Columbia University IRB
Review of Clinical Coordinating Center Submissions

SCOPE: This document provides guidance regarding the information that should be submitted to the IRB for review of a clinical coordinating center proposal.

EFFECTIVE DATE: April 8, 2013

GUIDANCE:
The role of a clinical coordinating center will vary according to the applicable contractual agreement or grant, but may include: protocol design, selection of sites, verifying credentials of principal investigators, development of template consent documents and case report forms, monitoring of the status of federalwide assurances for federally funded projects, monitoring of IRB approvals at each site, implementing plans for secure transfer and storage of data, providing training, monitoring compliance by the study team at each site, tracking enrollment, collecting unanticipated problem and adverse event reports, and managing the shipment and storage of investigational products.

If Columbia is serving as a clinical coordinating center, the following types of information should be considered for inclusion in the application for IRB review:

1. A description of the activities for which the clinical coordinating center will have responsibility
2. A description of the clinical study including aims, background and significance.
3. Sample protocol and informed consent documents to be distributed to each collaborating institution for review and approval by their IRB/ethics committee.
4. A list of all sites where subjects will be enrolled and/or data/samples will be collected.
   a. Include the names of the individual designated as being responsible for the conduct of the research study at each site.
   b. If the research study is funded by a federal agency (e.g., NIH) specify the Federalwide Assurance number assigned by the Office of Human Research Protection (OHRP) for each non-local site.
5. An outline of the organizational structure indicating any committees responsible for administrative duties, subject/data/site monitoring, facilitation of communications, data analysis, etc.
6. Description and planned frequency of start-up meetings and education or training sessions required of staff at all sites prior to enrollment of any subjects.
7. A description of the data to be sent to the data coordinating center, how it will be sent, and how it will be identified to protect the confidentiality of the subjects and respective data.
   a. indicate the specific department/office that will receive the data;
b. indicate that the investigators at the data coordinating center will review all data for completeness and indicate who is responsible for obtain missing data or correcting errors and how this will be managed;

c. specify how and where the data will be analyzed and who is responsible for the analyses;

d. describe where and how the data will be stored and for how long, who has overall control of the storage area, and whether or not the data will be shared with other investigators not listed on the current study;

e. indicate how the subjects’ confidentiality is protected during the transmission of data to other sites. If records or files are to be transmitted via the internet or shipped to another site, describe how the subjects’ confidentiality will be protected.

8. If the coordinating center will be responsible for distribution of drugs or devices, describe how they will be delivered to each site and how the dispensing/distribution will be monitored. Include all product inventory or accountability forms.

9. Describe who has the responsibility for the review of adverse events and safety data for the overall clinical trial and how and when they are reported to the coordinating center. If the coordinating center is responsible for oversight of safety monitoring, include a copy of the adverse event report forms to be used for reporting adverse event to the coordinating center.

10. Describe the central data and safety monitoring plan that will be used to oversee conduct of the study at all sites.

a. indicate if there will be a DSMB, and if so, include the names and disciplines of the DSMB members and indicate how often they will meet;

b. in addition, include the frequency of site monitoring visits, who will conduct them and what will occur at each visit.

11. Describe the process to submit the sample protocol and consent form(s) to all sites in order for them to obtain their IRB/ethics committee review approval.

12. If the research is federally-supported or conducted, describe the plan for ensuring that every collaborating site has either:

a. an OHRP-approved Assurance (i.e., plan to document the FWA number, IRB approval letter and IRB-approved consents from each site); or

b. for collaborating sites that do not have an OHRP-approved Assurance (regardless of sponsorship), obtain a letter (on the facility’s letterhead stationery) from the appropriate administrator of each facility and an investigator agreement (a sample of which can be found at: http://www.hhs.gov/ohrp/humansubjects/assurance/unaflsup.rtf) from each individual investigator. The letter should contain a commitment that human subjects research conducted for the coordinating center will be initiated only after approval by an appropriately designated IRB and approval from the coordinating center and that all such research must be conducted in compliance with 45 CFR 46; 21 CFR 50, 56, 312 and 812; and coordinating center policies. A statement that the institution will promptly report serious and unanticipated problems involving risks to subjects or others to the designated IRB and the coordinating center must also be included.
13. Provide plans for maintaining records of IRB/ethics committee review and approval of all protocol and consent forms for all collaborating sites throughout the duration of the study. Renewal for each site does not need to be submitted to the CUMC IRB. However, the PI of the clinical coordinating center is often responsible for ensuring that all modifications and renewals are reviewed and approved appropriately; i.e., modifications are approved prior to their implementation and protocols and consent forms are renewed in a timely manner with no lapse in the renewal. The renewal of the coordinating center protocol will need to include a list of all sites and current IRB approval dates.

14. Ensure that any substantive modification(s) to the protocol and/or sample informed consent documents related to risks or alternative treatments by any collaborating site is/are appropriately justified.

15. Describe a plan to ensure that informed consent is obtained from each subject in compliance with OHRP regulations.

16. If acting as the data coordinating center as well, please provide a description of the responsibilities of the data coordinating center principal investigator with regard to training of staff to ensure accurate, consistent instrument training and data management across all sites. Include specific details of any special equipment needed (e.g., scanners, computers, software) for data transfer.