NIH Single IRB Policy FAQs for Extramural Community

Policy Background and General Requirements

1. Why is NIH promoting the use of a single IRB for multi-site research studies?

The use of a single IRB of record for multi-site studies conducting the same protocol will help streamline the IRB review process and remove redundant hurdles to the initiation of such studies. The policy will allow research to proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies while maintaining appropriate human subjects protections.

2. What types of studies are expected to use a single IRB under the new NIH policy?

The NIH single IRB policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program.

The NIH single IRB policy does not apply to studies conducted under career development, research training or fellowship awards. Under the policy, "multi-site" is defined as two or more sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. The policy recognizes that it may not always be possible to use a single IRB, and it provides for exceptions (see Exceptions FAQ's below).

3. What are options for awardees to comply with the NIH single IRB policy?

An NIH awardee has several possible options for complying with the NIH single IRB policy including having the IRB at one of the participating sites agree to serve as the single IRB, using an independent IRB, or using the IRB as required in the Funding Opportunity Announcement (FOA) or Request for Proposal (RFP) (for example, certain cancer clinical trials funded by the National Cancer Institute (NCI) are required to use the NCI Central IRB (CIRB)). As required in the federal Protection of Human Subjects regulations (45 CFR 46), the IRB must be registered with the Office for Human Research Protections (OHRP) and must have the appropriate membership, including the professional competence necessary to review the proposed research.

This FAQ does not discuss the possibility of having an institutional IRB at a non-participating site serve as the IRB of record, an option included in the guidance. NIH might consider adding this option here and also linking to that guidance.

4. Where can I find more information on the NIH single IRB policy?

The policy was published in the NIH Guide to Grants and Contracts (NOT-OD-16-094) and the Federal Register (81 FR 40325) on June 21, 2016. More information about this policy may be found on the Office of Science Policy (OSP) website (http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review). NIH will continue to provide additional resources and guidance to this policy prior to the implementation date. Additionally, questions about the NH single IRB policy may be sent to SingleIRBPolicy@mail.nih.gov.

5. When does the sIRB policy take effect?

The sIRB policy takes effect on September 25, 2017. This date is four months later than the effective date that appears in the sIRB policy document. NIH decided to extend the effective date to provide additional time for implementation.

Policy Terms and Definitions

6. The NIH single IRB policy states that it applies to domestic "NIH-funded multi-site studies." What does "NIH-funded multi-site studies" mean?

For the NIH single IRB policy, "NIH-funded multi-site studies" mean that the same protocol involving non-exempt human subjects research is being conducted at more than one site and is being wholly or partially funded by NIH.

7. What is the difference between a central IRB and a single IRB?

Both are designed to help streamline IRB review, and the terms are sometimes used interchangeably. In general:

A Central IRB is the IRB of record that provides the ethical review for all sites participating in more than one multi-site study. The sites are usually in a network, consortium or particular program.

A Single IRB is the IRB of record, selected on a study-by-study basis, which provides the ethical review for all sites participating in a multi-site study.

8. What is meant by the "same research protocol" for the NIH single IRB policy?

Protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes are considered to be the "same research protocol." Additionally, sites that are accruing research participants for studies that are identical except for variations due to local context consideration would be considered to be conducting the "same research protocol." Investigators who have questions about whether specific research protocols fall under the policy should discuss them with the Program Official listed on the FOA.

It would be helpful to clarify that the term "site" or "participating site" includes the data coordinating center, coordinating center, and statistical center supporting conduct of the protocol as well (if that is accurate).

9. Is an IRB Authorization Agreement the same as a Reliance Agreement?

Yes. As these terms apply to the NIH single IRB policy, they are used interchangeably to describe the written agreement between sites to rely on one IRB for a specific study or related set of studies.

10. The NIH single IRB policy states the single IRB may serve as a Privacy Board as applicable. What is a "Privacy Board" and how does this relate to the NIH single IRB policy?

A Privacy Board is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of protected health information (PHI) for a research study. A Privacy Board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. A covered entity may use and disclose PHI, without an Authorization, or with an altered Authorization, if it receives the proper documentation of approval of such alteration or waiver from a Privacy Board. If a multi-site project also requires a privacy review under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), it may be appropriate for the single IRB to serve as the Privacy Board. For more information, see: https://privacyruleandresearch.nih.gov/privacy_boards_hipaa_privacy_rule.asp.

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Policy Applicability

11. Does the NIH single IRB policy apply to research funded only by grants or does it also apply to research funded through contracts?

The NIH single IRB policy applies to multi-site human subjects research regardless of the funding mechanism (e.g., grants, cooperative agreements, contracts or other mechanisms such as Cooperative Research and Development Agreements (CRADAs), Other Transactional Authority (OTA), and Interagency Agreements (IAA)). The policy applies whether the sites are subawards to a primary awardee or separate awards are made for participating sites.

12. Does the NIH single IRB policy apply in cases where the sites in a multi-site study are funded by multiple NIH awards?

Yes. The policy applies to NIH-funded collaborative research protocols where all sites for a particular study are conducting the same protocol, regardless of the number of NIH awards funding that study protocol.

13. Does the NIH single IRB policy apply when multi-site studies have both domestic sites and foreign sites?

If an award involves both domestic and foreign sites, the domestic sites would be expected to use a single IRB and the foreign sites could use their own IRBs or Ethics Boards. An award that involves only foreign sites would not be expected to use a single IRB under the NIH single IRB policy. Similarly, an award that involves one domestic site and multiple foreign sites would not be expected to use a single IRB.

14. Does the NIH single IRB policy apply to NIH-funded Small Business Innovation Research (SBIR) /Small Business Technology Transfer (STTR) awards?

Yes. The NIH single IRB policy applies to domestic sites in SBIR/STTR awards that are conducting multi-site research.

Clarify if all of the research is being conducted by the academic partner and the business partner is not engaged (by OHRP definition) except that they are the prime awardee, could this be an exception?

15. **Must NIH interventional multi-site studies under an Investigational New Drug (IND) application or Investigational Device Exemption (IDE) use a single IRB?**

Yes. Unless local review is required by U.S. Food and Drug Administration (FDA) regulations (21 CFR 312), NIH expects the domestic sites involved in these studies to undergo review by single IRBs.

16. Are NIH career development (K), research training (T), and fellowship (F) awards subject to the NIH single IRB policy?

No. Because these types of awards are generally focused on providing training/career development opportunities and primarily provide support primarily for living expenses and education with minimal support for research, these awards are not subject to the NIH single IRB policy.

17. If an NIH awardee has an ongoing multi-site trial that is still recruiting, must a single IRB be selected and take over the review for all participating sites?

The NIH single IRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after the policy effective date. Ongoing, non-competing awards will not be expected to follow the policy until the grantee submits a competing renewal application after the policy is in effect. For contracts, the policy applies to all solicitations issued on or after the effective date.

18. Does the NIH single IRB policy apply to delayed onset research?

Delayed onset refers to NIH applications that are submitted with the intent to conduct human subjects research during the period of support, but definitive plans could not be described in the grant application (45 CFR 46.118 and NIH Grants Policy Statement Section 8.1.3 Requests for Prior Approval; http://grants.nih.gov/policy/nihgps/index.htm).

The NIH single IRB policy applies to delayed onset awards proposed in applications received after the effective date. The information that must be submitted to the funding NIH institute or Center prior to starting delayed onset research should also include information about the single IRB to be used per the Terms of the Award.

19. Does the NIH single IRB policy apply to larger cooperative groups or networks that are funded before the policy effective date but with studies that will be determined/started after the effective date?

The NIH single IRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after the policy effective date. Ongoing, non-competing awards, such as the one described here, are not expected to follow this policy until the grantee submits a competing renewal application regardless of when the multi-site protocols begin.

NIH Grant Application/Contract Proposal Preparation:

20. Who is responsible for selecting the single IRB for an NIH award and when must this be done?

In the NIH application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of a single IRB that would be selected to serve as the IRB of record for all study sites. Where possible, the plan would identify the IRB that will serve as the single IRB. For delayed-onset research, where the IRB cannot be identified, applications/proposals should include a statement indicating that awardees will follow the NIH single IRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute or Center prior to initiating a multi-site protocol. NIH's National Center for Advancing Translational Sciences (NCATS) Streamlined,

Multi-site, Accelerated Resource for Trials (SMART) IRB Reliance Platform, has FAQs with tips for selecting a reviewing IRB.

The requirements will result in significant challenges for investigators and institutions. This response doesn't address the budgetary aspects that will result from delays in selecting the IRB and including the costs of the review in the budget. If the faculty member doesn't have the plan and associated costs in place at time of proposal submission, the costs of review will come out of the award, even though the costs were not included in the budget.

21. What should be considered by NIH applicants/offerors when selecting a single IRB?

In selecting a single IRB, applicants/offerors should consider the history and experience of the IRB, as well as its capacity to serve as the IRB of record for the particular protocol. The IRB must be registered with OHRP and must have the expertise necessary to review the proposed research.

22. Is the NIH applicant or lead institution for the multi-site study expected to serve as the single IRB?

No. Any of the participating sites may serve as the single IRB or an independent IRB or other qualified institutional IRB may be proposed. If possible, the plan to implement the NIH single IRB policy should be described in the application/proposal.

As stated previously, failure to identify the IRB and budget for the IRB review at time of proposal will result in less money to conduct the research.

23. For delayed onset multi-site research, what should be stated about single IRB review in the NIH application or proposal?

For delayed onset human subjects research, where the research cannot be described in the application or proposal but is likely to involve multiple sites, the intention to follow the policy should be stated. Awardees will be expected to identify an appropriate IRB of record prior to initiating a multi-site study.

24. How does an NIH applicant or offeror determine which sites must rely on the single IRB?

All domestic, engaged sites conducting the same protocol are expected to rely on the same single IRB. Sites conducting a different protocol and sites for which local review is required by federal, tribal or state law, regulation or policy are not required to rely on the single IRB. (See OHRP guidance: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)

25. Must the NIH applicant/offeror identify the participating sites in the application/proposal?

Yes. As currently required for grant applications, participating sites should be listed in the application in the Project/Performance Site Locations section to the extent possible. For contract proposals, offerors should follow the instructions in the RFP.

26. Must the participating sites proposed in the NIH application agree ahead of time to rely on the single IRB identified in the application?

It is strongly suggested that the sites agree to a single IRB arrangement prior to the submission of an application or proposal. Participating sites can indicate their willingness to rely on the selected single IRB in letters of support.

27. Can an NIH Funding Opportunity Announcement (FOA) specify the IRB that will serve as the single IRB?

Yes. Some FOAs will specify the use of a particular single IRB.

28. Will the single IRB that is identified in the NIH application/proposal be evaluated during peer review?

No. The proposed single IRB will not be evaluated as part of the peer review process and will not affect the overall assigned score of an application/proposal or the overall rating of the acceptability of the Protection of Human

Other issue for possible discussion with regulators:

Institutions are being asked to project and budget for costs when no definite method for such projection exists. For example, a study lasting five years may involve as little as two amendments or as much as fifty amendments and the institution has no method of assessing the number of amendments prior to the conduct of the research. Likewise, the institution has no method of assessing the number of reports that will be submitted for review.

Independent IRBs have tried to use a "subscription" based approach to charging for IRB services that includes all review services for a period of time, such as a year. This approach has failed each time and regulators should note that independent IRBs continue to charge fees for each service they provide.

It will be unfortunate if the institution's inability to project the costs of IRB review results in loss of funding for the actual research and undue financial burden on the institutions. NIH should acknowledge this issue and develop methods for institutions to recoup unbudgeted costs and return funding when the costs of the review were over-estimated.

Subjects section. Peer reviewers may note if the plan to comply with the NIH single IRB policy is not included in the application/proposal but this will not impact the score.

Reliance Agreements:

29. How should the cooperative relationship between the single IRB and the local sites in an NIH funded multi-site study be established?

The relationship between the single IRB and the local sites in an NIH funded multi-site study should be established through a formal, written Reliance Agreement.

30. Does NIH have any examples or guidance for Reliance Agreements?

OHRP has posted a template for a very simple Reliance Agreement ("IRB Authorization Agreement"): http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html.

NIH's National Center for Advancing Translational Sciences (NCATS) has developed detailed resources, including the Reliance Agreement that will be used by the Clinical and Translational Science Awards: the Streamlined, Multi-site, Accelerated Resource for Trials (SMART) IRB Reliance Platform, https://ncats.nih.gov/expertise/clinical/smartirb.

31. Who is responsible for executing the IRB Reliance Agreement?

The IRB Reliance Agreement must be approved and signed by institutional officials with appropriate signing authority for the single IRB and for each participating site.

32. Does every participating site need to sign the Reliance Agreement?

Yes. Every participating site is expected to sign the Reliance Agreement, unless they are granted an exception from the NIH single IRB policy.

This response does not address components of an institution as a relying site. It also doesn't address "piggy backing" which some institutions are doing. NIH might want to provide guidance specific to this scenario:

Suppose Institution A designates Institution B's IRB as the IRB for all HSR at Institution A.
Both Institution A and B participate in an NIH Multi-Site study.
Can Institution A "piggy-back" onto the agreement Institution B signs with the IRB designated for the multi-site study or must Institution A sign a separate agreement.

We have heard in the past from OHRP that in the scenario provided above each institution would not need to sign the reliance agreement. However, sIRBs all seem to be requiring that each separate entity must sign. Another example, a university is the IRB of record for two hospitals in a hospital system. These are the hospitals where their faculty practice. They have an MOU that defers contracting authority to the university/IRB for research, but sIRBs won't accept this and require each hospital to separately sign reliance agreements.

33. In what timeframe is an NIH awardee expected to execute the Reliance Agreement with participating sites?

Generally, NIH requests certification of IRB approval as part of the Just-in-Time process. However, NIH recognizes that, for some studies, obtaining signed Reliance Agreements among sites may take longer to complete. In such

cases, an acceptable time frame for establishing the single IRB and obtaining IRB approval will be agreed upon by the NIH funding Institute or Center and the awardee(s). Any award made without certification of IRB approval will include terms and conditions restricting all human subjects activities. Once the Reliance Agreements are signed and IRB approval is obtained, the NIH Institute or Center will lift the restrictions and the awardee may start the proposed multi-site human subjects research.

See comments to question 34.

34. Will signed Reliance Agreements from participating sites need to be inplace prior to NIH funding?

No. Signed agreements from participating sites will not be required to be in place prior to funding a multi-site study but must be in place prior to starting the proposed multi-site human subjects research.

Human subjects research may progress in stages resulting in institutions engaging in research at different times. Some institutions may begin engaging in human subject research later in the project. The FAQ should be revised/clarified to indicate that the IRB Authorization Agreement must be in place at any participating institution before that institution engages in human subjects research for the project (that signed agreements do not have to be in place at all sites prior to starting the research).

35. What does NIH believe should be documented in a Reliance Agreement?

In general, a reliance agreement should describe the responsibilities of all parties, and how communication between parties will occur, for example, notification of the outcome of regulatory review, how protocol changes will be handled and reporting of adverse events and non-compliance. (See National Center for Advancing Translational Sciences (NCATS) the Streamlined, Multi-site, Accelerated Resource for Trials (SMART) IRB Reliance Platform, https://ncats.nih.gov/expertise/clinical/smartirb for resources on IRB reliance agreements.

The discussion of reporting of adverse events is inconsistent with OHRP guidance that indicates expected adverse events do not need to be reported to the IRB. This could cause confusion and add language to the reliance agreements that is not necessary. Also, the specific things to be included will cause reliance agreements to be re-negotiated frequently. The reliance agreement should not include procedures that may change over the course of the study such as communication and notifications. Instead, it should identify which party is responsible (not the "how" it will occur.) SOPs should be developed that will operationalize the responsibilities of the reliance terms.

Responsibilities of the Single IRB and Participating Sites:

36. What are the responsibilities of the single IRB in an NIH funded multi-site study?

The single IRB is responsible for conducting the ethical review of NIH-funded multi-site studies, as specified under the HHS regulations at 45 CFR Part 46.

37. In addition to reviewing study protocols, is the single IRB also responsible for reviewing the associated NIH grant applications or contract proposals?

Yes. As required by the HHS regulations at 45 CFR Part 46.103(f), the single IRB should also review the associated NIH grant applications or contract proposals.

Note – The revised Common Rule eliminates this requirement effective January 19, 2018.

38. Does the NIH single IRB policy require the Privacy Board function to be conducted by the single IRB?

No. The functions of the Privacy Board may continue to be carried out by participating sites if the single IRB will not serve as the Privacy Board for a study.

39. The NIH single IRB policy states specific responsibilities for the Awardee, such as maintaining copies of Reliance Agreements and other documentation. May the awardee delegate tasks to another person or institution?

Yes. As noted in the NIH single IRB policy, responsibilities may be delegated, as appropriate, and as specified in Reliance Agreements.

40. How will the single IRB be made aware of a participating site's local context?

Participating sites need to inform the single IRB about relevant local context issues (e.g., state laws). A communication plan should be developed as part of the Reliance Agreement and should describe how such communication will be handled.

Again, the communication plan should not be part of the reliance agreement, as any changes would necessitate

renegotiation of the agreement. The agreement should specify that a plan/process is required and an SOP could be referenced with terms for the process of changing SOPs if necessary

41. In an NIH-funded multi-site study with a single IRB, who is responsible for reporting unanticipated problems and adverse events to OHRP?

The specific responsibility for reporting unanticipated problems and adverse events to the HHS Office for Human Research Protections (OHRP) will be specified in the Reliance Agreement, but, in general, these should be reported as specified in OHRP guidance.

Adverse events do not need to be reported to OHRP per OHRP guidance, only unanticipated problems (involving risks to subjects or others.)

42. What should the single IRB in an NIH-funded multi-site study do if serious or continuing non-compliance with the protocol is suspected or identified at a participating site?

These responsibilities should be defined in the Reliance Agreement. In general, the single IRB will refer instances of serious or continuing non-compliance to OHRP and/or the FDA, the participating sites' IRBs and the funding NIH Institute or Center as required.

This should clarify that the responsibility of determining serious or continuing noncompliance can be the responsibility of either the sIRB or the participating site (at which it occurs) and should be defined in the Reliance Agreement (as stated.) If the sIRB makes this determination, they could report it or the participating site could (again should be specified in Reliance Agreement who has this responsibility.) If the sIRB makes the determination the reliance agreement could indicate that any party at the participating site would be notified (this FAQ says the participating sites' IRB would be notified, but it could be someone, some entity other than the IRB and in fact the regulatory requirement that it be reported to "appropriate institutional officials" has been omitted).

43. If a participating site believes that the single IRB did not review the protocol and consent appropriately, what should the site do and who should the site contact?

Sites should refer questions/concerns to the designated single IRB administrator. The communication plan, which will be developed as part of the Reliance Agreement should describe if, when, and how determinations or considerations of concerns about single IRB review will be handled.

Note: It doesn't look like the SMART IRB agreement provides for communication of concerns.

44. If my institution is a participating site in an NIH-funded multi-site study but is not serving as the single IRB, what is the role of my institution's Human Subjects Protections Program (HRPP)?

Except for the required regulatory IRB review, the HRPP at participating sites will be responsible for meeting all of its current related responsibilities described in the HHS regulations (45 CFR 46). These may include: reviewing conflicts of interest and radiation safety; ensuring that site investigators obtain informed consent from prospective research participants; ensuring that site investigators meet local training requirements; overseeing the implementation of the approved protocol; and reporting local unanticipated problems, serious adverse events, and study progress to the single IRB. Participating sites must communicate information necessary for the single IRB to consider local context issues and state/local regulatory requirements. Other responsibilities may be specified in the Reliance Agreement.

Serious adverse events do not require reporting to the IRB unless they are unexpected per OHRP guidance. This guidance is moving back to reporting requirements that virtually all IRBs and institutions have done away with and is inconsistent with OHRP guidance on reporting. It is also inconsistent with the term "adverse event" used in prior FAQs.

45. If an institution in an NIH-funded multi-site study chooses to duplicate the single IRB review, are they permitted to make changes in the protocol or consent?

The single IRB is the IRB of record for a study. No other IRB may make changes to documents previously approved by the single IRB. A communication plan should be developed that describes how relying sites will provide information, e.g., about local context to the single IRB.

46. If a participating site in an NIH-funded multi-site study does not want the single IRB to review the study, for

example if local IRB review is part of an institution's overall safety or risk management plan tied to insurance, can the participating site use its own institutional IRB for review to thestudy?

In general, NIH expects all participating domestic sites to rely on the single IRB. While exceptions can be requested, these will only be considered if there is a compelling ethical justification or need for local IRB review. It is strongly suggested that applicants/offerors that are proposing multi-site studies inform the sites about NIH's single IRB requirement and obtain their agreement prior to submitting the application/proposal. While NIH cannot prevent a site from conducting a duplicate IRB review, NIH funds may not be used to pay for the cost of this duplicate review.

Award Considerations (Just-in-Time):

47. What information about the single IRB will need to be provided to NIH at the time of award?

If not provided in the application, the funding NIH Institute or Center may ask the awardee to identify the single IRB to be used and the plan to establish reliance agreements and communication between sites.

48. What will NIH's role be in approving the single IRB?

The funding NIH Institute or Center will either accept the single IRB proposed in an application/proposal or will work with the awardee to select an appropriate single IRB at the time of award or prior to the start of the multi-site study.

If the proposed sIRB is not accepted and must be renegotiated at time of award, will there be an opportunity to change the budget for sIRB costs at that time as well?

49. What will happen if the NIH application is not able to identify the single IRB, because the human subjects research study will not be designed until after award (delayed onset human subjects research)?

In general for delayed onset research, it is not possible to certify IRB approval prior to award, and terms and conditions restricting human subjects research will be placed on the award. Prior to the involvement of human subjects in research, the awardee is expected to submit to the funding NIH Institute or Center a complete Protection of Human Subjects section including the single IRB plan (name of the single IRB to be used and plan for reliance agreements and communication). Once the funding NIH Institute or Center has approved the protections for human subjects and the single IRB plan and received certification of approval from the IRB, the restriction on the award will be lifted.

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After the Initial Award:

50. What will happen if an applicant proposes to use a single IRB in the application but after award, does not follow the NIH single IRB policy?

Compliance with the applicant's single IRB plan proposed in the grant application will be a term and condition of award. Failure to comply with the terms and conditions of an award may result in enforcement actions.

51. May an NIH awardee conducting a multi-site study add participating sites after award?

Sites may be added with the approval of the funding NIH Institute or Center. Additional sites would be expected to comply with the single IRB selected to conduct ethical review for the multi-site study.

52. What should be done if the independent IRB serving as the single IRB for my NIH-funded multi-site study goes out of business after initial approval but while the study is on-going?

The awardee institution should make arrangements to have another registered IRB assume responsibility for regulatory review. Per OHRP Guidance on Continuing Review, the new single IRB should be given access to all prior relevant IRB records. If this would require additional funds, prior approval must be sought from the funding NIH Institute or Center.

The process for transfer of IRB review should be described in the terms of the Reliance Agreement

53. If an NIH-funded contract is modified to add a site, will the NIH single IRB policy apply?

Contractors should follow the contract terms and conditions with respect to handling modifications. For contracts that fall under the policy, sites that are added will be expected to comply with the NIH single IRB policy.

Exceptions to the NIH Single IRB Policy:

54. Are there exceptions to the NIH single IRB policy?

The NIH single IRB policy allows exceptions for domestic sites when review by a single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

NIH will consider requests for other exceptions to the policy and will determine if there is adequate justification to grant an exception. Most exceptions are expected to be site-specific, that is, the exception to single IRB review will be made for a particular site, but all other sites conducting the same protocol will rely on the single IRB. NIH anticipates granting very few of these exception requests.

Specific instructions on how to request an exception will be posted in the future at: http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review .

55. Will applicants/offerors need to request an exception if there is a federal, tribal, or state law/regulation/policy that prohibits single IRB review of the proposed non-exempt human subjects research in my grant application?

No. Exceptions to the NIH single IRB policy are automatic when local IRB review is required by federal, tribal, or state law/regulation/policy. The specific law/regulation/policy should be cited in the grant application/contract proposal and/or should be provided to the funding NIH Institute or Center as part of Just-in-Time requirements. Exceptions will only be made for the site(s) affected by the state law/regulation/policy; other sites not affected by the state law/regulation/policy will be expected to rely on the single IRB.

56. One of the participating sites is in a Tribal Nation that requires its own IRB review and will not rely on the single IRB. Must an exception request be submitted to the NIH?

No. Research involving Tribal Nations have an automatic exception but this should be noted in the grant application/contract proposal. However, if a Tribal Nation wishes to use the designated single IRB, they may do so.

57. If the requirement for Tribal IRB review is a matter of policy but is not codified in a law or regulation, does the exception to the NIH single IRB policy still apply?

Yes. If there is a specific Tribal policy relating to Tribal IRB review, the policy should be cited in the grant application/contract proposal.

58. If one of the sites in my study is foreign, do I need to apply for an exception to the NIH single IRB policy?

No. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy. A separate exception request will not be needed.