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Columbia University Single IRB Process for HHS Grants

HHS requires Single IRB (sIRB) review for multi-site research that involves two or more domestic institutions. These requirements originate from the NIH Single IRB Review Policy and the Federal Policy for the Protection of Human Subjects (45 CFR 46), Subpart A, aka the "Common Rule", so called because it has been adopted by 20 federal agencies.

The NIH sIRB Policy is applicable to new and competing renewal applications/proposals for NIH funding that were due on or after January 25th, 2018, and contract solicitations issued on or after January 25, 2018. It is applicable to NIH-funded multi-site domestic studies involving non-exempt human subjects research. The Policy does not apply to foreign sites, career development (K), institutional training (T), and fellowship awards (F), and current active awards. However, foreign sites may choose to rely on the sIRB that is selected for domestic sites.

The Common Rule requirement for sIRB review applies in general to grant applications for cooperative research submitted on or after January 20, 2020. Cooperative research projects are those projects covered by the Common Rule that involve more than one institution.

Please access the links below to review additional information in this document about each role that Columbia may have in a sIRB situation.

Columbia as the Applicant Organization or Columbia as the sIRB

When submitting to a Common Rule Agency a grant application that involves two or more domestic sites engaged in non-exempt human subjects research, when Columbia University is the applicant organization (i.e., will be the "Lead Site" or "Prime Awardee"), a decision must be made as to whether sIRB review is required and, if so, which institution will serve in that role. A Columbia Reliance Request Form should be submitted, sufficiently in advance of the grant deadline for review and adjudication. A minimum of one week is expected. HRPO staff will review the Form and convey to the Principal Investigator both the decisions and a Letter of Support to include in the application. The same process applies when Columbia is not the Applicant Organization but the PIs at Columbia and at the Applicant Organization prefer that Columbia serve as the sIRB.

It is recommended that the Applicant Organization develop a sIRB plan that covers the following elements:

- How the sIRB requirements will be addressed
- The name of the IRB that will serve as the sIRB of record
- Confirmation that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB
- Brief description of how communication between sites and the sIRB will be handled

- Confirmation that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites
- Plan for how each institution or entity will maintain records of the authorization/reliance agreements and of the communication plan

Certain information, as described below, must be included as part of the grant application. **NOTE**: some Funding Opportunity Announcements (FOAs) or contract solicitations may describe specific requirements to meet the sIRB requirements.

- Name of the institution that is proposed to provide sIRB review
- Costs for sIRB Activities

The process below describes the steps that must be followed when Columbia University is the applicant organization, or if another site is the applicant organization but it is proposed that the Columbia University IRB will serve as the sIRB for oversight of human subjects research covered under the grant.

Prior to submission of the grant application:

1. Submit a Reliance Request Form to the HRPO
   a. This request form will elicit the information necessary for the HRPO to determine if the sIRB request is appropriate and also to confirm whether the Columbia University IRB will serve as the sIRB
   b. The following information will be solicited:
      1) Name and title of PI
      2) Name of contact person on research team
      3) Grant Title
      4) Whether or not this application is for a single study, multiple studies, or a network/consortium that will design and/or conduct several studies
      5) A summary of the proposed study(ies) covered in the grant application
      6) An explanation of what role(s) Columbia University will serve in this research (e.g., Lead Site, Data Coordinating Center, Clinical Coordination Center, Repository, Research Site, etc.)
      7) Confirmation of which IRB is proposed to serve as the sIRB (Columbia University IRB or other); if other, provide a rationale for why Columbia University, if the Lead Site, should consider ceding this responsibility
      8) List of all research sites
      9) Projected length of study (how many years the study will be open in any capacity)
      10) Any other information that you think is relevant that the HRPO should be aware of to consider this request. If this application is for a Delayed Onset, this should be included
      11) Grant deadline
   c. A copy of or hyperlink to the Funding Opportunity Announcement should be included
   d. Upon submission of the Reliance Request, you will receive a reference number for the form and instructions for re-submitting an updated form if the application is funded

2. The HRPO will consider the request and will make every effort to respond within 5 business days

   a. If the request is denied, the rationale for this determination will be provided
   b. If the request is approved, the HRPO will provide a Letter of Support
      1) This letter will include support for the research and a proposed sIRB plan
   c. Information on what to include in the budget for sIRB costs will be provided at this time to the PI, by the HRPO

3. Once the Letter of Support is received, the grant PI and their team will need to work with each of the other research sites to confirm their agreement to rely on the proposed sIRB
   a. In many situations, this confirmation will be provided by the collaborating site's IRB Office

4. When the NIH Policy was initially released, it required that the grant application include a sIRB plan. The HRPO and SPA developed standard language to be covered in the sIRB Plan for when Columbia is the applicant organization. Although the inclusion of a sIRB plan is no longer required, use of this language to prepare a sIRB plan that will be maintained by the grant PI is recommended.

After a Just in Time (JIT) Notice is received:

1. Contact the HRPO irbreliance@columbia.edu to advise them of the JIT status; include the Qualtrics survey number in the email
2. The HRPO will meet with the Columbia PI and research team to review the roles and responsibilities of the sIRB and of the Lead research team
3. The HRPO will assist with determining the most appropriate Reliance Agreement, and provide assistance with obtaining executed Agreements
   a. If Columbia is the sIRB, review of the master protocol will proceed once the fully executed Reliance Agreements are obtained.
   b. If another IRB serves as the sIRB when Columbia is the Lead Site, the process for submitting to that IRB as well as the process for when Columbia is a Relying Site will be followed.

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Columbia University Single IRB (sIRB) Request Process

Columbia as a Relying Site (and not the Applicant Organization)

If Columbia University is engaged in human subjects research on a project where another site is the applicant organization on a grant application that is subject to the HHS sIRB requirements, the applicant organization will need to provide a sIRB plan to address the requirements of the NIH sIRB Policy. One of the requirements of the sIRB Policy is that each of the participating sites have agreed to rely on the proposed sIRB.

The process below describes the steps the Columbia researcher must follow in these situations:

1. Submit a Reliance Request to the HRPO
    a. This request form will elicit the information necessary for the HRPO to determine if the sIRB request is appropriate and also to confirm whether Columbia University agrees to rely on the designated sIRB
    b. The following information will be solicited:
        1) Name and title of PI on the grant
        2) Name and tile of the Columbia PI
        3) Name of contact person on Columbia research team
        4) Grant Title
        5) Whether or not this application is for a single study, multiple studies, or a network/consortium that will design and/or conduct several studies
        6) A summary of the proposed study(ies) covered in the grant application, as relevant to Columbia
        7) An explanation of what role(s) Columbia University will serve in this research (e.g., Data Coordinating Center, Clinical Coordination Center, Repository, Research Site, etc.)
        8) Confirmation of which IRB is proposed to serve as the sIRB
        9) List of all research sites
        10) Any other information that you think is relevant that the HRPO should be aware of to consider this request. If this application is for a Delayed Onset, this should be included
        11) Grant deadline
    c. A copy or hyperlink of the Funding Opportunity Announcement should be included
    d. Upon submission of the Reliance Request, you will receive a reference number for the form and instructions for re-submitting an updated form if the application is funded

2. The HRPO will consider your request and will make every effort to respond within 5 business days
    a. If the request is denied, the rationale for this determination will be provided
    b. If the request is approved, the HRPO will provide a Letter of Support confirming Columbia's agreement to rely on the proposed sIRB
        1) Note that this Letter of Support should NOT be considered approval to proceed with this project without following the rest of these steps

After the Notice of Grant Award (NOA) is issued and the sIRB issues a Reliance Agreement for CU review and execution:

1. Contact the HRPO at irbreliance@columbia.edu to advise them of the NOA and proposed reliance agreement
2. The HRPO will review and consult as appropriate with other offices (i.e., Office of the General Counsel, Office for Research Compliance and Training, Office for HIPAA Compliance) prior to review by the Institutional Official who will sign the agreement
3. The HRPO will meet with the Columbia PI and research team to review the roles and responsibilities outlined in the Reliance Agreement
4. Once the fully executed Reliance Agreement is obtained, submit the protocol in Rascal
    a. The process for submitting to the external IRB as well as the process for review when Columbia is a Relying Site will be followed.

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Template Language for the sIRB Plan when Columbia will be the sIRB

[Inclusion of a sIRB plan in NIH grant applications is no longer a requirement. It is recommended, however, that investigators submitting a grant application for which sIRB review is required prepare a sIRB plan for their own reference to ensure that requirements are met. The first paragraph of this template applies only if a grant is expected to have a delayed onset with respect to human subjects research procedures.]

This is a delayed onset study, and the determination of which entity will serve as the Single IRB of record cannot be determined at this time. If awarded, we will communicate our plans for use of a sIRB to our NIH Program Official prior to initiating the study.

A Columbia University (CU) Institutional Review Board (IRB) will be serving as the Single IRB (sIRB) in this proposed multi-site study involving human subjects research. As the sIRB, CU/CUMC *[select, as applicable]* will fulfill the requirements set out in 45 CFR Part 46, and 21 CFR Parts 50, 56, 312, 600, 812, as applicable, by conducting initial and continuing reviews of protocols for all participating domestic sites, including amendments, unanticipated problems, protocol deviations, and required reporting to federal oversight agencies. The sIRB will also serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

The participating sites identified in the Project/Performance Site Locations section of this proposal have indicated their willingness to rely on CU/CUMC [as applicable] as the selected sIRB and the PI has obtained documentation of their agreement via *[select: letter/note/email or some other means]*. In turn, the CU IRB has provided a Letter of Support indicating its commitment to serve as the sIRB. A copy of the Letter of Support is included with this attachment.

At the time of award, CU/CUMC *[select, as applicable]* sIRB representatives will meet with the PI and Research Study Team to review their responsibilities, as outlined in the relevant Reliance/Authorization Agreements (RA), as well as CU's sIRB Policies. It may be determined during this meeting that the use of the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance platform, funded by the National Center for Advancing Translational Sciences (NCATS), is the most efficient model for implementing the authorization agreements among the participating sites.

Prior to the signing of RAs between CU/CUMC *[select, as applicable]* and the participating sites, the sIRB will work with the PI and Research Study Team to ensure that the RA is signed by both institutions. The PI will communicate the terms of the agreements with each participating site, with the sIRB providing further instructions as needed. The finalization of the RAs will be indicated by the signatures of the sIRB Institutional Official and each participating site's Institutional Official.

Once RAs have been signed, the Lead PI and Research Study Team will be responsible for coordinating with its collaborators at the relying sites. As outlined in the RAs, the relying institutions will be expected to contact the Lead PI when there are study events, required reports, and other significant issues that must be reported to the sIRB. The Lead PI will coordinate with the sIRB for guidance. The sIRB will offer, as needed, to communicate directly with the relying sites to resolve issues.

The PI will obtain prior approval from NIH to request additional sites to the study. If approved, and these sites are using the same human subjects protocol, the PI will coordinate with the participating site to obtain a signed RA. The same processes as described above will apply.

The Columbia University Human Research Protection Office will maintain the signed RAs and will provide copies to the relying sites.

Requests for sIRB Exception

For sites requesting an exception based on compelling justification: Indicate which site(s) is(are) requesting an exception to the use of the sIRB and provide compelling justification based on ethical or human subjects protection issues or other well-justified reasons. NIH will determine whether to grant an exception following an assessment of the need. **Note:** If you intend to request an exception to the sIRB policy based on compelling justification, do not account for this exception in your proposed budget. The proposed budget must reflect any necessary sIRB costs without an exception (i.e., applicants should not assume that an exception will be granted when considering what sIRB costs to include in the budget).

NOTE: NIH has stated that exceptions will rarely be granted. Examples for when an exception may be appropriate are when Federal, State, Tribal, local laws/regulations/policies require local review, or when a compelling justification is made for local IRB review.