

Guidance on the Use of NIH Mandated Single IRBs at UC Merced

The [NIH mandate for the use of single IRBs](#) (sIRB) in certain human subjects studies went into effect on January 25th, 2018. This policy applies to any *NIH funded, non exempt human subject study with multiple sites following the same protocol*. The policy is designed to reduce administrative redundancy and inefficiencies while maintaining suitable human subjects protections. Plans for the use of sIRBs must be included in the grant application at time of proposal.

Because of the responsibilities of a sIRB, at this time, the UC Merced IRB cannot serve as the sIRB for any study given the level of responsibility needed, and the resources in the IRB office. However, the University of California has contracted with a variety of commercial IRBs (please see list in FAQs below) that can be used as sIRBs for UC Merced PI lead studies. Please note that there is a cost to use any commercial IRBs (fee structure depends on IRB and type of study/transaction). The PI is responsible for paying the cost for the use of a commercial IRB as the sIRB for their study, and the cost can be directly budgeted into the grant proposal. PIs should consult with the Sponsored Research Services Office to plan budgets accordingly.

PIs considering grant proposals that meet the requirements for the use of sIRBs should contact the UC Merced IRB office as soon as possible for a consultation. The UC Merced IRB will provide assistance to PIs planning to use a commercial IRB/sIRB.

Please see FAQs below for more detailed information on the use of sIRBs.

FAQs on the use of sIRBs at UC Merced

1. What is the NIH policy on the use of single IRBs?

The single IRB (sIRB) mandate requires NIH-supported multi site studies , where each site will follow 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 streamline the IRB review process and remove administrative burden and redundancy in the process.

Applicable competing NIH grant, cooperative agreements, 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.

2. Are there exceptions to the NIH policy?

Yes, the following are exceptions to the NIH Single IRB Policy. If you plan to use an exception, you must justify the exception(s) in the plan for IRB Review section of your proposal. Guidance from NIH on Exception to the Single IRB Policy may be found [here](#).

Policy-based – Where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation or policy.

Time-limited – Where ancillary studies are part of ongoing or parent studies. Single IRB not required until it is required of the parent study.

Compelling Justification – Require NIH Exceptions Review Committee Approval. Where there are other requests not associated with policy or time-limited exceptions if there is a compelling justification. NIH will determine whether to grant the exception.

3. Can the UC Merced IRB serve as a sIRB?

No. The UC Merced IRB will not be able to serve as a sIRB due to the responsibilities and demands of this designation when reviewing for multiple sites. The UC Merced IRB has limited resources and staff that do not allow it to serve as a sIRB at this time. UC has contracted with commercial IRBs that can serve as sIRBs in cases where the UC Merced PI is charged with designating the sIRB.

4. Who can serve as a sIRB?

Any IRB with a federalwide assurance (FWA), 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, Chesapeake, see below)
- A NIH IRB — This option is available only if NIH has specified its use in the FOA or RFP.
- A Trial Innovation Network (TIN) IRB — There are three TIN Central IRBs (Utah, Hopkins, Vanderbilt) that may be available free of charge.

Because the UC Merced IRB cannot at this time serve as the sIRB, we recommend PIs utilize the following commercial IRBs for this purpose.

[Western IRB/Copernicus \(WIRB\)](#)

[Quorum IRB](#)

[Chesapeake IRB](#)

[Schulman IRB](#)

Please note that Chesapeake IRB and Schulman IRB have recently merged, forming Advarra IRB. UC is currently in discussion as to how that will affect the UC contracts.

5. What is the cost of using a commercial IRB as the sIRB?

The cost of using a commercial IRB varies according to the type of project and the fee schedule for each individual company. We recommend PIs contact the commercial IRB of their choosing well in advance of the grant proposal submission to determine fee structure and cost of review of their study.

6. Who pays for the use of a commercial or other IRB as the sIRB?

The cost of the use of external or commercial IRB as the sIRB is the responsibility of the PI and should be the source of funds used to support the research study. The cost can be direct charged to any NIH grant and NIH has provided detailed information at the [sIRB FAQ](#) and a [specific costs guidance document](#).

7. When does the sIRB designation have to be made?

The PI must submit a plan describing the use of sIRB at the time of grant proposal submission. Ideally, the plan would identify who would serve as the sIRB at time of submission. For more information on what the plan should include please consult the [NIH FAQs on sIRB grant proposal preparation](#).