Human Subjects Information
Research Projects

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

Recruitment on Social Media

Specify the group/groups you will be posting to on social media. Include if they are a publicly available group or if the group is 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 the 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 the University of 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.

OnCore

Online Collaborative Research Environment (OnCore) is a comprehensive, Web-based Clinical Trial Management System (CTMS) used to manage clinical research involving human subjects. It was developed to support investigators and research coordinators as a centralized place to manage all their study protocols and subjects. It is also a tool to create a portfolio of active research studies by University of Arizona Health Sciences (UAHS) faculty. All clinical research studies involving human subjects within UAHS should be entered into OnCore (https://ctapps.uahs.arizona.edu). OnCore training is available through EDGE Learning (https://uaccess.arizona.edu).

Future use of data and/or specimens

Future use of data 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.

If data and/or specimens will be kept for future use, in the consent form include information on:

- How subject's data and/or specimens 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.

Guidance on Repositories – Storing Research Information for Future Use is available on the IRB website https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers

Certificate of Confidentiality

If the study is sponsored by NIH, the following certificate of confidentiality language needs to be reflected in the consent:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug

Administration. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.
Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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. Upload a copy of the Data Management and Sharing Plan with your submission in eIRB.
Data Management Plan language to be included in the consent document:

- 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
- Assess limitations on subsequent use of data and communicate these limitations to the participants

NIH sample consent language can be found at: https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf
Guidance on Repositories – Storing Research Information for Future Use is available on the IRB website https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers

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 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 when recruiting University of Arizona College of Nursing students and/or faculty.

If for a specific course, contact the Course Chair
For doctoral students, contact the Advanced Nursing Practice and Science Division Vice Chair (DNP) and/or PhD Program Director (PhD)
For undergraduate students and/or MEPN students, contact the Nursing & Health Education Division Chair
For faculty, contact the Advanced Nursing Practice and Science Division Chair

Research at Banner facilities

- Prior to submitting a proposal for funding or developing a research protocol that will include a Banner facility, contact Karen Johnson, PhD, RN, FAAN, Director of Banner Nursing Research (Karen.Johnson2@bannerhealth.com) who will function as the Research Navigator for the College of Nursing. Include in the email key specifics about the planned study: PI name, study title, aims, overview of methods, recruitment plans, key study personnel, and specific requests for use of Banner resources – specific site(s)/clinics for study where access is needed for study procedures, including badge access and access to electronic health records and/or use of Banner Wi-Fi or equipment. This will help facilitate early protocol planning and reduce potential barriers such as access to PHI, nursing staff time, and recruitment barriers due to overlap with other studies. Dr. Johnson will reach out on behalf of the PI to Banner unit directors, and/or other support entities within Banner with this information.
  Additional information is available on the College of Nursing website https://www.nursing.arizona.edu/resources/research
- Submit the IRB Protocol form and supporting documents to the Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. Obtain College of Nursing attestations.
- Submit the IRB Protocol form and supporting documents through the Research Administration Portal (RAP) https://comhub.medicine.arizona.edu/groups/RAP. It will be routed to Dr. Karen Johnson at Banner for feasibility review. Immediately following submission into RAP, notify by email Dr. Karen Johnson (Karen.Johnson2@bannerhealth.com) letting her know that the documents have been submitted in RAP. Include in the email PI name and study title. This notification will eliminate possible delays in feasibility review.
- Once you receive Banner approval, submit documents to University of Arizona IRB through eIRB for approval.

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 1 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.