Single IRB FAQs

What is a Single IRB?

A single IRB (sIRB) is an Institutional Review Board that oversees all sites participating in a multisite study.

When is the use of a sIRB required*?*

Effective January 25, 2018, the NIH will require the use of a sIRB for the review of non-exempt, multi-site, domestic, human subjects research protocols funded by the NIH.

Additionally, under the new Final Rule governing human subjects protections approved by the DHHS in January, 2017, most U.S. government funded cooperative studies that meet the criteria for non-exempt "human subjects research", and involve more than one site, will also require sIRB review. This requirement goes into effect January 20, 2020.

Some other networks, companies and foundations may also require sIRB review.

Will my NIH grant application be subjected to the new sIRB policy?

The NIH sIRB requirement applies to all competing grant applications, including new, renewal, revision or resubmission, submitted on or after the January 25, 2018 effective date.

What is the SMART IRB Master Reliance Agreement and can I use it?

The SMART IRB Master Reliance Agreement is a national reliance agreement that is designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants. SMART IRB is funded by the National Center for Advancing Translational Sciences (NCATS) and is intended to serve as a roadmap for institutions to implement the NIH sIRB policy. Although not yet a requirement, many institutions will use the SMART IRB Master Reliance Agreement as a basis for reliance. When possible, Johns Hopkins will use the SMART IRB agreement as the basis for reliance when serving as the sIRB.

To learn more about the SMART IRB reliance agreement and confirm whether your collaborators have signed on, please visit: www.smartirb.org.

How is Johns Hopkins handling requests to serve as a sIRB?

When Johns Hopkins agrees to serve as the sIRB, the School of Medicine IRB (JHM IRB) will serve as the sIRB for all JHU divisions (e.g., School of Public Health, Homewood).

How do I submit a request to have JHM IRB serve as the sIRB for my grant proposal or study?

JHM IRB has created a reliance request tool [survey] that is available on the JHM IRB website at https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/ . You must submit a request before making any commitment in your grant application that JHM is willing to serve as the sIRB. JHM IRB is required to review and approve your request before providing you with a letter of support and additional instructions for your grant application.

Is there anything special that I need to put into my grant application when asking JHM to serve as the sIRB for my study?

Once you have completed the reliance request survey, and you have been notified that JHM IRB agrees to serve as your single IRB, you will be provided a letter of support and a budget for sIRB fees.

What do I have to submit in eIRB2 when JHM agrees to serve as the sIRB for my study?

When you are ready to prepare your IRB application, contact the IRB Reliance Team [JHMIRBReliance@jhmi.edu] to set up an initial education session to discuss the sIRB review process and requirements.

Are there fees involved in using JHM IRB as a sIRB?

Yes, sIRB studies are subject to review fees. Investigators will need to incorporate sIRB fees as direct costs in their grant budget and should consult the IRB office for assistance with grant development.

See also: NIH Single IRB Policy

Can I add non-Hopkins study team members to my eIRB application?

Non-Hopkins investigators should not be added as "study team members" within the eIRB application, as this implies that JHM IRB covers their research activities and that non-Hopkins investigators are subject to our IRB training requirements. The eIRB application should be limited to Hopkins-affiliated investigators only.

There are special circumstances whereby we would consider granting new/extended access to a non-Hopkins affiliated person. For example, if a non-Hopkins individual will be serving in a coordinating center role or completing eIRB applications on behalf of the Hopkins PI. All exceptions must be reviewed and approved by the Reliance Team. Contact JHMIRBReliance@jhmi.edu for more information.

How are participating sites [pSites] added to my single IRB application?

Participating sites [pSites] are added after the initial IRB application is approved. pSites are added via a pSite application. During your initial consult with the JHM IRB reliance team, you will be provided with instructions and tools to assist with onboarding pSites to the required agreements and submitting pSite application for IRB review.

What is a combination [combo] site?

A study may involve a "combo site" when a) one or more PIs engage multiple component sites under the same FWA/legal entity [i.e., a children's hospital and adult hospital that are part of the same legal entity, or one PI is the grant PI and another PI will oversee site enrollment], or b) one PI engages multiple FWAs/legal entities for a study [e.g. the local "site" includes representatives from an academic institution and an affiliated hospital which is a separate legal entity]. In these circumstances, one local context questionnaire is created, allowing JHM IRB to collect local context information from the combo site through one form. **Please Note: Separate pSite applications are required for each legal entity.**

Are pSites required to submit a continuing or annual review to their local IRB?

pSites are not required to submit continuing review applications to their local IRB; however, pSites are required to submit enrollment data for inclusion on the JHM IRB continuing review application. pSites are required to complete the "JHM IRB Continuing Review Summary Sheet for Relying Sites", and the completed forms should be uploaded in Section 2 – Renewal Summary, Question 9 of your continuing review application.