Policy

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: III.M
Section: IRB Review Procedures
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: April 12, 2005
Revision Dates: September 22, 2006; July 1, 2015

Subject: Coordinating Center Application

Definitions:
Coordinating Center: A Coordinating Center (CC) may consist of a group of individual researchers or a single Investigator responsible for oversight of more than one performance site engaged in research. Additionally, a CC maintains sufficient mechanisms for the protection of research participants with regard to its activities and responsibilities.

Policy:
It is the policy of the Institutional Review Board (IRB) to acknowledge the existence of any Coordinating Center (CC) established by or affiliated with an Investigator.

I. The IRB must have sufficient knowledge to assure that a CC established or maintained by a Investigator is operating in accordance with applicable federal, state and local laws and HRPP Policies and Procedures for the protection of human research participants.

II. When the Investigator’s responsibility in the research is strictly limited to the Coordinating Center function, the Investigator should submit an “Application for Coordinating Center Activities” to the IRB for review and approval, prior to the initiation of any coordinating center responsibilities and activities that involve human research participants.

III. The Investigator functions as the coordinating center and as a recruitment site, an “Application for Human Research,” is submitted.

IV. The IRB Committees will review the “Application for Coordinating Center Activities” to acquire knowledge of the Investigator’s specific functions as the CC and to assure that sufficient mechanisms are in place for the protection of research participants when acting as a CC. The application will be reviewed by the IRB at the level of review for which it qualifies.

V. The IRB must determine and document that the Coordinating Center has sufficient mechanisms in place to assure that:
   A. Management, data analysis, and data and safety monitoring (DSM) systems are adequate, given the nature of the research involved;
   B. Sample protocols and informed consent documents are developed and distributed to each collaborating institution;
   C. Each collaborating institution holds an applicable OHRP approved Federalwide Assurance (FWA), when the research is supported with federal funds;
   D. Each protocol is reviewed and approved by the IRB at the collaborating institution prior to enrollment of participants;
   E. Any substantive modification by the collaborating institution to the sample consent information related to risks or alternative procedures is appropriately justified;
   F. Informed consent is obtained from each participant as determined by the appropriate reviewing IRB;
   G. The privacy of participants and the confidentiality of data are adequately maintained, given the sensitivity of the data involved; and
H. Risks to participants in relation to coordinating center responsibilities have been minimized.

VI. Throughout the research, the Investigator must assure that he performance sites "engaged" in research can provide the necessary expertise and resources to manage the day-to-day operations of the research and provide scientific leadership.

VII. The Investigator must assure the performance sites have written procedures for assuring prompt reporting to the IRB of:
   A. Any unanticipated problems involving risk to participants or others;
   B. Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
   C. Any suspension or termination of IRB approval for cause.

References:
The Belmont Report
45 CFR 46
HRPP Policy I.C