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Proposed Policy Changes for Human Subjects Research

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Draft NIH Policy on the Use of a Single IRB for Multi-Site Research

Scope

NIH generally expects all domestic sites of multi-site NIH-funded studies to use a single IRB of record.

While foreign sites in multi-site studies will not be expected to follow this Policy, they may elect to do so.

Responsibilities

All sites participating in a multi-site study will be expected to rely on a single IRB to carry out the functions that are required for institutional compliance with IRB review.

The single IRB will be the IRB of record for the other participating sites.

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All participating sites will be responsible for meeting other regulatory obligations, such as obtaining informed consent,…, and, reporting unanticipated problems and adverse events to the single IRB of record.

Agreements between the single IRB of record and other participating sites will be needed in accordance with 45 CFR part 46

As necessary, mechanisms should be established to enable the single IRB of record to consider local context issues during its deliberations.

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Identification of the IRB that will serve as the single IRB of record will be the responsibility of the extramural applicant or offerer, or the intramural principal investigator.

Use of the designated single IRB will be a term and condition of award. If the agreed-upon single IRB is a fee-based IRB, these costs will be included in the Notice of Award as a direct cost.

Exceptions to the Policy

Exceptions

Exceptions to the expectation to use a single IRB may be made with appropriate justification.

Exceptions will be allowed only if the designated single IRB is unable to meet the needs of specific populations or where local IRB review is required by federal, tribal, or state laws or regulations.

Problems We See With the Draft Policy

One-size fits all – may not result in the best IRB review model for the specific project.

Creates concerns about how and when a reviewing IRB is identified and about IRB and institutional HRPP protections that are impacted.

Has potential to adversely affect investigator timelines and to add burden in preparation of NIH funding proposals.

Single IRB review can create new cost burdens to the reviewing institution

General Issues

Not all IRBs, or associated HRPPs, are well positioned to take on these tasks. Inexperienced IRBs may have trouble scaling-up or responding to the influx of information necessary to address matters on a nationwide or international scale. Costs and necessary infrastructure may be prohibitive and not sustainable.

Concerns about institutional liability remain unaddressed. Many IRB reliance agreements are silent on the matter, assuming institutions have appropriate insurance coverage. However, liability issues are necessarily magnified in a multi-institutional situation where reliance on the decision-making of a single institution is mandated as a condition of participation.

Recommendations

We support the adoption of the single IRB of record model for multi-site research projects when each site is required to follow the same protocol and deviations from that protocol would have a detrimental effect on research results.

We note that research reviewed by the NCI CIRB fits these criteria, and we recommend that the NIH NOT impose this process for all studies, but rather pilot the proposed policy on research projects fitting the NCI CIRB model.

Key Challenges

Draft Policy –

- Does not clearly state that it would apply only to multi-site studies in which a single protocol is implemented at all sites
- Does not recognize the time and effort required to establish a central IRB, as well as to enter into agreements with all of the partner sites
- Contemplates establishing a new central IRB *de novo* for each multi-site grant
- Does not recognize that efficiencies are only realized if a model calls for review of several studies at many of the same participating sites over time

Key Challenges (cont)

- Growing number of “central” IRBs poses a logistical problem for research universities.
- IRBs do not function in a vacuum. They exist as a component of a larger Human Research Protections Program (HRPP).
- IRB software systems are often programmed to send notifications to partnering units based on answers to questions in the IRB application.
- Every time an external central IRB is used, the automated notification and information-sharing system is disrupted.

Challenges with the Current NIH Single IRB Model

- The model currently in use by NIH Institutes (other than the NCI) of employing varying single IRBs for multi-site studies adds to the difficulties of initiating studies.

- Currently each institution designated as a single IRB for multi-site NIH studies develops its own SOPs and partnering agreements.

- The end result is a growing mosaic of idiosyncratic IRB roles and responsibilities that our investigators and institutional IRB must learn and follow.

Accreditation

- NIH Draft Policy does not require single IRBs to be accredited. This is contrary to AAHRPP expectation.
- If only accredited IRBs are selected as the single IRB, this will add significant burden to those institutions.

Institutional Cost of Draft Policy Model

- Reliance on an external IRB does not save administrative costs.
  - Shifts resources from supporting internal IRBs to managing the external relationships as well as managing the loss of automated communications
- The Draft Policy states that the costs of using a fee-based IRB can be included in the direct costs of the grant
- There is no accommodation made for institutions which include the cost of the IRB in the Administration component of the F&A rate.
  - The added cost of operating as a central IRB will be an unfunded mandate.

Recommendations

- Keep the number of central/single IRBs to a minimum.
- There should be allowances for local IRB review in specific cases such as when a local investigator has a COI.
- The NIH should first require the use of the NCI CIRB.
- The NCI CIRB should be expanded to cover all NCI-funded multi-site studies.
- The NIH should consider expanding the NCI CIRB operating model to other Institutes.

Other Considerations

- The Draft Policy includes as a part of its justification that use of a single IRB can be useful in "minimizing institutional conflicts of interest…" It is ill-advised to justify this policy by saying that it can manage an issue for which there is no federal policy, regulation, or law.

- Justification of this Draft Policy because it is "in keeping with one of the proposed changes being considered to the Common Rule…"
  - Implementing a policy in advance of the rule is a practice that should be avoided at all costs. Rather, policy and guidance should be promulgated only after final regulations have been issued.