**Template language for NIH grant applications: description of compliance with single IRB requirement**

Below is *suggested* language to use in NIH grant applications. Language in brackets [ ] or shaded in gray may need to be modified as appropriate to the funding situation or the site designated as the single IRB.

**When the UNC IRB will serve as reviewing (single) IRB:**

As we are proposing a study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site, we will comply with the NIH requirement to utilize a single IRB (sIRB) for multi-site research. As the lead site, the UNC IRB will serve as the sIRB of record responsible for conducting the ethical review of the study for the participating sites. The UNC Office of Human Research Ethics (OHRE), which oversees the UNC IRB, has long participated in central IRB efforts coordinated by NIH and by many research networks. UNC is firmly committed to the principles of shared review in multisite research, enacting authorization agreements whenever possible. UNC typically executes 250 or more such agreements per year, allowing UNC to rely on another institution’s IRB, or vice versa. Of note, UNC joined with other CTSA hubs to use the NCATS Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform. The UNC OHRE is well-positioned to participate in reliance arrangements with IRBs at other organizations.

All sites participating in the multi-site study (list of all sites) have agreed to rely on the UNC IRB as the sIRB. If additional sites are added after the award, they too will rely on the sIRB. Each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites. Prior to initiating the study, all participating sites will sign an authorization agreement that will clarify the roles and responsibilities of the sIRB and participating sites. All participating sites will follow the UNC IRB Standard Operating Procedures (SOPs) throughout the life of the project. The participating sites will be responsible for meeting all regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB.

The UNC IRB as sIRB will collaborate with the awardee (name of Overall Principal Investigator) to establish a mechanism for communication between the sIRB and the participating sites, documenting this in a communication plan. The PI will hire a project manager who will serve as a liaison to the sIRB and to the participating sites to ensure required documentation is in place and IRB approval obtained for each site. Throughout the conduct of the study, the project manager will communicate with all participating sites regarding IRB modifications, annual renewals and adverse event reporting. The UNC OHRE, as the lead institution, will maintain records of the authorization/reliance agreements and of the communication plan.

**Study Team Communication Plan**

Study initiation conference calls will include a presentation by the [Overall Principal Investigator *or* identify presenter] to inform all sites about the reliance arrangement as well as the review processes and reporting requirements of the Reviewing IRB. In addition [name or role of person (e.g., coordinating center)] will provide each site with a summary of the Reviewing IRB’s reporting requirements to be distributed to their study teams.

The [identify Lead Study Team] will be responsible for ensuring ongoing communication with all participating study teams via teleconferences and regular emails throughout the study. Key communication points will occur to:

[NOTE: the list below is meant to provide examples; institutions should adapt as necessary]

* Disseminate IRB determinations and IRB-approved documents
* Educate study teams regarding the approved study and amendments to the study
* Alert study teams to problems that may affect the conduct of the study or the rights and welfare of research participants, such as unanticipated problems and serious noncompliance
* Inform study teams of any changes in study status (e.g., temporary suspensions of recruitment) or new information
* Facilitate submissions to the Reviewing IRB, including:
  + Inclusion of site-specific requirements in consent documents
  + Identification of any variability in study implementation across sites that must be communicated to the Reviewing IRB
  + Collection of information from participating sites to include in continuing review reports to the Reviewing IRB
  + Site-specific amendments
  + Personnel updates (as required by the Reviewing IRB)
  + Reportable events (e.g., noncompliance, unanticipated problems)
  + Closure reports
* Ensure revisions to applicable conflict of interest management plans are provided to the Reviewing IRB

**Budgeting for expenses related to single IRB (when UNC IRB serves as single IRB)**

* Investigators will need to budget for sIRB in their grant applications. If UNC will be the Reviewing IRB, the study team will need to budget for appropriate staffing to manage information going out to, and returning from the participating sites. An essential UNC study team member will need to be identified as the IRB liaison and will effectively serve as a project manager for all sites, and should be budgeted for accordingly. This would be listed as a direct cost in the budget.
* Currently, UNC IRB charges review fees only for industry-sponsored research. This is expected to change in the future, and many Reviewing IRBs may begin to charge fees for IRB review. However, no determinations have yet been made and there are no current fees associated with review of NIH sponsored multisite research at UNC. Additional information pertaining to budgeting and fees for sIRB review will be forthcoming.
* If a UNC investigator is the lead PI on the multisite trial, the UNC IRB will expect to be named the Reviewing IRB. Alternatively, the Reviewing IRB may be at the institution providing data coordinating center (DCC) activities for the multisite trial.