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 VT 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 VT 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 VT 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 on or after the implementation deadline will need to plan appropriately and allow sufficient time to address sIRB requirements within the grant proposal. NIH’s grant proposal will require inclusion of a written plan justifying the IRB-of-record and defining related procedures, which must be coordinated with the VT IRB and external sites. VT investigators are encouraged to contact the VT IRB as an initial step during this process so the IRB may assist with the process.

The lead PI will be required to assign a member (or members of the research team) as IRB liaison for the project. The liaison will be responsible for IRB administration activities such as IRB submission and correspondence coordination. 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 IRB submissions.

Note that to ensure compliance with sIRB requirements, investigators who intend to participate in multisite NIH research when the VT IRB will not be the reviewing IRB, but will cede review to another participating sites’ IRB will need to work with the VT IRB to facilitate the IRB’s assessment of VT personnel’s conflicts of interest disclosures, ethics training requirements, and customized consent forms to be utilized for subject recruitment at VT.

Further announcements will be posted on the IRB website including submission details, information regarding updates to the VT IRB application to accommodate the sIRB process, revised reliance agreement guidance, and other related topics.

VT investigators interested in discussing the new requirements may e-mail the VT IRB at irb@vt.edu or call (540) 231-3732.
You may review the NIH posting regarding sIRB review here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html