Overview of Process for Requesting Reliance on an Independent/Central IRB
(In this document, the term "central IRB" refers to Independent/Central IRBs.)

1. UNC researcher identified as investigator/site for an industry-sponsored, multi-center, clinical research study for which any one of the approved central IRBs have been appointed as the central IRB of record by the Sponsor or CRO.

2. UNC researcher submits abbreviated application to UNC IRB via IRBIS. The abbreviated application captures information related to institutional responsibilities and IT data security level. The UNC IRB also acts as a Privacy Board which includes approving HIPAA authorization forms and granting limited HIPAA waivers (permitting identification and initial contact with potential research participants).

3. UNC researcher also completes UNC Conflict of Interest (COI) disclosure. COI disclosures are automatically emailed to researchers from the COI office, when the IRB application is submitted.

4. UNC COI office reviews all COI disclosures. Following review (either expedited, in-office or by committee), an email is sent to individual researchers. The email includes details of the COI management plan and COI language to be inserted into the consent form.

5. UNC IRB reviews application and emails investigator IRB Permission/stipulation letter. This letter provides 1) permission to register with the central IRB, 2) injury language to be inserted into the consent form, 3) outstanding institutional requirements that must be satisfied prior to reliance on central IRB can be granted and, 4) a link to a document repository that includes instructions for registering with the central IRBs.

6. UNC researcher registers with central IRB. In addition to completing a central-IRB specific registration application, the central IRB will require submission of the UNC IRB Permission letter and COI information emails (if COI identified).

   Please note: If the central IRB does not approve the consent form language provided by the relevant UNC office, the central contacts either the UNC COI office (if COI consent form language is not approved) or the Office of Clinical Trials (if consent form injury language is not approved) to finalize mutually agreeable language. The COI or OCT office will communicate any changes regarding consent form language to UNC IRB.

7. The central IRB approves the investigator/study site and provides the investigator with an IRB approval letter and approved consent documents.

8. Once approved as study site and no outstanding institutional requirements, the researcher responds to the UNC IRB Permission/Stipulation letter, by responding to all outstanding stipulations and providing the UNC IRB with a copy of the central IRB approval letter and consent form.

9. UNC IRB reviews consent form to ensure that expected (i.e., mutually acceptable) COI and injury language are included. If no outstanding institutional approvals, the UNC IRB sends the UNC researcher an “official” reliance letter, permitting research to begin. If applicable, the UNC IRB will provide an approved HIPAA Authorization form and grant a limited waiver of HIPAA.

10. Research may begin. Please review the UNC reliance letter for an outline of your ongoing institutional responsibilities.

Version 10/29/2013