

Human Subjects Helpful Hints

The following information resulted from feedback from the Human Subjects Protection Program (University of Arizona IRB) and the College of Nursing Departmental Review Committee and hopefully will be helpful as you complete application forms and other documents. Keep checking back for more hints.

DNP Project conducted at a Banner facility

- Meet with the Director of Professional Practice at the facility to discuss preliminary ideas for the DNP project and Banner submission requirements
- Submit required documents to Banner for their review
- Obtain a letter of support for the project from the Director of Professional Practice
- Submit Determination of Human Research form to the Office of Research & Scholarship (apasv@email.arizona.edu) for review in the College of Nursing. Include the NRDUC Supplemental Questionnaire
- Office of Research & Scholarship will submit documents to the University of Arizona IRB
- University of Arizona IRB will submit determination letter to Banner NRDUC Committee for approval
- Approval from NRDUC Committee
- Approval from Director of Professional Practice to begin project

Research at Banner facilities

- Contact 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.
- Submit the Research Intake Application (RIA) to the UAHS Research Administration. Instructions and the form can be found at <https://research.uahs.arizona.edu/clinical-trials/research-intake-form>.
- Submit the Application for Human Research to the Office of Research & Scholarship (apasv@email.arizona.edu) for review in the College of Nursing. The Application for Human Research can be reviewed in the College of Nursing while waiting for Banner feasibility review but Banner feasibility approval must be obtained before documents can be submitted to the University of Arizona IRB

Cancer Related Research

For cancer related research, approval from Arizona Cancer Center Scientific Research Committee (SRC) is required. Contact Dr. Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu) for additional information.

Future use and long term storage of data or specimens

- Refers to keeping data and/or specimens for future research including unspecified future research beyond the University requirement of 6 years after project conclusion or for studies involving children, 6 years after the youngest child reaches age 18 years
- Include a section in consent document that reflects future use/no future use

Data Security

- Ensure that data and information, including identifiable private information or identifiable biospecimens, have appropriate data security
- Encryption is strongly recommended
- Box @ UA recommended for confidential research data
- REDCap recommended for online surveys and forms
- Guidance for researchers is available at data <http://security.arizona.edu/data-classification-and-handling-standard#classifications>

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
- An Investigator is any person who is responsible for the design, conduct or reporting of research performed as part of the University
- The University of Arizona IRB will contact the COI office to check that all personnel on the project have completed the training and financial disclosure and if any conflicts have been resolved
- Requirements include:

Conflict of Interest Training

Conflict of Interest training can be obtained at

<http://rgw.arizona.edu/compliance/conflict-interest-program>

Training is valid for four years

Disclosure of Significant Financial Interests

The Disclosure of Significant Financial Interests form can be found at

<http://rgw.arizona.edu/compliance/conflict-interest-program>

Required annually and within 30 days of acquisition of a new significant financial interest not previously disclosed

Required Statement

For research studies, include the following statement on recruitment material (flyers, scripts, emails, etc.):

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.

The statement may be shortened

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. Loescher and/or Dr. Prettyman
For undergraduate students and MEPN students, contact Dr. Connie Miller
For faculty, contact Division Directors

30 Day Rules

- PI Attestation and signatures/confirmation email must be dated within 30 days of submission to the University of Arizona IRB
- If the University of Arizona IRB requests changes to forms or other documents, revisions must be submitted to the University of Arizona IRB within 30 days of the email