.

vii. For DHHS supported research and for FDA regulated research, justification for approval of research involving children, addressing each of the categories and criteria specific under Subpart D of the DHHS and FDA human subject regulations. The IRB chair is responsible for providing notification to OHRP of the IRB's finding concerning research requiring review by a panel of experts.

viii. Special protection warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons, regardless of source of support for the research.

ix. Rationale for the IRB's determination of significant risk or non-significant setting, with specific reference to the criteria specified under the 45 CFR 46.101(i) DHHS waiver or the FDA exception at 21 CFR 50.24

x. Any IRB discussion or determination regarding
   - unanticipated problems involving risks to subjects or others.
   - serious adverse events; and
   - any other items on which the IRB takes formal action.

h) **Report of Expedited Reviews, Exemption Determinations, and Externally Reviewed**

A list of research approved since the last convened meeting utilizing review procedures as well as research determined to be exempt for Prisma Health IRB review is submitted to the convened IRB for review. This list is attached to the meeting agenda for committee review and is retained with committee minutes.

i) **Duration of the Meeting**

The IRB minutes will record when the meeting came to order and when the meeting was adjourned.

j) **Documentation of Review by an External IRB**

When Prisma Health rely on an external IRB, the HRPP will maintain a protocol file to include copies of the following:

i. Of agreement to rely on an external IRB (reliance agreement). *See Chapter 17 for further review of Reliance Requirements,*

ii. External IRB approval for the investigator's participation in the research,

iii. Copy of the External IRB approved protocol, informed consent, other research materials and the reviewing IRB's approval,

iv. Copy of any external IRB approved changes in the research,

v. Copy of any external IRB continuance approval,

vi. Copy of any reports of non-compliance, unanticipated problems involving participants or other, suspension or terminations,

vii. If available, copy of the final report or other document closing and/or completion,

viii. Such documentation will be provided the local IRB from the participating investigator and maintain in the Prisma Health protocol management system.

k) **Dissemination of IRB Minutes**

All IRB minutes are provided to the Institutional Official and relevant sections of minutes will be provided to Principal investigators with a specific request to the HRPP Director.