

1. What are the “cost principles” referred to in the NIH sIRB Policy?

The cost principles are described in regulation at 45 CFR 75 Subpart E, and are implemented by reference in the NIH Grants Policy Statement ([Section 7.2](#)). They establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or indirect (F&A) costs, and set forth allowability and allocability principles for selected items of cost.

[Back to Top](#)

2. May direct costs be used to support administrative tasks of supporting a single IRB?

Direct charges for the salaries of administrative and clerical staff are allowable, but only if all of the following conditions are met: (1) administrative or clerical services are integral to a project or activity; (2) individuals involved can be specifically identified with the project or activity; (2) such costs are explicitly included in the budget; and (4) the costs are not also recovered as indirect costs. Such charges must also meet the criteria for allowable costs described in 45 CFR 75.403. Under the NIH Standard Terms of Award, these costs do not require NIH prior approval as long as the above conditions and criteria are met, and the recipient has appropriate supporting documentation. Please see the [NIH Grants Policy Statement Section 8.1.1.5](#).

[Back to Top](#)

3. Can the use of an independent (commercial) IRB as a single IRB be a direct cost?

Yes. Independent IRBs, which are **not** affiliated with a research institution, are neither included under another institution’s F&A rate agreement nor do they have Federally-negotiated indirect cost rate agreements of their own. Therefore, the fees charged by independent IRBs may be charged as a direct cost when they are serving as the single IRB. Please refer to [NOT-OD-16-109](#) for further guidance on single IRB cost allocation.

[Back to Top](#)

4. Is there a ceiling on costs for single IRBs? Will NIH provide a standard formula for calculating single IRB costs?

NIH has not established a prescribed ceiling or formula for single IRB costs. It is the recipient's institutional responsibility to determine and calculate single IRB costs. As with all charges to NIH grants, costs must be reasonable and necessary, allocable, consistently treated, and conform to the limitations and exclusions as contained in the terms and conditions of award. Please see the [NIH Grants Policy Statement Section 7.2](#) and 45 CFR 75.403 for more information on allowable costs.

[Back to Top](#)

5. May the costs of single IRB consideration of site-specific issues be charged as a direct cost?

Yes. Incremental or increased costs above what is included in an organization's indirect cost pool, such as the single IRB's review of site-specific considerations, may be charged as direct costs. However, the organization must ensure that such costs are not also recovered as indirect costs. Please refer to [NOT-OD-16-109](#) for guidance on single IRB cost allocation.

[Back to Top](#)

6. May recipient institutions develop standard fees for single IRB review costs, and charge these fees to NIH awards as direct costs according to a set schedule (e.g., per site, per year, per event, etc.)?

Recipient institutions have the flexibility to develop their own fee structures for single IRB costs in the manner that is most appropriate for their institutional systems and procedures, including a service center, fixed fee, or other appropriate methods. NIH will not dictate how recipients implement these structures, except to apply cost principles and administrative requirements.

Some fee structure arrangements may meet the criteria for a specialized service facility. Requirements for specialized service facilities are found at 45 CFR 75.468. NIH encourages recipients to identify an appropriate fee structure that supports the recipient's requirements

and audit structure.

[Back to Top](#)

7. May institutions remove IRB costs from the indirect cost pool in order to direct charge the full cost of a single IRB review?

Yes, institutions may choose to remove all IRB costs from their indirect cost pool thereby charging all IRB costs, including single IRB costs, as direct costs. However, institutions considering making this change should consult with their cognizant Federal agency for indirect costs so that the potential impact on the institution's indirect cost rates can be assessed.

[Back to Top](#)

8. Institutions will incur significant infrastructure costs in order to convert to single IRB, including: altering and/or supplementing systems, processes and personnel in order to serve as single IRB and track activity accordingly, hiring new administrative staff. Will NIH support these costs?

Infrastructure costs are typically allowable as F&A costs under NIH grants. NIH does not currently have a mechanism for providing additional funding to support sIRB infrastructure development.

[Back to Top](#)

9. When single IRB activities are charged as direct costs, under which budget category on the SF424 (R&R) detailed budget form should these direct costs be listed?

Applicants may include the various costs associated with single IRB review under any detailed budget category that is appropriate for the cost being requested (e.g., salary & fringe for individuals listed under Personnel, or fees listed under Other Costs), in accordance with the recipient's method of charging single IRB costs.

[Back to Top](#)

10. I am planning to submit an application prior to the effective date of the NIH single IRB Policy, but we intend to use a single IRB review model. Is it acceptable to include single IRB costs in our requested direct cost budget before this date?

Yes. The cost principles have always afforded applicants the ability to include any costs meeting the direct cost criteria (i.e., applicable cost principles, the NIH Grants Policy Statement, and their institutional policies) in the application budget.

[Back to Top](#)

11. If including direct costs for single IRB puts my application over \$500,000 direct costs, must I follow the NIH policy requiring applicants requesting \$500,000 or more in direct costs to contact IC Program staff at least six weeks prior to submission?

Yes. Applicants must still follow the required procedures for applications requesting \$500,000 or more in direct costs in any one budget period. Single IRB costs are not excluded from this policy.

[Back to Top](#)

12. If I request costs related to single IRB as a direct cost in my grant budget, should those costs be excluded from the indirect cost base when calculating my indirect costs?

Institutions should refer to their Federally-negotiated indirect cost rate agreement for guidance on how indirect costs must be calculated, including identifying any exclusions. Institutions should consider the impact of costs such as single IRB when negotiating indirect cost rate agreements.

[Back to Top](#)

13. Our next F&A proposal is not due for several years. May we alter our manner of charging IRB costs prior to renegotiating our F&A rate?

The cost principles have always allowed for recipients to charge IRB costs as direct charges. Recipients must ensure that costs are not recovered as both direct and indirect costs. We encourage institutions that are considering changes to their cost allocations to consult with their cognizant Federal agency for indirect costs so that the potential impact on the institution's indirect cost rates can be assessed. It is not necessary to wait until the next F&A rate negotiation to consult with your cognizant Federal agency. Recipients may determine if and when to approach their cognizant Federal agency for indirect costs.

[Back to Top](#)

14. If the proposed single IRB must be renegotiated at the time of award, will there be an opportunity to change the budget for single IRB costs at that time as well?

As always, NIH IC staff will engage the applicant in pre-award evaluation and negotiation of the award to ensure that the budget is appropriate to the work proposed. If it is necessary to revise the budget based on the selection of the single IRB, revised budget information may be requested prior to award.

[Back to Top](#)

15. May recipient institutions work with commercial IRBs or other organizations in order to identify pricing options for a single IRB?

Yes. NIH encourages applicant and recipient institutions to consult any available resources as needed, including commercial IRBs, in order to obtain needed costing information.

[Back to Top](#)

[Load More](#)