Chapter 6

Structure and Membership

The Prisma Health IRB shall have sufficient expertise in those clinical and social behavioral areas in which Prisma Health researchers commonly become involved, and shall be knowledgeable about all relevant regulatory requirements, and strive to remain impartial and objective in its reviews.

In accordance with DHHS and FDA regulations, this Institution's IRBs are comprised of persons from various disciplines and departments, including non-scientific members, and community representatives not otherwise affiliated with Prisma Health.

The Prisma Health IRB operates independently of all other committees that review Prisma Health research.

1. APPOINTMENT OF IRB MEMBERS, LENGTH OF SERVICE, AND DUTIES

a) The IRB Chairs will appoint IRB members to serve for three-year terms; however, there are not term limits placed on length of service, and terms will automatically renew unless otherwise requested by the appointed member, or deficiencies identified in the committee member's performance or attendance that cannot be resolved.
b) Candidates for membership on the IRB may be recommended to the IRB Chairperson by the HRPP Director, and/or officials of Prisma Health departments or institutions that conduct human subject research reviewed by the Prisma Health IRB. Personnel will be selected across departments and disciplines which represent the types of research proposals submitted for review and approval.
c) The Prisma Health IRBs will also maintain a consulting core in specific areas of clinical and behavioral health research where submissions are infrequent, however require specific content expertise for an effective review.
d) The Prisma Health IRBs comply with the membership requirements of DHHS regulations 45 CFR 46.107 and FDA regulations at 21 CFR 56.107 as follows:
    i. Each Prisma Health IRB will have at least 5 members.
    ii. Prisma Health IRB members will possess varying background to promote complete and adequate review of research activities commonly conducted at this Institution and institutions for which the Prisma Health IRB is the designated IRB.
    iii. Prisma Health IRB members will be sufficiently diverse related to race, gender, cultural background, and sensitivity to community attitudes to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of research participants.
    iv. Prisma Health IRB members will include persons able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional practice.
    v. No Prisma Health IRB will consist entirely of members of one profession.
    vi. Each Prisma Health IRB will include at least one member whose primary expertise is in a scientific area.
    vii. Each Prisma Health IRB will include one member whose primary concerns are non-scientific.
    viii. Each Prisma Health IRB will include at least on member who is not otherwise affiliated with this Institution and who is not part of the immediate family of a person who is affiliated with this Institution or other institutions for which the Prisma Health IRB is the designated IRB.

ix. Members vote to approve, require modifications in, disapprove, or defer research submitted to the Prisma Health IRB.
x. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their areas of expertise, and serve as general reviewers on all research discussed at convened meetings.
xi. Members may be asked to conduct expedited reviews on behalf of the IRB.
xii. Scientific members may have expertise in research involving human subjects and will be recruited from staff among Prisma Health institution or from the community.
xiii. Non-scientific members may have expertise in human rights or social issues and/or ethical or legal issues considered to be relevant to human subject research and will be recruited from staff among a Prisma Health institution or from the community.
xiv. Unaffiliated community-based members and members of their immediate families will have no formal or information affiliation with any Prisma Health institution other than their service on the IRB.
xv. Unaffiliated member presence is required for quorum at no less than 10 meetings annually.
xvi. All IRB members will be evaluated on an ongoing basis to ensure appropriate participation and performance in the conduct of their research reviews. Criteria by which IRB members may be evaluated include the following:
    - Attendance at meetings
    - Completion of IRB member orientation and human subject protection training
    - Knowledge of how to obtain access to regulatory guidance
    - Demonstrated expertise and/or interest (appropriate to IRB role)
    - Any member of the IRB may be removed by the Institutional Official, the IRB Chair or HRPP Director for the following:
        - failure to perform the duties of the IRB member, including failure to attend at least two-thirds (8) of the IRB meetings held within any 12-month period.
        - or for scientific misconduct, conflict of interest, or behavior such that review of research by the Prisma Health IRB is made difficult or impossible.

2. APPOINTMENT OF IRB CHAIRPERSONS, LENGTH OF SERVICE AND DUTIES

Each Prisma Health IRB will have a chairperson who is well information concerning regulations relevant to the involvement of human subjects in research. The Chairperson of Prisma Health IRBs is appointed by the Prisma Health Institutional Official in accordance with DHHS and FDA regulatory requirements. There are no term limits places on length of service as IRB Chairperson.

In conjunction with the Vice President for Research Compliance and Administration, the Institutional Official, the Chief Academic Executive Officer, the Chief Academic Officer, the Office of the General Counsel, appropriate Department Chairs, and others as appropriate, the IRB Chair promotes a culture consistent with the objectives of Prisma Health's Human Research Protection Program (HRPP), with special emphasis on the respect for and protection of individuals participating in research at Prisma Health. In promoting such a culture, the Chair is directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, disapproval, or determination of exemption from further review of research protocol submissions to the IRB.

a) Responsibilities of the Institutional Review Board Chair

i. Preside over meetings of the fully convened IRB and ensure that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws and University policy.
ii. Review and approve protocol submissions that qualify for expedited review pursuant to federal regulations, ethical principles, state laws and Institutional policies, or delegate such authority to a qualified and experienced IRB member to conduct such review and approval.
iii. Ensure that membership of the IRB is recruited, appointed, and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to approve (or disapprove) research protocols that represent the breadth of research submitted to the IRB by approved researchers.
iv. Serve as a liaison between the HRPP affiliated research communities to promote communication and understanding of the concerns of the IRB, the research community and other HRPP partners.
v. Ensure that reports related to safety, noncompliance, unanticipated problems in research and adverse events are reviewed, attended to, and reported pursuant to federal regulations, state laws and Institutional policy.
vi. Respond to local and federal investigations relating to protocols and actions, as required.
vii. Designate a senior IRB Member to assume the responsibilities of the Chairperson during any period of the Chairperson's absence.
viii. In collaboration with the HRPP Director, review IRB policies and procedures annually to confirm current compliance with all Federal, State, and local requirements for the protection of human subjects.
ix. In conjunction with the Vice President for Research Compliance and Administration, the Chief Academic Executive Officer, the Chief Academic Officer for each market, the Office of the General Counsel, appropriate Department Chairs, and others as appropriate, develop and revise HRPP and IRB policies, procedures, and guidelines to stay current with societal thinking, regulatory changes, and national best practice standards.

b) Removal of an IRB Chairperson

The Prisma Health FWA Institutional Official may relieve an individual as IRB Chairperson for failure to fulfill the duties listed above and for: failure to perform the duties an IRB member, including failure to attend at least two-thirds of the IRB meetings held within any 12 month period; and scientific misconduct, unreported conflict of interest, or behavior such that review of research by the IRB is made difficult or not conducive to committee interaction or recommendations.

3. ALTERNATE IRB MEMBERS

Each Prisma Health IRB, at the discretion of the committee chair and/or HRPP Director, may recruit alternate members to substitute for regular members of the IRB.

Alternate members will have voting rights, except that they may not vote at a meeting where the respective regular member is in attendance. Alternate members will be included in determining or establishing quorum at meetings where their respective regular members are absent.

4. CONSULTANTS TO IRB

At its discretion, each Prisma Health IRB may recruit (non-voting) Consultants whose presence at the meeting would aid the IRB in conducting its duties.

Continuing Consultants serve a fixed term and generally attend Prisma Health IRB meetings when available. They may have access to all documents submitted to the IRB, may participate in IRB deliberations, and make recommendations to instruct IRB determinations. However, Continuing Consultants may not vote on IRB determinations. Continuing Consultants will not be included in determining or establishing quorum at IRB meetings.

5. CONFLICTS OF INTEREST

No Prisma Health IRB member or consultant to the IRB may participate in the IRB's initial or continuing review of any project or the review of amendments or other submissions in which the member has a conflicting interest, except to provide information requested by the IRB. Prisma Health IRB members, including the Chairperson, who have conflicting interest, are required to disclose such interests in accordance with *Chapter 18* and to absent themselves form deliberations, quorum counts, and vote on the relevant protocol. Such abstentions are recorded in the meeting's minutes.

IRB members may not conduct any review type, including expedited review of any protocol submission where there may exist a conflict of interest.

Financial Disclosures will be reviewed for each new submission and at the time of continuing review by the IRB Coordinators.

IRB members may also conduct research and may also have ongoing advisory relationships with clinical trial sponsors, it remains their ongoing responsibility to disclose any real or apparent conflicting interests toa appropriate institutional official and to abstain from any IRB deliberations on which they may be conflicted.

6. EDUCATION AND PROFESSIONAL DEVELOPMENT OF IRB MEMBERS

All IRB members are required to take Human Subject Protections (HSP) training. Investigators and research personnel and staff as well as IRB members are responsible for monitoring the expiration of the HSP training, assuring that requirement on continuing basis. It must be completed every three years.

Investigators with expired training will have review of the studies suspended until the training is made current.

IRB members whose training has expired will not be permitted to participate in meetings or conduct review until such time that training is made current.

7. LIABILITY COVERAGE

IRB members are volunteers performing official functions on behalf of Prisma Health. As such, Prisma Health's general and professional liability policies cover Prisma Health and non-Prisma Health IRB members. These coverages extend to duties performed on behalf of Prisma Health within the scope of the IRB. For additional information, please contact Prisma Health Legal Counsel.