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

Background

On June 21, 2016, 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. In that original plan, there was much required documentation, including a sIRB plan that was required as part of the application submission process.

On January 22, 2020, the NIH issued a policy ([NOT-OD-20-058](#)) entitled "Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research." **NIH states that it adheres to the [Revised Common Rule](#) which makes the use of the sIRB a standard among federal agencies sponsoring research.**

Effective with applications with due date dates of May 25, 2020 and later, the NIH updated its forms set and instruction guide from Forms E to Forms F. The NIH removed the requirement for a sIRB plan in the NIH application. Since that requirement has been removed, the GCO no longer requires additional documentation from participating sites when ISMMS is the prime applicant of the NIH grant or contract and the GCO also removed its requirements when ISMMS is the subaward on an NIH grant or contract.

The purpose of this memo is to do the following:

- to provide additional guidance on the NIH sIRB policy
- to clarify the requirements of the sponsored project submission process for federally funded projects that require a sIRB
- to clarify requirements of the NIH Just in Time (JIT) process

I. Additional Guidance on NIH Policy and Procedure

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?](#)

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

A) 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

A) Contact Program for the Protection of Human Subjects (PPHS) Office

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. In many instances when Mount Sinai is the prime applicant of the NIH grant or contract they can serve as the sIRB; however, that is not always the case. Please do contact PPHS and see the following section as well for more information.

B) Criteria in which ISMMS PPHS Office will not Serve as the sIRB

The ISMMS PPHS Office 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.

C) Budget

Include the use of the sIRB as a direct cost in your budget or your subawardee's budget as appropriate.

If ISMMS is going to serve as the sIRB, please submit the [HRP-230](#) to the PPHS at least two weeks prior to grant submission in order to receive the ISMMS IRB cost.

D) NIH Application Requirements

This section is applicable when ISMMS is the prime applicant submitting the NIH grant.

Please answer section 3.2 on the NIH application, which is excerpted below removing the Agency for Healthcare Research and Quality (AHRQ) requirements and the additional resource links. Please review it in its entirety [here](#).

If you do indicate "Yes" to the question below, you may be prompted in InfoEd to add an attachment. In this case, please add the following statement. "As per the Forms F instructions, the PI plans to provide a statement naming the sIRB of record in the Just-in-Time submission prior to award."

3.2 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?



Select "Yes" or "No" to indicate whether this is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site.

Select "N/A" only if any of the following apply (do not select "N/A" if none of the following apply):

- You answered "Yes" to "[Question 1.2 Is this Study Exempt from Federal Regulations? \(Yes/No\)](#)"
- You are a training grant applicant.

Applicants who check "Yes" are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

Note: The NIH sIRB policy applies to participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy.

Additional Instructions for Training:

Check "N/A," as the sIRB policy does not apply to training awards.

For more information:

- HHS regulations and requirements for the Protections of Human Subjects can be found at [45 CFR 46](#).
- See NIH's [Single IRB Policy for Multi-site Research](#) for more information.
- See the [FAQ about answering "No"](#) for this question on the [Applying Electronically FAQ](#) page.

If yes, describe the single IRB plan

For NIH Applicants, the single IRB plan is no longer required. See additional information in the content section below.

Content:

For NIH applicants, the single IRB plan is no longer required. **Do not provide an attachment. The applicant must provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.**

For Studies with Legal-, Regulatory-, or Policy-based Claims for Exception as described by the sIRB Policy: As part of the Just-in-Time submission prior to award, indicate that review by an sIRB will not be possible for all or some sites (specify which sites) because local IRB review is required by an existing federal/state/tribal law or policy. Include a specific citation to the relevant law, policy, or regulation.

For sites requesting an exception based on compelling justification: Indicate which site(s) is 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).

E) NIH Just in Time Requirements

This section is applicable when ISMMS is the prime applicant submitting the NIH grant.

Provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.

III. Additional Resources

A. Federal

- [Revised Common Rule Single IRB clause](#)
- [US Dept of Health and Human Services \(HHS\) Office for Human Research Protections Single IRB Requirement](#)

NIH

- [Single IRB Policy for Multi-site Research](#) (Policy Webpage)
- [Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research \(NOT-OD-20-058\)](#)
- [Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research \(NOT-OD-16-094\)](#)
- [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](#)
- [Request for ISMMS to Serve \(R2S\) as the Reviewing IRB](#)
- [Requests to Rely \(R2R\) on an External IRB](#)

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](#)