Title:	Multi-Site Studies Where UNC-Chapel Hill is the Lead Site or Coordinating Center		
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Multi-site studies where UNC-Chapel Hill is the lead coordinating center

This scenario arises when:

- UNC-Chapel Hill is the lead coordinating center responsible for overall study conduct; or
- A UNC-Chapel Hill employee serves as principal investigator for the entire multi-site study, (unless coordinating function located elsewhere as in some NIH-sponsored groups), or
- UNC-Chapel Hill is the sponsor (initiates contracts with and disburses funds to other sites).

Under these circumstances, the UNC-Chapel Hill PI has additional responsibilities beyond those for a single site study which include notifying the UNC-Chapel Hill IRB of the multi-site nature of the study. *The Lead Site/Coordinating Center Investigator Responsibilities addendum* should be completed when UNC-Chapel Hill is the lead site or coordinating center for a multi-site study.

The UNC-Chapel Hill PI is responsible for the management of information that is relevant to the protection of subjects for activities that do not occur at UNC, such as:

- Unanticipated problems involving risks to subjects or others,
- Interim results,
- Protocol modification

This information is captured in the Protocol Addendum: The *Lead Site/Coordinating Center Investigator Responsibilities* addendum.

When the UNC investigator is the lead investigator of a multi-center study, the IRB evaluates whether the management of information that is relevant to the protection of subjects is adequate. In addition, the PI should notify the Office of Sponsored Research or the Office of Clinical Trials when the project is externally funded. If there is a contractual agreement between UNC-Chapel Hill and the research site(s) the contract should address the responsibilities described in this addendum.

For such multi-site studies, it is the responsibility of the UNC-Chapel Hill PI to provide to the UNC-Chapel Hill IRB assurance that the study at that site will be conducted in compliance with federal regulations (including 45 CFR 46 and HIPAA), all applicable state and local regulations, and ethical principles governing research involving human subjects. Each site must have IRB approval for the study whether by the site's IRB or by an external IRB before the study can be conducted at that site. For studies that are federally funded it may be necessary for each site to have its own Federalwide Assurance (FWA) with OHRP, depending on the

nature of its engagement (see OHRP guidance at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm.

In many cases, investigators at an FWA institution will have a local IRB to which they are responsible; if no such affiliation exists, then the UNC-Chapel Hill IRB may serve as the IRB of record for that investigator. These agreements should be negotiated at the time of initial review or as sites are added (See SOP 901 for more information).

The UNC-Chapel Hill PI is responsible for collecting and maintaining documentation of IRB approvals at each of the participating sites. Submission of these approvals and related documents (e.g., consent forms for participating sites) to the UNC-Chapel Hill IRB is not required, unless requested.

The UNC-Chapel Hill PI is responsible for developing a Data and Safety Monitoring Plan and for implementing a system for reporting and reviewing all unanticipated problems (UP) and adverse events (AEs). If the IRB deems formal oversight by an independent Data and Safety Monitoring Board (DSMB) to be necessary and there is no external DSMB provided, the IRB may require oversight by a UNC-Chapel Hill DSMB.