

Human Subjects Information Research Projects

The following information will hopefully be helpful as you complete application forms and other documents.

Recruitment on Social Media

Specify the group/groups you will be posting to on social media. Include if they are considered a publicly available group or if the group is considered private. If private, obtain approval (letter or email) from the individual running the group stating that you have permission to post your recruitment material.

Required Statement on Recruitment Material

Remember that all recruitment material (flyers, scripts, emails, etc.) must include the IRB required statement. It may be shortened, but the main concept must remain: An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Required Language in Consent Document if Giving Compensation

The following text is required in the consent document if participants will receive compensation:

Any payment for participation in a research study is considered taxable income for you. If your payment for this research study or a combination of research studies is \$600 or more for all or any dollar amount for undocumented noncitizens in a calendar year (January to December), you will receive the appropriate IRS Form for tax reporting purposes from the University. Please note, if you are an employee of University of Arizona, any compensation from a research study is considered taxable income.

For any compensation or reimbursement, you receive, we are required to obtain identifiable information such as your name, address, and [for amounts >\$50] Social Security number for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data. If you do not want us to collect this information, you can still participate in this study, but you will not be able to receive any payment for your participation.

Cancer Related Research

For cancer related research, approval from Arizona Cancer Center Scientific Review Committee (SRC) is required. The submission process can be found at <https://cancercenter.arizona.edu/researchers/clinical-research/scientific-review-committee>.

Future use of data or specimens

Future use of data or specimens refers to keeping data and/or specimens for future research including unspecified future research.

Include a statement in the consent document that reflects future use/no future use of data and/or specimens.

In the consent form, include information on:

- How subject's data will be managed, used in future research, and shared.
- If known, what repository will be used to store the participant's data and what data will be stored/shared.
- A statement that clarifies if data and/or specimens will be stored as identifiable, coded, or de-identified.
- Assess limitations on subsequent use of data and communicate these limitations to the participants.

NIH sample consent language can be found here: <https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf>

Data Management and Sharing Plan

If your study is funded by the NIH or another agency that requires a Data Management and Sharing Plan, relevant information from your plan will need to be included in the consent form.

Data Security

Ensure that data and information, including identifiable private information or identifiable biospecimens have appropriate data security.

- Encryption is strongly recommended
- Box@ UA Health is recommended for confidential research data
- REDCap is recommended for online surveys and forms

Guidance on Data Security and Records Retention is available on the IRB website <https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers>

Conflict of Interest

The University of Arizona Conflict of Interest (COI) in Research policy applies to all University of Arizona research investigators and applies specific requirements to PHS funded investigators. It requires that all University of Arizona investigators complete COI training and disclosure of Significant Financial Interests. An investigator is any person who is responsible for the design, conduct or reporting of research performed as part of the University.

In addition, all named personnel (including Principal Investigator, Senior/Key Personnel, or other named personnel "COI Discloser" for example data manager, project coordinator, clinical research coordinator, research/lab technicians, advisors, etc.) participating in federally funded research activities, including sub-federal awards, must have submitted a disclosure within the past 364 days prior to the submission of any

federal proposal. A disclosure can be any of the following: Annual Disclosure Certification, Research Certification, or an Update. The Office for Responsible Outside Interests (OROI) will be responsible for verifying COI disclosures for federally funded proposals. OROI will confirm that all personnel listed in UAccess Research (UAR) as a Principal Investigator, Senior/Key Personnel, or COI Discloser have an up-to-date conflict of interest disclosure at the time of proposal submission. Only proposals having up-to-date disclosures will be submitted.

Information and links can be found at <https://research.arizona.edu/compliance/office-responsible-outside-interests/individual-conflict-interest-research/conflict-interest-procedures>

Requirements include:

Conflict of Interest Training

Conflict of Interest training can be obtained through EDGE Learning <https://uaccess.arizona.edu>

Training is valid for four (4) years

Disclosure of Significant Financial Interests

Disclosure of Significant Financial Interests can be completed in eDisclosure (<https://uaccess.arizona.edu>)

Disclosure is required annually and within 30 days of acquisition of a new significant financial interest not previously disclosed

Conflict of Interest (COI) Research Certification

All investigators and study personnel must complete a research certification for each research study they are involved with before IRB approval is granted. Please note that these study specific Research Certifications are in addition to the annual COI Disclosure Certification.

Study specific Research Certifications are generated on a project-by-project basis, and to complete them, investigators need to:

- Log into eDisclosure (<https://uaccess.arizona.edu>).
- From the Dashboard, locate the “My Inbox” tab to locate a list of their outstanding Research Certifications. You can locate the project title by clicking the Research Certification.

COI Resources:

Instructions for completing the research related COI certification can be found at https://research.arizona.edu/sites/default/files/data/Submitting%20a%20Research%20Certification_1.pdf

Email coi@arizona.edu with questions about the COI process and requirements

Recruitment of University of Arizona College of Nursing Students and/or Faculty

A letter of support is needed if recruiting University of Arizona College of Nursing students and/or faculty

If specific to a course, contact the Course Chair

For doctoral students, contact Dr. Ruth Taylor-Piliae (PhD) and/or Dr. Lindsay Bouchard (DNP)

For undergraduate students and MEPN students, contact Dr. Connie Miller
For faculty, contact the Department Chair

Research at Banner facilities

- Prior to submitting a proposal for funding or developing a research protocol that will include a Banner facility, contact the Systems Director of Banner Nursing Research and the Banner RN Director of Clinical Nursing Research for the facility. Include in the email key specifics about the planned project: project name, aims, overview of methods, and specific requests. This will help facilitate early protocol planning and reduce potential barriers such as access to PHI, nursing staff time, and overlap with other projects. The Nursing Research Director(s) will reach out on behalf of the PI to Banner unit directors, and/or other support entities within Banner with this information.
- Prior to submitting your IRB application to the University of Arizona IRB, you must obtain approval from Banner. Submit the IRB Protocol form and supporting documents through the Research Administration Portal (RAP) to University of Arizona Health Sciences (UAHS) Research Administration <https://comhub.medicine.arizona.edu/>
- Submit the IRB Protocol for Human Subjects Research form and supporting documents to the Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. The IRB Protocol for Human Subjects Research form and supporting documents can be reviewed in the College of Nursing while waiting for Banner feasibility review but Banner approval must be obtained before documents can be submitted to the University of Arizona IRB through the eIRB system.

Research with Native Communities

- Any research conducted on sovereign native land is governed under the authority of that individual Native nation.
- Sovereignty is the inherent right of a people to self-government, self-determination, and self-education, including governance within their lands/territory. Sovereign status is a defining feature of Native nations and it differentiates them from other communities with whom the University of Arizona may engage. Understand that any research or institutional engagement conducted on sovereign native land is governed under the authority of that individual Native nation.
- Throughout the research process, understand that sovereign Native nations have the legal right to approve or deny requests for research conducted with Native communities; halt research activities without disclosing their reasons; decide whether the outcomes of research activities conducted within their jurisdiction will be disclosed/disseminated in oral or written form; and negotiate exclusive or shared ownership of research data.
- Each Native nation has its own laws, codes, regulations, procedures and/or departmental guidelines governing activity occurring on tribal land.
- Each Native nation is the exclusive owner of all property on its lands and fully controls the disposition, development and use of its physical and intellectual property.
- Arizona Board of Regents (ABOR) Tribal Consultation Policy (ABOR 1-118) functions as the highest level of authority, outlining ABOR's expectations and requirements when

engaging with Native Nations, by recognizing fundamental principles of tribal sovereignty, consultation, and respect. ABOR 1-118 requires that all human and non-human research projects, including both unfunded and funded sponsored projects must be supported by documented evidence of consultation and approval (ABOR 1-118 B(2)(b)).

- As a Research I Land Grant Institution, the University of Arizona has developed its own consultation guidelines (see the University of Arizona Consultation Guidelines). It is the responsibility of the University of Arizona faculty, student, or professional to determine and abide by the Native nation's required procedure or protocol for review, approval, and regulation of research or institutional engagement, and to abide by the University of Arizona Consultation Guidelines.
- The Native Peoples Technical Assistance Office (NPTAO <https://nptao.arizona.edu/>) serves as the liaison for Native Affairs to the Office for Research, Innovation and Impact (RII). Through engagement and collaboration with Native Nations throughout Arizona, NPTAO provides research support and capacity building, training and education in Indigenous law and governance for Native peoples, and technical assistance for tribal community development.