THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

National Institutes of Health (NIH)

Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research

Beginning **January 25, 2018**, domestic sites of NIH-funded multi-site studies involving non-exempt human subjects research will be required to utilize a **single IRB of Record (sIRB)** for the ethical review of human subject protections.

- NIH funding through grants, cooperative agreements, contracts, or the NIH Intramural Research Program
- NIH competitive applications (new, renewal, revision, resubmission) received on or after 1/25/18
- NIH contract solicitations issued on or after 1/25/18

sIRB applies to:	sIRB does not apply to:
• Multiple sites conducting the same protocol • Domestic research (U.S. awardees and sites) • Ethical review of protocol and informed consent	• Foreign sites • Career development (K), institutional training (T), or fellowship awards (F)

Policy-based exceptions are automatically granted when identified in the sIRB plan because they would be prohibited by a federal, state, or tribal law, regulation or policy.

- Tribes
- VA sites

The NIH sIRB Exceptions Review Committee (ERC) will review and consider requests for ***other exceptions*** with compelling justification in the sIRB plan for reasons other than that the sIRB is unable to meet the needs of a specific population. These exceptions are expected to be rare.

University of Arizona IRB Interactions

The University of Arizona (UA) Human Subjects Protection Program (HSPP) is accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP).

Contact UA HSPP as soon as possible to discuss sIRB projects!

UA HSPP prefers to be the sIRB of record if UA serves as the lead NIH applicant or coordinating center. UA may cede to IRBs with an equivalent of AAHRPP accreditation.

Reliance Platforms (tools to share sIRB materials)

SMART IRB Participating Institution

irbchoice optimal flexibility

Before you begin an NIH application to fund a multi-site study, contact the UA HSPP to verify institutional approvals are in place to serve as sIRB or rely on a non-UA IRB.

See UA Ceded IRB Review Guidance - UA does not currently have standing agreements with Commercial IRBs for federally funded research. An Application for Ceded IRB Oversight is required and approved on a per protocol basis for human research primarily conducted at another organization. Reliance agreements can take months to finalize. Contact UA HSPP ASAP.

Email HSPP at VPR-IRB@email.arizona.edu

Investigator/Study Team Responsibilities:

- Confirm the proposed sIRB is willing to serve (not researchers) before submitting the proposal
- Submit a UA request to HSPP if ceding IRB review
- Report and update the sIRB according to their policies and procedures.
- Submit copies of renewals and study closures to the UA HSPP
- Submit all local unanticipated problems (UP) or reportable items to the UA HSPP as well as the sIRB
- Submit HIPAA authorization forms to the UA HSPP for review if the sIRB does not review.

Banner-University Medicine collaboration requires Banner informed consent language.

Reliance Agreements (aka IRB Authorization Agreement (IAA)) clarify the roles and responsibilities of the sIRB and participating sites. Contact UA HSPP to discuss local context issues.

Communication Plan:

Keeping the details of the communication plan separate from the reliance agreement will allow for communication plan adjustments without requiring a signed reliance agreement amendment.

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Proposal Preparation:

Beginning January 25, 2018, the **sIRB plan** is uploaded as an attachment in section 3.2 in the **Study Record: PHS Human Subjects and Clinical Trials Information** form (part of **SF424 (R&R) FORMS-E**). This new form consolidates all human subjects and clinical trial-related information in one place and expands the information required for studies that meet the NIH definition of a clinical trial. Follow any specific sIRB instructions in the Request for Proposal (RFP).

- The sIRB Plan will not be evaluated in proposal peer review.
- List participating sites in the Project/Performance Site Locations section to the extent possible.
- NIH does not require a letter of support from the sIRB but the lead study team should confirm sIRB arrangements with the sIRB and participating site IRBs prior to proposal submission.
- NIH requests certification of IRB approval as part of the Just-in-Time process. However, NIH recognizes that, for some studies, obtaining signed Reliance Agreements among sites may take longer. Any award made without certification of IRB approval will include terms and conditions restricting all human subject activities until Reliance Agreements are in place and IRB approval is obtained.

Single IRB Plan Content:

The sIRB Plan should include the following:

- NIH Single IRB (sIRB) policy, statement confirming participating sites will adhere to the policy, naming policy-based exceptions and following NIH Guidance to request other exceptions.
- The name of the proposed sIRB, when possible, describing sIRB qualifications.
- Anticipated communication between the sIRB and all sites.
- Indicate that a reliance agreement will be signed by all sites prior to study human subject activity.
- Indicate which institution will maintain records of reliance agreements and the communication plan.

Sample sIRB Plan language

Single IRB Review: {NAME_OF_sIRB} is qualified and will serve as the single IRB of record for this study for the lead site, data coordinating center and all participating sites with the following exceptions:

- Veteran's Affairs, *Southern Arizona VA* Health Care System (SAVAHCS) will obtain separate IRB review due to a policy-based exception from the single IRB requirement
- {NAME_OF_TRIBAL_ORGANIZATION} will obtain separate IRB review because its tribal policies require local IRB review
- We are requesting an exception from the single IRB requirement for {NAME_OF_INSTITUTION} for the following reasons:
- {LIST ADDITIONAL EXCEPTIONS AS NEEDED}

Language for Delayed-Onset Research

Single IRB Review: According to NIH Policy, the applicant will communicate regarding selection of a qualified single IRB of record with the funding NIH Institute/Center prior to initiating the multi-site study.

Budgeting:

NIH 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

- **Primary Activities** (ethical review of protocol & review of informed consent template) are considered an indirect cost (Facilities and Administrative) at UA.
- **Secondary Activities** (site specific considerations) may be considered a direct cost.

Allowable Direct Costs:

IRB Fees: UA IRB fees are part of our federally negotiated F&A rate and should not be budgeted as a direct cost. However, if a commercial IRB will serve as the sIRB of record, their fee is an allowable direct cost.

IRB Liaison: If the proposed study involves many sites and requires significant (lead) study team effort to facilitate document management, coordination and communication with the sIRB, research study coordinator salary may be included in the study direct cost budget.

Additional Resources: NIH Single IRB Policy for Multi-site Research: sIRB FAQs and Cost FAQs * NIH Application Guide: SF424 (R&R) FORMS-E (see G. 500 for PHS Human Subjects and Clinical Trial Information form) * NIH Clinical Trial definition (NIH Human Subjects Questionnaire) * SMART IRB Resources: PI Checklist and sIRB Communication Plan