NIH single IRB for multisite research mandate effective January 25, 2018

The NIH policy on the use of a single IRB (sIRB) of record for multisite research became effective on January 25, 2018. The policy applies to the domestic sites of NIH-funded multisite studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards. The policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018. Ongoing, non-competing awards will not be expected to comply with this policy unless the grantee submits a competing renewal application.

UNC Investigators and research teams preparing grant applications due on or after the implementation date will be expected to include a plan for sIRB review in the application. The plan should include the following:

1. Identify the sIRB of record (the Reviewing IRB)
2. Indicate that:
   -All sites, including any added after award, agree to rely on the chosen sIRB
   -Sites will sign a reliance agreement that will include a communication plan, and
   -Indicate who will maintain records of the agreement.

The lead PI's institution may often be identified as the Reviewing IRB. 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. Investigators are encouraged to consult with the UNC IRB prior to including an sIRB plan in their application if they have questions about whether or not UNC should cede review or assume the responsibility of being the Reviewing IRB.

Investigators will also 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 be identified as the IRB liaison and will effectively serve as a study coordinator for all sites, and should be budgeted for accordingly. 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.

UNC Investigators and research teams who expect to participate as a site in NIH sponsored research when UNC will cede review to another IRB will still be required to submit an abbreviated application through IRBIS. UNC IRB will conduct a local review to address institutional requirements, manage UNC personnel and any relevant ancillary reviews (e.g. UNC Radiation Safety, Investigational Drug Service, Biosafety), and work with the Reviewing IRB to complete their local context information and execute the reliance agreement. UNC personnel participating in ceded research will be expected to meet UNC conflict of interest and ethics trainings requirements.

UNC Investigators and research teams leading NIH sponsored research when UNC IRB will be the Reviewing IRB will have more responsibilities for managing the application and submission materials received from participating sites. The initial IRBIS application will include the request for UNC to provide IRB review and list the participating sites and their local PI and site liaisons only. The goal of the initial

review will be to ultimately approve the protocol and model consent form. Sites will then be provided with the UNC approval letter, an approved model consent form and a local context worksheet by the UNC study liaison. Site staff will assist with customizing their consent and completing their local context worksheet. Participating sites will be activated or approved by the UNC IRB during subsequent modification submissions as their materials are returned to the UNC IRB liaison and submitted for review.

Additional information and an updated guidance document providing detailed instructions on this new reliance process will be forthcoming.

You may review the NIH posting regarding sIRB review here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

If you have additional questions about reliance agreement or the sIRB review process, please do not hesitate to call the UNC OHRE main line at 919-966-3113, or email your questions to IRBReliance@unc.edu.