

# NIH mandates single IRB review of multisite research

**Effective Date: January 25, 2018**

The National Institutes of Health (NIH) Policy on the use of a single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

This policy applies to the domestic sites of NIH-funded multi-site 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 new mandate applies to domestic awardees and participating domestic sites only. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. 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.

## How will the NIH sIRB mandate impact UNC investigators and research teams?

**Currently approved, ongoing NIH-funded multisite research:** There will be no action required and the research will continue to be reviewed both at UNC and the participating sites' IRBs for modifications and annual renewals until a competitive renewal is required to secure continued funding for the research after January 25, 2018. The UNC IRB will not review requests to implement sIRB review for currently ongoing research unless a competitive renewal is required to secure additional funding.

**NIH-funded multisite research yet to be IRB approved:** Investigators and research teams planning to submit NIH-funded multisite research after the implementation deadline will need to plan appropriately for sIRB review. If the research will be led by a UNC-based investigator and the UNC IRB will be the reviewing IRB, there will be considerations relevant to administrative costs and staffing that will need to be included in the grant proposal. The lead PI will be required to assign a member of the research team as IRB liaison for the project. This person will be responsible for the initial IRBIS submission to approve the protocol and model consent form, as well as the subsequent modification submissions to on-board participating sites who have ceded review to UNC. The liaison will have primary responsibility for tracking and managing information sent out to, and returning from the participating sites, in addition to managing the project's IRBIS submissions. Investigators who intend to participate in multisite NIH research when the UNC IRB will not be the reviewing IRB, but will cede review to another participating sites' IRB will experience minor changes from the current process for relying on an external institution or central (commercial) IRB. These cases will still require an application in IRBIS, and the review will require UNC IRB assessment of UNC personnel's conflicts of interest disclosures, ethics training requirements, and customization of any consent forms to be utilized for subject recruitment at UNC.

Additional announcements will be forthcoming, including submission details, further updates to the IRBIS application to accommodate the sIRB process, revised reliance agreement guidance, cost specific information, information regarding the Smart IRB exchange and other related topics. The UNC IRB has been piloting a number of new NIH projects through a new review process. These test cases have and will continue to illuminate challenges which must be addressed as we move toward implementing a review process to meet the NIH mandate.

UNC investigators interested in requesting that UNC serve as the single IRB for their NIH-funded multi-site research **prior** to the implementation deadline of January 25, 2018 should contact John Roberts, OHRE Reliance Manager at [jtr@unc.edu](mailto:jtr@unc.edu). Until January 2018, requests will be considered on a case-by-case basis. Due to limited resources, the UNC IRB may not be able to fulfill this role until the implementation deadline.

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, please do not hesitate to call the UNC OHRE main line at 919-966-3113, or email your questions to [irb\\_questions@unc.edu](mailto:irb_questions@unc.edu).