



Ceded IRB Review

Investigators working at multiple institutions and with multiple IRBs may choose to have one IRB become the IRB of record over some or all participating sites (commonly referred to as *ceded review, reliance agreements, or deferral of IRB oversight.*) This 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. These agreements are designed to reduce duplication and increases efficiency by designating a single IRB review when more than one site is involved in a research project.

The University of Arizona has standing agreements in place for the following entities regarding ceded IRB review:

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| <p>Commercial IRBs who are accredited organizations through the Association for the Accreditation of Human Research Protection Programs (AAHRPP)</p> <ul style="list-style-type: none"> • Western IRB (WIRB) for any multi-center, industry sponsored or 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. • The UA does not have standing agreements with other Commercial IRBs. However, the UA IRB will cede their review on a per protocol basis for any multi-center, industry sponsored or non-federally funded clinical study where the University of Arizona is not the coordinating center (e.g. Schulman, Quorum, or Chesapeake). |
| <p>National Cancer Institute Central IRB (NCI CIRB) - These studies cannot include prisoners. CIRB does not review HIPAA authorization language. If the HIPAA Language is combined into the consent, they will approve it as part of the approved consent form.</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>The University of Arizona investigator is a collaborator on Human Research primarily conducted at another organization where:</p> <ul style="list-style-type: none"> • 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.) |
| <p>Various hospitals connected to Arizona Health Sciences (Medicine, Nursing, Pharmacy, and Public Health) scholarly projects in the Phoenix area.</p> |

The UA HSPP will not consider deferring IRB oversight to another IRB when:

- The project involves prisoners or other vulnerable populations that require special considerations.

Ceded IRB Review

- UA serves as a coordinating center for a *non-industry* sponsored clinical trial (regardless of phase);
- The proposed IRB of record does not have sufficient knowledge of local context (as required by federal guidelines) 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;
- Studies for which administrative or campus policies otherwise prohibit or limit options for IRB deferral.

Responsibilities of the UA when relying on another IRB

Before a project may be ceded to another IRB the institution must verify that all institutional approvals are in place prior to issuing the approval to cede. The HSPP is the clearinghouse for such requests, and a request for deferral of IRB oversight must be submitted to HSPP. The HSPP will verify that all institutional approvals have been obtained, including but not limited to:

- Scientific review
- Payor coverage analysis
- Site authorizations
- Conflict of Interest
- Radiation safety or biological safety
- Office of Global Initiatives
- CITI training

In addition to required local approvals, the HSPP will verify the protocol, consent, and other study documents comply with local and state law, and AAHRPP accreditation standards. This is required for all ceded studies, even those where the UA has existing standing agreements.

Responsibilities of the UA as the reviewing IRB

A full IRB application must be submitted to the UA IRB for review and approval by a UA affiliated individual as Principal Investigator. The Multi-site appendix must be submitted for each site where the UA IRB is requested to assume oversight. All requirements of the UA must be met as usual for review of each site, and individual documentation from each site will be required via signed agreements (see below).

Responsibilities of the UA as the coordinating center

For sites where the UA is the lead institution (may also be called the coordinating center) and the external site has its own IRB, a copy of the initial IRB approval must be submitted to the HSPP office for file completion. At the time of UA continuing review, documentation of continued oversight is necessary to demonstrate continued compliance. The UA Principal Investigator should maintain appropriate documentation of site approvals and consent forms.

Ceded IRB Review

IRB Authorization Agreements (IAA)

Federal regulations require that an IRB authorization agreement (IAA) be signed by both institutions. All studies will require that an IAA be obtained, unless 1) the project has been deemed exempt, or 2) organizations for which UA has a standing agreement in place. The IAA includes a detailed list of obligations for both the Relying and Receiving IRB.

This process can sometimes go quickly, but it is not uncommon for it to take months. How long it may take to finalize an agreement depends on several factors, including the responsiveness of the other IRB and its experience with ceded agreements, as well as, whether language in the IAA requires negotiation. Study teams are advised to keep this in mind when considering requesting ceding to another IRB.

Occasionally a collaborator is not affiliated with an institution at all, but will be engaged in human research activities for 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.

Responsibilities of the UA Investigator when ceding review to a relying IRB

Once a study has been ceded to another IRB, the UA investigator is responsible to report and update the ceded IRB according to their policies and procedures. The UA HSPP also should be notified for:

Post Review Correspondence

After a project has been ceded to another IRB, the UA IRB is no longer the IRB of record for the study. Many times the UA HSPP does not receive copies of correspondence with the investigator, including updating renewal periods. 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 UA IRB has not submitted any renewals or study closure within two years of the ceded review the PI will be contacted asking about the status. If the PI doesn't reply to the email within 30 days the project will be closed in our system.

Reportable Items

The UA does require that **all local** unanticipated problems (UP) or reportable items be submitted to the HSPP for our files. **Submit this information on the F216 'Notify IRB' form.** This is so the HSPP can maintain local knowledge regarding local subjects and problems with the ceded study. Many times, copies of paperwork submitted to the ceded IRB will suffice for documenting the items. Sometimes a separate F224, reportable item form, may be required. See the HSPP Guidance, Reporting local information. Please contact the HSPP with questions when a UP or local reportable item arises.

Concluding the study



Ceded IRB Review

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 of Arizona can complete their records. **Submit this information on the F216 'Notify IRB' form.** Note: If the UA is the reviewing IRB, submit the appropriate HSPP Form (F212b) to conclude the study.

HIPAA Authorizations

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

Renewal periods

The renewal period is given to the project by the ceded IRB. The UA HSPP does not issue approval periods for ceded studies.

Responsibilities of the Reviewing IRB

Policies regarding accepting IRB oversight for other institutions vary widely and some IRBs will NOT serve as IRB of record for another institution or investigator. Study teams are expected to contact the proposed IRB of record regarding whether it is willing to serve as IRB of record before submitting a request to cede IRB review. Confirmation should be obtained from the proposed IRB of record's staff and not from other researchers at that institution.

At a minimum, the Reviewing IRB is responsible for:

- Maintaining a current and active Federalwide Assurance (FWA) with the Department of Human Research Protections (OHRP).
- Agreeing to accept responsibility for all activities and actions of the investigator as it relates to the proposed study.
- Conducting initial and continuing reviews, review amendments to approved protocols and reportable events, all in accordance with applicable state and federal laws, regulations, guidance, and rulings related to the protection of human subjects.
- Suspending or terminate IRB approval of research, and shall notify the Relying IRB in writing of all determinations resulting from review of unanticipated problems, serious or continuing noncompliance, and other noncompliance with approved protocols.
- Notifying the Relying IRB in the event that the Reviewing IRB receives an inquiry from any governmental official related to research under the purview of the Reviewing IRB. The Reviewing IRB shall inform the Relying IRB immediately, and shall provide any new information to the Relying IRB during the course of such inquiry.



Ceded IRB Review

- Maintaining records of all studies. The records will include, at a minimum, the date the application was submitted, the application and all related correspondence, including revised applications, correspondence between the IRB and the investigator, review determinations, dates of approval, location of research activity, minutes related to review activities, all study documents released with the approval or exemption determination, as well as oversight actions. The Reviewing IRB shall make these records available to the Relying IRB. The Reviewing IRB shall retain these records for the period of time required by all relevant federal and state laws, statutes and regulations and the Reviewing IRB's Institutional policy.

Responsibilities of the Relying IRB

At a minimum, the relying IRB is responsible for the following:

- Maintain a current and active Federalwide Assurance (FWA) with the Department of Human Research Protections (OHRP).
- In the event that the Relying IRB is audited or receives a notice of action (e.g. FDA 483) from any government official related to research under the purview of the Reviewing IRB, the Relying IRB will inform the Reviewing IRB immediately, and shall provide any new information to the IRB during the course of such inquiry.
- In the event the Relying IRB imposes sanctions or actions against a researcher or research study (e.g. non-compliance, Conflict of Interest determination), the Relying IRB will inform the Reviewing IRB immediately, and shall provide any new information to the IRB during the course of such action.