Chapter 3

Commitment to Protection of Research Participants

Prisma Health is committed to the protection human subjects by meeting all relevant ethical standards and all requirements of the human subjects protection regulations.

The Common Rule requires that every institution engaged in Federally supported human subjects research file an "assurance" to formalize its commitment to protect human subjects (45 CRF 46.103(a)). Prisma Health must provide written assurance to Federal agencies that it will comply with all federal laws and regulations governing the protection of human subjects research.

1. Protection of Research Participants as a Priority

The safety and wellbeing of all patients is a Prisma Health priority, and the organization is on a journey to creating a culture of excellence. An extension of that priority is the protection of research participants and is the foremost mission of the Human Research Protection Programs.

Prisma Health has an approved Federalwide Assurance (FWA 00001380) on file with the OHRP. The Prisma Health Vice President for Research Compliance and Administration serves as the Human Subject Signatory Official (hereinafter referred to as the "Institutional Official" or IO) for the Prisma Health FWA.

The FWA authorizes Prisma Health to conduct human subjects research that is supported by DHHS or any of the other Federal "Common Rule" agencies.

The Prisma Health FWA covers all human subjects research conducted (i) by any employee of Prisma Health or (ii) within any Prisma Health facility or with Prisma Health equipment or resources and these research projects are bound by Prisma Health policies and requirements of human subjects protection.

Under the terms of the Prisma Health FWA, all research involving human subjects reviewed by Prisma Health IRBs designated under the FWA is guided by the ethical principles in *The Belmont Report: Ethical Principles for the Protection of Human Subjects of Research* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. Prisma Health Registered Institutional Review Boards

Prisma Health operates two review boards to accommodate the volume, clinical discipline, and research type of human subjects research conducted at Prisma Health. The review boards are registered with OHRP and are designated in the Prisma Health FWA to conduct reviews of research involving human subjects:

IRB Panel A – IRB00000805 and IRB Panel C – IRB00002227

IRB Panel A may review all Prisma Health research including pediatric files, other than oncology trials. IRB Panel C serves to review all Oncology research. Reviewers from both panels provide review of minimal risk and greater than minimal risk studies.

The Prisma Health OHRP may designate additional internal or external review boards as it deems necessary. No Prisma Health component may operate or designate an IRB without concurrence of the Prisma Health FWA Institutional Official.