Human Subjects Helpful Hints
Quality Improvement Projects

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

DNP Project (Quality Improvement) conducted at a Banner facility
For DNP students conducting quality improvement projects at a Banner facility, the following are the steps in the review and approval process.
- Meet with the Director of Professional Practice at the Banner facility to discuss preliminary ideas for the DNP project and Banner submission requirements.
- Obtain a letter of support from the Director of Professional Practice.
- Upload the letter of support along with your application and supporting documents into the Banner IRIS electronic program. The application will be reviewed by the Banner Research Determination Committee (RDC).
- Obtain approval letter for your project from RDC.
- Send a copy of the approval letter to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu).
- Review by the University of Arizona IRB is not required.

DNP Project (Quality Improvement) conducted at Southern Arizona Veterans Administration Health Care System (SAVAHCS)
- Enter project into the LEAF portal (description of the project). A multidisciplinary team will review the project to determine the necessary approvals (QI, EBP, Research, Pre-research).
- A mentor/guide will be assigned to you, the project PI, to help you through the process and the paperwork and ensure that all necessary approvals and paperwork are completed.
- Complete the F309 Determination of Proposed Oversight
- Submit the completed and signed F309 and a request for non-research determination letter via www.gov.IRBNet.org
- The IRB Administration will review the F309 then forward it to the IRB Chair for a determination.
- If the IRB Chair determines the project is not research, the IRB Chair will sign the IRB determination letter with finding of non-research in VAIRRS/IRBNet.
- IRB administration will notify the PI, the involved service chief, the Chief of Quality, and the Redesign Office of the determination so they can provide all further oversight.
- Submit IRB Protocol for Determination of Human Research and all supporting documents to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. Include the IRB determination letter from the VA.
- Submit the IRB Protocol for Determination of Human Research and supporting documents in eIRB.
DNP Project (Quality Improvement) conducted at Tucson Medical Center (TMC)

- Meet with the Associate Director of Clinical Research to discuss preliminary ideas for the DNP project and submission requirements.
- Submit required documents to TMC for their review.
- Obtain a letter of support for the project from the Associate Director of Clinical Research.
- Submit IRB Protocol for Determination of Human Research and all supporting documents to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review.
- Submit the IRB Protocol for Determination of Human Research and supporting documents in eIRB.

Recruitment on Facebook and/or Twitter

Specify the group/groups you will be posting to on Facebook and/or Twitter. 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.

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 recommended for confidential data.
- REDCap 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](https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers)

Recruitment of College of Nursing Students and Faculty

A letter of support is needed if recruiting College of Nursing students or faculty. If specific to a course, contact the Course Chair
For doctoral students, contact Dr. Taylor-Piliae (PhD) and/or Dr. Prettyman (DNP)
For undergraduate students and MEPN students, contact Dr. Connie Miller
For faculty, contact Division Directors

Projects with Native Communities

- Any project 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 project, research or institutional engagement conducted on sovereign native land is governed under the authority of that individual Native nation.
Throughout the process, understand that sovereign Native nations have the legal right to approve or deny requests for any projects conducted with Native communities; halt project activities without disclosing their reasons; decide whether the outcomes of project activities conducted within their jurisdiction will be disclosed/disseminated in oral or written form; and negotiate exclusive or shared ownership of project 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 support and capacity building, training and education in Indigenous law and governance for Native peoples, and technical assistance for tribal community development.