1 Purpose
This SOP applies when:

- UNC-Chapel Hill is the lead coordinating center responsible for overall study conduct; or
- A UNC-Chapel Hill employee serves as the Principal Investigator for the entire multi-site study, or
- UNC-Chapel Hill is the study sponsor (initiates contracts with and disburses funds to other sites).

2 Policy
Under any of the above circumstances, the UNC-Chapel Hill PI has additional responsibilities beyond those for a single site study, which include:

1. 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.

2. Managing information that is relevant to the protection of subjects for research activities that do not occur at UNC, such as:
   - Unanticipated problems involving risks to subjects or others,
   - Interim results,
   - Protocol modifications.

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

3. Providing the UNC Chapel Hill IRB assurance that the study will be conducted in compliance with applicable federal regulations, state and local regulations, and ethical principles governing research involving human subjects.

When a UNC investigator is the lead investigator of a multi-center study, the UNC 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 Programs, the Office of Clinical Trials or other appropriate office 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.

Each site engaged in the research must have IRB approval for the study, whether by the site’s IRB or by an external IRB, before research activities can be conducted at that site.
In many cases, investigators at an FWA-holding 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. Agreements obligating the UNC-Chapel Hill IRB to serve as the single IRB of record 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.