Human Research Protection Program

Policy and Procedures Manual

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Changes History Page

ITEM – Page	Scope of Changes	Date Approved
Policy and Procedures Manual	Initial approval	11/1/2022
Chapter 21	Initial Approval	2/20/2023
Chapter 15	V2_Editorial changes for clarity Conditions for Waiver of Parental Consent Requirement for Age of Majority Consent.	2/20/2023

INTRODUCTION

Included are the policies and procedures governing human subjects' research and the requirements for the review and approval of research by the Prisma Health Institutional Review Boards (IRB)

Prisma Health Organization Description

Prisma Health was formed to create a better state of health for South Carolina. As the largest and most comprehensive integrated healthcare organization in the state, Prisma Health strives to reach that goal by providing high-quality patient care, decreasing health disparities, removing access barriers, developing new clinical services and academic programs shaping health policies and addressing healthcare affordability: Prisma Health team members are dedicated to living the purpose: Inspire health, Serve with compassion, Be the difference.

In support of this mission, the Prisma Health, Health Science Center (HSC), provides a platform for academic the organization's partners, Clemson University, Furman University and University of South Carolina to work together to pave the way for breakthroughs in healthcare delivery, access, and affordability through a unique, dynamic collaboration. The mission of the Prisma Health HSC is: To improve the wellbeing of our community through collaboration, education, inquiry, and innovation.

This collaboration provides access to more than 40 academic, professional and workforce development programs, a medical school, a nursing program, clinical and translational research, and the region's largest healthcare delivery system, the Prisma Health HSC is dedicated to helping the health professionals of today and tomorrow meet the real-world needs of the community.

All human research studies operation under the auspices of a system-wide Human Research Protection Program (HRPP) with oversight and management from Office of the Executive Vice President and Provost, the Vice President for Research Compliance and Administration, and the Chief Medical Research Officer as the responsible organizational officials for its operation. Individual elements of the HRPP operation include the following:

- Education and training of all personnel involved in human subject research to include researchers, research staff, IRB committee members and IRB staff.
- Submission and review of human research protocols by independent review committees (Institutional Review Boards) with relevant expertise and community representation.
- Human subject outreach, communication, and education
- Financial management and review
- Risk management
- Research integrity
- Conflict of interest disclosure and management
- Monitoring of all approved human subject research, and
- Quality improvement programs

Programs and processes are in place to educate and reach out to the community about

human subjects research and mechanism are in place to for voicing complaints, issues, concerns and suggestions from research participants and the broader community. Information provided through these resources provide insight into areas for improvement.

The integrated elements of the Human Research Protection Program provide a robust and interactive framework for the ongoing management and improvements of the program serving both research participants and researchers.