FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Single Institutional Review Board (sIRB): Implementation and Costing Perspectives Updates

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Overview

- Implementation Date
- Context & Applicability
- Costing Topics
- Implementation Options

Implementation Date

- Extended to September 25, 2017 (NOT-OD-17-027)
  - Effective for applications submitted on or after this date

- Institutions have an additional 4 months

Context & Applicability

- Applies to:
  - Domestic sites of multi-site studies
  - Each site conducting same protocol involving non-exempt human subjects research

Context & Applicability

- A plan submitted with the application

- Requests for exceptions
  - Automatic exceptions will be made when sIRB review would be prohibited by a federal, tribal, or state law, regulation, or policy
  - All other exception requests not based on law/regulation/policy must be approved by NIH

Current Status at your institution?

- What type of institution are you representing?
  - Participating site (pSite), sIRB of record, both pSite and sIRB, neither, or don't know
- How many multi-site studies are conducted at your institution for which your institution serves as the sIRB?
  - Don't review multi-studies, <5, 5 – 10, >10, not sure
- Will the number of multi-site studies where you cede review to an sIRB increase? If so, by how many?
  - Continue to not cede review, <25%, 26 – 50%, 51 – 75%, or >75%

Current Status at your institution?

- How do you plan to comply with the new policy?
  - Make minor improvements, outsource the oversight, consider new system, or not sure
- Where is your institution on the Implementation Readiness Paradigm?
  - Concerned about implementation timeframe (staffing, technology, business process) and need more time?
  - Working on it and waiting to see…
  - Relieved about the delay…
  - No Concerns
  - Don't know
- Where is your institution on costing/direct charge decision?
  - Waiting for more clarity
  - Hope to direct charge if system, process, & regulations will allow
  - Not planning on direct charging when you are the sIRB
    - Because too difficult to make system changes, manage costs and not worth it?
    - Because culturally there is institutional resistance now (and may revisit in the future)?

Costing Guidance

- Primary activities:
  - Activities associated with conducting the ethical review of the proposed research protocol and the review of the template informed consent document.
- Secondary activities:
  - Activities associated with the review of site specific considerations (unlike circumstances) for all of the participating sites.

Costing Guidance

- Policy does not require sIRB costs to be direct charged.
  - Institutions retain flexibility in deciding how they will assign costs.

- Cost Allocation Services (CAS) supports guidance provided re: distinction between primary & secondary costs (NOT-OD-16-109)

Uniform Guidance

- 2 CFR 200, Appendix III C.8.b:
  - "Institutions should not change their accounting or cost allocation methods if the effect is to change the charging of a particular type of cost from F&A to direct, or to reclassify costs, or increase allocations from the administrative pools identified in paragraph B.1 of this Appendix to the other F&A cost pools or fringe benefits."

- sIRB costs may be charged direct without violating UG if:
  - Institution can sufficiently differentiate the costs that are charged indirectly vs. directly (new costs)
  - OR if it's categorized as an unlike circumstance

- Be aware that some costs may be intermingled and therefore run the risk of violating the Uniform Guidance if recovered as both direct and indirect.

Costing Topics

- Incremental Costs
- Unlike Circumstances

Implementation Options For Discussion

- Independent/commercial IRB
- Fee structure established by institution
- Remove all IRB costs from F&A pool
- Other options & ideas?

Commenters' Suggestions for sIRB Evaluation Criteria

(excerpted from Final NIH Policy on the Use of a sIRB (NOT-OD-16-094))

- Evidence of a commitment to the highest ethical standards and ability to meet rigorous standards for quality and protection of research participants, e.g., through accreditation or assessment…
- Well-established track record of compliance and performing high quality reviews, e.g., no regulatory errors or failures to address Common Rule… requirements or FDA regs;
- Appropriate expertise and experience to review the proposed research and the capacity to review the study protocol and participating sites;
- Adequate institutional infrastructure and support, and evidence of quality and robustness of the institution's human research protection program;
- Sufficient staff to handle communications between all sites for initial review, continuing review, adverse events, amendments, etc.;
- Available interoperable information technology resources to facilitate communication and exchange of information between the participating institutions;
- Sufficient resources to negotiate and track authorization agreements;
- Ability to account for the IRB costs for review and management and how those costs will be met;

NIH Guidance on Costing

- NIH representatives suggested at the September 2016 FDP meeting and in follow-up that if IRB costs are not included in an institution's indirect cost rate agreement the institution could charge the full costs, both primary and secondary, of the sIRB review when acting as the reviewing site.
  - Does your institution include/not include IRB costs in your indirect cost agreement?

NIH Guidance on Charging Costs (paraphrased)

- **Primary activities** – protocol and template informed consent review for all sites.

- **Secondary activities** - investigator qualifications, institutional capabilities, state/local regulatory requirements, and community ethos. Reviewing reportable events from all participating sites, e.g., unanticipated problems, protocol deviations and reporting them as necessary; receiving and reviewing complaints regarding the conduct of the study; notifying all participating sites of serious or continuing non-compliance and all other determinations; and communicating with sites on matters related to sIRB determinations.

Guidance on Charging Costs

- To the extent IRB costs are included in the indirect cost pool, the UG allows for greater flexibility in direct charging administrative costs.
- If the cost of the review can be specifically identified with a particular grant an institution should have the ability to include the full cost of the review in the proposal budget.
- As institutions reorganize their IRB enterprise to comply with the new NIH policy, it will be imperative that the maximum costing flexibility is provided.
- Discussions with NIH on these issues are ongoing.

Infrastructure Costs

- Institutions will incur significant infrastructure costs to alter or supplement their systems, processes and personnel.
  - How will these costs be reimbursed?
  - Can they be factored into the rate that is direct charged? – indications from NIH are that they cannot.

- Would NIH consider providing IT infrastructure grants for upgrading or replacing IRB systems?

sIRB Costs: Options for Direct Charging

- Develop a direct charge rate that includes costs for an institution's IRB office and other specific costs.
  - Separating costs into primary and secondary costs would be difficult and burdensome.
- Can the costs be charged through a service center mechanism?
  - Pros and cons of charging through a service center

Discussion and Questions

NIH Resources

SingleIRBpolicy@mail.nih.gov

GrantsCompliance@nih.gov

Implementation FAQs: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review