

## Coordinating Centers

### Overview:

The term 'Coordinating Center' (CC) covers a number of very different research-related activities that range from a data center focused on the aggregation, management, and analysis of data from multiple sites, to 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. Because the nature of these activities may vary from study to study, depending in part on the design of the study and the type of funding mechanism (e.g., cooperative agreements may differ significantly from program projects), it is critically important that investigators accurately describe to the IRB exactly what their responsibilities are – as detailed in the grant application or contract. 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. Most coordinating center applications receive expedited review but it is possible that a full board review may be needed, depending on the nature of the coordinating center responsibilities.

### Description:

Listed below are examples of possible responsibilities that should be considered. Only include those activities in your IRB application for which the PI of the coordinating center is assuming responsibility. As previously stated, review your contractual agreement or grant scope of work to determine which activities are the responsibility of the CC and which are responsibility of the local site, site IRB, or other study-related centers (since large scale multi-site studies may distribute different 'coordinating' responsibilities to different programs. The following is not an all-inclusive list, but it provides descriptions of activities most commonly seen in CC applications.

### Possible General Coordinating Center Responsibilities

- Selecting appropriately qualified study sites and principal investigators, and providing study-specific training to research teams
- Collecting and maintaining critical documents from affiliated investigators, e.g. resume/CV, medical license, certification of completion of training, laboratory certifications and laboratory norms, signed COI disclosure forms, etc.
- Ascertaining that each protocol is reviewed and approved by the IRB at the collaborating institution prior to enrollment of participants at that site
- Ensuring, if the study is federally funded, that each collaborating institution holds an applicable OHRP-approved Federal Wide Assurance (FWA)

- Designing and developing the protocol, template informed consent documents, case report forms, manual of operations, etc.
- Managing data and statistical analysis
- Protecting the confidentiality of data during collection, transmission, and storage
- Ensuring informed consent is obtained and documented from each participant in compliance with federal regulations and local IRB approvals
- Registering participants, tracking participant enrollment, and coordinating randomization
- Tracking, reporting and maintaining documentation of all serious adverse events and unanticipated problems and disseminating the information to sites
- Providing periodic updates to affiliated investigators on participant enrollment, general study progress, and relevant scientific advances
- Assuring that all relevant IRB correspondence (continuing review and amendments) and study status changes are communicated to all sites
- Documenting receipt, shipment and storage of study specimens, drugs and/or devices
- Auditing and monitoring, on a periodic basis, at the external sites to assess research study progress and compliance with the IRB approved protocol
- Securing compliance at external sites that are not adhering to the current version of the research protocol and/or good clinical research practices
- Terminating the involvement, if necessary, of non-compliant investigators and reporting such action to the IRB

### **Possible Data Coordinating or Statistical Center Responsibilities**

This type of application places emphasis on how the PI will assume responsibility for collection, storage, management and statistical analysis of data collected. In most cases, this type of center application can be reviewed through an expedited process.

- Designing data forms
- Providing instruction on use of the forms
- Managing data and statistical analysis
- Overseeing secure data transmission and storage
- Protecting confidentiality of data and ensuring its integrity

## Considerations:

If the University of Pittsburgh is acting in the capacity of both a coordinating center and as a site enrolling subjects, two separate protocols must be submitted to the IRB -- an application that outlines the responsibilities of the coordinating center and an application that describes the activities of the University or UPMC site. In general, if only two sites will be participating, the IRB may not require a coordinating center application be submitted (contact the IRB Office before creating the application).

It may not be necessary for a multi-site project to have a coordinating center application associated with it if all research procedures are being conducted by the same University/UPMC investigators. For more information, contact the IRB.

If the study involves a University-based, investigator-initiated IND or IDE clinical investigation at an external site, prior approval is required by the [Office for Investigator Sponsored IND and IDE Support \(O3IS\)](#).

If the study involves international sites, all documents in a foreign language must also include an English translation.

## IRB Application:

Since the responsibilities of a coordinating center are the main focus for IRB review, there is a separate pathway for creating a Coordinating Center (CC) application. Listed below are some tips to assist in building this in OSIRIS. If you have any questions, email us at [askirb@pitt.edu](mailto:askirb@pitt.edu) while building the application and before submission and we will gladly assist you.

Triage section:

T1.0 Select "New Coordinating Center Application"

This pathway was designed to collect information related to the CC PI responsibilities, study team, sites and other demographic data.

<b>T1.0</b>	<b>Select the type of application:</b>
	<input checked="" type="radio"/> Project Type
	<input type="radio"/> New Research Study
	<input checked="" type="radio"/> New Coordinating Center Application

T4.0 Answer Yes to select exempt review only if the CC role is limited to the receipt of **de-identified** data/specimens and the CC study team was not involved in their collection.

<b>T4.0</b>	<b>Does the proposed study qualify for 'exempt' IRB review or for a determination of either 'not research' or 'no human subject' involvement?</b>
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The Pitt IRB reviews Coordinating Center (CC) activities to ensure that the University/UPMC investigator can appropriately manage the responsibilities outlined. It also reviews all documents that are designed or disseminated by the CC and that will be viewed by the research subject, including recruitment materials).

- CC2.1            If Yes, upload the study protocol and/or consent documents in question CS11.0
- CC2.2            If Yes, upload the data collection tools in question CS11.0 which should include any pictures or images as the IRB must assess the appropriateness and/or sensitivity
- CC3.1/CC 4.0    At a minimum, you are required to upload the letters of authorization to conduct research at the site and a qualified local collaborator must be listed who will oversee the conduct of the research at each site. The site may not initiate the research study until the local IRB/Ethics review approval is granted. If local IRB/Ethics approval has not been obtained at the time of the initial Coordinating Center submission, a modification to the application must be created to upload the local IRB/Ethics approval letter.
- CS11.0            Upload the CC protocol only if the PI is responsible for the design and development of the multi-site template consent form.

Do not upload copies of the case report forms to be used by investigators at each site into the IRB application. However, because they are subject to review by the University of Pittsburgh Education and Compliance Office for Human Participant Research (ECO), they should be maintained in the regulatory binders by the study PI.

### **Consent Document:**

Cover Sheet section, CS11.0 Upload the consent forms only if the Pitt PI is responsible the design and development of the multi-site template

### **Adding New Sites:**

When the IRB has approved the Coordinating Center application, you are ready to start enrolling sites. Create a Modification and upload the proper documentation as requested.

CC3.1 Address foreign/culturally different sites

CC4.0 Address U.S. sites

### **Modifications:**

If the Coordinating Center is responsible for the protocol and/or consent templates, then UPitt IRB approval must be granted before distribution of revised materials to the sites.

## **IRB Review of Coordinating Center Applications:**

Since coordinating centers are most typically responsible for administrative aspects of the study, they usually involve no direct interaction or intervention with study participants. For that reason, the principal risk is a potential breach of confidentiality.

When the IRB reviews a general coordinating center application, depending on the center's stated responsibilities, the IRB must determine and document that the center has a sufficient plan in place to ensure:

- Program management, data analysis, and data and safety monitoring processes are adequate, given the nature of the research involved
- Sample protocols and informed consent documents are developed and distributed to each collaborating institution
- Each collaborating institution holds an applicable OHRP-approved FederalWide Assurance (FWA) if the study is federally funded
- Each protocol is reviewed and approved by the IRB at the collaborating institution prior to enrollment of participants at that site
- Informed consent is obtained from each participant in compliance with federal regulations
- Any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified

When the IRB reviews a data coordinating or statistical center application, depending on the center's stated responsibilities, the IRB must determine and document that the center has a sufficient plan in place to ensure:

- The privacy of participants and the confidentiality of data are adequately maintained
- Each protocol is reviewed and approved by the IRB at the collaborating institution prior to transmission of data

## **Additional Information:**

HHS Guidance on Engagement of Institutions in Human Participant Research:

<http://www.hhs.gov/ohrp/policy/engage08.html>

University of Pittsburgh Resources:

Education & Compliance Office for Human Participant Research: <http://www.ecohsr.pitt.edu/>

Office for Investigator-Sponsored IND and IDE Support (O3IS): <http://www.o3is.pitt.edu/>