



Single IRB Review

Background

The National Institute of Health (NIH) mandated single IRB (sIRB) review for any multi-site study that receives NIH funds effective January 25, 2018 (commonly referred to as *ceded review, reliance agreements, or deferral of IRB oversight*). In addition, the Office for Human Research Protections (OHRP) mandated single IRB review effective January 19, 2020, for all other federal agencies that have adopted the human subject rules (e.g., Common Rule). Effective January 21, 2020, the HSPP requires single IRB review for any project 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 UA 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.

For projects that are not funded or supported by federal funds, investigators may choose to have one IRB become the IRB of record over some or all participating sites, but this is not required.

The University of Arizona has standing agreements in place with the following entities regarding sIRB review:

<p>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 University of Arizona is <u>not</u> the coordinating center. These include pediatric, as well as, adult studies and drug, device, or observational studies.</p> <ul style="list-style-type: none"> • These commercial IRBs will review HIPAA Authorization language in consent documents. • The UA IRB has negotiated an informed consent template that is available on the HSPP website.
<p>National Cancer Institute Central IRB (NCI CIRB) – These studies <u>cannot</u> include prisoners. In addition, CIRB does <u>not</u> review HIPAA authorization language. CIRB also requires the HIPAA Authorization to be standalone document.</p>
<p>National Marrow Donor Program (NMDP) – When these studies involve the CIBMTR Research Database and Research Sample Repository. The UA IRB has negotiated an informed consent template that is available on the HSPP website.</p>
<p>SMART IRB is a platform for IRBs to share IRB approval for single IRB review. The UA is a member of SMART IRB.</p>
<p>IRB Reliance Exchange (IREx) is a platform for IRBs to share IRB approval for single IRB review. The UA is a member of IRBEx.</p>
<p>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</p>
<p>Various hospitals connected to University of Arizona Health Sciences (Medicine, Nursing, Pharmacy, and Public Health) scholarly projects in the Tucson and Phoenix area.</p>



Single IRB Review

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

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

- The 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 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 HSPP 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 single IRB review must abide by the Arizona Board of Regents policy on Native American consultation (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.

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 not limited to, the following approvals:

- Scientific review
- Payor coverage analysis
- Site authorizations
- Conflict of Interest
- Radiation, biological, or chemical safety
- UA Travel Registry
- CITI training
- Feasibility review for access to Banner Health
- eDoc number



Single IRB Review

In addition to required local approval, the HSPP will verify the protocol, consent, HIPAA Authorization, list of 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 Principal Investigator 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 Principal Investigator must submit an IRB application to the UA IRB for review and approval. In addition, for each site where the UA IRB will assume oversight, include the **'Appendix for Multi-Site Research,' 'Multi-Site List of Research Personnel,'** and local site approvals (if applicable). These forms provide the UA HSPP with necessary information about the individual site(s).

If the project is already approved, and a site is being added after UA IRB approval, submit the request to review for another site as an amendment via the **'Amendment and Reportable to Approved Human Research'** form. Include the **'Appendix for Multi-Site Research,' 'Multi-Site List of Research Personnel,'** and local site approval (if applicable) for each site being added.

The UA Principal Investigator is responsible for tracking and communicating with each site's investigator any requirements of the UA IRB; including but not limited to renewal requirements, reporting obligations, 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 Principal Investigator 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 Human Subjects Protection Program. Review will begin when the fee is submitted. Fees are based on review, regardless of whether the project is actually 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 1) the project is deemed exempt, or 2) 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



Single IRB Review

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, whether 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 at all 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 Human Subjects Protection Program 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 and Forms](#) webpage.

Responsibilities of the UA Investigator when ceding review to a relying 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 renewals 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 Items

The UA HSPP requires that **all local** unanticipated problems (UP) or reportable items be submitted to the HSPP for our files. **Submit this information on the 'Amendment and Reportable to Approved Human Research'** form via a 'Notify IRB' 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 item arises.

Amendments

The UA HSPP requires an amendment submission in cases of PI/Co-PI changes, addition or removal of key personnel (i.e., alternate contact, primary coordinator, etc.) who need to be added to or removed from automatic system notifications, and when Banner required consent language is altered.

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. Submit a copy of



Single IRB Review

the conclusion paperwork from the reviewing IRB so the University can complete their records. **Submit this information on the Notify IRB' form.** Note: If the UA is the reviewing IRB, submit the appropriate HSPP Form to conclude the study.

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.

Renewal periods

If the project is significant risk and has a renewal requirement, the renewal period is determined by the reviewing IRB. The UA HSPP does not issue approval periods for single IRB studies where it is not the reviewing IRB.

Conflict of Interest

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 [COI webpage](#).

Under the University's COI policy, an Investigator is “any person who is responsible for the design, conduct or reporting of Research.” This includes all persons who are 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. For questions, please contact the COI Office at (520) 626-6406.