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.

**Appropriate Scientific/Scholarly Review**

Approval by the appropriate scientific/scholarly reviewer (college, school, department, center, or section) is documented by a signature on the appropriate 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](http://azcancer.arizona.edu/) (SRC), regardless of the investigator’s home department.

**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](https://rgw.arizona.edu/compliance/conflict-interest-program).

**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](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 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 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
Approvals Required Before IRB Submission

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

Currently, the IRB acts as the Privacy Board pursuant to HIPAA (45 CFR 164.512(j) (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 these HIPAA documents 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.

The specific criteria for IRB review of a request for waiver or alteration of HIPAA authorization requirements are specified in HIPAA at 45 CFR 164.512(ii)(2)(ii). These criteria essentially are that (1) the research project involves minimal privacy risk to the participants because of adequate plans for protection of identifiers; (2) that the research could not practically be conducted without the waiver or alteration of the HIPAA authorization requirement; and (3) that the research could not practically be conducted without access to and use of the protected health information.
Approvals Required Before IRB Submission

All issues regarding privacy in Human Research should be addressed in the IRB application and protocol.

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 side (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.