

Policy Background and General Requirement

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 where each site will conduct 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.

[Back to Top](#)

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).

[Back to Top](#)

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

An NIH award recipient 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, including the IRB of a non-participating site, 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 Part E](#)), 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. See also NIH guidance on [Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research](#).

[Back to Top](#)

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](#). 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.

[Back to Top](#)

5. When does the single IRB policy take effect?

The single IRB policy is effective for grant applications received for due dates on or after January 25, 2018. For contracts, the policy applies to all solicitations issued on or after January 25, 2018. Please note that this date is eight months later than the effective date that appears in the published single IRB policy. NIH decided to extend the effective date to provide additional time for implementation.

[Back to Top](#)

Load More

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.

[Back to Top](#)

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.

[Back to Top](#)

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.” If a study involves a separate site for study coordination or coordination of data and statistical analyses and the site is conducting the same protocol as the other participating sites, then all sites would be expected to rely on the

designated single IRB.

Investigators who have questions about whether specific research protocols fall under the policy should discuss them with the Program Official listed on the FOA.

[Back to Top](#)

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.

[Back to Top](#)

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.

[Back to Top](#)

Load More

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), and Interagency Agreements (IAA)). The policy applies whether the sites are subawards to a primary award recipient or separate awards are made for participating sites.

The NIH Single IRB policy does not apply to Other Transaction Agreements (OTAs).

[Back to Top](#)

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.

[Back to Top](#)

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.

[Back to Top](#)

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.

[Back to Top](#)

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

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.

[Back to Top](#)

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.

[Back to Top](#)

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.

[Back to Top](#)

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 ([CFR 46.118 and NIH Grants Policy Statement Section 4.1.15 Human Subjects Protections](#)).

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 must also include the single IRB plan per the Terms of the Award.

[Back to Top](#)

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.

[Back to Top](#)

Load More

[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 award recipients will follow the NIH single IRB policy and will provide a single IRB plan 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.

[Back to Top](#)

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.

[Back to Top](#)

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 another qualified IRB may be proposed. If possible, the plan to implement the NIH single IRB policy should be described in the application/proposal.

[Back to Top](#)

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 delayed onset justification attachment must include information regarding how the study will comply with the single IRB policy and state that the award recipient will provide a single IRB plan prior to initiating the study.

Back to Top

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>)

Back to Top

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.

Back to Top

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

Sites should agree to a single IRB arrangement prior to the submission of an application or proposal. The applicant should indicate the participating sites' willingness to rely on the selected single IRB in the single IRB plan.

[Back to Top](#)

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.

[Back to Top](#)

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 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.

[Back to Top](#)

Load More

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?

It is expected that the relationship between the single IRB and the local sites in an NIH

funded multi-site study be established through a formal, written Reliance Agreement.

Back to Top

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-fwass/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>.

Back to Top

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.

Back to Top

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. (See exception in FAQ below)

Back to Top

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

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 timeframe for establishing the single IRB and obtaining IRB approval must be agreed upon by the NIH funding Institute or Center and the award recipient(s). Awards will not be made without certification of IRB approval; however, in extenuating circumstances the grant award will be made without certification of IRB approval but 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 by revising the Notice of Award and the award recipient may then start the proposed multi-site human subjects research. A Reliance Agreement must be in place at a participating site before that site engages in human subjects research for the project.

Back to Top

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

No. Signed reliance 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. A Reliance Agreement must be in place at a participating site before that site engages in human subjects research for the project.

Back to Top

35. What does 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 who will responsible for reporting of [unanticipated problems](#) 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.)

Back to Top

36. When institutions A and B participate in a multi-site study, when would it be possible for one institution to sign a reliance agreement for the other?

Assuming both institution A and Institution B are engaged in the research there are 3 options for one institution to sign for the other:

- If the two institutions (A and B) agree that those conducting the research are acting as agents of only one of the institutions, then only one institution would be engaged and thus only one reliance agreement would be necessary for that engaged institution to rely on an external IRB and sign for both institutions. Note the revised Common Rule provides flexibility in how an institution and an external IRB can document the institution's reliance on the external IRB for IRB oversight. § __.103(e) requires the institution and the organization that operates the external IRB to document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the Common Rule requirements (e.g. in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).
- One of the engaged institutions (e.g., institution A) could defer IRB oversight to the other engaged institution (e.g., institution B) through a reliance agreement between the two institutions (A and B), and institution B could defer IRB oversight to an external IRB. The reliance agreement between institution B and the external IRB, as well as the IRB reliance agreement between institution A and institution B would need to reflect such reliance.
- If both engaged institutions (institution A and institution B) have their own FWAs, but operate under an "umbrella" institution, a single IRB reliance agreement with an external IRB can cover both institutions provided that the individual who signs the reliance agreement possesses the legal authority to bind both FWA-holding institutions.

[Back to Top](#)

Load More

Responsibilities of the Single IRB and Participating Sites

37. 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.

[Back to Top](#)

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

Yes. As currently 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.

[Back to Top](#)

39. 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.

[Back to Top](#)

40. 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.

[Back to Top](#)

41. 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.

Back to Top

42. 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](#).

Back to Top

43. 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.

Back to Top

44. 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. Disagreements should be handled as specified in Standard Operating Procedures for communication between relying institutions and the single IRB.

[Back to Top](#)

45. 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](#) involving risks to subjects or others, 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.

[Back to Top](#)

46. 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.

[Back to Top](#)

47. 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 the study?

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. Applicants/offerors that are proposing multi-site studies should inform the sites about NIH's single IRB requirement and obtain their agreement prior to submitting the application/proposal. It is important to note that the cost of conducting a duplicate IRB review is unallowable and may not be charged to an NIH grant.

[Back to Top](#)

Load More

Award Considerations (Just-in-Time)

48. If not addressed in the application, what information about the single IRB will need to be provided to NIH at the time of award?

If a single IRB plan is not provided in the application, or if the plan provided is incomplete or unacceptable, the funding NIH Institute or Center may ask the applicant to provide an acceptable single IRB plan prior to award.

[Back to Top](#)

49. 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 award recipient to select an appropriate single IRB at the time of award or prior to the start of the multi-site study.

[Back to Top](#)

50. 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, if it is not possible to certify IRB approval prior to award, terms and conditions restricting human subjects research will be placed on the award. Prior to the involvement of human subjects in research, the recipient is expected to submit to the funding NIH Institute or Center a complete Protection of Human Subjects section and the single IRB plan. 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 Notice of Award will be revised to remove the restriction on the award.

[Back to Top](#)

Load More

After the Initial Award

51. 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.

[Back to Top](#)

52. 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.

[Back to Top](#)

53. 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.

[Back to Top](#)

54. 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.

[Back to Top](#)

Load More

Exception to the NIH Single IRB Policy

55. 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 approve 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.

[Back to Top](#)

56. 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's single IRB plan. 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.

[Back to Top](#)

57. 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 has an automatic exception, but this should be noted in the grant application/contract proposal's single IRB plan. However, if a Tribal Nation wishes to use the designated single IRB, they may do so.

[Back to Top](#)

58. 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's single IRB plan.

[Back to Top](#)

59. 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. An exception for foreign sites is not needed because the single IRB policy applies to only domestic sites. Any foreign site of a multi-site study to which the single IRB policy applies is not subject to the single IRB policy, and it need not use the single IRB.

[Back to Top](#)

[Load More](#)