LEAD PRINCIPAL INVESTIGATOR RESPONSIBILITIES
sIRB GUIDANCE AND CHECKLIST

Effective January 25, 2018, the National Institutes of Health (NIH) will initiate a policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research. The expectation is that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services (HHS) regulations for the Protection of Human Subjects at 45 CFR Part 46.

This document provides sIRB guidance from proposal preparation to initiation of the research for a Lead Principal Investigator seeking NIH-support through a grant, cooperative agreement, or contract for a multi-site study involving human participants.

I. Proposal Stage (At least 6-8 weeks before proposal deadline)

- Contact Valerie Sanchez, IRB Reliance Administrator: 949-824-7735 / IRBReliance@uci.edu:
  - Discuss whether UCI IRB can act as the single IRB (sIRB) or whether an external IRB would be appropriate. In general, UCI can serve as the sIRB for a multi-site protocol involving no more than four sites, including UCI. Provide study details, including draft of Master Protocol and template consent form.
  - Identify all sites that will be engaged in human subjects research.
  - Identify who will act as the Coordinating unit (e.g., your study team, a coordinating center, or both). This unit will coordinate with the sites and the sIRB. The coordinating unit and the Lead PI assumes additional responsibilities when sIRB review is used.
  - Determine whether existing IRB agreement(s) (such as SMART IRB, UC Campuses agreement) could be used for all sites or if additional agreement(s) are necessary.

- If UCI agrees to serve as the sIRB for the study, you will need to ensure the Coordinating unit, completes the following:
  - Submits relevant documentation to request sIRB using the IRB submission process required UCI IRB.
  - Work with the UCI IRB to determine IRB Fees. IRB Fees are based on the specifics of the research study including the number of sites, the anticipated duration of the study, and the anticipated number of modifications/amendments. Note UCI will also charge fees to negotiate IRB agreements not already in place (e.g., SMART, UCs).
  - Works in collaboration with the UCI IRB to determine and document specific roles and responsibilities for communicating and coordinating key information among all participating sites, including Relying Institutions; this includes developing a plan for

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1 Exceptions to the sIRB policy will be granted if the use of a sIRB is prohibited by federal, state, or tribal laws or regulations. Also granting an exception will be considered if a request is made and a compelling justification is provided for why an exception is needed.

2 Excludes career development, research training or fellowship awards

* Modified version of SMART IRB Overall Principal Investigator/Lead Study Team Guidance and Checklist
communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).

☐ **If necessary to find another sIRB:**

- Check with other participating sites to see if their IRB could serve as the sIRB. Consider working with independent IRBs (e.g., Western IRB, Quorum, Shulman, Chesapeake).

- Work with the sIRB to determine IRB Fees. IRB Fees are based on the specifics of the research study including the number of sites, the anticipated duration of the study, and the anticipated number of modifications/amendments. **Note some sIRBs will also charge fees to negotiate IRB agreements not already in place.**

- Works in collaboration with the sIRB to determine and document specific roles and responsibilities for communicating and coordinating key information among all participating sites, including Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).

☐ **The Lead PI is expected to submit to NIH with the proposal:**

- A plan describing the use of a sIRB that will be selected. The plan should:
  - Include a statement confirming that participating sites will adhere to the sIRB Policy.
  - Description of how communications between all participating sites and sIRB will be handled.

- A budget that includes direct cost funding for the costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification. **NOTE:** Costs must be reasonable and consistent with cost principles, as described in the NIH Grants Policy Statement and the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

  ☐ **NOTE:** If direct costs are anticipated to be over $500,000 Applicant/offeror is required to contact the IC Program staff six weeks prior to submission

  ☐ If, in *delayed-onset research*, a sIRB has not yet been identified, applications/proposals should include a statement that awardees will follow the sIRB Policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study.

**II. Pre-Award Stage**

After submitting the proposal to NIH but before the award has been issued, the **Lead Site** should:

☐ Work with the Reviewing IRB, as requested, to establish any required IRB Authorization Agreements.

☐ Coordinate gathering key information such as local context from all sites.
Promptly respond to questions or requests for information from Reviewing IRB.

Provide the Site Investigators with the IRB policies of the Reviewing IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.

Ensure that Site Investigators understand and fulfill any documentation requirements of their local HRPPs (e.g., tracking, ancillary reviews, local consent boilerplate).

III. Post-Award Stage
Once the award has been issued, the Coordinating Unit should:

- Provide Relying Sites with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- Prepares and submits IRB applications on behalf of all sites, including initial reviews, local modifications, personnel updates, local reportable events, and study wide amendments and information for continuing review.

As part of preparing the IRB application, the Coordinating Unit (e.g., Lead Study Team) must:

- Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Administrative Contacts (ACs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
- Assist Relying Site Study Teams and/or ACs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the Reviewing IRB’s template form and include applicable site-specific required language from each Relying Institution.