OVERVIEW

• Overview

• Context & Applicability

• Costing Topics

• Implementation Options
OVERVIEW

• Policy issued June 21, 2016
• 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
Applies to:

• Domestic sites of multi-site studies
• Each site conducting the same protocol involving non-exempt human subjects research
• 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


Resources

- **NEW: Cost FAQs:** [http://osp.od.nih.gov/sites/default/files/FAQs_on_sIRB_Costs.pdf](http://osp.od.nih.gov/sites/default/files/FAQs_on_sIRB_Costs.pdf)
- **SMART IRB Reliance Platform:** [https://smartirb.org/resources/](https://smartirb.org/resources/)

Mailboxes

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