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**Boston
Children's
Hospital**

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Owner Susan Kornetsky:
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Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Multi-Site Research When a Boston Children's Hospital Investigator Oversees a Coordinating Center Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy defines a Coordinating Center and provides guidance on the application and review process.

Definitions

Coordinating Center: This term covers a number of very different research-related activities such as:

1. A data center focused on the aggregation
2. Management and analysis of data from multiple sites
3. A study-wide center responsible for overseeing all aspects of a multi-site study, including the development of consent forms, the preparation of a "manual of operations", the coordination of data collection, and the overall governance of all research activities at all sites

Policy Statements

A Boston Children's Hospital Principal Investigator (PI) wishing to act as the PI for a **Coordinating Center** for a multi-site research study must receive IRB approval for these activities:

1. Studies in which there will be **no subject enrollment** at Boston Children's Hospital: A specific

Coordinating Center protocol that outlines the responsibilities of the Center and the PI must be submitted to the IRB for review and approval prior to initiating the Center's functions.

2. Studies in which **there will be subjects enrolled** at Boston Children's Hospital: A Boston Children's Hospital PI may submit a separate protocol or describe the Coordinating Center functions in the research protocol submitted for the subject related activities.

Procedures

The nature of **Coordinating Center** activities may vary from study to study, depending in part on the design of the study and the type of funding mechanism, it is critically important that investigators accurately describe to the Institutional Review Board (IRB) exactly what their responsibilities are.

1. Most Coordinating Center applications receive expedited review, but it is possible that convened IRB review may be needed, depending on the nature of the Coordinating Center responsibilities.
2. It is the expectation of the IRB that those serving as a Coordinating Center will have adequate resources and expertise to carry out these responsibilities and have processes in place to ensure appropriate oversight.

The IRB will review the application materials submitted to determine if the operations of the Coordinating Center has sufficient mechanisms in place to ensure that:

1. Management, data analysis, and data safety and monitoring plan (DSMP) systems are adequate, given the nature of the research involved.
2. Sample protocols and informed consent documents are developed and distributed to each collaborating institution.
3. Each collaborating institution holds an applicable Office of Human Research Protections (OHRP) approved assurance of compliance with the Department of Health and Human Services (HHS) regulations for the protection of human subjects
4. Each protocol is reviewed and approved by the IRB at the collaborating institution(s) prior to the enrollment of subjects or appropriate reliance agreements are in place.
5. Any substantive modification by the collaborating institution(s) of sample consent information related to risks or alternative procedures is appropriately justified.
6. Informed consent is obtained from each subject in compliance with HHS regulations or that appropriate waivers of alterations are considered and approved when applicable.

The IRB will receive from the Coordinating Center PI an IRB protocol submission containing documentation of how the center will ensure that the above activities will be performed appropriately, and a listing of active sites.

At the time of initial review, the IRB will assess the procedures for prompt dissemination of protocol information to all participating sites. Assessment of protocol information includes unanticipated problems involving risks to participants, protocol modifications, and interim findings.

Related Content

- IRB Policy: Single IRB Review (For more information on Reliance Agreements)

Approval Signatures

Step Description

Approver

Date

COPY