



## Other Approvals Required Before IRB Submission

The University of Arizona has requirements for prior approvals from other administrative offices, other compliance units, or other organizations prior to submitting materials to the IRB for review. Listed below are the required approvals that must be submitted with the IRB application for review. If the approvals are not received with the submission, the HSPP will return the submission until the approvals have been obtained. **It is the responsibility of the Principal Investigator to ensure that all required approvals by the organization are obtained prior to 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 UA Health Sciences research intake form (RIF). Information on the RIF and Q&A can be obtained [here](#).

### ***Conflict-of-Interest 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 please contact the COI program at 626-7879 and <https://rgw.arizona.edu/compliance/conflict-interest-program>.

### ***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. Click [here](#) to visit the Export Control website.

### ***Research, Laboratory, and Safety Services (RLSS)***

RLSS assists monitors and provides required regulatory oversight for research and clinical entities within the University of Arizona and University of Arizona Health Network that involve the potential for exposure to harmful radiations, hazardous chemicals and regulated biological materials. The [RLSS](#) website may be accessed for specific instructions about obtaining an RLSS Radiation, Chemical or Biological Approval. Radiation, chemical and biological safety program staff as well as the approval holder and committee support staff assist PI's or their designees throughout their entire compliance program's unique Approval processes. Once an RLSS Approval is established, PI's are guided into compliance with applicable rules and regulations through a series of routine and contingency engagements that include; laboratory inspections, required training, regulated waste support services, shipping/transport support services, personnel exposure monitoring, hazard



## Other Approvals Required Before IRB Submission

assessments, emergency response, radiation detection equipment calibration, and liaison with the Approvals governing safety committee.

Note: For research conducted at Banner-University Medical Center Phoenix, radiation safety and biosafety review are not conducted by RLSS. Instead, review is conducted by Banner Health's radiation or biosafety committees. Please contact Sue Colvin at [Sue.Colvin@bannerhealth.com](mailto:Sue.Colvin@bannerhealth.com) for questions about this process.

### ***RLSS Radiation Approvals***

Research and clinical PI's involved with the uses of licensed radioactive materials (RAM) or certain ionizing and non-ionizing radiation generating devices must apply to establish an RLSS Radiation Approval prior to beginning any work with such material or devices. Radiation Approvals are granted to PI's by one of the following Radiation Safety Committees; The University Radiation Safety Committee, The Medical Radiation Safety Committee and the Non- Ionizing Radiation Safety Committee. Uses 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.

### ***RLSS Biosafety Approvals***

Research and clinical PI's involved with the use of regulated biological materials must apply to establish an RLSS Biosafety Approval prior to beginning any work with such material. Biosafety Approvals are granted to PI's by the Institutional Biosafety Committee. Uses of facilities authorized for bio hazardous 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.

### ***RLSS Chemical Safety Approvals***

Research and clinical PI's involved with the use of hazardous chemicals on a laboratory scale must apply to establish an RLSS Chemical Safety Approval prior to beginning any work with such material. Chemical Safety Approvals are granted to PI's by the University Chemical Hygiene Officer. The possession of, regulated explosives, controlled substances, highly toxic or corrosive compressed gasses require the satisfactory completion of a chemical safety audit prior to delivery and/or use.

### ***Office of Global Initiatives***

The University of Arizona approved a revised Interim Policy for International Travel Safety and Compliance that is effective as of May 1, 2012. The new policy outlines guidelines for travel to higher risk countries identified by the U.S. Department of State and the Center for Disease Control. This policy applies to all University of Arizona (UA) faculty, staff, students and volunteers who travel internationally as part of University of Arizona research, education, service or employment. Travel policy and procedures can be found [here](#).

### ***HIPAA Privacy Program***



## Other Approvals Required Before IRB Submission

Currently, the IRB acts as the Privacy Board pursuant to HIPAA ([45 CFR 164.512\(i\) \(1\)\(i\)](#)) for the University of Arizona and related research at Banner Health. The Privacy Board function under HIPAA is to review and approve or disapprove requests for waiver or alteration of HIPAA's authorization requirements for access to and use of protected health information. The IRB's review and approval of HIPAA waiver requests occurs most often in the context of Human Subjects research review, within the performance of the IRB's broader responsibilities for the protection of human research participants, including privacy and confidentiality protections.

### ***Grants and Contracts Office***

The Sponsored projects and Contracting Services is responsible for reviewing sponsor contracts and funding agreements for compliance with HSPP policies, processes, and procedures.

### ***Site Authorization***

The IRB requires that when research activities that take place at an outside site (e.g. school district, non-profit, or other collaborating facility), approval is submitted as part of the IRB submission packet. An approval, or other documentation of ongoing correspondence regarding the research activity, should suffice. Final IRB approval may be contingent upon the local site approval.

### ***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. Approval by the appropriate scientific/scholarly reviewer (college, school, department, center, or section) is documented by a signature or email submitted with the application form. If supplemental documentation is granted as part of the review, it should be included as an attachment to the application. The scientific/scholarly reviewer cannot be affiliated with the project in any way to eliminate any potential conflicts of interest. The PI, Co-PI, or any other research staff are not considered an appropriate reviewer.

For student projects where a graduate committee or mentor/mentee relationship exists and the research project is in the student's name, the signature of the advisor can be used as the scientific/scholarly review.

All cancer-related projects must have approval by the [Arizona Cancer Center Scientific Review Committee](#) (SRC), regardless of the investigator's home department.

Acceptable Methods for Scientific Assessment



## Other Approvals Required Before IRB Submission

1. Nationally-based, federal funding organizations (NIH, NSF) when research projects have been subjected to full peer review (e.g., review by a study section or grant committee).
  - Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
  - Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.
2. Nationally based non-federal funding organizations (March of Dimes, American Academy of Pediatrics) employing peer review mechanisms for awarding of funding
  - Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
  - Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.
3. Locally constituted mechanisms using peer review for awarding of funding, or for permission to use resources, including:
  - UACC Scientific Review Committee (SRC)
  - Departmental peer review (Advisors may sign on behalf of students they mentor regarding scientific review)

□

### ***Review Requirements***

The scientific 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



## Other Approvals Required Before IRB Submission

accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?

- Are all the proposed tests or measurements requested necessary to answer the scientific question?
- Are the investigators well qualified to conduct this study?
- Is the proposed research novel and new?