

Human Subjects Information Quality Improvement Projects

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

Quality Improvement (QI) and Evidence-Based Practice (EBP) Projects Conducted at Banner Health Facilities

For DNP students who are Banner Health employees conducting quality improvement/ evidence-based practice projects at a Banner Health facility, following are the steps in the review and approval process.

- Meet with the EBP Coordinator, Shelly Fleiner (shelly.fleiner@bannerhealth.com) early in the process to review the DNP Project Approval Process and timeline for implementation. The process generally involves three (3) sequential steps before implementation of your project.
 - Initial Project Feasibility Approval
 - Local Project Proposal Review
 - Submission to the Banner Health (BH) Research Determination Committee (RDC)
- Before submitting to the Banner Health RDC Committee, pass your DNP Project Proposal Defense with your DNP Project Committee at the College of Nursing and obtain approval from DNP Project Chair to move forward with the Banner Health Research Determination Committee (RDC) review process. It may take 4-6 weeks for the review process.
- The BH RDC application, Letter of Support, and all supporting documents will be uploaded in the BH iRIS electronic program in advance of the RDC review date.
- Obtain Final Outcome Letter for your project from the BH RDC.
 - Read the letter carefully to ensure your project was approved as 'not research'. If it was approved as research, you will need University of Arizona IRB approval.
- Send a copy of the Banner Health RDC outcome letter to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu).
- Review by the University of Arizona IRB is not required for projects approved by Banner Health RDC as 'not research'.

DNP Project (Quality Improvement) conducted at Southern Arizona Veterans Administration Health Care System (SAVAHCS)

For DNP students conducting a quality improvement project at Southern Arizona Veterans Administration Health Care System (SAVAHCS), the following are the steps in the review and approval process.

- 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 Principal Investigator (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 SAVAHCS.
- Submit the IRB Protocol for Determination of Human Research and supporting documents to the University of Arizona IRB through eIRB.

DNP Project (Quality Improvement) conducted at Tucson Medical Center (TMC)

For DNP students conducting a quality improvement project at Tucson Medical Center (TMC), the following are the steps in the review and approval process.

- Meet with the 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 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. Include a copy of the letter of support from the Director of Clinical Research.
- Submit the IRB Protocol for Determination of Human Research and supporting documents to the University of Arizona IRB through eIRB.

DNP Project conducted at an institution that has an IRB

If the institution where your quality improvement project will be conducted has an IRB, complete the appropriate documents and submit them to the institution's IRB to obtain approval/determination for your project from that institution. Obtain IRB approval/determination from that institution prior to submitting documents to the University of Arizona IRB for approval/determination. The following is for institutions other than the specific institutions listed above.

- If your project is approved as quality improvement (Not Human Research) at that institution, complete the IRB Protocol for Determination of Human Research.
- If your project is approved as research at that institution with Expedited status or full committee approval, complete the IRB Protocol for Projects Using External IRBs to cede IRB oversight to that institution

- If your project is approved as research at that institution with minimal risk or Exempt status, complete the IRB Protocol Request Exempt/Flexible Review or IRB Protocol for Human Subjects Research. In this case you will have IRB approval at both institutions, the external site and the University of Arizona.
- Submit the IRB Protocol form and all supporting documents to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. Include a copy of the IRB approval/determination letter.
- Submit the IRB Protocol form and supporting documents to the University of Arizona IRB through eIRB.

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.

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 data.
- REDCap is recommended for online surveys and forms.

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

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 DNP Program Director and/or PhD Program Director

For undergraduate students and/or MEPN students, contact the Nursing & Health Education Division Chair

For faculty, contact the Associate Dean for Academic and Faculty Affairs

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 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 support and capacity building, training and education in Indigenous law and governance for Native peoples, and technical assistance for tribal community development.