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Committee Highlights Problems With "Single IRB Review" of Multisite Studies

We continue this month with coverage of a very controversial and potentially disruptive and expensive federal initiative spearheaded by the National Institutes of Health (NIH). Instead of calling for a national meeting or any other approach on this particular research compliance issue, NIH has proposed a mandatory, across-the-board regulatory change with significant impacts on Institutional Review Boards.

The NIH proposal, issued on December 3, 2014, calls for the required use of a single IRB for human subject experiments that involve multiple study sites. As we have been reporting, numerous national groups have objected to NIH's proposal, but not because it is entirely without merit. Instead, objectors are pointing out that the major regulatory change is being proposed without any precursor studies of the effects of the changes, any discussion of costs and benefits of the proposal, any record of IRBs and institutions trying to implement the changes, or analysis of whether the changes yield positive effects for anybody.

The proposal in question is titled "Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research" (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html). The policy would affect all human research funded by NIH.

Unnecessary Burdens on Institutions Possible With "Single IRB Review" of Multisite Studies

One source of objections is the national-scope body known as the Secretary's Advisory Committee on Human Research Protections (SACHRP). We have already reported on the SACHRP's general recommendations on the NIH proposal. We now present SACHRP's input to NIH titled "Evaluation of Impact on Relying and Reviewing Institutions."

> "Mandatory single IRB review could serve to create burdens on all institutions. Most institutions have systems that are not necessarily designed for the purpose of managing multi-site research and thus service as a central IRB would require substantial resources, increased cost and re-tooling of processes for the site that serves as the IRB of record.
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> A significant barrier to institutional adoption of a single IRB for multi-site research is the information technology required to ensure adequate review, communication, and oversight. Systems currently serving IRBs and institutional human research protection programs differ from one another, are complex and expensive, and are not interoperable.
>
> Institutions incur significant expense to build technical solutions customized and appropriate to the needs of their institution. Changing the existing technology to incorporate communication and

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc.

NOTE #2: Articles may be continued in subsequent issues.

Also In This Issue

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