



Applying the sIRB Policy to Your Next NIH Proposal

EFFECTIVE JANUARY 25th 2018

The National Institutes of Health (NIH) has issued a policy on the use of a single Institutional Review Board (IRB) for multi-site research with the expectation that a single IRB (sIRB) of record will be used for the ethical review of NIH funded, multi-site, non-exempt human subjects research protocols. 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.

For projects that are non-NIH funded or not funded studies FAU's policy is to also encourage a single IRB review as appropriate. The process will be applied to all research conducted at FAU except those projects where federal, tribal or state law, regulation or policy prohibits the review by a single IRB. It is also important to note that some institutions will not agree to a reliance agreement for those studies not required to follow sIRB requirements.

What this means:

- In the NIH application/proposal for research funding, the applicant (PI) is expected to submit a plan describing the use of a single IRB to serve as IRB of record for all study sites
- The PI will need to select the sIRB. This can be pre-determined by the study sponsor or grant, established by prior arrangement (e.g. network central IRB) by the IRB from the lead PI's institution, or selected based on expertise in the study area (e.g. type of procedures to be performed or subject population). It is important that the PI discuss this with Sponsored Programs and Research Integrity at the proposal development stage of the proposal application.
- The PI needs to budget the costs associated with the sIRB as applicable.





Budget the costs associated with sIRBs:

If your institution is the prime awardee and serving as the sIRB:

IRB Review activities for your institution	Indirect Cost
IRB Review activities for all other participating sites	Direct Cost

If your institution is the prime awardee and a different participating site is serving as the sIRB:

IRB Review activities for your institution	Direct Cost
IRB Review activities for participating site serving as sIRB	Indirect Cost
IRB Review activities for all other participating sites	Direct Cost

If your institution is the prime awardee and a commercial IRB is serving as the sIRB:

IRB Review activities for your institution	Direct Cost
IRB Review activities for all other participating sites	Direct Cost

NIH sIRB policy information and resources

[NIH FAQ on the Single IRB Policy for Multi-Site Research](#)

[NIH Guidance on Implementation of the Single IRB Policy](#)

For questions regarding the sIRB process please contact:

[Assistant Director of Research Integrity, Ximena Levy](#)

For questions regarding NIH budget proposal for sIRB please contact:

[The Office of Sponsored Programs](#)

