Subject: Coordinating Center Procedures

Procedure:

This procedure provides guidance for the review of human research activities that are considered part of the function of the coordinating center (CC) when the CC falls under the jurisdiction of the Institutional Review Board (IRB).

I. Investigator Responsibilities.
   A. The Investigator is responsible for assuring that the responsibilities of the Coordinating Center are carried out in an ethical manner and include adequate human research protections.
   B. When developed or distributed by the Coordinating Center, template informed consent documents must include all the required elements of informed consent. In addition, the Investigator should assess the need for inclusion of any additional elements of informed consent (See HRPP Procedure IV.A.2).
   C. Any proposed changes to IRB approved documents are submitted to the IRB using the “Amendment Request”. The Investigator must receive IRB approval before implementing any changes to the IRB-approved research study or Coordinating Center responsibilities (See HRPP Policy III.J).
   D. When the Investigator serves as the CC, all adverse events and unanticipated problems involving risk to participants or others that occur at a performance site engaged in research are to be submitted to the IRB using the “Report of Adverse Events and Unanticipated Problems Involving Risk to Participants or Others”.
   E. The Investigator is responsible for submitting to the IRB, for review and approval, a separate application for Coordinating Center for each study in which the Investigator’s involvement includes coordinating center functions for more than one performance site engaged in research.
   F. The Investigator must verify that any substantive modification by the collaborating institution of the sample informed consent information related to A. risks or alternative procedures is appropriately justified and approved by the collaborating institution’s IRB prior to initiation of the research.
   G. The Investigator must assure the performance sites have written procedures for assuring prompt reporting to the IRB of:
      1. Any unanticipated problems involving risk to participants or others;
      2. Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
      3. Any suspension or termination of IRB approval for cause.

II. IRB Committee Responsibilities.
   A. The Application for CC Activities may be reviewed under expedited review procedures if the activities associated with the function of the coordinating center outlined in the application meet an expedited review category as established by the federal regulations (See HRPP Policy III.D).
   B. If the activities associated with the function of the CC do not meet an expedited review category, the application will be assigned to the full IRB Committee for review and approval (See HRPP Policy III.E). At the time of full Committee review, the Committee may make the determination that the activities of the CC involve no more than minimal risk and the study will qualify for expedited review procedures in accordance with 45 CFR 46.110(f)(9).
C. The IRB Committee, Chair or designated Committee Member will review the application, protocol, any sample informed consent documents, and other applicable documents to determine whether the CC has sufficient mechanisms in place to assure the following:
1. Management, data analysis, and data and safety and monitoring (DSM) systems are adequate, given the nature of the research involved;
2. Sample protocols and informed consent documents are distributed to each collaborating institution;
3. Each collaborating institution holds an applicable OHRP Approved Federalwide Assurance (FWA), when the research is supported with federal funds.
4. Each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of participants;
5. Any substantive modification by the collaborating institution of the sample consent information related to risks or alternative procedures is appropriately justified and approved by the collaborating institution’s IRB.
6. Informed consent is obtained from each participant as determined appropriate by the collaborating institution’s IRB.
7. The privacy of participants and the confidentiality of data are adequately maintained, given the sensitivity of the data involved; and
8. Risks to participants in relation to coordinating center responsibilities have been minimized.

D. The IRB Committee, Chair or designated Committee member will review the sample informed consent document prepared or distributed by the Coordinating Center to the participating centers to assure the inclusion of all the elements of informed consent and any additional elements, as applicable. The collaborating institution’s IRB will have oversight responsibility for assuring the presence of the elements of consent and the inclusion of the appropriate information regarding local research context. The IRB Chair or designated Committee Member will verify and sign the Committee Action Letter (CAL) and/or Final Approval Letter (FAL).

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will conduct a pre-review. The RCA will determine whether the application includes all information required and will request additional information, if needed, from the Investigator to assist the IRB Committee in making a determination.
B. Emails requesting pre-review changes are to be sent by the RCA to the Investigator.
C. When consultants to the IRB are utilized, the RCA will assist in obtaining a completed confidentiality agreement, a conflict of interest statement, and other required documentation prior to the distribution of review materials.
D. Letters requesting revisions from reviewers, and final approval letters are to be drafted using the appropriate template and forwarded to the IRB Chairperson or the designated Committee Member for signature.
E. Amendments, adverse events, and continuing reviews are to be processed according to corresponding HRPP policies and procedures.
F. Appropriate database entries are to be completed, including Committee notification of all research activities that receive approval under expedited review procedures on the next available agenda.