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Single IRB (sIRB) Manual (HRP-803)

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Table of Contents

What is the purpose of this manual?	5
Overview and General Information	5
What if UMN IRB agrees to serve as sIRB?	5
What UMN policies must be adhered to by participating sites?	6
Will the UMN IRB serve as the Privacy Board (HIPAA) for participating sites?	6
Will UMN charge a fee for serving as sIRB?	7
What should be considered in a budget for an sIRB study?	7
Roles and Responsibilities	7
What are the responsibilities of the Overall Study / Lead UMN Principal Investigator?	7
What are the responsibilities of a Participating Site Principal Investigator?	7
What are the responsibilities of the institutions engaged in human research where UMN IRB is serving as sIRB?	8
sIRB Submission Preparation	8
Is a reliance agreement required for participating sites if UMN IRB serves as sIRB?	8
How do I know if a participating site has a reliance agreement with UMN?	8
How do I create a multi-site/collaborative research protocol?	8
How do I create a multi-site/collaborative research consent form?	9
How do I develop a communication plan for multi-site/collaborative research reviewed by a sIRB?	9
What should be included in the Overall Study submission to the UMN sIRB?	10
What should be included in the participating site submission to the UMN sIRB?	10
How do participating sites share local context and institutional requirements with the UMN IRB?	11
What if there are changes to a participating site’s local context or institutional requirements?	11
Will participating site study teams have access to ETHOS?	11
sIRB Initial Submission and Review of Overall Study and Participating Sites	11
What is the IRB review process for multi-site research using UMN as the sIRB?	11
What must the overall study/lead UMN PI do after the Overall Study receives initial UMN sIRB approval?	12
When are participating sites reviewed by the UMN IRB?	12
sIRB Post Approval Review of Overall Study and Participating Sites	12
How are modifications for multi-site research submitted for IRB review?	12
What participating site changes do not need to be submitted to UMN IRB?	13

How are modifications for participating sites submitted to UMN IRB? 13
How is continuing review submitted to UMN IRB for multi-site research? 14
How are reportable events submitted to UMN IRB for multi-site research? 15
How are reportable events related to a participating site submitted to UMN IRB? 16
How do I submit study closure for multi-site research? 16
How do I submit study closure for a participating site? 16
Appendix A-1: p-Site Investigator/Study Team Roles and Responsibilities Checklist..... 18
APPENDIX B: Communication Plan 20
APPENDIX C: IRB Liaison Job Description 22

What is the purpose of this manual?

The “sIRB MANUAL (HRP-803)” is designed to guide researchers through policies, procedures, and resources related to the conduct of Human Research that is overseen by the University of Minnesota’s Institutional Review Board (UMN IRB) when it serves as a single Institutional Review Board (sIRB) for multi-site/collaborative studies. This content is specific to IRB obligations.

Along with this manual, current Human Research-related policies, SOPs, Worksheets, Checklists and templates may be found in the [HRPP Toolkit Library](#). Collectively, the Toolkit Library creates a complete picture of Human Research Protection Program (“HRPP”) and Institutional Review Board (“IRB”) expectations and a guide to seeking IRB review and approval. The Toolkit is also used by HRPP staff and IRB members to enhance compliance with federal, state and local requirements for conducting research and protecting human participants.

As you read through this manual and supporting documents, you may find the definitions and descriptions in “[SOP: Definitions \(HRP-001\)](#)” particularly helpful.

To ensure you are always referencing the most current version of Toolkit and related documents, please access them in real time from the IRB website rather than downloading and storing them on your computer.

Note: Information regarding the responsibilities of the UMN as the Reviewing IRB (single IRB) and the Relying Institution can be found in the reliance agreement specific to your applicable protocol. General information on the institution versus IRB responsibilities can be found in the resource: [Institution v. IRB Responsibilities: A Guide for Reviewing IRBs and Relying Institutions Using the SMART IRB Agreement or Other IRB Reliance Agreements](#).

[Return to Table of Contents](#)

Overview and General Information

What if UMN IRB agrees to serve as sIRB?

If UMN agrees to serve as sIRB, the UMN PI will receive a letter from HRPP indicating acceptance of the sIRB request to designate UMN as the sIRB for a project or group of projects. and a template letter of support that can be used for communicating with participating sites (p-Sites).

Once you receive the letter from HRPP agreeing to be designated as sIRB, the overall study/lead UMN PI must:

- Share the letter with Sponsored Projects Administration (SPA)
- Review your roles and responsibilities as described in this sIRB Manual (HRP-803)
- Schedule consultation meeting with HRPP to review the sIRB process and next steps after receiving notification of award development of a communication plan prior to submission of the initial study protocol for IRB review (Note: This step should occur **after** receiving notification of award). Failing to meet with the HRPP staff to discuss the process can result in significant delays in the review of the sIRB study.

[Return to Table of Contents](#)

What UMN policies must be adhered to by participating sites?

UMN IRB recognizes that there may be local context requirements, including institutional and state laws that are unique to a participating site (see “How do participating sites document local context requirements?” for more information). However, when the UMN IRB is serving as the sIRB, it is the expectation that participating sites will follow all policies and procedures described in the HRPP Toolkit. If the participating site cannot follow the overall study protocol and UMN IRB requirements, then the participating site cannot rely upon UMN IRB for IRB review.

The overall study/lead UMN PI is responsible for ensuring that each participating site study team is aware and understands these requirements.

The following UMN IRB policies are highlighted as a courtesy to p-Site PIs as these policies are likely different from other institutions:

- **Research Involving Adults with Absent, Diminished, or Fluctuating Capacity to Consent to Research**
UMN IRB has specific requirements for assessing adult capacity to consent to research. See Toolkit Documents: [HRP-110 POLICY: Capacity to Consent](#), [HRP-090 SOP: Informed Consent](#), [HRP-091 SOP: Written Documentation of Consent](#), and [HRP-417 CHECKLIST: Cognitively Impaired Adults](#)
- **Research Involving Non-English Speakers**
UMN IRB has specific requirements regarding short form use. See Toolkit Documents: [HRP-090 SOP: Informed Consent](#), [HRP-091 SOP: Written Documentation of Consent](#), [HRP-317 WORKSHEET: Short Form Consent Documentation](#), [HRP-507 Short Form Consent Translations](#)
- **Research Involving Children**
UMN IRB will determine whether assent of some, all, or none of the children is required in the initial review of the overall study protocol. See Toolkit Documents: [HRP-013 SOP: Legally Authorized Representatives, Children, and Guardians](#) and [HRP-416 CHECKLIST: Children](#)
- **IRB Reporting Requirements**
UMN IRB prompt reporting requirements may not be the same as a participating site IRB requirements. See Toolkit Documents: [HRP-103 Investigator Manual](#) (see “What should be reported promptly to the University of Minnesota IRB”) and [HRP-321 WORKSHEET: Review of Information Items](#)

[Return to Table of Contents](#)

Will the UMN IRB serve as the Privacy Board (HIPAA) for participating sites?

Participating sites are responsible for adhering to their institution’s HIPAA policies. UMN IRB also requires participating sites to use their institution’s standalone HIPAA Authorization form(s). Participating site PIs should ensure that the HIPAA Authorization permits the sharing of protected health information (PHI) as necessary for the conduct, review, and oversight of the overall study.

The University of Minnesota may serve as the Privacy Board for the purposes of granting a waiver or alteration of the HIPAA authorization, as appropriate. UMN IRB’s role as the Privacy

Board for participating sites will be based upon the reliance agreement between the University of Minnesota and the participating site.

See Toolkit Document: [HRP-441 CHECKLIST: HIPAA Waiver of Authorization](#)

[Return to Table of Contents](#)

Will UMN charge a fee for serving as sIRB?

The University of Minnesota will not be charging for sIRB review at this time. However, the University of Minnesota does plan to charge for sIRB review in the future. That change will be communicated in advance prior to enforcement. This manual will be updated to reflect that change and the process for obtaining a budget estimate.

What should be considered in a budget for an sIRB study?

The overall study/lead UMN PI is responsible for ensuring all cost-related requirements are followed. UMN PIs that are unsure of what to budget for an sIRB study, should seek guidance before developing the budget.

UMN anticipates that studies with more than a handful of sites will require significant additional staffing resources to manage the complex communications, coordination, and document management associated with the use of a sIRB across sites. This role is being called the “IRB Liaison” by many other institutions. It is typically a staff member on the overall study/lead study team. This may be 0.1 – 1.0 FTE, depending upon the size and complexity of the study. See [Appendix C](#) for an example job description.

[Return to Table of Contents](#)

Roles and Responsibilities

What are the responsibilities of the Overall Study / Lead UMN Principal Investigator?

The overall study/lead UMN PI is responsible for the overall conduct of the study, including all responsibilities outlined in the “[INVESTIGATOR MANUAL \(HRP-103\)](#)” and current Human Research-related policies, SOPs, Worksheets, Checklists and templates found in the [HRPP Toolkit Library](#). See [Attestation of PI Responsibilities when UMN IRB Serves as sIRB \(download\)](#) (HRP-828) for additional responsibilities.

[Return to Table of Contents](#)

What are the responsibilities of a Participating Site Principal Investigator?

The p-Site PI is responsible for providing the information or performing the activities described in this manual and in [Appendix A-1, p-Site Investigator/Study Team Roles and Responsibilities Checklist.](#) Each p-Site remains responsible for ensuring the safe and appropriate performance of the research at your site. Follow your institution’s process and requirements for relying on an external IRB, including completion of locally required ancillary reviews.

[Return to Table of Contents](#)

What are the responsibilities of the institutions engaged in human research where UMN IRB is serving as sIRB?

Institutions and IRBs must agree, under the execution of a reliance agreement, the roles and responsibilities of each institution engaged in multi-site / collaborative research reviewed by a single IRB (sIRB).

See SMART IRB's "[Institution versus IRB Responsibilities: A Guide for Reviewing IRBs and Relying Institutions Using the SMART IRB Agreement or Other IRB Reliance Agreements.](#)"

See also "Is a reliance agreement required for participating sites if UMN IRB serves as sIRB?" in this manual.

[Return to Table of Contents](#)

sIRB Submission Preparation

Is a reliance agreement required for participating sites if UMN IRB serves as sIRB?

Yes. Before one institution can rely on another institution's IRB for the oversight of the study, the two institutions must document that reliance arrangement through execution of a Reliance Agreement, including when UMN IRB serves as sIRB. The Reliance Agreement documents respective authorities, roles and responsibilities between the University of Minnesota and the other institution. The University of Minnesota will primarily use [SMART IRB](#) for establishing reliance agreements with other institutions. A reliance agreement is not required for UMN affiliated sites such as Gillette and MHealth Fairview. See "How do I know if a participating site has a reliance agreement with UMN?"

[Return to Table of Contents](#)

How do I know if a participating site has a reliance agreement with UMN?

Contact the HRPP (relyirb@umn.edu) to confirm whether a participating site has an existing reliance agreement with UMN. If there is not a reliance agreement on file, the HRPP will coordinate the reliance process with the institution(s), as appropriate.

[Return to Table of Contents](#)

How do I create a multi-site/collaborative research protocol?

The overall study/lead UMN PI is responsible for creating a multi-site research protocol that can be followed by all participating sites. Hence, the protocol must be written in a site-neutral way so that it can be easily implemented by participating sites (e.g., ability to accommodate/implement differences in protocol driven standards of care, or other study procedures, or access to available resources such as protocol required devices etc.). If a participating site cannot conduct the protocol as approved by the University of Minnesota that site cannot rely on the University of Minnesota IRB and should not be selected as a participating site for the study.

Standardization — everyone doing the same things in the same way — is critical in a clinical research study and particularly critical for multisite trials. Research that is not conducted in a standardized manner is unethical because it may put research participants at risk while yielding

invalid data. The IRB recommends PIs to consider consulting the [Clinical Research Support Center \(CRSC\)](#) for support in developing a study design, feasibility, and start up processes.

[Return to Table of Contents](#)

How do I create a multi-site/collaborative research consent form?

The UMN PI must draft an overall study consent template, using the template, “[Master Consent for Multi-Site or Collaborative Research \(HRP-593\)](#).” This must be submitted as part of the overall study submission in ETHOS. The Master Consent (HRP-593) is composed of two parts:

- **Part 1 - General Information** provides information applicable to all study sites and cannot be modified by participating sites.
- **Part 2 - Site Information** provides information specific to the participating sites relying on the UMN IRB. Part 2 is left partially drafted and should be completed after the review and approval of the overall study.

For the initial submission of the overall study, the UMN PI should provide two consents for IRB review:

1. Master Consent with Part 1 complete and Part 2 incomplete.
2. UMN specific site consent, using the Master Consent where Part 1 and Part 2 are complete.

[Return to Table of Contents](#)

How do I develop a communication plan for multi-site/collaborative research reviewed by a sIRB?

The UMN PI is responsible for working with the UMN HRPP office to establish a communication plan for each study that will use the UMN sIRB. A template communication plan is available in [Appendix B](#).

Key communication responsibilities related to the reliance arrangement must be outlined in a communication plan that is provided to each p-Site along with the initial study approval.

General Information.

The University of Minnesota IRB will follow its this sIRB Program Manual along with current Human Research-related policies, SOPs, Worksheets, Checklists and templates found in the University of Minnesota [HRPP Toolkit Library](#).

Study-Specific Information, Documents and Notifications.

Study-specific determination of the UMN IRB will be communicated directly to the UMN PI via the University of Minnesota IRB system, ETHOS. The University of Minnesota study team assumes the primary responsibility for communicating with the UMN IRB and each p-Site study team regarding the protocol under the UMN sIRB. The UMN PI/Study team must provide the p-Site with information on how IRB approvals and documents are shared with the p-Site (e.g. study-specific box drive, email, etc.).

Site-Specific Communication.

Site-specific determinations of the UMN sIRB for institutions relying on the UMN IRB will be communicated directly to the UMN PI via the University of Minnesota IRB system, ETHOS. The UMN PI/Study team is responsible for communicating and sharing the UMN sIRB determinations, approved documents, and/or requests for clarification to the p-Site. The UMN

PI/Study team must provide the p-Site with information on how IRB approvals and documents are shared with the p-Site (e.g. study-specific box drive, email, etc.).

Communicating with the UMN sIRB.

Relying institutions may communicate directly with the UMN sIRB regarding questions or concerns by emailing relyirb@umn.edu. IRB staff will respond via email or phone.

[Return to Table of Contents](#)

What should be included in the Overall Study submission to the UMN sIRB?

The UMN IRB will first review the overall study (e.g., study protocol, template consent(s), recruitment materials, investigator brochure etc.). The overall study protocol must be written to cover the overall study (see “How do I create a multi-site/collaborative research protocol?”). University of Minnesota site-specific study activities should be include in the “[Local Protocol Addendum \(HRP-508\)](#)” not the overall study protocol. The UMN PI (or designee) is responsible for submitting these materials to the UMN IRB in ETHOS for the initial review of the overall study. See the Multi-Site Study Submission Checklist and “How to Submit a sIRB Study in ETHOS” located on the [sIRB and Reliance webpage](#).

[Return to Table of Contents](#)

What should be included in the participating site submission to the UMN sIRB?

The following documents must be provided to the overall study/lead UMN PI for submission to the UMN IRB, serving as sIRB for each p-Site:

- **Reliance Agreement:** The reliance agreement must be signed by the p-Site’s Institutional Official or designee (a specific person designated for signing reliance agreements your site. The p-Site IRB office should be contacted to facilitate this process). Refer to the section “What is a reliance agreement and how do I know what agreement will be used?” for more information.
- **Local Context and Institutional Requirements:** This form collects information about the p-Site’s local context and institutional requirements including: applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to this research that could affect the conduct or approval of the research at the participating site. See “How do participating sites document local context and institutional requirements?”
- **Recruitment Materials:** Adapted recruitment materials for the site, if applicable.
- **Multi-Site-Consent-Form (Part 2):** Insert local information for the p-Site where indicated in Part 2 of the consent, if applicable. If the research involves children and assent will be obtained, the adapted assent form should also be included. See below section “How do I create the participating site consent form?” for more information.
- **HIPAA Authorization:** p-Site’s HIPAA Authorization Form, if applicable. P-Sites should not use the UMN HIPAA Authorization Form.

For the overall study/lead UMN PI: See the p-Site Submission Checklist and “How to Submit a p-Site in ETHOS” located on the [sIRB and Reliance webpage](#).

[Return to Table of Contents](#)

How do participating sites share local context and institutional requirements with the UMN IRB?

UMN IRB recognizes that there may be local context requirements, including institutional and state laws that are unique to a participating site. Each participating site PI must complete [Form: Local Context and Institutional Requirements \(HRP-822\)](#) to identify local context and institutional requirements to support the sIRB review. The overall study/lead UMN PI will submit the completed form with any other p-Site documents to the UMN IRB. The UMN IRB, as sIRB, will review the participating site's form at the time of the initial p-Site submission review. The overall study/lead UMN PI will serve as a liaison between the p-Site and the UMN IRB and communicate any requests for clarifications, communications, and IRB decisions to the p-Site PI.

[Return to Table of Contents](#)

What if there are changes to a participating site's local context or institutional requirements?

To update information such as contacts at the p-Site IRB/IRB office, p-Site Institutional Official, consent boilerplate language, or p-Site state, local or institutional policy, work with your p-Site IRB office to submit a revised local context form. The revised local context form must be sent to the overall study/lead UMN PI for submission to the UMN IRB for review as a modification (see "[How to submit a modification for a participating site?](#)")

[Return to Table of Contents](#)

Will participating site study teams have access to ETHOS?

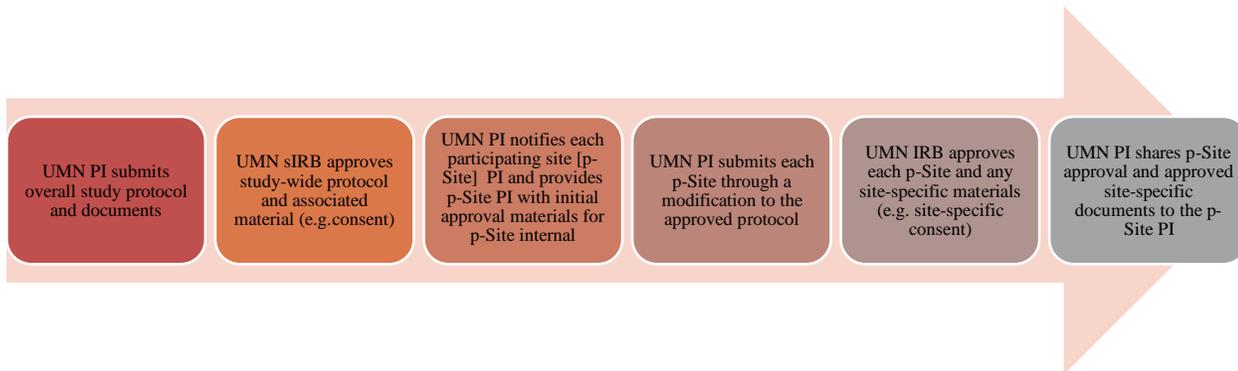
Participating site study teams will NOT have ETHOS access. All submissions and sharing of IRB approvals and documents must be communicated via the overall study/lead UMN PI (or designee). You are responsible for identifying a mechanism for ensuring IRB approved documents are shared with the p-Site PI and that mechanism should be identified in the communication plan shared with the p-Site study team.

[Return to Table of Contents](#)

sIRB Initial Submission and Review of Overall Study and Participating Sites

What is the IRB review process for multi-site research using UMN as the sIRB?

The UMN IRB will first review the overall study protocol and the UMN specific site. No participating sites outside of UMN will be approved during this initial review. Once the overall study is approved, the UMN PI will coordinate with participating sites to complete participating site applications for the sIRB to review. The following graphic provides an overview of the IRB review and submission process.



[Return to Table of Contents](#)

What must the overall study/lead UMN PI do after the Overall Study receives initial UMN sIRB approval?

The overall study/lead UMN PI must communicate, coordinate, and prepare participating site submissions. Review the UMN IRB approval letter for important information and next steps for preparing participating site submissions.

IMPORTANT: Even if the overall study is approved, this does not mean that the participating sites have been approved.

See [Attestation of PI Responsibilities when UMN IRB Serves as sIRB \(download\)](#) (HRP-828) for additional responsibilities.

[Return to Table of Contents](#)

When are participating sites reviewed by the UMN IRB?

The UMN IRB will first review the overall study (e.g., study protocol, template consent(s), recruitment materials, investigator brochure etc.). If approved, the overall study/lead UMN PI will coordinate with participating sites to prepare p-Site submissions for IRB review and approval. The HRPP will work on finalizing the reliance agreement(s). See “[What should be included in the participating site submission to the UMN sIRB?](#)”

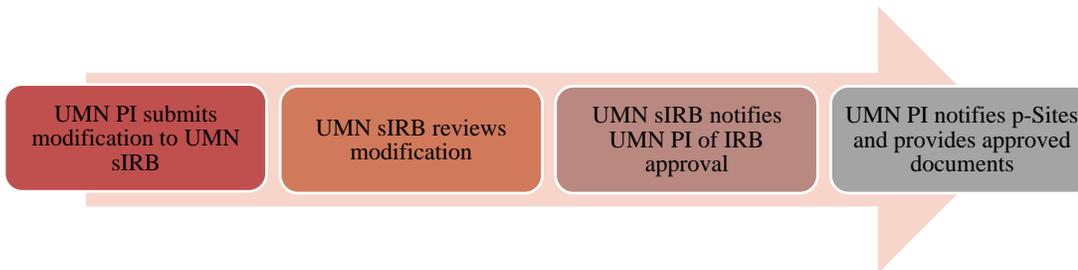
[Return to Table of Contents](#)

sIRB Post Approval Review of Overall Study and Participating Sites

How are modifications for multi-site research submitted for IRB review?

Modifications to the study protocol, procedures, or other IRB approved materials are expected in the conduct of research. Modification may be study-wide or p-Site-specific. The overall study/lead UMN PI is responsible for submitting modifications to the UMN sIRB (study-wide and p-Site-specific). The UMN sIRB will review all modifications to the approved study protocol or p-Site applications and provide notification to the overall study/lead UMN PI. You can access instructions for how to submit a Modification located on the [sIRB and Reliance webpage](#).

Study-wide Modification Process



Study-wide Modification. The UMN study team is responsible for submitting any changes or updates to the study protocol or any study-wide documents or other approved materials. More information about modifications can be found in the “[Investigator Manual \(HRP-103\)](#).” The UMN PI (or designee) is then responsible for notifying each p-Site of the approval and providing update documents and whether re-consent of participants is required.

If a modification impacts the consent form and/or other p-Site-specific materials, each p-Site will need to have a modification submitted to update the p-Site specific materials. That modification will be submitted to UMN sIRB and approved after the initial study-wide modification approval.

- The UMN PI (or designee) is responsible for working with the p-Site PI to make the site-specific changes to the consent using tracked changes.
- The p-Site PI is responsible for working with the UMN PI or designee to make the p-Site site-specific change to the consent and/or other material using tracked changes.
- The UMN PI is responsible for submitting that modification for the p-Site.
- The UMN sIRB will review the p-Site modification and communicate the approval in ETHOS.
- The UMN PI (or designee) is then responsible for notifying the p-Site of the approval and providing updated approved documents. Only the p-Site affected by the approved modification will be notified.

Note: A p-Site PI is responsible for notifying the University of Minnesota Principal Investigator (or designee) if they feel the study protocol or any study-wide materials require modification.

[Return to Table of Contents](#)

What participating site changes do not need to be submitted to UMN IRB?

Participating sites may need to submit a modification that is specific to that p-Site such as a change in PI or change in contact information within the consent form. However, participating sites do not need to submit changes in study personnel (except changes in the role of p-Site PI). However, if there is a change related to conflicts of interest for any personnel, this change must be submitted to the UMN IRB.

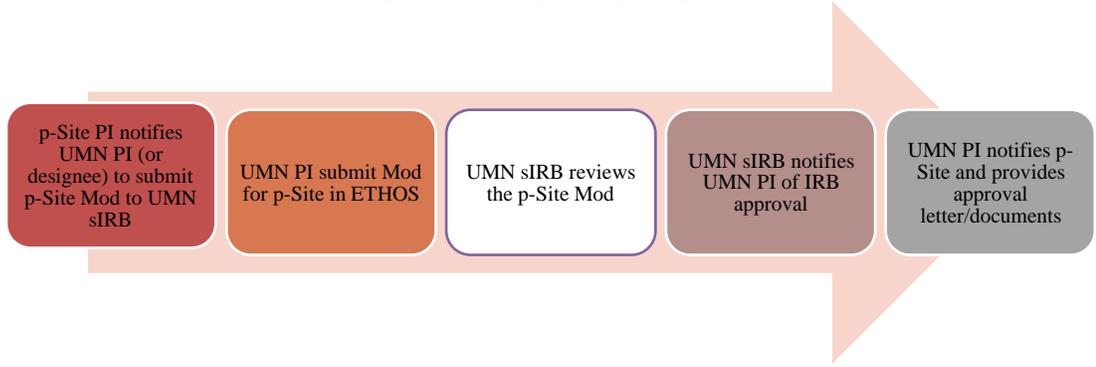
Participating sites are responsible for ensuring new study personnel are appropriately trained and have met all p-Site institutional requirements for training.

[Return to Table of Contents](#)

How are modifications for participating sites submitted to UMN IRB?

It is the p-Site study team’s responsibility to notify the overall study/lead UMN PI (or designee) regarding any change that requires a modification for that p-Site. Approved materials should be

revised to clearly reflect any changes using tracked changes. The following graphic provides an overview of the modification process for participating sites.



The overall study/lead UMN PI must submit the modification, on behalf of the participating site, in ETHOS for IRB review. The UMN PI must review the change prior to submission to ensure consistency with the study protocol and procedure related to the overall study.

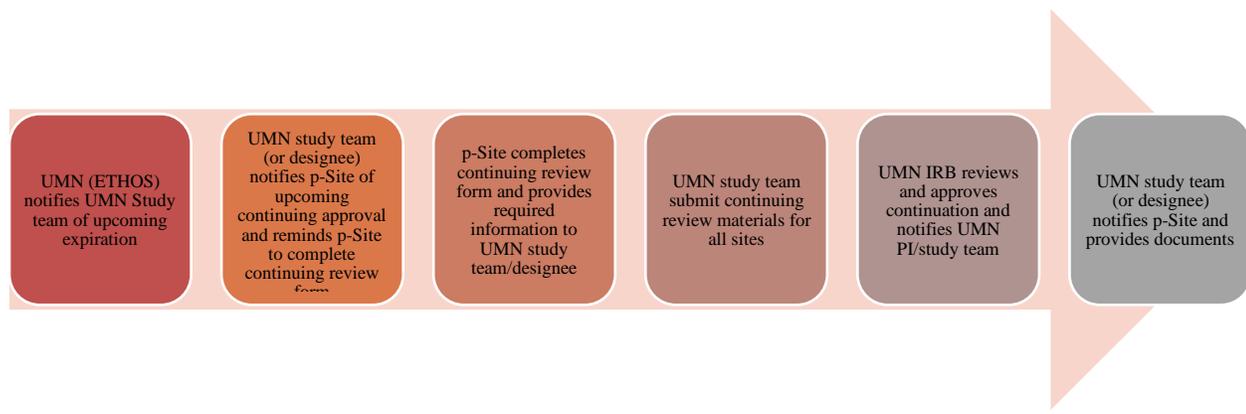
The UMN sIRB will review the p-Site modification and communicate the approval in ETHOS. The UMN PI (or designee) is then responsible for notifying the p-Site of any requests for clarification, the approval and providing updated approved documents.

Job aids on how to complete these tasks in ETHOS are located on the [sIRB and Reliance webpage](#).

[Return to Table of Contents](#)

How is continuing review submitted to UMN IRB for multi-site research?

Continuing reviews (if applicable) are required based on the expiration date of the study protocol. Each site relying on the University of Minnesota IRB will have the same expiration date regardless of the initial approval date for the p-Site. The following graphic provides an overview of the process for continuing review of multi-site research where UMN IRB is serving as sIRB.



The following provides the process, roles, and responsibilities for preparing and submitting for continuing review:

- The UMN PI will be notified via the automated reminder from ETHOS of the due date for a continuing review.

- The UMN PI is responsible for notifying each p-Site of the upcoming continuing review date. The UMN PI will instruct each p-Site to complete the p-Site Progress Report and return it to the UMN PI (or designee). This form can be found in the Toolkit Library under “[Forms.](#)”
- The UMN PI must send the continuing review information for each p-Site as a Comment in ETHOS and notify the IRB Coordinator to input this information into the p-Site continuing review forms in order to submit the overall study continuing review submission at least 30 days prior to the approval expiration date. See “How do I submit continuing review for multi-site research?” located on the [sIRB and Reliance webpage](#).
- The UMN sIRB will conduct continuing review for the study and notify the UMN study team of the continuing approval via ETHOS.
- The UMN PI (or designee) is responsible for notifying and providing documentation of the continuing approval and any approved materials to p-Sites.

IMPORTANT: If any p-Site does not timely provide a p-Site continuing review report, that p-Site’s approval will lapse and all research must cease until the p-Site submits its continuing approval information and obtains continuing review approval.

IMPORTANT: If the UMN PI does not submit a continuing review until after the IRB approval for the study expires OR the UMN PI does not timely submit for continuing review and the study expires before the UMN IRB can reapprove the study, the UMN IRB will notify the UMN PI of the expiration of IRB approval via ETHOS and each p-Site IRB office, if such notification is required under the reliance agreement. The UMN PI is responsible for directly and promptly communicating the expiration of approval to each p-Site PI. All research must cease until continuing approval is provided by the UMN IRB.

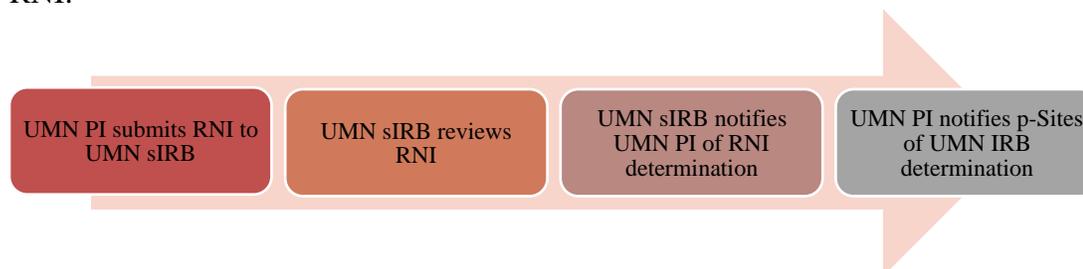
Job aids on how to complete these tasks in ETHOS are located on the [sIRB and Reliance webpage](#).

[Return to Table of Contents](#)

How are reportable events submitted to UMN IRB for multi-site research?

RNIs may be study-wide or p-Site-specific. The UMN PI is responsible for submitting all RNIs to the UMN IRB (study-wide or p-Site-specific) in accordance with UMN IRB’s prompt reporting requirements ([Investigator Manual \(HRP-103\)](#)” in the section entitled “What should be reported promptly to the University of Minnesota IRB?”).

The following graphic provides an overview of the RNI submission process for a study-wide RNI:



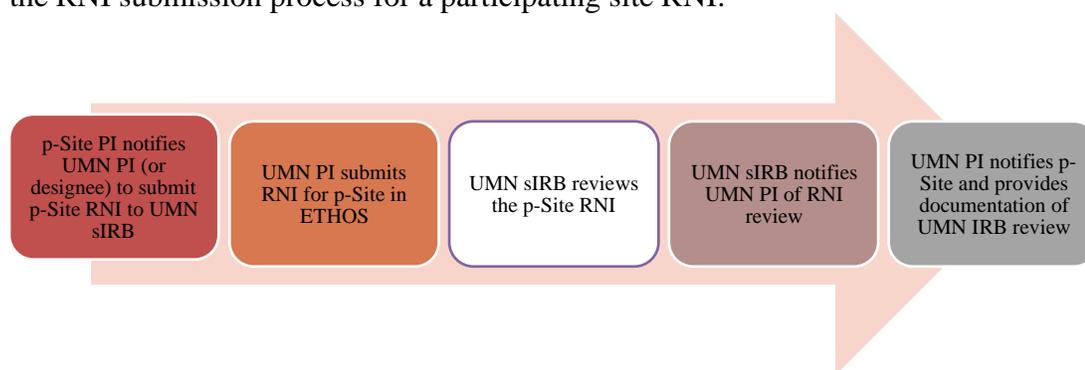
The overall study/lead UMN PI serves as the liaison between the participating site and UMN IRB for addressing requested clarifications, corrective actions, and communication of IRB decisions.

See “How to submit an RNI for multi-site research” for ETHOS specific instructions.

[Return to Table of Contents](#)

How are reportable events related to a participating site submitted to UMN IRB?

Each p-site must report events that meet UMN IRB prompt reporting requirements ([Investigator Manual \(HRP-103\)](#)) in the section entitled “What should be reported promptly to the University of Minnesota IRB?”) to the overall study/lead UMN PI. The UMN PI submits the RNI on behalf of the participating site to UMN IRB for review. The following graphic provides an overview of the RNI submission process for a participating site RNI:



See “How to submit an RNI for multi-site research” for ETHOS specific instructions.

[Return to Table of Contents](#)

How do I submit study closure for multi-site research?

Researchers are required to notify the UMN IRB when the study meets the requirements for study closure (See “When do I closeout a study with the IRB?” in the [Investigator Manual \(HRP-103\)](#)). Closure may be p-Site-specific (See “How do I close a participating site?”). See “How to Submit Study Closure” for ETHOS specific instructions.

[Return to Table of Contents](#)

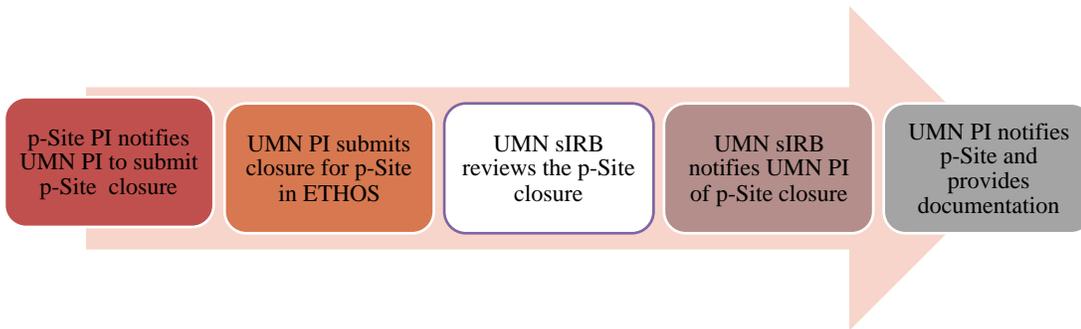
How do I submit study closure for a participating site?

Closure may be p-Site-specific if the participating site has completed both of the following:

- obtaining data through interaction or intervention with subjects, or obtaining identifiable private information about the subjects; and
- using, studying, or analyzing identifiable private information.

The following graphic provides an overview of the p-Site closure process:

To close out a participating site, the overall study/lead UMN PI should coordinate the completion of the Participating Site Closure Form and submit the form on behalf of the participating site(s). The UMN PI serves as the liaison between the participating site and UMN IRB for addressing requests for clarifications and IRB communications.



See “How to submit a participating site closure” for specific ETHOS instructions.

[Return to Table of Contents](#)

Appendix A-1: p-Site Investigator/Study Team Roles and Responsibilities Checklist

As Principal Investigator at the **Relying Institution** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

Follow your institution's process and requirements for relying on an external IRB, including completion of locally required ancillary reviews (e.g., radiology, nursing, and pharmacy). If your institution agrees to rely on the UMN IRB, you may be asked to provide your institution's IRB/HRPP office with:

- The details about the study (including your (the p-Site) study team's role), the name of the sIRB (University of Minnesota), and the lead investigator's name and institution
 - A copy of the study wide protocol and template consent documents(s)
 - The names and roles of all key study personnel on the local study team
 - Any management plans for potential conflicts of interest (COI) relevant to the study that will rely on the UMN IRB, including any new or altered management plans put in place throughout the lifespan of the study.
- Promptly respond to questions or requests for information from the UMN PI/Study Team (or their designee) as well as from the UMN IRB.
- Participate, as required, in conference calls regarding a study as requested by the UMN PI/Study Team, UMN IRB, or your local IRB/HRPP.
- Become familiar with the reportable event policy of the UMN IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the UMN IRB to be reported and within the timeframes required. For more information on how to submit reportable events and new information to the UMN sIRB refer to the section in this Manual entitled "How are reportable events submitted to the UMN IRB?"
- Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).
- Work with the UMN PI/Study Team and the IRB/HRPP contact from your institution to incorporate locally required language into the consent template to be used by your p-Site, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form. For more information about the consent form refer to the section in this Manual entitled "How do I create the informed consent?"
- For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by the UMN IRB.
- Notify your p-Site IRB administration/HRPP of any staff changes at your p-Site so they can confirm their training is current and help ensure any relevant COI management plans are communicated to the UMN IRB.
- Notify the UMN PI/Study Team of:
- Any reportable events that occur locally, according to regulations and the UMN IRB's policy.

- Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
- Any management plans, including any updates to these plans, as relevant to the study.
- Any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

Follow all determinations of the UMN IRB.

Only implement changes of protocol, including local variations, after the UMN RB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.

Provide, upon request, access to study records for audit by your local institution, the UMN IRB's institution, and other regulatory or monitoring entities.

APPENDIX B: Communication Plan

Purpose: This form is used by the UMN sIRB, the overall study/lead UMN PI – UMN Study Team and the p-Site to identify and document key communication roles for a study relying on the UMN IRB. The below is the default position for the University of Minnesota when serving as sIRB.

1 Organizational Responsibilities	
Activity	Responsible Party
Education and Training: Providing education to researchers and research staff of the p-Site	<input type="checkbox"/> Reviewing IRB (UMN IRB) <input checked="" type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Conducting Scientific Review	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Organization responsible for deciding whether allegations of non-compliance has basis in fact.	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Organization responsible for deciding whether each incident of non-compliance is serious or continuing.	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Obtaining management plans for researcher and research staff conflicts of interest. NOTE: The management plan must be provided to the UMN IRB.	<input type="checkbox"/> Reviewing IRB (UMN IRB) <input checked="" type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Managing organizational conflicts of interest. NOTE: The management plan must be provided to the UMN IRB.	<input type="checkbox"/> Reviewing IRB (UMN IRB) <input checked="" type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Ensuring continued oversight of active studies until closure or a mutually agreed upon transfer of the studies should early termination of the reliance agreement occur.	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
Privacy Board for issuing waivers of HIPAA authorization	<input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution <input type="checkbox"/> Other, specify:
2 Study-Specific Responsibilities	
Training & Qualifications: Providing the UMN IRB with confirmation that study teams at p-Site(s) have completed relevant trainings and are qualified to conduct the proposed research. Note: This information will be submitted to the UMN IRB via the UMN Local Context Form.	<input type="checkbox"/> Reviewing IRB (UMN IRB) <input checked="" type="checkbox"/> Relying Institution HRPP/IRB Contact <input type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:
Local Context Information: Providing local context information (e.g., consent language, local laws, and institutional requirements). Note: This information will be submitted to the UMN IRB via the UMN Local Context Form. That completed form must be provided to the UMN PI/Lead Study Team for uploading in the UMN IRB system, ETHOS.	<input type="checkbox"/> Reviewing IRB (UMN IRB) <input checked="" type="checkbox"/> Relying Institution HRPP/IRB Contact <input type="checkbox"/> Lead Study Team <input checked="" type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:

<p>IRB Application Materials: Preparing and submitting the study materials for initial or continuing review or submitting modifications to the sIRB.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Site-specific Materials: Preparing and submitting p-Site-specific materials to the sIRB.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>IRB Determinations and IRB-Approved Documents: Providing sIRB determinations and approved study materials to p-Sites.</p> <p>Note: The UMN IRB will communicate IRB determinations and IRB-approved documents to the Lead Study Team via ETHOS.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Templates: Providing study document templates (e.g., consent forms, recruitment materials) to participating sites.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Policies of the sIRB: Providing the lead study team with all relevant sIRB policies</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>p-Site Continuing Review Information: Obtaining and collating CR information from all participating sites.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Reportable New Information: Reporting RNI information to the sIRB for p-Sites.</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Closing a Study: Reporting study closures to the sIRB</p>	<p><input type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners</p>	<p><input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>
<p>NIH Genomic Data Sharing (GDS) Studies: Submission of Institutional Certification (Consult with Genomic Program Administrator from the funding NIH Institute or Center to discuss the appropriate certification)</p>	<p><input checked="" type="checkbox"/> Reviewing IRB (UMN IRB) <input type="checkbox"/> Relying Institution HRPP/IRB Contact <input type="checkbox"/> Lead Study Team <input type="checkbox"/> p-Site Study team <input type="checkbox"/> Other, specify:</p>

APPENDIX C: IRB Liaison Job Description

Working Position Title: IRB Liaison

Estimated Full Time Equivalent (FTE): Depends upon the complexity of the study and the number of sites. It is estimated that most studies with 10 or more sites will require 1.0 FTE dedicated to this role. Smaller studies may be able to combine this role with another role such as general study coordination.

Summary of job duties:

The IRB Liaison will work directly with the overall study/lead UMN PI as part of the lead site team in order to facilitate and coordinate IRB review and other compliance requirements across all participating sites of a multi-site clinical trial. The IRB Liaison will serve as a central hub for communication among sites as well as between the sites, the IRB and other compliance offices. This liaison will serve as the primary point of contact between the reviewing IRB and the overall study.

Primary duties may include:

- Understand and communicate the policies and processes of the reviewing IRB, and be familiar with the research and the sites
- Work with the sites and their research compliance or IRB offices to establish reliance agreements with the reviewing IRB
- Coordinate the timing of initial review and modifications across all sites
- Assist the participating sites with completing and submitting materials to the reviewing IRB, which may include preparing and submitting all materials on their behalf
- Facilitate the continuing IRB review for the entire study by collecting information from all sites and submitting it to the reviewing IRB
- Serve as an intermediary between the reviewing IRB and the participating sites
- Obtain local context considerations (e.g., a state's age of majority) for each site and ensure that the information is provided to the reviewing IRB
- Assist the participating sites with responding to IRB requests
- Plan IRB and other regulatory approval timelines and troubleshoot challenging situations
- Coordinate the payment of IRB fees by the lead site
- May require travel in order to accomplish job duties, e.g., when assisting a participating site in responding to an inspection request from the reviewing IRB.

Qualifications:

Because this is a crucial role that requires a complex set of skills, the most qualified individuals will have significant regulatory experience related to multi-site studies and/or clinical trials. This person needs a strong knowledge of the regulatory requirements for single IRB review and must be able to nimbly respond to changes in the implementation of this new policy across many different institutions. They also need to have enough scientific and regulatory background to understand the study and anticipate other regulatory and institutional requirements that may apply at each site and affect the IRB process (e.g., Radiation Safety review, Institutional Biosafety Committee review, etc.). The IRB liaison will need to establish relationships and maintain close communications with a wide variety of people and offices quickly. Outstanding demonstrated ability to communicate quickly and effectively with a wide range of stakeholders is strongly recommended.

Suggested Additional Qualifications:

- Specific education or training in biomedical regulatory affairs
- Project management experience or certification
- For grant applications

Grant Budget Justification Example:

TBN, Research Study Coordinator/IRB Liaison

Effort = 12.0 months calendar (100% FTE) in Years 1-5 [adjust FTE & years to match the study]

A Research Study Coordinator will be hired to serve as the IRB Liaison for all participating sites in order to facilitate the complex and time-sensitive communications among sites, and between the participating sites and the single IRB (sIRB). Under the direction of the Lead PI, the IRB Liaison will facilitate and coordinate IRB approval and related regulatory compliance activities for all participating sites. This includes serving as an intermediary between the sIRB and the sites in order to: (1) establish reliance agreements; (2) facilitate timely initial review, modifications, and continuing review; and (3) establish and maintain communication plans among all stakeholders to ensure consistency among IRB-approved consent forms, other materials, and procedures among all sites.