Quick Reference Guide
Coordinating Center Activities

This Quick Guide discusses IRB submission requirements when OHSU is undertaking coordinating center activities in a multi-site research study. Coordinating center activities are directly relevant to the regulatory criteria for IRB approval, including minimizing risks to subjects, ensuring appropriate safety monitoring, and protecting the confidentiality of data.

New Study Submission:

- **Include a Coordinating Center Management Plan.** This may either be part of the protocol or a stand-alone document and should describe OHSU's role in the study, OHSU's responsibilities as the coordinating center, and a detailed plan for carrying out those responsibilities.
- **If sites' IRBs will be approving their own Consent and Authorization Forms, provide a Consent and Authorization Form Template.** You will distribute the template to participating sites, but it will not necessarily be the final approved version at all sites. Also submit any template recruitment documents.
- **If OHSU is also a participating site, both coordinating center and site activities must be addressed in a single IRB submission.** The study documents should clearly delineate OHSU's roles and responsibilities as both a site and a coordinating center.

Example coordinating center activities may include:

- Site identification and evaluation
- Tracking site IRB approvals and site-specific consent forms (note that, unless specifically requested, you do not need to submit these items to the OHSU IRB)
- Subject eligibility and registration process
- Data capture plan, data submission requirements and management processes
- Aggregate study data review plans
- Communication and training plans
- Dissemination plans for new information or changes in the research project
- Safety reporting processes
- Issue escalation processes

Continuing Review:

- **The Annual Event Summary** should include data from all sites involved with the study.
- **Provide any DSMB recommendations.** If your study has a study-specific data and safety monitoring board (DSMB), submit the board's recommendation(s) made since initial submission or last CRQ unless issues are identified by the DSMB. If issues have been identified that impact the conduct of the research, the recommendation and action plan should be submitted in an interim report to the IRB by the appropriate method (unanticipated problem, protocol deviation or modification).
- **Address the Coordinating Center Management Plan** (may be a separate memo or included as new information in the CRQ form)**.**
    - Describe what occurred during the reporting period according to the plan and any deviations from the plan.
    - Provide a summary of any significant issues that have occurred in the coordination center activities for the study such as audits, corrective action plans, or other issues that could have or did significantly impact the research.

Interim Submissions (Modifications, Unanticipated Problems, Protocol Deviations):

- **Unanticipated Problems (UP) and Protocol Deviations (PDs):** UPs and PDs regarding OHSU activities, including coordinating center activities, must be reported to the OHSU IRB according to OHSU policies and procedures. OHSU researchers are not necessarily responsible for reporting study-wide UPs and PDs unless the Coordinating Center Management Plan dictates otherwise.
- **DSMB Recommendations:** If issues have been identified by the DSMB that impact the conduct of the research, the recommendation and action plan should be submitted in an interim report to the IRB by the appropriate reporting method (unanticipated problem, protocol deviation or modification).