Issuing Department: Human Subjects Protection Program
Policy Number: 2011-017.0
Policy Title: Statistical, Operational or Coordinating Center

Purpose

The purpose of this policy is to outline obligations of investigators and the Institutional Review Board when this institution is acting as a statistical, an operations or a coordinating center for a multi-site clinical trial.

Definitions

See policy 2011-007.0 for the definition of the following term:

Clinical Trial

Policy

If personnel at this institution lead an operational, statistical or coordinating center for a multi-site clinical trial, this institution is engaged in research. If activities of personnel at this institution in the conduct of the trial involve no interaction or intervention with subjects, and the principal risk associated with activities is limited to the potential harm resulting from a breach of confidentiality, the IRB need not review each collaborative protocol. However, the IRB must find and document that the operations, statistical or coordinating center has sufficient mechanisms in place to ensure that:

- management, data analysis, and data safety and monitoring systems are adequate;
- sample protocols and informed consent documents are developed and distributed to each collaborating institution;
- each collaborating institution holds an approved assurance(when federally funded/supported);
- each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects;
- any substantive modification by the collaborating institution of sample consent information related to risk or alternative procedures is appropriately justified; and
- informed consent is obtained from each subject or an approved waiver of consent is in place; and
- the privacy of subjects and the confidentiality of data are adequately maintained

Procedure

The investigator must complete and submit the form applicable to UConn Health acting as the statistical, operational or coordinating center as part the IRB submission packet. The form address the key points noted above.

Designated IRB staff will provide the IRB reviewer with the reviewer checklist that prompts for consideration of whether the responses provided by the PI are sufficient.

- IRB will take action as necessary if responses are not adequate

Related Policies

2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

Guidance on Engagement of Institutions in Human Subject Research - http://www.hhs.gov/ohrp/policy/engage08.html

Document Attributes

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Reviewed and Approved By:

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