Subject: The Role of the IRB Optimization Committee

Definitions:
Optimization Committee (OC): A representative group of IRB Members, HRPP Staff, and HRPP Administration that work in partnership to assure the protection of human research participants, maintain compliance with Federal regulations, and to promote consistency between IRB Committees.

Policy:
The Human Research Protections Program (HRPP) will maintain an active Optimization Committee (OC) as a resource to enhance human research protections.

I. The Mission of the Optimization Committee.
The OC has been organized to identify and assure careful integration of new HRPP policies and procedures necessary to optimize the operation of the HRPP Administrative Office and the IRB Committees while maintaining compliance with the federal regulations and assuring the protection of human research participants.

II. The Optimization Committee Authority.
The OC will discuss and make recommendations regarding IRB issues. However, final decisions remain the responsibility of the IRB Committees.

III. The Optimization Committee Responsibilities.
The OC will document the discussion of the issues through minutes signed by the Chairperson of the OC. Recommendations for agenda items may originate from an IRB Committee, HRPP Regulatory Compliance Analyst, or any other Institutional Committee or Investigator.

IV. Committee Composition.
The OC will consist of the HRPP Medical Director, the Chairpersons of each IRB Committee, the HRPP Director, the HRPP Managers, and the Regulatory Compliance Analyst Team Leaders of each IRB Committee. The HRPP Medical Director will serve as the Chairperson of the OC. Legal Counsel is an ex-officio member of the OC. In addition, IRB Committee members, Investigators, or other individuals will be invited to the meetings as their presence is warranted.

V. Ethical Principles.
The OC agrees to uphold the standards of human subjects protections as set forth in The Belmont Report and is in accordance with federal, state and institutional rules and regulations related to research involving humans and where applicable, the Good Clinical Practice Guidelines as adopted by the Food and Drug Administration when applicable.