

Roles & Responsibilities of Coordinating Centers and Multi- site Research Study Project Managers

Multi-Site Study Projects

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Roles & Responsibilities

- The roles and responsibilities of the Coordinating Center or lead study site are very diverse and may differ based on institution (e.g. UW, Seattle Children's, VA, FHCRC).
- They may also be study-specific.
- However, here are some common roles and responsibilities to help put the puzzle together.



Roles & Responsibilities

Pre-study

Coordinating Center (TASKS)	Project Manager (EXECUTED)
Creates protocol manual	Works with PI and co-investigators to write a protocol manual, later distributes IRB-approved copies to sites.
Establishes data collection process, including SOPs	Works with PI and data manager to set-up database and data collection tools.
IRB submission	Submits IRB application to local IRB. Later distributes copies of IRB-approved protocol and other documents to sites for editing and submission. Reviews IRB applications for study sites.
Training staff at study sites	Establishes schedule of pre-study training conference. May conduct study initiation visit.
Establishes regulatory binder system	Creates and maintains regulatory binders for Coordinating Center, and assists other sites with binders.

Roles & Responsibilities

Throughout study

Coordinating Center (TASKS)	Project Manager (EXECUTED)
IRB assistance and oversight	Maintains records of IRB submissions, approvals, and expiration dates for all study sites; provides guidance or review on IRB forms, tracks annual review.
Distributing protocol changes/IRB modifications	Posts IRB documents and memorandum to central website or shared with sites via email.
Routine communication with study sites	Monthly conference calls, quarterly steering committee meetings, and if possible, annual in-person team meetings.
Monthly progress reports	Uses templates to post monthly reports to a central website, SharePoint, or distributed via email; reports are often discussed during monthly conference calls.
Bi-annual DSMB reports	Collaborates with data manager to prepare tables, reports, and presentations for meetings.

Roles & Responsibilities

Throughout study

Coordinating Center (TASKS)	Project Manager (EXECUTED)
Data oversight	Monitors data collection and submission of data (e.g. CRFs) from all sites.
AE monitoring and reporting	Sites typically notify the project manager of adverse events. The project manager submits SAE reports to the DSMB and IRB as outlined in the protocol manual.
Monitoring and auditing visits	Responsible for preparing for monitoring and auditing visits, and if applicable, reviewing reports from visits to other study sites.
Dissemination of results	Distributes data summaries to investigators and coordinators at study sites; this may occur periodically throughout study or only at the end of data collection and analysis.

In summary, organization is key in multi-site research study project management!

- Coordinating Center
- Multi-site project manager
- Study sites (aka participating sites, performance sites)
- Site study coordinators

