NIH Single IRB (sIRB) Policy for Multi-Site Research

On June 21, 2016 the National Institutes of Health (NIH) issued a policy for single Institutional Review Board (sIRB) of NIH-funded human subjects research protocols conducted at two or more U.S. sites. The goal of the policy is to enhance and streamline the IRB review process for multi-site research so that research can proceed as effectively and expeditiously as possible, without diminishing human subjects protections. Minimizing duplicative IRB reviews should also reduce administrative burdens and allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.

What is a Single IRB?

- A single IRB is an arrangement where one IRB provides review services for multiple sites participating in a human-subjects research protocol.
- Local IRB is an IRB that provides review services for research conducted by researchers at their institution.

When Does this NIH Policy go in Effect?

- January 25, 2018

Who Does this Affect?

- NIH applicants of multi-site clinical studies where *each site will conduct the same non-exempt protocol* funded through grants, cooperative agreements, or contracts (includes new, renewal, revision, or resubmission) with due dates on or after January 25, 2018
- **Exceptions:** foreign awardees; international sites; where 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.

I'm preparing a NIH proposal, what do I need to do?

- Review the Principal Investigator (PI) sIRB Guidance and Responsibilities Checklist. The document provides guidance from proposal preparation to initiation of the research for the Lead PI. Also see the NIH sIRB webpage.
- Contact Valerie Sanchez, IRB Reliance Administrator, at 949-824-7735 / IRBReliance@uci.edu to discuss whether your UCI's IRB will act as the 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.
- The PI is expected to submit to NIH with the proposal a plan describing the use of the 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.

Additional Resources on NIH Policy:

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research: NOT-OD-16-094
- 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
- NIH Single IRB Policy FAQs for Extramural Community on Implementation of sIRB Policy
- NIH Single IRB Policy FAQs for Multi-Site Research Costs