Other Approvals Required

The University of Arizona (UA) has requirements for approvals from other administrative offices, other compliance units, or other organizations prior to submitting materials to the Institutional Review Board (IRB) for review. Listed below are the required approvals that must be submitted in eIRB, as applicable. If the approvals are not received with the submission, the Human Subjects Protection Program (HSPP) will return the submission to the research team until the approvals are obtained. **It is the responsibility of the Principal Investigator (PI) to ensure that all required approvals by the organization are obtained before beginning the research.**

Banner Health

Approval from Banner Health is required before a researcher may access patients, records, specimens, or any Banner Health facility. This approval is noted as "feasibility review approval" and is obtained by submission of the research project to the University of Arizona Health Sciences (UAHS) Research Administration Portal (RAP).

For non-funded research: UAHS will provide the research team with feasibility review approval. A copy of this approval must be uploaded to eIRB **before** the application is submitted in eIRB. This approval is required before the IRB will begin its review.

For funded research: After the Coverage Analysis (CA) has been approved, UAHS will provide feasibility review approval, which will include the UAccess Research (UAR) Institutional Proposal (IP) number. **Before submitting the application in eIRB**:

1. Researchers **must** link their funding in eIRB using the IP number provided by UAHS; and
2. Upload a copy of the feasibility review approval to eIRB. This approval is required before the IRB will begin its review.

Office of Outside Interests (OROI) Review

All individuals who meet the definition of "investigator" conducting research on behalf of the University of Arizona are required to comply with the "Policy on Investigator Conflict of Interest in Research" including required Conflict of Interest training and certification of the "Disclosure of Significant Financial Interests". For questions, contact the OROI at 520-626-6406, coi@arizona.edu, or the OROI webpage: https://research.arizona.edu/compliance/office-responsible-outside-interests.

Export Control Review

Some projects may fall under the jurisdiction of federal export control laws and regulations and require an export control review for possible issues. The export control regulations potentially restrict the overseas shipping, transmission, or transfer of certain categories of information, technologies, software, and items to foreign persons outside the U.S. or inside the U.S. (a "deemed export"). These laws and regulations also affect projects and interaction with foreign sponsors or entities, attending conferences abroad, and taking university property, including data and other information, when traveling outside the U.S. Visit the Export Control webpage: https://research.arizona.edu/compliance/export-control-program.

THE UNIVERSITY OF ARIZONA Research & Partnerships

Other Approvals Required

Environmental Health & Safety (EHS) Radiation Approval

Research and clinical PIs involved with the use of licensed radioactive materials or certain ionizing (i.e., bone scan, bone mineral analyzers - DEXA, DXA, QCT, radioactive source - CT, PET, MUGA, mammogram, X-Ray/radiography, radiotherapy machines, fluoroscopy, radiopharmaceuticals/radioisotope/radionuclide) and non-ionizing (i.e., lasers, radiofrequency) radiation generating devices must apply to establish EHS Radiation Approval prior to beginning any work with such material or devices. Radiation Approval is granted by the University Radiation Safety Committee Human Use Subcommittee (HUS). Use of facilities containing radioactive material recognized by the Nuclear Regulatory Commission as being in "Quantities of Concern" require potential users to undergo fingerprinting and a background check in advance of unescorted access. A copy of the EHS Radiation Approval must be uploaded to eIRB at the time of IRB submission.

Note: For research conducted at Banner-University Medical Center Phoenix, radiation safety and biosafety review are not conducted by EHS. Instead, review is conducted by the Banner Health radiation or biosafety committees.

EHS Biosafety Approval

Research and clinical PIs involved with the use of regulated biological materials must apply to establish EHS Biosafety Approval prior to beginning any work with such material. Biosafety Approval is granted by the Institutional Biosafety Committee (IBC). Use of facilities authorized for biohazardous material identified by the United States Center for Disease Control as "Select Agents and Toxins" require users to undergo fingerprinting and a background check in advance of unescorted access. A copy of EHS Biosafety Approval must be uploaded to eIRB at the time of IRB submission.

EHS Chemical Safety Approval

Research and clinical PIs involved with the use of hazardous chemicals on a laboratory scale must apply to establish an EHS Chemical Safety Approval prior to beginning any work with such material. Chemical Safety Approval is granted by the University Chemical Hygiene Officer. The possession of regulated explosives, controlled substances, or highly toxic, or corrosive compressed gas require the satisfactory completion of a chemical safety audit prior to delivery and/or use. A copy of the EHS Chemical Safety Approval must be uploaded to eIRB at the time of IRB submission.

Site Authorization

When research activities will take place at an external site (e.g., school district, non-profit, or other collaborating facility), approval from that site is required before research can begin. Approval, or other documentation of ongoing correspondence regarding the research activity, will suffice. Final IRB approval may be contingent upon the local site approval. A copy of the Site Authorization approval must be uploaded to eIRB before the IRB will begin its review.

Advisor/Co-I Review

When the proposed PI does not meet the University of Arizona PI Eligibility policy, a Co-Investigator (Co-I), or Advisor, is required. The designated Co-I/Advisor/mentor must be listed on the Local Study Team Members page in eIRB as both an "Advisor" **and** "Co-Investigator." Attestation from the Advisor/Co-I is required upon eIRB submission. Attestations will be accepted in one of the following

formats:

- The Advisor/Co-I logs a comment in the study workspace in eIRB documenting their approval;
- An email from the Advisor/Co-I is uploaded to eIRB documenting their approval; or
- The Advisor/Co-I signs the *Advisor/Co-I Attestation for Human Subjects Research* form and uploads it to eIRB.

The Advisor/Co-I certifies to oversee and monitor the conduct of the research by communicating regularly with the PI; assist with the resolution of any problems or concerns encountered during the research; and assure that the UA IRB is notified in the event of an adverse event or unanticipated problem.

Scientific/Scholarly Review

To justify the inclusion of human subjects in research, and to assess the balance between any risks that may be imposed upon human subjects, an assessment is required to evaluate the scientific question and appropriateness of the methods planned to answer the scientific question. The role of the IRB is not to assess science unless the project is so poorly designed that it affects risks or benefits.

Scientific assessment is required for all human research. The actual protocol being submitted to the IRB must have been reviewed in its current form. **<u>One</u>** of the following Scientific/Scholarly Reviews is required upon eIRB submission:

1. **Nationally based, federally funded organization (i.e., NIH, NSF) subject to full peer review**
    a. Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
    b. Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.
    c. No signature required for eIRB submission
2. **Nationally based, non-federally funded organization (i.e., March of Dimes, American Academy of Pediatrics) subject to peer review**
    a. Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
    b. Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.
    c. No signature required for eIRB submission
3. **Locally constituted peer review**
    a. UA Cancer Center Scientific Review Committee (SRC): All cancer-related projects must have approval by the SRC, regardless of the investigator's home department.
    b. College/department peer review (Advisors may sign on behalf of students they mentor regarding scientific review)
    c. Signature required for eIRB submission unless SRC approval applies

Attestation for locally constituted peer review will be accepted in the following formats:

- For SRC approval, upload the SRC approval letter in eIRB.
- For college/department peer review:
    - The reviewer logs a comment in the study workspace in eIRB documenting their approval if they are listed as a guest in eIRB.
    - An email from the reviewer is uploaded in eIRB documenting their approval.
    - The reviewer signs the *Scientific/Scholarly Review Attestation for Human Subjects Research* form and uploads it to eIRB.

If supplemental documentation is granted as part of the review, it should be uploaded to eIRB. The scientific/scholarly reviewer cannot be affiliated with the project in any way to eliminate any potential conflicts of interest, with the exception of an advisor/mentee role.

The Scientific/Scholarly review should include assessment of the following:

- Is the rationale for the study clearly stated and is the rationale scientifically sound?
- Are the aims and corresponding hypothesis clearly stated?
- Is the primary outcome (and secondary outcomes, as appropriate) clearly defined?
- Are there adequate preliminary data in the literature (or from the investigator) to justify the proposed research? Has an adequate literature review been done to support this study?
- Is the question or hypothesis being tested providing important knowledge to the field?
- Is the design of the study appropriate for the questions that are posed?
- Have the validity and reliability of measures been established or are there methods proposed for establishing validity and reliability?
- Is the proposed subject population appropriate?
- Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?
- Are all the proposed tests or measurements necessary to answer the scientific question?
- Are the investigators well qualified to conduct this study?
- Is the proposed research novel and new?

Responsible Physician Review

When a project involves medical procedures for which the PI is not licensed to conduct, a Responsible Physician must be appointed. The designated Responsible Physician must be listed on the Local Study Team Members page in eIRB as a "Responsible Physician." In addition, attestation from the Responsible Physician is required upon eIRB submission. Attestations in one of the following formats will be accepted:

- The Responsible Physician logs a comment in the eIRB study workspace documenting their approval;
- An email from the Responsible Physician is uploaded to eIRB documenting their approval; or
- The Responsible Physician signs the *Responsible Physician Attestation for Human Subjects Research* form and uploads it to eIRB.

Other Approvals Required

The Responsible Physician certifies that they are a physician licensed by the State of Arizona; they will be responsible for ensuring that all procedures that are part of the project, and procedures that require the attendance of a licensed physician, will have a suitable physician present during the procedures; and they will inform the IRB before any procedures are conducted if they are unable to attend the procedures.

Department/Center/Section Review

The following human research submissions must include attestation from the PI's home Department/Center/Section reviewer:

- All new project submissions (NOTE: The *Advisor/Co-I Attestation for Human Subjects Research* form can be used to document departmental review for student and medical resident PIs.)
- Reportable New Information (RNI) submissions if the event involves substantial risk to participants, a data breach, another significant issue, or as otherwise requested by the IRB.

Attestations from the Department/Center/Section reviewer will be accepted in one of the following formats:

- The Department/Center/Section reviewer logs a comment in the eIRB study workspace documenting their approval if they are listed as a guest in eIRB;
- An email from the Department/Center/Section reviewer is uploaded to eIRB documenting their approval; or
- The Department/Center/Section reviewer signs the *Department/Center/Section Review Attestation for Human Subjects Research* form and uploads it to eIRB.

The Department/Center/Section reviewer certifies that all departmental requirements are met, and the investigator has adequate resources to conduct the research.