

MEMORANDUM

To: Research Community

From: P. Pearl O'Rourke, MD
Director, Human Research Affairs

Date: February 16, 2017

Regarding: *Single IRBs for Multi-site Research*

In the past few years interest in the use of a single IRB (sIRB) for multi-site research has grown significantly. In fact, there are two new initiatives that mandate sIRB review for certain types of research. We want you to be aware of these initiatives, when they go into effect, and also what is required today. Key facts are bulleted immediately below.

- **NIH Policy:** This new policy (described in detail below) mandates sIRB review for NIH funded multi-site research conducted at domestic sites. This new policy requirement must be implemented **by September 25, 2017**.
- **Changes to the Common Rule (federal regulations regarding protection of human subjects in research):** The recently published revision of the Common Rule includes a mandate for sIRB review for domestic sites engaged in federally funded or conducted multi-site research. This regulatory requirement **goes into effect January 20, 2020**.
- **What is required today?** There is no regulation, guidance or policy that mandates use of a sIRB today. But some funding agencies have required sIRB as a condition of grant award - or have indicated preferential funding to those sites willing to use a sIRB.

Today, the new NIH policy is most relevant for investigators who participate in multi-site studies. The following information includes details about this policy and what investigators must include in their research planning. Details regarding the revised Common Rule will be provided in the future.

NIH Mandate for single IRB FAQs

What is the implementation date?

The implementation date for the NIH single IRB policy is September 25, 2017. (This was extended from the initial implementation date of May 25, 2017.)

This means that all applicable competing grant applications (new, renewal, revision, re-submission) that have a submission date of September 25, 2017 or later and all

proposals submitted in response to contract solicitations issued on or after September 25, 2017 must be in compliance with this policy.

What research is covered by this policy?

The policy covers multi-site domestic research funded in whole or in part by NIH. This applies to research supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. Of note, it does *not* apply to career development (K-awards), research training (e.g., T-32) or fellowship awards (F-awards) and it does *not* apply to foreign sites.

If I have an on-going multi-site study that will continue after 9/25/17, will a single IRB be required for all participating sites?

Non-competing renewals will not be expected to follow this policy.

Competing renewals with receipt dates on or after 9/25/17 will be expected to follow this policy, although PIs may apply for an exception in the renewal application.

Will exceptions be granted?

If use of a single IRB is prohibited by federal, tribal or state laws, regulations or policies, an exception will be granted. NIH states that other exceptions will be considered if there are compelling justifications - but at present there are no details regarding the process for requesting such an exception. We expect guidance from NIH. At that time additional details will be provided by the IRB office and/or Research Management Pre-Award.

What must the PI include in the grant application?

- Identification of the reviewing single IRB (sIRB).
- Documentation that all participating sites have agreed to use the identified sIRB. Currently, this is usually in the form of a letter of commitment from each of the participating sites. We expect further guidance on this from NIH.
- Description of the communication plan between the sIRB and all sites.
- A budget that includes funding required by the sIRB as a direct cost.
- If clinical research is proposed later in the course of the grant, the application should include a statement that when appropriate, a single IRB will be used.

How can the sIRB budget be developed?

- If an independent/commercial IRB will be used, the PI must negotiate a budget with the chosen independent/commercial IRB and include the costs in the grant application/contract proposal as direct costs.

- If working with an academic IRB, there may also be direct costs associated with IRB activities that should be included in the budget.
- The NIH has developed scenarios on when costs are considered direct or indirect. These are under review and detailed guidance will be provided shortly.

Once an award is received, what is the role of the lead PI with respect to IRB review?

- Ensure that authorization agreements between the sIRB and all sites are in place, and maintain necessary documentation.
- Ensure a mechanism for communication between the sIRB and all participating sites.

If you are the lead PI at PHS, what steps are required?

During grant application *development*:

Refer to Partners Research Navigator for information on central IRBs. This site includes information on:

- Use of Partners HRC as the sIRB.
- Reliance on external IRBs including:
 - Commercial/independent IRBs
 - IRBs based at other AMCs

Contact Maria Sundquist in the IRB Office to determine:

- If the proposed research falls under the NIH policy.
- Who will serve as the sIRB.
- Appropriate Partners IRB direct costs (if applicable) to include in your budget for sIRB review of other sites [based on number of sites, number of submissions, and other project-specific information].
- If IRB reliance agreements are already in place or need to be negotiated.

With the IRB direct cost information, work with your department and Partners pre-award grants managers to include these costs in your budget.

If you are a site PI being asked to rely on a sIRB selected by the overall PI, what steps are required?

Refer to Partners Research Navigator for information on central IRBs. This site includes information on reliance on external IRBs, including:

- Commercial/independent IRBs
- IRBs based at other AMCs

Contact Maria Sundquist in the IRB Office to determine:

- If the proposed research falls under the NIH policy.
- If an IRB reliance agreement is already in place with the reviewing sIRB or will need to be negotiated.

NIH plans to provide more guidance on the implementation of this policy, and we shall provide updates as they become available. If you have any immediate questions, you can contact: Maria Sundquist at msundquist@partners.org.