Chapter 4

Commitment To and Shared Responsibilities for the Protection of Research Participants

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among Prisma Health administrators, investigators and their research staff, the subjects who enroll in research, and the IRB members and staff.

1. Institutional Responsibilities

The Prisma Health Executive Officer (CEO) has ultimate authority for the oversight and monitoring of the Institutional Policy for the Protection of Human Subject. The Executive Vice President, Chief Clinical Officer, the Vice President, and Chief Academic Officer also support the Human Research Protection Program delegating operational and regulatory compliance oversight to **FWA Institutional Official.**

The Prisma Health Vice President for Research Compliance and Administration serves as the Institutional Official for assuring Federal Agencies that Prisma Health complies with all Federal regulations governing the protection of human research subjects.

The Institutional Official is fully responsible for overseeing the protection of human research participants within Prisma Health including:

a) Overseeing the development and implementation of Institutional policies governing the Prisma Health IRB, all human subjects research, and all investigators and research personnel at this Institution.
b) Maintaining channels of communications and forums for discussion among all parties involved in the human subject protection program and oversight process at Prisma Health.
c) Ensuring that the Prisma Health IRB is provided with sufficient resources, technology, and staff to support its substantial review and record keeping responsibilities.
d) Overseeing the operations and administration of the Prisma Health IRB and determining that the Prisma Health IRB functions in accordance with the assurances provided in compliance with all Federal, State, and local laws and regulations that govern the protection of human research participants in the conduct of research.
e) On a going basis, the Institutional Official and the HRPP Director evaluate the performance of the IRB chairs.
f) The HRPP Director informs the Institutional Official of any issues of concern raised at an IRB meeting and / or identified though reports to the IRB. The Director will provide summaries of action taken in response to such reports and follow up as requested and / or required. Agenda and minutes of all Prisma Health IRB meetings are provided to the Institutional Official as standard communication prior to each meeting.
g) Ensuring notification of OHRP and the FDA of such incidents in accordance with applicable Federal regulations. Such notice will be accomplished in coordination with the HRPP Directors, the appropriate IRB Chairperson, and as appropriate, Prisma Health Compliance Officer, Legal and Risk Management, and if appropriate the Director of Quality and Safety.
h) Overseeing implementation of a research compliance monitoring process that provides monitoring reports as appropriate to the Institutional Official, and others as required.

The Institutional Official may delegate any of these responsibilities to the HRPP Director as deemed appropriate and necessary.

2. ACTIVATION

IRB approved research cannot be implemented until the research protocol has received institutional approval and activation by the Clinical Research Management Office (CRMO). The CRMO oversees activation and ensure all required operational approvals are in place prior to the initiation of the research. The number and type of operational approvals depend on the nature of the research, but may typically include budgeting, contracts, clinical support department feasibility, EPIC study profile build, and study team operational readiness. If required changes to the research are identified during operational review and activation process, and cannot be incorporated prior to IRB review and approval, the study will be put on hold until an amendment is approved and activated.

3. CLINICAL RESEARACH MANAGEMENT OFFICE (CRMO)

The CRMO serves as the resource for information on operational issues and requirements for clinical research. The department develops and provides education and processes to support execution of contracts and financial management of clinical research. The department also manages interaction and communication with sponsor, clinical research organizations, and other entities on behalf of the institution, researchers, and departments on issues related to clinical trials.

4. IRB POLICY COMMITTEE

The IRB Policy Committee is responsible for establishing polices that impact the IRB review of research involving human subjects. This includes, but is not limited to, such issues as assent for pediatric participants, reporting of adverse events, reporting of deviations and violations, etc. While institutional policies are critical, the IRB may choose to not follow a particular policy because of the requirements of a specific protocol under its review.

The members of the IRB Policy Committee are the chairs of each registered committee, as well as any committees that may be created in the future. Membership also includes the HRPP Director, and selected committee members. Consultants to the IRB may also be requested to serve as ad hoc members of this committee for review of policies that may impact or affect specific populations of research participants or procedures.

The Human Research Protection Office maintains a list of this committee and records of any meetings and determinations.

5. DIRECTOR, OFFICE FOR HUMAN RSEARCH PROTECTION

The Director of the Human Research Protection Program serves as the Human Protections Administrator under the Prisma Health FWA. The Humans Protections Administrator is the institutional official to whom the Vice President for Research Compliance and Administration (FWA Institutional Official) delegates day-to-day oversight of the human research protection program under the FWA, including the receipt of notification of IRB findings and actions.

The HRPP Director has primary responsibility for assuring the protection of the rights, safety, and welfare of research participants in research at Prisma Health. The Director for Human Research Protection (HRP) will supervise the HRP Team which coordinates the IRB review panels and oversight of the research protocols and principal investigators at Prisma Health. Key responsibilities include planning, developing, and implementing processes, systems, and educational programs by collaborating with research teams and offices at Prisma Health, Clemson, Furman, University of South Carolina, and the PH-USC Medical Group. Working in collaboration with the Peer Research Directors in the Office of Research Services, this role will be a member of the leadership team that works to ensure Prisma Health complies with regulatory requirements, facilitates quality research activities, and promotes efficiencies that reduces barriers to the research community.

6. ACADEMIC VICE CHAIR

Under the authority of the Department Chair the Academic Vice Chair is responsible for developing and managing the academic (education and research) budget (medical education funds, research funds, research incentive funds, educational endowments and grants, philanthropic funds designated for education and research); developing department policy on salary support, incentives and performance evaluation of faculty engaged in academics (education, research) faculty development toward professional development and academic appointment and promotion; partnering with the HSC leadership and Academic Vice Chairs of other departments to lead the planning and thoughtful growth of Prisma Health in collaboration with HSC and its University Partners and to implement the HSC strategic plan (including the Academic Whitepaper); and participate on committees to drive strategic planning and implementation and culture development.

7. DIRECTOR, CLINICAL RESEARCH UNIT

The Director, Clinical Research Unit will play a critical, integrative role leading and managing the Clinical Research Unit (CRU) to support clinical research, operations, and administrative needs. The Director will also provide clinical research management through expertise and leadership across medical specialties within Prisma Health. The Director will facilitate processes so that investigators and research staff can grow and expand their clinical investigations and clinical research portfolios.

8. INSTITUTIONAL REVIEW BOARDS

The Prisma Health IRBs are formally designated to review and monitor human subjects research and to protect the rights and welfare of the research participants. They also provide oversight and monitoring of such protections. The mission of the Prisma Health IRBs is to review research involving human subject and to ensure that the risks and benefits of the research are appropriate and that there is full compliance with Federal regulations for the protection of human subjects in research. The Prisma Health IRBs review all research involving human subjects and have the authority to approve, require modifications to, or disapprove all research activities, including proposed changes in previously approved human subject research.

9. PRINCIPAL INVESTIGATORS

a) As the individual responsible for implementation of research, the principal investigator bears direct responsibility for protecting every research participant. This responsibility starts with protocol design, which must minimize risks to participants while maximizing research benefits. In addition, the principal investigator and all members of the research team must comply with the findings, determinations, and requirements of the IRB. The principal investigator must also be responsibility for the adequacy of both the informed consent documents and informed consent process, regardless of which members of the research team obtain and document consent.

b) Principal Investigators must ensure:
   i. That all human subject research, which they conduct at this Institution or its components, or they conduct as employees of this Institution, has received prospective review and approval by the IRB.
   ii. That continuing IRB review and approval of the research are secured in a timely fashion.
   iii. That the research is always conducted in compliance with all applicable Federal, state, and local regulatory requirements and with the determinations of the IRB.

iv. That the investigator has reviewed this Institution's FWA, DHHS Regulations for the Protection of Human Research Subjects, relevant FDA regulations, and the Belmont Report.
v. That no changes in approved research are initiated without prior approval of the IRB, except where necessary to eliminate apparent immediate hazards to participants; and no research may be continued beyond the IRB-designated approval period.
vi. That the IRB is notified of (i) any injuries or unanticipated problems involving risks to participants or others; (ii) any serious adverse events experienced by participants, (iii) any adverse events reported to the study sponsor; and (iv) any serious or continuing non-compliance with applicable regulatory requirements or determinations of the IRB of which they become aware.
vii. That a closure report is submitted to the IRB within three months after the completion or discontinuance of a research project, or withdrawal of the exemption of a research project.
viii. That complete and accurate records are maintained regarding all communications with the IRB, the sponsor, and any Federal Agency, and that such records are made available to the Institutional Official, HRPP Director or other appropriate Prisma Health offices immediately.
ix. That any participant concerns, complaints, or requests for information are adequately addressed and resolved in a timely manner. Any compliant of a participant that indicates previously unforeseen risks, or any complaint that cannot be resolved should be reported to the IRB immediately.

10. OTHER MEMBERS OF THE RESEACH TEAM

Every member of the research team is responsible for protecting human subjects. Co-investigators, study coordinators, nurses, research assistants, and all other research staff have a strict obligation to comply with all IRB determinations and procedures; adhere rigorously to all protocol requirements; inform investigators of all adverse events or unanticipated problems requirements; inform investigators of all adverse events or unanticipated problems involving risks to participants or others; oversee the adequacy of the informed consent process; and take whatever measures are necessary to protect the safety and welfare of participants.

Researcher and all study team members at every level are responsible for notifying the IRB promptly of any serious or continuing non-compliance with applicable regulatory requirements or determinations of the IRB of which they become aware, whether they themselves are involved in the research. Researchers may also notify the Institutional Official, HRPP Director, Compliance Officer, or Legal Counsel directly of any compliance concerns they may have.

11. RESESARCH PARTICIPANTS

Participants may be viewed as having certain responsibilities as well. They can be expected to make every effort to comprehend the information researchers present to them so that they can make an informed decision about their participation in good faith. While participating, they should also make every reasonable effort to comply with protocol requirements and inform the investigators of unanticipated problems. Participants always have the right to withdraw from their participation in research at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.

12. PATIENT ENGAGEMENT STUDIO (PES)

a) The mission of the Patient Engagement Studio is to meaningfully integrate the patient voice in all stages of research by promoting collaboration with scientists and clinicians to optimize health and research outcomes.
b) The vision of the Patient Engagement Studio embraces a future in which we have bridged the gap between patients and science.
c) Creating research and innovation that serves the patient.
a) Providing access and opportunities for patient experts, clinicians, and researchers to build effective, collaborative relationships.
b) Considering patient perspectives in ethical issues.
c) Including diverse patient perspectives which are accessible for all phases of research.
d) Supporting and expediting the dissemination of research in both academic and patient-friendly settings.

The Patient Centered Outcomes Research Institute (PCORI) provides general guidance on how health service practitioners may comprehensively integrate patients into the research process. This rubric guides researchers toward more effectively involving patients in research. PES is a resource for all within the Academic Health Sciences Center that conducts research, continuous quality improvement and innovation that impacts patients and other stakeholders within the health system. The studio provides a structured opportunity for patients, community stakeholders, physicians, and academic researchers to collaborate in planning, conducting, and disseminating results of research projects and health system innovations.

13. ADDITIONAL INSITUTIONAL COMMITTEES

All Prisma Health human subjects research must also be reviewed by (i) the Radiation Safety Committee in the sites designated region if the research involves ionizing radiation exposure; and/or the Biosafety Committee designated by the participating site if the research involves recombinant DNA.

14. CLININCAL TRIALS EDUCATION

Prisma Health IRB is required under its OHRP-approved FWA to have a plan to provide education about human subject protections for research investigators, research staff, IRB members and HRPP staff.

As part of the Prisma Health commitment to the protection of human subjects, investigators and key research study staff are required to complete human subject protection education. The HRPP Director in consultation with committee chairs and Institutional Official assess on an ongoing basis the educational requirements needed for Prisma Health personnel to participate in the conduct of and / or review and approval of human subject research.

15. HRPP ASSESSMENT AND ONGOING IMPROVEMENTS

The Institutional Official and the Director, HRPP and when required in coordination with other Research Services departments and integrated services of the Human Research Protection Program, annually evaluate goals and performance of the program. Based on this assessment issues such as staffing, physical space, the accessibility of organizational resources to provide advice and guidance to the HRPP. [see Chapter 20]