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NIH Single IRB Mandate: Effective For Applications Due on or After

January 25, 2018

The single IRB (sIRB) mandate [2] is an NIH policy that requires certain types of NIH-supported studies involving multiple sites where each site will conduct the same protocol involving non-exempt human subjects research to use a single IRB to accomplish IRB review and approval for all domestic participating sites. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible.

Applicable competing NIH grant, cooperative agreement, or contract applications (new, renewal, revision, or re-submission) that fall under this policy, with submission due dates on or after January 25, 2018 must include a plan describing the use of a sIRB for the study.

Because the single IRB mandate is a change in the way IRBs function, most academic medical centers are having to create new processes across multiple programs. We are collaborating nationwide to ensure a smooth transition. Updates will be posted as they are available. **Please contact the UCSF IRB by email as soon as possible or at least 90 days prior to the application submission due date ? click this link to request an sIRB consultation.**[3]

Note that NIH has explicitly stated in its sIRB FAQ [4] that "the proposed single IRB will not be evaluated as part of the peer review process and will not affect the overall assigned score of an application/proposal or the overall rating of the acceptability of the Protection of Human Subjects section."

Which Studies Must Follow the NIH Policy?

This information was obtained from the NIH policy statement [5] and the NIH FAQs on the Single IRB Policy for Multi-Site Research [4]. See these resources for significant additional details not provided here.

The NIH policy applies to all studies that are:

- Funded through grants, cooperative agreements, or contracts with submission due dates to NIH on or after January 25, 2018*, **and**
- Involve non-exempt human subjects research, **and**
- Involve multiple sites, all of which are conducting the same protocol.

** This includes multi-site studies where most sites are conducting the same protocol but one or a few sites are responsible solely for overall study coordination, laboratory services, statistical services, or other study support functions.*

The policy **does not** apply to studies that are:

- Funded to foreign awardees, **or**
- Conducted at foreign sites (though domestic sites of the same study must be reviewed by a sIRB), **or**
- Funded through career development, research training or individual fellowship awards, **or**
- Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy, **or**
- Collaborative projects in which multiple sites are involved but different sites may

complete different parts of the study.

NIH will consider other requests for exceptions [6] if there is a compelling justification, but expects these kinds of exceptions to be infrequent.

Who Can Serve as the sIRB?

Any IRB with a federalwide assurance (FWA), or registration, filed with the Office for Human Research Protections (OHRP) can serve as a sIRB. This includes:

- The IRB at the applicant/offeror (lead) PI's site
- The IRB at a participating site
- The IRB at a non-participating site
- Commercial IRBs (WIRB, Quorum, Schulman, Advarra)
- A NIH IRB ? *This option is available only if NIH has specified its use in the FOA or RFP.*
- An IRB specifically set up for an already-established-and-funded research network or consortium ? *This option is available only if the study you are proposing will be conducted under the auspices of the network/consortium.*
- A Trial Innovation Network (TIN) IRB ? *There are three TIN Central IRBs (Utah, Hopkins, Vanderbilt) that may be available free of charge.*

In most situations, the lead PI, in collaboration with the IRB office at the lead PI's institution, will select the sIRB. The selected IRB must be willing to serve as the sIRB and all of the participating sites must agree to rely on the sIRB.

It is important that the lead PI contact their RMS RSC [7] and the UCSF IRB Office by email using this link [3] as soon as possible, or at least 90 days prior to the application submission due date. In all applicable situations, the lead PI ? in collaboration with the IRB office at the lead PI's institution ? will select the sIRB. The selected sIRB must be willing to serve as the sIRB and all of the participating sites must agree to rely on the sIRB.

Will UCSF Serve as the sIRB Under This Policy?

At this time, the UCSF IRB has limited capacity, both in staffing and infrastructure to serve as a single IRB. We have hired an experienced consulting firm to assess our current capacity and the resources necessary to serve as a sIRB.

Decisions will be made on a case-by-case basis. If UCSF is the lead institution, contact the IRB by email using this link to request a single IRB consultation [3] as soon as possible or at least 90 days prior to the application submission due date.

The following factors will be taken into consideration:

- Number of sites
- PI's study staff and capacity to take on coordinating responsibilities
- Number of unique consent forms (i.e. consent, parental permission, assent, control group, etc.)
- Risk level of study

Responsibilities of the Lead Study Team

As part of the grant preparation process, the lead PI for a multi-site study that will use a sIRB should identify who will take on the role of the Lead Study Team. This may be the lead PI's own study team, a coordinating center, both, or a Contract Research Organization (CRO).

New responsibilities

The Lead Study Team has responsibilities associated with the use of a sIRB. These are described in the Overall Principal Investigator/Lead Study Team Guidance and Checklist [8].

Adequate attention to these new responsibilities is essential for realizing the potential efficiencies of using a sIRB. The lead PI should carefully consider the staffing of the Lead Study Team when constructing the grant budget

IRB Liaison

The IRB anticipates that studies with more than a few sites will require significant additional staffing resources to manage the complex communications, coordination, and document management associated with the use of a sIRB across sites. This role is being called the "IRB Liaison" by the UCSF and many other institutions. It is typically a staff member on the Lead Study Team. This may be 0.1 – 1.0 FTE, depending upon the size and complexity of the study. See the template Communication Plan for Single IRB Review [9] for a description of the key communication roles related to sIRB review.

What sIRB Information Should Be Included in Grant Applications?

See Section D "NIH Grant Application/Contract Proposal Preparation" of the NIH FAQ Single IRB Policy and Multi-site Research [4] and (for specific details) Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide [10].

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

- **A plan describing the use of a sIRB unless otherwise stated in the RFP or solicitation for contracts** (see details below). The plan should identify the IRB that will serve as the sIRB and should address any requests for exceptions from the policy. The HRPP has developed sample plan language that can be adapted for your grant.
- The name of the single IRB
- An estimate of the direct costs (if any) for IRB review, in the grant budget (see details below)
- A Letter of Support from the UCSF IRB (provided via consultation with UCSF IRB)

Single IRB Plan for Grant Application

Beginning with NIH applications due on or after January 25, 2018, all NIH-supported studies involving multiple sites, where each site will conduct the same protocol involving non-exempt

human subjects research, will include a plan for the use of a single IRB ^[11] to accomplish IRB review and approval for all domestic participating sites. For details, see Section 3.2 of the PHS Human Subjects and Clinical Trials Form Information Application Guide ^[10].

Content

- Describe how you will comply with the NIH Single IRB (sIRB) policy. If you are requesting an exception for some or all participating sites, follow the NIH Guidance Requesting an Exception ^[6].
- Provide the name of the IRB that will serve as the sIRB of record.
- Indicate 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.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate 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.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

Delayed-onset multi-site research

Delayed-onset human subjects studies are those for which there is no well-defined, detailed plan for human subjects involvement at the time of submission. If the delayed-onset research is likely to involve multiple sites that will conduct the same protocol, the delayed onset justification attachment must:

- Include information about how the study will comply with the sIRB policy, and
- State that a sIRB plan will be provided prior to initiating the study.

New PHS HSCTI Form in FORMS-E application packages

The new PHS Human Subjects and Clinical Trial Information (HSCTI) form included in the new FORMS-E ^[12] application package must be included in grant applications and contracts proposing human subjects and/or clinical trial research, with submission due dates on or after January 25, 2018. This new form is a "smart" (i.e., branching) webform that consolidates all human subjects and clinical trial-related information into one place, and also expands the information required for studies that meet the NIH definition of a clinical trial ^[13]. **The sIRB plan ^[11] is uploaded as an attachment to Question 3.2 of the study record in the new PHS HSCTI form in FORMS-E.**

FORMS-E application instructions ^[10] (see Section G.500, Question 3.2) are available from NIH on the How to Apply ? Application Guide ^[14] website. On October 24, 2017: FORMS-E application packages will start being published for NIH FOAs with due dates on or after January 25, 2018.

Cost of Single IRB Review

The costs for IRB review at a single institution by that institution's IRB have typically been considered an indirect cost covered under an institution's Facilities and Administration (F&A) rate (except for industry-initiated-and-sponsored studies).

However, NIH expects that many sIRBs will charge fees to review other sites. The fees should be included in the grant budget. *This is a new responsibility.*

Which IRBs charge fees for serving as a single IRB?

sIRBs that do not charge fees	<ul style="list-style-type: none">• A NIH IRB, established to review specific types of NIH-funded studies• An IRB set up specifically for a NIH-funded research network (e.g., PETAL network IRB)
sIRBs that charge fees	<ul style="list-style-type: none">• The commercial IRBs (e.g., WIRB, Schulman, Chesapeake, Quorum)
sIRBs that may or may not charge fees	<ul style="list-style-type: none">• All other IRBs

Obtaining annual cost information for sIRB review

At least 90 days prior to the application submission due date, collaborate with the UCSF IRB to decide which IRB will act as the single IRB for the study. If a commercial IRB is selected, the PI will contact the commercial IRBs directly to discuss the study and request a quote for each budget period to be included with the application budget. This information is required for the Research Services Coordinator to prepare the application budget.

Contact the commercial IRBs directly for current fee structure:

- WIRB ^[15]
- Quorum ^[16]
- Adverra (formerly Schulman and Chesapeake) ^[17]

For all other IRBs: Contact the UCSF IRB through IRB@ucsf.edu ^[18]. We will discuss the options with you and then provide you with the contact information at the selected IRB so that you can confirm their willingness to serve as the sIRB and obtain the fee estimates for your grant budget.

Grant budget guidance

NIH has provided detailed information at the sIRB FAQ [4] and a specific costs guidance document [19], including topics such as:

- Which budget category on the SF424 (R&R) form should be used
- Which costs should be charged as direct vs. indirect costs under different IRB review scenarios
- The relationship with the \$500,000 cap on direct costs
- Where to put the sIRB cost information on the budget forms [20]

If you have questions, contact:

- The NIH Grants Management Specialist identified in your FOA or RFP and/or
- UCSF IRB [21]
- Your Research Services Coordinator at the UCSF Office of Sponsored Research [7]

What is SMART IRB?

SMART IRB [22] is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH sIRB policy. Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation.

SMART IRB Resources for PIs

- SMART IRB (smartirb.org) [23]
- Template Communication Plan for SMART IRB [9]
- Overall Principal Investigator/Lead Study Team Guidance and Checklist [8]

What Happens After the Grant Is Funded?

Regardless of who will be serving as the sIRB, every study needs to be submitted in iRIS. You will be asked questions about the sIRB and the form will branch accordingly. Contact the IRB once you receive the Notice of Award.

For guidance on other reliance scenarios, please see the Working With Other Institutions page [24].

Resources on NIH Policy

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research: NOT-OD-16-094 [5]
- NIH Guidance on Implementation of the Single IRB Policy [25]
- Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research: NOT-OD-16-109 [19]
- NIH Single IRB Policy FAQs for Extramural Community on Implementation of sIRB Policy [26]
- NIH Single IRB Policy FAQs for Multi-Site Research Costs [27]

Our thanks to the University of Washington Human Subjects Division [28] for providing us some

of this information.

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Source URL: <https://irb.ucsf.edu/nih-single-irb-mandate>

Links

[1] <https://irb.ucsf.edu/#grant-info>

[2] <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

[3] [mailto:SingleIRB@ucsf.edu?subject=Single%20IRB%20Consultation%20Request&body=Title%20of%20study%20needing-irb-](mailto:SingleIRB@ucsf.edu?subject=Single%20IRB%20Consultation%20Request&body=Title%20of%20study%20needing-irb-review%0A%0As%20each%20site%20conducting%20the%20exactly%20same%20protocol%20and%20study%20)

[review\)%0A%0As%20each%20site%20conducting%20the%20exactly%20same%20protocol%20and%20study%20](mailto:SingleIRB@ucsf.edu?subject=Single%20IRB%20Consultation%20Request&body=Title%20of%20study%20needing-irb-review%0A%0As%20each%20site%20conducting%20the%20exactly%20same%20protocol%20and%20study%20)

[4] https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm

[5] <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

[6] <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html>

[7] <https://osr.ucsf.edu/find-my-osr-staff>

[8] https://smartirb.org/sites/default/files/PI_checklist.pdf

[9] https://smartirb.org/sites/default/files/Communications_Plan_Form.pdf

[10] <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm>

[11] <http://osr.ucsf.edu/sites/osr.ucsf.edu/files/TEMPLATE-singleIRB%20Plan.docx>

[12] <https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>

[13] <https://grants.nih.gov/policy/clinical-trials/definition.htm>

[14] <https://grants.nih.gov/grants/how-to-apply-application-guide.html>

[15] <https://www.wirb.com/Pages/ContactUs.aspx>

[16] <https://www.quorumreview.com/about-us/contact-us/>

[17] <http://www.sairb.com/news/integrated-advarra-fee-schedule-now-available/>

[18] <mailto:irb@ucsf.edu>

[19] <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html>

[20] <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.300-r&r-budget-form.htm>

[21] <https://irb.ucsf.edu/contact-us>

[22] <https://SMARTIRB.ORG/>

[23] <https://smartirb.org/>

[24] <https://irb.ucsf.edu/working-other-institutions>

[25] <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html>

[26] <https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/>

[27] <https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faq-on-costs/>

[28] <https://www.washington.edu/research/hsd/>