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NIH Signals “Paradigm Shift” with Policy on Multi-Site Studies

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Federally-funded clinical trials conducted at multiple sites will move to a single Institutional Review Board (IRB) review scheme under a new National Institutes of Health (NIH) Policy. The NIH has finalized its policy to have a single IRB (sIRB) of record conduct the required ethics review for multi-site studies. The NIH cited “systemic inefficiencies” without any increased protection of human subjects under the current system in which a separate IRB conducts the ethics review for each site.

Who does this affect?

The sIRB policy covers NIH-funded non-exempt human subjects research, and applies to the domestic sites of multi-site studies conducting the same research protocol at each site. Foreign sites are not covered. Neither are career development, research training or fellowship awards. This policy does **not** necessarily apply to industry-sponsored trials or drug and device studies subject to FDA regulation only.

What is required?

An sIRB must be in place before a multi-site study begins, whether identified in the application or in a separate notice to NIH from the awardee. The sIRB’s costs can be included in the applicant’s grant request, consistent with existing policies.

Awardees, the sIRB and NIH will need to work together to ensure the sIRB and participant sites are communicating and understand each other’s authorities, roles and responsibilities. The sIRB will be responsible for carrying out the regulatory requirements for IRB review in 45 CFR 46 (HHS Protection of Human Subjects) at each participant site. Other regulatory requirements, like obtaining informed consent, overseeing the protocol, and reporting progress and problems to the sIRB, will stay with the participating sites.

A participating site must use the registered sIRB, but is not barred from using an additional IRB. If it does, NIH funds will not cover the costs for the separate IRB review. NIH specifically states that “IRB ethical review at a participating site would be counter to the intent and goal of this policy. . . . ” Some

stakeholders commented that the sIRB model would struggle to address local considerations, like institutional commitments and regulations, standards of practice, vulnerable population considerations and investigator competence or conflicts of interest. Some also wanted NIH to encourage, but not require, the use of an sIRB. Ultimately, the NIH "found no compelling reason to narrow the essential scope of the final policy," but "recognize[d] that the policy will begin a paradigm shift in IRB review."

What can we expect?

In recognition of this "paradigm shift," the NIH sIRB policy will not go into effect until May 25, 2017. The NIH plans to give guidance and resources to help awardees with the change.

Before the final policy was issued, many stakeholders took the opportunity to comment on the proposed draft. Despite some opposing viewpoints, there were consistent requests for more guidance and detail from NIH on how to implement the new structure, so these additional tools fleshing out NIH's simple two-page policy will be eagerly awaited.

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