I. NIH Policy on Single IRB (sIRB) Review

The NIH single IRB (sIRB) mandate applies to most grants and contracts submitted to the NIH after January 25, 2018 that involve multi-site, non-exempt human subjects research where the sites are conducting the same research protocol. The policy requires the use of a single IRB to accomplish IRB review and approval for all domestic sites. Information related to the definition of an "NIH clinical trial," which may apply to a multi-site, non-exempt human subjects research proposal submission, can be found in the “Clinical Trials” Policy. If you have questions about the sIRB policy, please contact Kate Menke in Brown's HRPP.

A. What Studies Must Follow the NIH Policy?

The NIH policy applies to all studies that are:

- Funded through grants, cooperative agreements, or contracts and
- Involve non-exempt human subjects research, and
- Involve multiple sites, all of which are conducting the “same protocol”

The policy does not apply to studies that are:

- Funded to foreign awardees and/or conducted at foreign sites, or
- Funded through career development, research training or fellowship awards, or
- Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation or policy

B. What is Meant by “Multi-Site” Research?

“Multi-site” means that the same research protocol is being conducted at one or more domestic sites and that each site is under the control of a local participating investigator. This typically involves a lead site that receives the grant or contract directly from NIH and then establishes a subaward or subcontract to each participating site. The research could be a clinical trial, an observational study, or a basic clinical research study.

C. What is Meant by Conducting the “Same Research Protocol”?

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. 

*If you have questions about whether your proposed research meets this definition, NIH encourages you to talk to your Program Officer.*

**D. How will sIRB Review be Paid for?**

The costs for IRB review have traditionally been included as indirect costs under the institution’s Facilities and Administration (F&A) rate and could not be described or direct-charged separately. The NIH sIRB policy expects that sIRBs will charge fees. Those fees will be the responsibility of the lead site. NIH has provided guidance on which IRB review fees should be charged as direct vs. indirect costs under different IRB review scenarios:

- *If you are the lead site and will use an independent, commercial IRB as the sIRB, you must work with the HRPP to obtain that IRB’s fee structure.* Brown has established a pre-negotiated Reliance Agreement with Quorum IRB to facilitate this process.
- *If you are the lead site and will use the IRB of another institution (e.g. one of the participating sites) as the sIRB.* IRB fees vary among institutions. You will need to work directly with the sIRB to get information about their fees.

**II. What do I Need to do Before the Grant is Submitted?**

**A. If Brown is a participating site (not the lead site)**

You must provide the lead PI a letter of support from the Brown HRPP that Brown will rely on the chosen sIRB. This must be included in the grant proposal. Contact HRPP at IRB@Brown.edu at least one week before the internal OSP grant submission deadline to request this letter. Your request should provide:

- The name of the Brown PI
- The name of the lead PI and the lead site
- The name of the sIRB, if already selected
- The title of the study/grant
- The grant deadline
- A brief description of the study or link to the NIH request for Applications (RFA)
- Any additional relevant information, such as whether the [SMART IRB Master Reliance Agreement](#) will be used.

**B. If Brown is the lead site**

You will need to:

1. Contact the HRPP at least three (3) weeks before the internal OSP grant submission deadline, to discuss the proposed use of Brown as the sIRB. *In cases where your research involves >3 separate sites conducting the same protocol (inclusive of Brown as a site), you will likely be directed to work with Quorum as your commercial IRB.* Refer to this [Handbook for using Quorum IRB](#) for more information about using the commercial IRB. You will need to obtain a letter of support from HRPP that describes Brown (or Quorum IRB) as the selected sIRB and Brown’s willingness to rely on this IRB. Your request should provide:

   - The name of the Brown lead PI
• The number of sites
• The title of the study/grant
• The grant deadline
• A brief description of the study or a link to the NIH Request for Applications (RFA)

2. Obtain letters of support from the IRB office of all participating sites, indicating their agreement to rely upon Brown (or Quorum IRB) as the chosen sIRB. The HRPP has developed a template letter that may be used to facilitate this process. For sites that do not have their own IRBs but have an established FWA (Federalwide Assurance) with OHRP: the letters should be signed by a compliance officer or other person with authority to act on behalf of the site.

3. Provide relevant information about the sIRB plan in the grant application (including the budget) and include the letters of support. See the next section for complete information about grant information.

III. What Information should be Included in Grant Applications?

NIH will expect the following information in grant applications for multi-site research after January 25, 2018:

A. A plan describing the use of a sIRB: The plan should identify the IRB that will serve as the sIRB and should address any requests for exceptions from the policy. This information should be in the human subjects section of the grant proposal. HRPP has developed sample plan language that can be adapted for this use.

B. Letters of support from the Brown HRPP and each of the sites that will rely on the sIRB: Each site participating in the study must document its agreement with the IRB review arrangement in a letter of support. This letter is not the same as the formal IRB reliance agreements that may need to be established after the grant is awarded. See the section above for more information about the letters of support.

C. IRB fees that will be charged as direct costs: HRPP will assist you in obtaining fee information as part of the process of identifying the most appropriate sIRB for your study. If you will be using Quorum IRB, you may also contact David Kim (206-436-3297) at Quorum IRB for assistance in developing an appropriate budget for your study.

D. A description of the resources (personnel, budget) you will need to manage IRB communications: HRPP anticipates that studies with more than a handful of sites will require significant additional staffing resources to manage the complex communications and document management associated with the use of a sIRB and with IRB-related coordination across sites. This role is being called the “IRB Liaison” by HRPP and at many other institutions nationwide. It is typically a staff member on the research team at the lead site. HRPP has developed a template that can be adapted for use in the Budget Justification sections of a NIH grant. HRPP is available to advise on individual study needs, including an IRB liaison FTE that may be appropriate for the study.

IV. What Happens after the Grant is Funded?

HRPP anticipates that most studies funded under the sIRB policy will begin to receive notification of award in mid-2018.

The Brown lead PI should be prepared to:
1. **Train a number of the Brown research team to serve as the “IRB liaison”:**
   The HRPP plans to offer orientation, training and resources to IRB liaisons working with Brown PIs. Contact Kate Menke for more information.

2. **Contact the HRPP to request the use of an external IRB:**
   Alert the HRPP that you have received funding and are ready to begin the process of establishing the sIRB review with an external site IRB or a commercial IRB (i.e., Quorum). You will be asked to complete an [IAA Application (form #3)](https://example.com) to provide the information we need to establish reliance agreements with other sites.

3. **Facilitate the establishment of reliance agreements between the sIRB and sites:**
   Each participating site will need to establish a reliance agreement, also known as an IRB authorization agreement (IAA), with the sIRB. The reliance agreement documents the arrangement and also establishes expectations about communication, reporting, and procedures. Brown University, many peer institutions, and many sIRBs have already signed a “generic” Master Reliance Agreement called the [SMART IRB Agreement](https://example.com). The SMART IRB agreement eliminates the need to establish a study-specific agreement. *Studies and institutions making use of this existing agreement will have a streamlined startup process.*

4. **Submit for IRB review:**
   In general, most sIRB review for multi-site studies will involve two steps:
   i. Submitting the generic protocol and consent materials for review by the sIRB.
   ii. Submitting site-specific information such as investigator qualifications, site specific recruitment and consent information, and other local context information (e.g. state laws about the age of majority) for review by the sIRB.

V. **Local Context Review**
   IRBs must consider many different regulations as part of their review, including state and local policies. Some external IRBs will require information about the state and local policies that apply to Brown University research. External IRBs request this information in a variety of ways (e.g. worksheets, surveys, questionnaires). If external IRB requires this information for the study, the Brown HRPP will work with the Brown PI to provide information about local context considerations.

VI. **Researcher Responsibilities for Externally Reviewed Research**
   A. Brown University PIs are responsible for following the policies of the external IRB. This includes submitting to the reviewing IRB using their forms and processes (or assisting the lead site with that process), following their reporting requirements for unanticipated problems and new information about the study, and complying with the stipulations of the IRB’s approval.

   B. Brown University PIs are also responsible for:
      - Ensuring that any relevant financial conflicts of interest are disclosed to the reviewing IRB as required.
      - Obtaining any required ancillary review and approvals (e.g. biosafety, radiation, safety, etc.) and providing the results of these reviews to the reviewing IRB if requested.
      - Making copies of IRB approvals available for inspection.