

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). Single IRB review is required 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 increases 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:

Commercial IRBs including Western IRB, Quorum IRB, Copernicus Group IRB, and Schulman IRB where the research involves a multi-center, industry sponsored non-federally funded clinical study where the University of Arizona is not the coordinating center. These include pediatric, as well as, adult studies and drug, device, or observational studies.

- These commercial IRBs will review PHI Authorization language in consent documents.
- The UA IRB has negotiated an informed consent template that is available on the HSPP website.

National Cancer Institute Central IRB (NCI CIRB) - These studies cannot include prisoners. In addition, CIRB does not review HIPAA authorization language. If the HIPAA Language is combined into the consent, CIRB will approve it as part of the approved consent form.

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 (IREX) is a platform for IRBs to share IRB approval for single IRB review. The UA is a member of IRB Choice.

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 Arizona Health Sciences (Medicine, Nursing, Pharmacy, and Public Health) scholarly projects in the Phoenix area.

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The UA may decide to allow for single IRB review outside of the standing agreements noted above and the NIH 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.
- 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 the following approvals, but not limited to:

- Scientific review
- Payor coverage analysis
- Site authorizations
- Conflict of Interest
- Radiation safety or biological safety
- Office of Global Initiatives travel approval
- CITI training
- Feasibility review for access to Banner Health

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In addition to required local approval, the HSPP will verify the protocol, consent, 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.

If the project is already approved and a site is being added after IRB approval from the UA has been obtained, submit the request to review for another site as an amendment. Include the multi-site appendix with the amendment form, and local site approval (if applicable). Addition of new sites are considered a minor amendment.

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, a multi-site appendix and all attachments must be submitted per site. This appendix provides the UA HSPP with the necessary information about the individual site.

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, 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 commercial sponsor, the UA HSPP will charge a fee of \$1000 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.

For sites supported by NIH funds, the UA HSPP currently does not charge a fee to be the single IRB for a multi-site study.

IRB Reliance Agreements

Agreeing to be the sIRB for a multi-site study is much like a contract negotiation. 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 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.

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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 a 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.

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 'Notify IRB' form** along with copies of the materials submitted to the reviewing IRB. This is so the HSPP can maintain local knowledge regarding our 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 will need to receive an amendment submission in cases of PI changes or 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 participants. Submit a copy of 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

Some IRBs will not or do not approve HIPAA authorization forms. If the relying IRB does not review authorization forms, the investigator must submit the authorization form to the UA HSPP for review. Please ask the reviewing IRB what their policy is regarding HIPAA authorization forms. If necessary, submit an F213 request for amendment to the HSPP for review.

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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.

The responsibilities of the Reviewing IRB are to:

- Maintain an OHRP-approved Assurance for human subjects research;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects;
- Maintain records of Institution A -approved research as per institution policies, with relevant IRB records available upon request by the relying institution including minutes, approved documents, and other records that document the IRB determination;
- Review and manage individual and institutional conflicts of interest per Institution A policies and procedures in collaboration with Institution B;
- Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessary modifications to the study, and make a final decision of approval or disapproval of the study;
- Conduct continuing review of the research and review study amendments;
- Conduct review and make determination regarding serious, unexpected, and related adverse events; serious or continuing noncompliance and other unanticipated problems; including for determining whether each allegation has a basis in fact.
- Obtain additional approvals from DHHS, if applicable, for involvement of pregnant women, fetuses, neonates, children, and/or prisoners;
- Within a reasonable timeframe, request that research approved under this agreement be audited as the IRB may determine to protect the rights and welfare of subjects, and to ensure ongoing compliance with all human subjects rules and regulations;
- Either directly, or through the appropriate coordinating center, inform the Principal Investigator at Institution B in writing of Institution A's determinations including contact information for questions/concerns, approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
- Either directly, or through the appropriate coordinating center, notify the Principal Investigator at Institution B of new materials that have been reviewed and any changes in the study approval status;
- Promptly notify the Principal Investigator at Institution A, the Principal Investigator at Institution B, and appropriate officials at Institution B of any Institution A determinations that require reporting to institutional officials and/or regulatory agencies. Institution A, through the UA Human Subjects Protection Program (HSPP), will submit required reports to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
- Make available to Institution B the roster of Institution A membership and Standard Operating Procedures (SOPs);



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- Ensure that Institution A members receive orientation and continuing education on topics relevant to human subjects protection;
- Ensure that Institution A has adequate meeting space and sufficient staff to support review and recordkeeping duties;
- Notify Institution B immediately if there is a suspension or restriction of Institution A's authorization to review a study; and
- Notify Institution B of any changes in Institution A SOPs that might affect the institution's reliance on Institution A reviews or performance of the research at the local institution.
- Should termination of the agreement occur, Institution A will continue to oversee the activities until closure or a mutually agreed upon transfer of the study occurs.

The responsibilities of the relying IRB (Institution B) are to:

- Maintain an OHRP-approved Assurance for human subjects research; and be responsible for ensuring the reviewing IRB is consistent with the requirements of the relying organization's FWA and whether they apply the FWA to some or all research;
- Promptly notify unless Institution A if Institution B becomes aware of events that change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
- Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects;
- Maintain records of approved research by Institution A at Institution B as per institution policies;
- Ensure that research subject to this agreement may not be approved by Institution B if it has not been approved by Institution A.
- Ensure qualifications and training of research staff are commensurate with the research activity.
- Conduct scientific review.
- Review, manage and monitor individual and institutional conflicts of interest per Institution B's policies and procedures and report such conflicts to Institution A for final determination on the relevance to the proposed human research;
- Ensure that local reviews relevant to the research, e.g. radiation, chemical, biological safety, are obtained prior to conducting research the Institution.
- Provide the names and addresses to Institution A of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
- Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by Institution A, submit amendments prior to implementation unless to protect the immediate safety and welfare of subjects; submit timely renewals; monitor protocol compliance and report promptly per Guidance Reporting local information any protocol deviations, unanticipated problems or noncompliance); provide any monitoring reports; manage any major protocol violations and any serious adverse events occurring at the institution; promptly report any changes; conduct monitoring in coordination with Institution A; and providing a mechanism by which complaints about the research can be made by local study participants or others; and

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- When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and release of medical records or donation of human specimens) to verify for Institution A that these documents comply with applicable federal, state or local laws, institutional requirements, Confidentiality requirements, or IRB policies of Institution B.