NIH Competitive Grant and Contract Application Compliance with NIH Single IRB (sIRB) Requirement for Multi-Site Studies Using the Same Human Subject Protocol

Introduction
The National Institutes of Health (NIH) has issued a policy (NOT-OD-16-094) requiring that multi-site studies using the same protocol to conduct non-exempt human subject research at more than one domestic site use a single IRB (sIRB). This policy is in effect for competitive grant applications with due dates 1/25/18 and after and for contract solicitations published starting 1/25/18. As part of the sponsored project submission process, the Principal Investigator (PI) will need to provide additional documentation to the Grants and Contracts Office (GCO) if the Icahn School of Medicine at Mount Sinai (ISMMS) is the prime institution or to the prime institution submitting the application if ISMMS is the subrecipient. If ISMMS is the prime, the PI will also include a sIRB plan in the NIH grant or contract application, supporting documentation from the named sites, and the cost of the sIRB on the budget. This memo is intended to provide additional guidance on the NIH sIRB policy, template language for the sIRB plan, and required documentation that is part of the sponsored project submission process.

I. NIH Policies and Procedures
The NIH asks the following question (3.2) in the SF 424 grant application:

Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

A) Please refer to the NIH instructions in the link above for the content of the sIRB plan required in the grant application. For contact proposals, please follow the instructions in the Request for Proposal (RFP).

B) Refer to the NIH resource page Single IRB Policy for Multi-site Research and section IV of this memo for additional resources.

C) Investigators who have questions about whether specific research protocols fall under the policy should discuss them with the Program Official listed on the Funding Opportunity Announcement (FOA).

D) Definitions and Clarifications
These definitions are excerpted from NIH’s glossary of terms and FAQs.

1. Multi-Site:
“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 the NIH.” It is also defines as “two or more sites.”
2. Protocol:
“Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.”

The NIH is referring to your IRB protocol. Do not confuse this with your NIH overall application. The NIH is asking if the sites are using the same IRB protocol. If the protocols are designed such that each site has its own distinct IRB protocol (e.g., different methodologies, different outcomes, different research questions asked), then they are not shared and they are not expected to rely on a Single IRB. Please refer to this NIH FAQ on the same IRB protocol for more information.

3. Non-Exempt Human Subjects Research
This policy applies to non-exempt human subjects research. This applies to research that is much broader than clinical trials or studies that prospectively enroll subjects. The policy may apply to studies where no new subjects are enrolled as well as to studies where data was already previously collected and only datasets are used.

4. More than One Domestic Site
“Foreign sites participating in NIH-funded, multisite studies will not be expected to follow this policy.”

II. ISMMS Policy and Procedures – ISMMS as the Prime Applicant of an NIH Grant or Contract
A) PI should contact the Program for the Protection of Human Subjects (PPHS) office at irb@mssm.edu early in the process to discuss plan and pricing if he/she would like to request that the ISMMS IRB serve as the sIRB. The costs of the sIRB of record for the study must be included in the budget.

B) The ISMMS IRB may serve as the sIRB if the application has five or fewer sites, in addition to the ISMMS site, and all of the sites participate in the SMART IRB initiative.

Required Documentation for Applications when ISMMS is serving as the sIRB
1. ISMMS PPHS Letter of Intent to Serve as sIRB.
   PPHS will provide a letter to the PI agreeing to serve as the sIRB and will include the cost of this service.

2. Approval from the Named Sites
   The sites named in the application, if any, must agree to the sIRB plan. Examples of acceptable supporting documentation are as follows:
   • The named sites can include an additional certification statement in their Statement of Intent to Establish a Consortium Agreement (SOI),
   • A link to the institution’s posted policy,
• A separate approval letter/memo/email signed by a business official
Upload the required documents in 1. and 2. above in the Internal Documents tab in InfoEd.

Failure to obtain the documentation listed above may result in the PI not being allowed to submit the application or removal of the named participating site from the application.

3. sIRB Plan in the NIH Grant Application
   The grant application must include a sIRB plan. Please refer to the NIH instructions > 3.2 for information on the content of the plan.
   PIs may adapt language from Template Description of SMART IRB to include.
   Upload the plan as a pdf attachment in the Human Subjects/Clinical Trials Information Form > Add New Study > 3.2.

4. Budget
   Include the cost for the use of the sIRB as a direct cost line item in your budget. The amount must match the amount on the PPHS approval letter.

C) The ISMMS IRB will not serve as the sIRB under the following circumstances:
   • There are more than five sites in addition to the ISMMS site and/or
   • The named sites are not participating in SMART IRB at the time of the award.
However, the ISMMS IRB can advise the PI of alternative sIRBs that may be acceptable. Other participating, accredited SMART IRBs and commercial IRBs with which ISMMS has an existing master agreement are acceptable alternatives.

Required Documentation for Applications when ISMMS is not serving as the sIRB

1. ISMMS PPHS Intent to Rely Statement
   Mount Sinai’s PPHS has posted a statement indicating their willingness to rely on a sIRB. Below is an excerpt from the PPHS statement.
   “When ISMMS will be a relying site (regardless of whether ISMMS is the prime awardee), the ISMMS IRB agrees to cooperate with the Single IRB plan when the Reviewing IRB is either:
   • accredited and utilizing the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement), or
   • an external IRB with which ISMMS already has an existing master agreement.”
   If the posted PPHS intent to rely statement is not sufficient for the institution serving as the sIRB, please contact the PPHS office at irb@mssm.edu.

2. Alternate sIRB Letter of Intent to Serve as the sIRB
   The alternate sIRB must provide a letter/memo/email signed by a business official to the PI agreeing to serve as the sIRB and include the cost of this service.

3. Approval from the Named Site(s)
   The sites named in the application, if any, must agree to the sIRB plan. Examples of acceptable supporting documentation are as follows:
• The named sites can include an additional certification statement in their Statement of Intent to Establish a Consortium Agreement (SOI),
• A link to the institution’s posted policy,
• A separate approval letter/memo/email signed by a business official

Upload documentation for 1. - 3. above in the Internal Documents tab in InfoEd. Failure to obtain the documentation listed above may result in the PI not being allowed to submit the application or removal of the named participating site from the application.

4. sIRB Plan in the NIH Grant Application
The grant application must include a sIRB plan. Please refer to the NIH instructions > 3.2 for information on the content of the plan.
PIs may adapt language from Template Description of SMART IRB to include. Please do review the language carefully and adapt if appropriate.
Upload the plan as a pdf attachment in Human Subjects/Clinical Trials Information Form > Add New Study > 3.2.

5. Budget – Include price of sIRB when planning your budget. This would be considered a direct cost.

III. ISMMS Policy and Procedures – ISMMS as the Subrecipient of an NIH Grant or Contract

A) Please obtain instructions regarding any forms or documentation the prime institution will require. Many institutions may accept PPHS’s reliance statement described below.

B) Mount Sinai’s PPHS has posted a statement indicating their willingness to rely on an sIRB. Below is an excerpt from the PPHS statement.
“When ISMMS will be a relying site (regardless of whether ISMMS is the prime awardee), the ISMMS IRB agrees to cooperate with the Single IRB plan when the Reviewing IRB is either:

• accredited and utilizing the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement), or
• an external IRB with which ISMMS already has an existing master agreement.”

If the PPHS intent to rely statement is not sufficient for the prime institution, please contact the PPHS office at irb@mssm.edu. As written above, the prime institution may require other forms or documentation.

C) The PI must contact ISMMS PPHS early if the proposed sIRB, which is chosen by the prime institution, does not qualify as per the specifications in III.B above. Failure to obtain ISMMS PPHS approval of the proposed sIRB may result in ISMMS not accepting the award should the project be funded.

IV. Additional Resources

A. NIH
• Single IRB Policy for Multi-site Research (Policy Webpage)
• Frequently Asked Questions
• Glossary of Terms
• Single IRB and Exception Process Webinar

B. PPHS
   Single IRB Policy for Multi-Site Research - NIH Policy Change Effective 1/25/18

C. GCO
   • Subawards SOP: ISMMS as the Prime Institution
   • Subawards SOP: ISMMS as the Subawardee
   • NIH Competitive Subaward Checklist: ISMMS as the Prime Institution
   • NIH Competitive Subaward Checklist: ISMMS as the Subawardee

D. SMART IRB
   • SMART IRB – National IRB Reliance Initiative
   • Participating Institutions
   • Template Language for sIRB Plan in Grant Application
     Please do review the language carefully and adapt if appropriate.