KSU Single IRB Policy

The Single IRB Mandate:

The single IRB (sIRB) mandate is a new federal policy that requires certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites. This NIH Policy takes effect January 25th, 2018. This policy **applies to**:

- Research funded by the NIH.
- Only domestic sites of NIH-funded multi-site studies.
- Each site will conduct the **same** protocol involving non-exempt human subjects research.

The policy **does not apply to**:

- Career development, research training or fellowship awards.
- Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.
- Collaborative projects in which multiple sites are involved but different sites may complete different parts of the study.
- Conducted at foreign sites.

NIH provided resources:

- NIH FAQ on the Single IRB Policy for Multi-Site Research
- NIH Guidance on Implementation of the Single IRB Policy

For the Principle Investigator (PI):

- The KSU IRB **will not serve** as the sIRB for multi-site studies that meet the definition of the NIH sIRB Policy. Independent IRBs such as Western IRB (WIRB), which are not affiliated with an institution, can be used or an IRB of one of the other participating institutions can be designated to serve as the sIRB of record.
- A letter of support from the IRB/URCO agreeing to rely on the identified sIRB should be attached to the grant application. IRB/URCO cannot guarantee its willingness to support the use of a sIRB that has been selected without its consultation and approval.
- The NIH Single IRB Policy requires the following information be **included in grant applications** for multi-site research submitted on and after January 25, 2018:
    - **Human Subjects section:**

        - A Single IRB Plan describing the use of a sIRB and specifying which IRB will serve as the single IRB.

    - **Budget and Budget Justification:**
        - Any IRB fees that will be charged as direct costs, and any personnel costs directly related to managing the IRB arrangements.
            - See the PHS G.300 – R&R Budget Form for information about where in the budget form to put this information.
    - **Optional:**
        - A Letter of Support from the sIRB, agreeing to serve as the sIRB.
        - A Letter of Support from the participating sites, agreeing to a single IRB arrangement.

If the Grant is funded:

- The sIRB reliance agreement must be completed and signed. This is different than the Letter of Support.
    - Agreements must be signed by the sIRB of record and the Institutional Official (IO). Contact the IRB/URCO for assistance with this agreement.
- Determine the roles and responsibilities of each institution.
- Complete, and submit, application to sIRB for review and approval.

Please contact URCO at (785-532-3224) if you have any questions.