# Chapter 5

## IRB Roles and Authorities

*An Institutional Review Board (IRB) is a committee created by and under Federal regulations for the review, approval, and monitoring of research involving human subjects.*

*In accordance with the Common Rule, DHHS regulations, and FDA regulations, the Prisma Health IRB has the authority and responsibility for approving, requiring modification in (to secure approval), or disapproving human subject research. The IRB also has the authority to suspend or terminate research for continued non-compliance with the Common Rule, DHHS regulations, and FDA regulations, or its own findings, determinations, and requirements. No official or committee of Prisma Health institutions may permit the conduct of human subjects research that has not been approved by the Prisma Health IRB.*

### 1. HUMAN SUBJECT PROTECTIONS UNDER FEDERAL REGULATIONS

Federal Regulations at 45 CFR Part 46 require that institutions engaging in human subjects research supported by the Department of Health and Human Services (DHHS) devise mechanisms for the protection of human subjects. The regulations require that each institution conducting human subjects research file a written "Assurance" of protection for human subjects.

The Prisma Health IRB must comply with requirements of all relevant regulatory agencies including the DHHS Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA).

### 2. OVERSIGHT OF THE PRISMA HEALTH IRB

The Institutional Official is ultimately responsible for oversight of regulatory compliance for all human subjects research conducted under the auspices of Prisma Health. The Human Subject Signatory Officials at the institutions, which have designated the Prisma Heath IRB to review their research, also retain responsibility for the oversight of research conducted within their institutions.

The independence of the IRB and the protection of research participants are the priorities of the Human Research Protection Program. To that end, the HRPP Director or IRB Chairs may consult appropriate senior officials for any reason relative to the protection of research participants.

### 3. PURPOSE AND MISSION OF THE IRB

The Prisma Health IRB's primary responsibility is to protect the rights and welfare of participants involved in human subjects research. In doing so, the Prisma Health IRB monitors human subjects research to determine that it is conducted ethically and in compliance with applicable Federal regulations, applicable State laws, the Prisma Health Federalwide Assurance, and these policies and procedures for the protection of research participants. Prisma Health will not serve as the IRB of record for any international sites.

The Prisma Health IRB fulfills these responsibilities by conducting prospective and continuing review of human subjects research, including review of the protocol or proposals, informed consent process, procedures used to enroll participants, and any adverse events or unanticipated problems reported to the IRB. Prospective review and approval of research or changes to previously approved research ensures that research is not initiated without IRB review and approval.

In communications to investigators, the Prisma Health IRB will make investigators aware of the requirement to submit protocol changes to the IRB for review and approval before initiation of such changes, except where necessary to eliminate apparent immediate risks/harms to participants.

## 4. SCOPE OF THE PRISMA HEALTH IRB AUTHORITY

As noted, the Prisma Health IRB has authority and responsibility for approving, requiring modifications in (to secure approval), or disapproving human subjects research. The Prisma Health IRB also has the authority to suspend or terminate research for serious or continuing non-compliance with the Common Rule, DHHS regulations, and FDA regulations or its own findings, determinations, and requirements. The Prisma Health IRB has the authority to observe and/or monitor Prisma Health research to whatever extent it considers necessary to protect research participants. No official or committee of the Prisma Health Institutions may permit the conduct of human subjects research that has not been approved by the Prisma Health IRB.

Research that has been approved by the Prisma Health IRB remains subject to any additional review deemed necessary and appropriate by the Institutional Official at each participating Prisma Health site. Each institution retains the authority to prohibit the conduct of research within its respective facilities or by its respective employees, which it deems not to be in its best interests (e.g., research that is not consistent with the mission of the institution, research that would require skills or resources that are not readily available, or research that might result in unacceptable fiscal or reputational risks).

a) **Requirement for Prospective Review and Approval**. Prospective review and approval by the Prisma Health IRB is required for the following:

   i. Research projects that involve human participants and that are conducted by students, clinical staff, or Prisma Health staff; and

   ii. Research projects that involve human participants and that are conducted by students, clinical staff, and other Prisma Health staff at the Prisma Health locations and regions across South Carolina.
      - Baptist
      - Baptist Parkridge
      - Easley
      - Greenville Memorial
      - Greer
      - Laurens County
      - Oconee
      - Patewood
      - Richland
      - Simpsonville
      - Toomey

b) **Adding a New Site to an Existing Approved Protocol**. Any investigator desiring to add a new site to an existing IRB approved protocol must submit the request with all required materials to the Prisma Health IRB.

c) **Authority to Take Action**. The Prisma Health IRB is empowered to take any action necessary to protect the rights and welfare of human participants involved in Prisma Health research. The Prisma Health IRB has the authority to approve, require modifications in, or disapprove the respective institution's human subjects research.

d) **Power to Suspend or Terminate Enrollment.** The Prisma Health IRB may suspend or terminate the enrollment and/or ongoing involvement of human participants in research as it determines necessary for the protection of those participants, especially in instances of serious continuing non-compliance. The Prisma Health IRB has the authority to observe and/or monitor the respective institution's human subjects research to whatever extent it considers necessary to protect research participants and assure compliance with applicable laws and regulations

e) **Cases of Serious or Continuing Non-Compliance.** In cases of serious or continuing non-compliance, the Prisma Health IRB may: (i) disqualify an investigator from conducting a particular research project or general research activity at any institution; (ii) require education and training in the ethics and regulations of human subjects research; or (iii) any other reasonable measures deemed appropriate to protect the rights and welfare of research participants.

f) **Access to Regulatory Correspondence.** All persons conducting research subject to review by the Prisma Health IRB, must promptly provide the IRB with copies of any reports, audit findings, or correspondence to or from any regulatory agency (such as OHRP or FDA) that bear upon the protection of participants in research in which they are involved. The Prisma Health IRB will review such correspondence to determine if action is needed to protect research participants.

g) **Access to Institutional Officials.** The IRB, any IRB member, or the HRPP Director may bring any matter (e.g., concerns of undue influence) directly to the attention of the Institutional Official, Prisma Health Compliance, or Prisma Health Legal Counsel when taking appropriate corrective action after consulting with the IRB Chair, Compliance Officials or Legal Counsel.

h) **Prisma Health IRB Relationship with other Prisma Health Committees.** The Prisma Health IRB may require that human subjects research also be reviewed by other committees or department as appropriate, including the Departmental Scientific Review Committee(s), Biosafety Committee(s), Radiation Safety Committee(s), Research Pharmacy, Nursing, Biomedical Engineering, Pathology, or Infection Control, etc.

## 5. APPEAL OF IRB DETERMINATIONS

a) **No Overrule Permitted**. No Prisma Health Committee or official may set aside or overrule a determination by a Prisma Health IRB to disapprove or modifications required in human subjects research. No Prisma Health committee or official may permit the conduct of human subjects research that has not been approved by the Prisma Health IRB.

b) **Notice to Investigator of Disapproval**. The Prisma Health IRB must provide the research investigator with a written statement of its reasons for disapproving or requiring modifications in proposed research and must give the investigator an opportunity to respond in person or in writing.

c) **Investigator Response and Appeal**. The Prisma Health IRB will evaluate the investigator's response in reaching its final determination.

## 6. RELATIONSHIP OF THE PRISMA HEALTH IRB TO OTHER INSTITUTIONS

The Prisma Health IRB may be designated for review of research under another institution's (external to Prisma Health) Assurance only with written agreement of the Institutional Official and in accordance with applicable regulatory requirements. Any such designation must be accompanied by a written agreement specifying the responsibilities of Prisma Health and the Prisma Health IRB under the other institution's Assurance. The Prisma Health IRB has no authority over, or responsibility for, research conducted at other institutions in the absence of such a written agreement.

## 7. RELATIONSHIP OF THE PRISMA HEALTH IRB TO IND/IDE SPONSORS

Unless specifically required by an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) sponsor, no written notification of the IRB decisions will be provided to IND/IDE Sponsors by the Prisma Health IRB. The Principal Investigator serves as the communication link between the Prisma Health IRB and the Sponsor for this purpose. For FDA regulated test articles, such linkage is agreed to by the Sponsor and Principal Investigators when they sign the FDA Form 1572, Statement of Investigator.

## 8. ONGOING MONITORING INITIATIVES

The Prisma Health IRB is responsible for reviewing all audit findings or other reports (e.g., quality audit summaries, medical monitor reports, DSMB, or DSMC reports) related to any Prisma Health research. In doing so, the Prisma Health IRB should determine and document in the IRB records whether corrective action may be warranted.

## 9. PRIVACY BOARD FUNCTIONS AND DETERMINATIONS

The Prisma Health IRB is the designated Privacy Board as required by HIPAA 45 CFR 164.501, 164.508, 164.512(i). Functions of the Privacy Board includes review and determination of request for Waiver or Alteration of Consent Authorization and the use or disclosure of Protected Health Information in Research.

## 10. IRB SELF-ASSESSMENTS AND MONITORING

In coordination with the HRPP Director, the Prisma Health IRB will conduct regular meetings and regular process review to identify areas of operation and review which may require further enhancement and improvement. This includes an evaluation of membership and composition of the IRB to ensure appropriate expertise relative to the portfolio of the research conducted under the auspices of Prisma Health.

Additionally, the Chairs and HRPP Director will provide ongoing feedback as needed to the IRB members regarding areas of review and operation that require strengthening. This may be accomplished by addressing ongoing committee education, specific member remediation, or topic specific "just in time" education to prepare for less common review topics.