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NIH Hears Earful of Woes About sIRB Policy; Confusion Surrounds Costs, Roles, Exceptions

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The five-plus-hour workshop was designed to share experiences among colleges and universities conducting NIH-supported research using the single institutional review board (sIRB) model, which NIH now requires for certain trials. But by its conclusion, the meeting ended up being much more of a giant cry for help from NIH to loosen—and clarify—the sIRB mandate.

NIH has touted the use of an sIRB as a way to reduce inefficiencies that may result when multiple IRBs are involved in large trials. But its 2016 policy, which went into effect in January, has proved controversial from the start.

The sIRB policy is mandatory for all agency-funded multisite trials using the same protocol—and NIH defined multicenter as having two or more study locations. Even HHS' own advisory committee on human subjects protections has said the policy should generally apply when six or more sites are involved.

Although NIH is the largest government funder of human subjects research, the sIRB mandate will apply to recipients of funding from the other nearly two-dozen agencies as of January 2020. It could be argued that those living under the sIRB policy now are the most experienced, and their woes may foreshadow much more widespread challenges two years from now.

The sIRB policy was supposed to go into effect in May 2017, but was twice delayed. The final policy notice explained that a plan to use an sIRB is required for "all competing grant applications for due dates on or after January 25, 2018." It also applies to NIH intramural studies.

Multicenter studies with foreign sites don't have to comply, and the policy doesn't apply when it conflicts with state law. NIH also promised to consider exceptions on a case-by-case basis, but it has provided no specific guidance or detailed examples of when it might allow them.