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Complete Healthcare Compliance Manual 2024
Resource: Sample Single IRB Review Guidance Summary

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The University of Arizona: Research, Discovery & Innovation	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 studiescannot include prisoners. In addition, CIRB doesnot 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.

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.