Chapter 7

IRB Administrative Support

DHHS regulations at 45 CFR 46.103(b)(2) require that Prisma Health provide its IRB with sufficient meeting space and staff to support the IRB reviews and responsibilities.

1. RESOURCE ALLOCATION

The Institutional Official has responsibility for establishing and maintaining systems for the protection of human participants in research conducted within this Institution or by its employees. To this end, the Institutional Official, the HRPP Director, and the IRB Committee Chairs meet annually to discuss the state of the human research protection program and any areas of concern or opportunities for improvement. The group will assess the number of committees and their membership to determine if they are appropriate to serve the organization's research activities.

Operational needs are also assessed, to include space and technology requirements, accessibility of organizational resources to support the mission of the HRPP, as well as resources to support education of investigators, study staff, and IRB members and staff. This group will also review findings of internal audit processes that are conducted on a continuous basis.

2. REPORTING LINES AND SUPERVISION

IRB Coordinators and the Compliance Analyst report to the HRPP Director. For administrative purposes the HRPP Director reports to the Institutional Official; however, at any time, the HRPP Director may bring any matter directly to any Institutional Executive Leader if appropriate.

3. INTITIAL TRAINING AND PROFESSIONAL DEVELOPMENT OF IRB STAFF

Prisma Health IRB is required under its OHRP Assurance (FWA) to have a plan to provide education about human participants protections for HRPP staff supporting the IRB. At a minimum, all IRB Coordinators must complete initial human subjects protection training, such as the CITI course. This education must be completed every three years either through the CITI training modules or equivalent. Compliance with this requirement is monitored by the HRPP Director at the time of annual review. Any staff not in compliance with these training requirements will be put on a performance improvement plan.

HRPP staff will be provided resources to attend national or regional human subject protection conferences on a periodic basis as funding is available.

The HRPP Director will coordinate regular educational sessions on a variety of topics related to protecting human subjects. Opportunities for live and virtual trainings are made available through regulatory and professional organizations.

HRPP staff is encouraged to take advantage of other educational opportunities as they are made available.

4. DUTIES OF IRB COORDINATORS

The HRPP Director, with the appropriate assistance of the IRB Coordinators and other HRPP staff, is responsible for ensuring that the following IRB functions are accomplished in a professional manner that complies with all relevant regulatory requirements:

a) Overseeing the operations and administration of the Prisma Health IRB and determining that the Prisma Health IRB functions in accordance with the assurance provided that complies with all Federal, State, and local laws and regulations governing human subjects protection in the conduct of research.

b) Ensuring that the HRPP Director and the relevant IRB Committee Chair is promptly notified

regarding:

- any unanticipated problem involving risks to participants or others,
- any serious or continuing non-compliance with Prisma Health IRB by research investigators, and
- any for-cause suspension or termination of IRB approval.

c) Ensuring notification of OHRP and FDA of such incidents in accordance with applicable Federal regulations. Such notice will be accomplished in coordination with the HRPP Director, the IRB Chairperson, and as appropriate, Legal Counsel and Risk Management.

d) Supporting implementation and maintenance of a research compliance monitoring process that provides monitoring reports and identifies opportunities for improvement.

e) Review of new protocols to ensure completeness of the application and required associated and supporting documentation for the proposed research.

f) Conducting a limited pre-review of proposed informed consent documents, ensuring compliance with regulatory guidance on reading literacy and all required elements.

g) Maintaining the official roster of IRB Committee Members and scheduling IRB meetings.

h) Distributing pre-meeting materials with sufficient time to allow IRB members an opportunity to review them in preparation prior to scheduled meetings.

i) Compiling the minutes of IRB meetings in compliance with regulatory requirements.

j) Maintaining all IRB documentation and records in accordance with regulatory requirements.

k) Assisting new IRB committee members in competing orientation procedures and meeting required educational standards.

l) Securely and properly archiving records of all IRB determinations and communications.

m) Facilitating communication between investigators and study teams with the IRB.

n) Appropriately utilizing the protocol management system for tracking submission progress and actions.

o) Serving as a resource to the research community on regulatory information and requirements as well as providing guidance related to forms and submission procedures.

p) Drafting reports and correspondence to investigators on behalf of the IRB or IRB Chairperson regarding the status of the research, including conditions for initial or continuing approval of research and responses to reports of adverse events or unanticipated problems.

q) Maintaining quality control of IRB support functions.

r) Assisting in evaluation, audit, and monitoring of human subjects research as directed by the HRPP Director and/or the Institutional Official.

s) Receiving and managing participant inquires, concerns, and complaints regarding conduct of research. Work with investigators, patient relations office, and/or legal counsel as

appropriate to the situation. If an expressed concern or complaint involves potential non-compliance or an unanticipated problem involving risks to participants or others, ensuring that it is reviewed in accordance with appropriate policies.

t) The IRB provide multiple avenues for investigators and research staff to ask questions, express concerns, and/or make recommendations. The IRB main phone number [864-455-8996] and the IRB email [IRB@prismahealth.org] are available. This information is available on the HRPP website: https://academics.prismahealth.org/research-and-innovation/research-administration/office-of-human-research-protection. Contact information is available on all approval letters and general communications from the office and all sources are monitored on a regular basis. The HRPP Director and the IRB staff regularly participate in departmental and divisional meetings with investigators, research leadership, and staff to provide education as well as provide guidance and response to specific issues raised by the research teams.

5. DUTIES OF THE HRPP DIRECTOR

The HRPP Director serves as the Human Protections Administrator under the Prisma Health FWA. Under the direction and supervision of the HRPP Director, IRB coordinators are responsible for determining and documenting all IRB activities in order to fully satisfy all relevant regulatory requirements. Individuals in this role must have detailed, working knowledge of the protection of human subjects in research.