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NIH SINGLE IRB POLICY: COSTING PERSPECTIVE

DIVISION OF GRANTS COMPLIANCE AND OVERSIGHT

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION

National Institutes of Health

OVERVIEW

- **Overview**
- **Context & Applicability**
- **Costing Topics**
- **Implementation Options**

OVERVIEW

- **Policy issued June 21, 2016**
- **Implementation date extended to <u>September 25, 2017</u> (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 the same protocol involving non-exempt human subjects research**

CONTEXT & APPLICABILITY

- **Plan submitted with the application**
- **Requests for exceptions**
  - 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 obtain NIH approval

COSTING GUIDANCE

- **Policy does not require sIRB costs to be direct charged.**
  - Institutions retain flexibility in deciding how they will assign costs, in accordance with the Cost Principles.
  - Since cost principles remain unchanged, if using sIRB prior to the September 25 implementation date, applicants may choose to include sIRB costs in their direct cost budget.

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

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.

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."

Certain sIRB costs may be charged direct without violating Uniform Guidance if:

- Institution can sufficiently differentiate the costs that are charged indirect vs. direct
- Costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect

DIRECT CHARGING OF COSTS

- **NIH consulted with OMB and CAS concerning the option for recipients to direct charge certain costs associated with sIRB implementation**
- **Cost principles have always permitted recipients to classify and charge costs as direct**
- **This does not constitute a change in accounting or cost allocation methods**
- **OMB and CAS agreed with NIH's position that this is consistent with the cost principles and with the provisions of Uniform Guidance**

IMPLEMENTATION OPTIONS FOR DISCUSSION

- **Fee structure established by institution**
- **Recharge or service center (specialized service facility; see 45 CFR 75.468)**
- **Remove all IRB costs from F&A pool**
- **Independent/commercial IRB**
- **Other options & ideas?**

RESOURCES

Guide Notices

- **sIRB Policy:** https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html
- **Cost Scenarios:** https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html

Resources

- **Implementation FAQs:** http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review
- **NEW: Cost FAQs:** http://osp.od.nih.gov/sites/default/files/FAQs_on_sIRB_Costs.pdf
- **SMART IRB Reliance Platform:** https://smartirb.org/resources/

Mailboxes

- SingleIRBpolicy@mail.nih.gov
- GrantsCompliance@nih.gov