Template sIRB Plan when proposing COMIRB serve as sIRB

Contact the COMIRB Director before proposing that COMIRB serve as sIRB.

Template sIRB Plan for funding proposals (to be revised as appropriate for the specific proposal):

This application is a multi-site study involving non-exempt human subjects research. Domestic sites will comply with the NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research by relying on a single IRB (sIRB) through the SMART IRB Reliance Initiative.

The IRB at the University of Colorado | Anschutz Medical Campus, the Colorado Multiple IRB (COMIRB), will be the sIRB of record. COMIRB is in full compliance with federal regulations governing IRB review, including having appropriate membership for review of this proposal. COMIRB has been AAHRPP accredited since 2009.

All identified domestic participating sites have agreed to rely on COMIRB for IRB review. Any domestic sites added after award will be rely on COMIRB.

Communication between the sites and the sIRB will be coordinated by the Lead PI and study team at the University of Colorado Denver | Anschutz Medical Campus. Communication between COMIRB and relying IRB offices will be coordinated by COMIRB.

Roles and responsibilities of the sIRB and participating sites will be documented prior to initiating the study through the SMART IRB reliance agreement for all domestic sites that have joined SMART IRB. Roles and responsibilities will be documented though individual IRB Authorization Agreements between COMIRB and any domestic sites that have not joined SMART IRB.

Note: A more detailed plan will be requested by COMIRB at the time IRB approval is needed.

Other Resources:

For general requirements for sIRB plans for NIH and other PHS agencies, see Section 3.2 of the PHS Humans Subjects and Clinical Trials Information.

To confirm whether sites have joined Smart IRB, see SMART IRB Participating Institutions.