TITLE: **Deferral of IRB Oversight**

PURPOSE: Ensure that all Human Research being conducted on behalf of the University of Arizona is done with appropriate IRB oversight.

RESPONSIBILTIES: Organization Official or Designee

GUIDELINES:

The University of Arizona requires that all Human Research being conducted on behalf of the University of Arizona be done with appropriate IRB oversight. All requirements, policies, and procedures of the University of Arizona apply for human research overseen by the University of Arizona IRB, even when IRB review is conducted by another entity.

- All **non-exempt** Human Research requires a signed Institutional Agreement. The Organizational Official is the authorized individual to sign Institutional Agreements.
- When Human Research meets the regulatory criteria for **exemption** (45 CFR 46.101(b)), an Institutional Agreement is not required. The IRB that is conducting the review must have a valid Federalwide Assurance (FWA) on file with the Office for Human Research Protection (OHRP).

The University of Arizona **may rely upon the IRB of another organizatio**n, provided the request is to defer to one of the following:

- Banner Health Network for covered individuals conducting research at covered sites.
- Commercial IRBs with whom the University of Arizona has an agreement and which are accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).
    - The UA does not have standing agreements with other Commercial IRBs. However, the UA IRB will cede their review on a per protocol basis when 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).
- National Cancer Institute Central IRB (CIRB) for cooperative oncology group studies already approved by CIRB. CIRB studies cannot include prisoners.
- 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.
- IRB Share for multi-site studies comprised of participating institutions utilizing shared review documents and a shared review process.
- The IRB of another institution or organization where
    - The University of Arizona investigator is a collaborator on Human Research conducted by that organization;
    - The PI of the organization will have direct oversight of the University of Arizona investigator;
    - The organization agrees in writing 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.
- Various hospitals connected to Arizona Health Sciences (Medicine, Nursing, Pharmacy, and Public Health) scholarly projects in the Phoenix area.

Another organization **may rely on the University of Arizona IRB**, provided one of the following is true:

- The primary awardee institution is the University of Arizona and the investigator's role at another research site does not include interaction or intervention with subjects; OR
- The primary awardee institution is the University of Arizona and, if interaction or intervention is involved, the collaborating investigator is under the direct oversight of the University of Arizona investigator.

The status of the partnering institution's FWA and IRB registration (if an IRB exists) must be current.

Local requirements must be taken into account when deferring projects.

PROCEDURES:

Determine if the entity is engaged in research, using "W310 – Engagement Determination".

Entities requesting a deferral of IRB oversight for their project, either to the UA or to another institution, must meet the guidelines above.

Where a multi-project agreement does not exist, complete a project-specific Institutional Agreement or Individual Investigator Agreement. Research that meets the regulatory requirements for exemption (45 CFR 46.101(b)) does not require a signed institutional agreement.

- Upon approval, forward a copy of the signed agreement to the investigator and alternate contact.
- Instruct the investigator to obtain the Organizational Official's signature at the partnering institution.
- Submit a copy of the completed, signed agreement to the UA HSPP.

Follow SOP-030: IRB Formation.

Follow SOP-070: IRB Records.

MATERIALS:

- SOP-070: IRB Records
- SOP-030: IRB Formation
- Operations Manual
- W310 – Engagement Determination
- Institutional Agreement document
- HSPP Guidance Ceded IRB Review

REFERENCES:

- 45 CFR 46.114; 45 CFR 46 Subpart E
- 21 CFR 56.114
- OHRP Guidance on Engagement in Research

REVIEW/REVISIONS:

From 10/01/2010 version: Revised the requirements on to whom the UA would defer IRB oversight. Removed "such Human Research does not include interaction or intervention with subjects" and replaced with "the PI of the organization will have direct oversight of the University of Arizona investigator; and the organization agrees to take responsibility for the University of Arizona investigator"; Removed reference to MOU and replaced with "agreement."

From 08/01/2011 version: Added reference to Operations Manual; Clarified deferral of exempt and non-exempt Human Research; Clarified that the Organizational Official is authorized individual to sign Institutional Agreements.

From 01/2014 version: Renumbered from P&P- 045; References to P&P-080 and P&P-070 revised to SOP-030 and SOP-070, respectively, to reflect new numbering system.