SQUIRE PATTON BOGGS

National Institutes of Health Extends Effective Date of sIRB Policy

Recently, the National Institutes of Health (NIH) extended the effective date of its policy on the use of the single Institutional Review Board (IRB, or sIRB if a single IRB) to January 25, 2018. NIH created the sIRB policy to establish the expectation that a sIRB be used in the ethical review of multisite, domestic, non-exempt human subject research funded by NIH. The extension will apply to all competing grant applications with due dates on or after January 25, 2018.

sIRB Policy

NIH drafted the sIRB policy to enhance and streamline the IRB review process for multisite research studies and eliminate duplicate IRB reviews. The purpose of the policy is to establish the expectation that a sIRB would be used to conduct the ethical reviews required by 45 C.F.R. Part 46 for domestic multisite studies involving non-exempt human subject research funded by NIH. The policy applies to domestic sites that conduct studies according to the same protocol. The policy would not apply to foreign sites that participate in the studies, career development, research training or fellowship awards.

As part of the policy, applicants/offerors would be expected to submit a plan describing the use of the selected sIRB, including a statement confirming that the other participating sites will adhere to the sIRB policy. The participating sites will rely on the sIRB to carry out the functions that are required for institutional compliance, but are responsible for obtaining informed consent, overseeing the implementation of the approved protocol and reporting any unanticipated problems and study progress to the sIRB. Importantly, the policy does not expressly prohibit a participating site from duplicating the sIRB, but NIH funds may not be used for the cost of this duplicate review. The applicant/offeror should also describe how communications between the sites and the sIRB will be handled.

According to the policy, sIRBs are responsible for conducting the ethical reviews of NIH-funded multisite studies for the participating sites, including carrying out the regulatory requirements under 45 C.F.R. Part 46. sIRBs may also serve as the Privacy Board to fulfill the requirements of the HIPAA Privacy Rule and will collaborate with the successful applicant/offeror to establish a mechanism for communication between the sIRB and participating sites.

Stakeholder Feedback

Many stakeholders commented on NIH's draft policy, published in a notice in the *NIH Guide for Grants and Contracts* in December 2014. While the comments were generally positive, academic institutions and IRBs were concerned about how a non-local IRB may protect local, vulnerable populations and that "site-specific practices for recruitment and retention, especially for vulnerable populations, would pose challenges for an sIRB." Possibly to respond to such comments, the final NIH policy allows for exceptions to the sIRB policy when review by a sIRB would be prohibited by a federal, tribal or state law, regulation or policy, or for a compelling reason.

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