THE UNIVERSITY OF ARIZONA Research & Partnerships

Single IRB Review

Background

The National Institute of Health (NIH) mandated single IRB (sIRB) review for multi-site studies that receive NIH funds effective January 25, 2018. sIRB is commonly referred to as *ceded review* or *deferral of IRB oversight*. In addition, the Office for Human Research Protections (OHRP) mandated sIRB review, effective January 19, 2020, for all other federal agencies that have adopted the human subject rules (e.g., Common Rule).

The Human Subjects Protection Program (HSPP) requires sIRB review for collaborative, **non-exempt** human subjects research that involves multiple institutions funded or supported by federal agencies that have adopted the Common Rule. Note: The Department of Justice and the Food and Drug Administration have not adopted the single IRB mandate.

Single IRB means that the University of Arizona (UA) Institutional Review Board (IRB) either assumes (*reviewing IRB*) or gives up (*relying IRB*) its oversight of the research activity to another equally qualified IRB. sIRB is designed to reduce duplication and increase efficiency by designating a sIRB review when more than one site is involved in a research project.

The UA IRB will not oversee or defer to an outside institution on studies deemed exempt or reviewed under a flexible review. Each investigator will need to obtain approval from their local IRB. The UA IRB can oversee individuals not affiliated with an outside institution on exempt studies on a case-by-case basis.

The UA has standing agreements in place with the following entities regarding sIRB review:

Commercial IRBs, including WCG IRB, Inc. and Advarra IRB, where the research involves a multi-center, industry sponsored, non-federally funded clinical study, where the UA is not the coordinating center. The UA IRB has negotiated informed consent templates with these commercial IRBs that are available on the eIRB platform and HSPP website.
National Cancer Institute Central IRB (NCI CIRB) – These studies cannot include prisoners. In addition, CIRB does not review HIPAA authorization language. CIRB also requires the HIPAA Authorization be a standalone document.
National Marrow Donor Program (NMDP) – When these studies involve the Center for International Blood and Marrow Transplant Research (CIBMTR) Database and Research Sample Repository. The UA IRB has negotiated an informed consent template that is available on the HSPP website.
SMART IRB is a platform for IRBs to share IRB approval for single IRB review. The UA is a member of SMART IRB.
IRB Reliance Exchange (IREx) is a platform for IRBs to share IRB approval for sIRB review. The UA is a member of IRBEx.
Arizona State University (ASU) or Northern Arizona University (NAU) – when ASU or NAU is the primary grantee agency and a co-investigator of the project is at the University of Arizona.
Various hospitals connected to UA Health Sciences (Medicine, Nursing, Pharmacy, and Public Health) scholarly projects in the Tucson and Phoenix area, and research conducted at Phoenix Children's Hospital.

The UA may decide to allow for sIRB review outside of the standing agreements and NIH and OHRP policies noted above when:

The University of Arizona investigator is a collaborator on human research primarily conducted at another organization where:

- The Principal Investigator (PI) of the organization will have direct oversight of the University of Arizona investigator;
- The organization agrees to take responsibility for the University of Arizona investigator; and
- The other organization is Association for Accreditation of Human Research Protection Programs (AAHRPP) accredited. Note: For organizations that are not AAHRPP accredited, decisions are made on a per-protocol basis to ensure that the organization can maintain equivalent standards to AAHRPP accreditation.

The UA may NOT consider sIRB review when:

- The project involves prisoners, Native Americans, or vulnerable populations that require special considerations. To ensure appropriate protections are in place, projects involving Native Americans requesting sIRB review must abide by the Arizona Board of Regents policy on Native American consultation (ABOR 1-118).
- The proposed IRB of record does not have sufficient knowledge of local context or a robust human subject program (as required by federal guidelines and AAHRPP accreditation) to assume IRB oversight for sites that fall under UA HSPP purview;
- A UA study team member has a conflict of interest that requires a management plan, and the management plan prohibits or limits activities that the individual can engage in related to human subjects research; or
- A UA study team member has a history of non-compliance with IRB policies or processes.
- The study is approved as Minimum Risk 2018 or Exempt.

Requirements before the UA will agree to sIRB review by another site

Before a project can participate in a sIRB agreement, the University must verify that all institutional approvals are in place prior to issuing the approval to allow another IRB to review the project. A request for sIRB submitted to the UA HSPP must include, but is not limited to, the following approvals:

- Scientific review
- Site authorizations
- Conflict of interest
- Radiation, biological, or chemical safety
- UA Travel Registry
- CITI training
- Feasibility review for access to Banner Health resources
- eDoc number for federally funded or industry sponsored studies

In addition to required local approval, the HSPP will verify the protocol, consent, HIPAA Authorization, research personnel, and other study documents comply with local and state law, AAHRPP accreditation standards, and agreed upon Informed Consent and PHI Authorization template language for our hospital partners. This is required for all sIRB review studies, even those where the UA has existing standing agreements.

Responsibilities of the UA Investigator when the UA is the reviewing IRB

The UA PI and the HSPP share joint responsibility for any research project where the UA IRB is the IRB of record for other research sites. The UA PI must submit an IRB application to the UA IRB for review and approval of the overall study. In addition, each Participating Site (pSite) where the UA IRB will assume oversight should be added to eIRB via the "Add Participating Sites" activity in the study workspace. For each pSite added, include the *Appendix for Multi-Site Research* and local site documents (if applicable). These forms provide the UA HSPP with necessary information about the individual site(s).

If a single site study becomes a multi-site study, submit the request to change the study type via a Modification in eIRB. From there, each pSite where the UA IRB will assume oversight should be added to eIRB via the "Add Participating Sites" activity in the study workspace. Remember to include the *Appendix for Multi-Site Research* and local site documents approval (if applicable) for each site being added.

If you are unable to locate the pSite you wish to add in eIRB, please contact the HSPP at vpr-irb@arizona.edu.

The UA PI is responsible for tracking and communicating with each site's investigator any requirements of the UA IRB; including but not limited to Continuing Review requirements, reporting obligations, submission of modifications where appropriate, and sharing any IRB determinations.

All requirements to conduct research at the UA apply to each site where the UA IRB will be the IRB of record. Each site will be required, via signed reliance agreements (if applicable), to agree to these terms before the UA IRB will assume oversight.

The UA PI is responsible for maintaining appropriate documentation of site approvals and consent forms and must produce documentation upon request to the HSPP.

IRB fees for reviewing for other sites

For sites supported by a federal or commercial sponsor, the UA HSPP will charge a fee of $2,000 for each additional site where the UA IRB will be the single IRB. There are ongoing compliance obligations and reporting obligations for both the site and the University.

All IRB fees are due upon submission to the HSPP. Review will begin when the fee is processed. Fees are based on review, regardless of whether the project is initiated.

IRB Reliance Agreements

Agreeing to be the sIRB for a multi-site study is much like a contract negotiation. If applicable, each institution must sign an agreement that outlines the responsibilities and expectations of the reviewing and relying IRBs. All studies require a signed agreement unless UA has a standing agreement in place with the organization(s). Please contact the HSPP to engage in the agreement process at the earliest opportunity, as it may take time to negotiate the terms.

How long it may take to finalize an agreement depends on several factors, including the responsiveness of the other IRB and its experience with reliance agreements, as well as, if language in the agreement requires negotiation. Study teams should keep this in mind when considering sIRB review.

Occasionally, a collaborator may not be affiliated with an institution but will be engaged in human research activities on behalf of a UA project. The UA IRB may serve as the IRB of record for this individual, but it is very case specific. The UA IRB will require a separate signed individual authorization agreement. Please contact the HSPP to discuss.

The HSPP staff will coordinate with the investigator to ensure all agreements are in process before processing for approval.

UA Reliance Agreement templates can be found on the HSPP Single IRB Research webpage.

Responsibilities of the UA Investigator when Ceding Review to a Reviewing IRB

Once the University has agreed to allow another IRB to conduct the review, the UA investigator has a responsibility to report and update the relying IRB according to their policies and procedures. The UA HSPP requires notification of certain study related items when another IRB has conducted the review:

- ***Post Review Correspondence***
  It is the responsibility of the investigator to submit copies of Continuing Reviews and study closures to the HSPP so we can keep our records up to date. If the HSPP does not receive copies of notices, the PI will be contacted asking about the status.

- ***Reportable New Information (RNI)***
  The UA HSPP requires that **all local** unanticipated problems (UP) or reportable items be submitted to the HSPP. See HSPP Guidance, *Reportable New Information*.

  Submit this information in eIRB as an RNI along with copies of the materials submitted to the reviewing IRB. This is so the HSPP can maintain knowledge regarding local participants and problems with the study.

  If the UA IRB needs to engage in a serious event, we will do so as required to ensure ongoing compliance with local policies for any single IRB study. Please contact the HSPP with questions when a UP or local reportable event arises.

- ***Modifications***
  The UA HSPP requires a Modification submission in eIRB for any changes to study personnel, funding, or Banner-required consent language.

- ***Concluding the Study***
  Investigators are responsible for concluding all human research activities as soon as possible after the project is completed or no longer involves human research activities. Conclude the External IRB submission via the "Report Continuing Review Data" in the study workspace in eIRB. Include a copy of the conclusion letter from the reviewing IRB so the University can complete their records. Note: If the UA is the reviewing IRB, submit a Continuing Review in eIRB instead.

- ***HIPAA Authorizations***
  The UA HSPP will not review or approve HIPAA Authorization forms for external sites. It is the responsibility of the home institution's IRB or Privacy Board to review and approve HIPAA Authorizations, if appropriate. Please ask the reviewing IRB what their policy is regarding HIPAA Authorization forms.

- ***Continuing Review Periods***
  If the project has a continuing review requirement, the continuing review period is determined by the reviewing IRB. The UA HSPP does not issue approval periods for External IRB submissions.

- ***Conflict of Interest (COI)***
  If a person is added to a project who meets the definition of a COI Investigator, that investigator must manually add the project to their COI disclosure. Instructions for this are found on the Office for Responsible Outside Interests (OROI) webpage.

  An investigator is "any person who is responsible for the design, conduct or reporting of research" regardless of their title. While this may include students, trainees, collaborators, volunteers and consultants if those individuals have some degree of independence in performing some aspect of the design, conduct or reporting of the research, it does not include individuals whose performance is purely ancillary or occurs solely under immediate supervision.

  For example, "Investigator" includes individuals who are directly involved in the research intervention or consenting or evaluation of human research subjects but does not include hospital or office staff who provide only ancillary or intermittent care and do not make direct and significant contributions to the research data.

  AAHRPP, our institutional accrediting body, requires the IRB to ensure any financial conflicts of interest related to human subjects' research are appropriately identified and managed. In addition, OHRP requires that IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that could adversely affect the rights and welfare of research participants.

  For questions, contact the OROI at coi@arizona.edu or (520) 626-6406.