

Frequently Asked Questions

Q: Where do I find human subjects forms?

A: The forms can be found on the Human Subjects Protection Program website

<https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index>. There are two (2) forms for new projects: Determination of Human Research form and the Application for Human Research.

Q: I am doing my project at another institution. Do I need to get IRB approval at both institutions?

A: You may want to consider ceding IRB oversight to the other institution. After you receive IRB approval at the other institution, complete the Application for Human Research. This form can be found on the Human Subjects Protection Program website

<https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index>. A question on the form asks, 'Is the research utilizing a single IRB for review that is not the University of Arizona IRB?' Check 'Yes'. When 'Yes' is checked, the information requested in the application will change. Include the Institutional Agreement signed by the other institution.

Q: Where do I find the Institutional Agreement?

A: This form can be found at <https://rgw.arizona.edu/compliance/human-subjects-protection-program/single-irb-research> or Dr. Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu) can send you a copy of the form.

Q: I received IRB approval at another institution for my quality improvement project, is the Determination of Human Research form the appropriate form to complete?

A: If your project was approved as quality improvement at the other institution, complete the Determination of Human Research form. If your project was approved as research with exempt status or expedited status at the other institution, complete the Application for Human Research and consider ceding IRB oversight to the other institution (see information above).

Q: I will be doing my quality improvement project at a Banner facility. Are there additional steps?

A: For a DNP quality improvement project conducted at a Banner facility, contact the Director of Professional Practice. Submit required documents to Banner and once they are reviewed, you will receive a letter of support for your project from the Director of Professional Practice. Submit the 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. The College of Nursing Departmental Review Committee will review the documents then Dr. Pasvogel will submit them to the University of Arizona IRB. The University of Arizona IRB will submit the determination letter to Banner NRDUC Committee for approval. Once approval is obtained from Banner NRDUC Committee, the Director of Professional Practice who will send a final letter authorizing start of the project.

Q: Where can I find a template for a consent document?

A: Consent templates can be found at <https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates>

Q: I would like to use a Disclosure form rather than a signed consent document. Where can I find one?

A: Templates for a Disclosure form can be found on the College of Nursing website <https://www.nursing.arizona.edu/resources/research-human-subjects-templates>

Q: Once I complete the Determination of Human Research form or the Application for Human Research, where do I send it?

A: Send the completed form to Dr. Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu) for review in the College of Nursing. Include the form and additional documents as appropriate.

Q: I need additional signatures on the form. How do I get these?

A: Send the completed form and other documents to Dr. Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu) for review in the College of Nursing. Dr. Pasvogel will obtain all required signatures/confirmation emails and submit the documents to the University of Arizona IRB.

Q: Where do I find additional information about a specific topic?

A: Guidance is available at <https://rgw.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers>. Information is also available on the College of Nursing website.

Q: How long does it take to get approval?

A: On average, it takes 1-3 months to get approval/determination. This may increase depending on when you submit the forms and how quickly you respond to requested revisions.

Q: Where are signed consent document (consent forms, parental permission forms, assent forms, PHI authorization forms) stored?

A: Signed consent documents must be stored at the University of Arizona. One option is to store signed consent documents in the Office of Research & Scholarship, College of Nursing room 410.

Q: How long are signed consent documents stored?

A: Per University of Arizona policy, signed consent documents are stored for 6 years after the conclusion of the study or if the study involves children, 6 years after the youngest child reaches the age of majority (18 years old).

Q: I need to make a change to my approved research project. What do I do?

A: You may need to submit an amendment form - Amendment or Reportable to Approved Human Research. This form can be found at <https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index>. Please read the guidance included with

your approval regarding when an amendment form is required. If you have questions, please contact the University of Arizona IRB (VPR-IRB@email.arizona.edu) or Dr. Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu).

Q: I have questions. Whom should I ask?

A: For students, your Committee Chair should be able to answer your questions. Another resource is Dr. Alice Pasvogel in the Office of Research & Scholarship (apasv@email.arizona.edu or (520) 626-6656). You can also contact the University of Arizona IRB (VPR-IRB@email.arizona.edu).

Q: What training do I need to complete?

A: You need to complete CITI human subjects training, Conflict of Interest (COI) training and financial disclosure, and HIPAA training. Information about required training and links to the training is available on the College of Nursing website <https://www.nursing.arizona.edu/resources/training>.

CITI Training – Complete the Basic Course for Social and Behavioral Investigators or the Basic Course for Biomedical Investigators. Training is good for 4 years then you need to complete the Refresher Course. If you completed CITI Training at another institution and it is still valid, add the University of Arizona as a learner institution and complete the modules specific for the University of Arizona.

Conflict of Interest Training and Disclosure - Conflict of Interest Training and Disclosure is required for University of Arizona investigators. Training is good for 4 years, then you will need to complete a refresher course. Financial Disclosure must be completed annually. It does allow for reporting of no financial interests. If there is a conflict of interest, it must be resolved before the application is submitted to the University of Arizona IRB. The IRB has been checking this and will notify the PI if disclosure has not been completed or conflicts have not been resolved. Please make sure you and all those included on the List of Research Personnel are up to date with COI training and financial disclosure.

HIPAA Training - University of Arizona policy requires that all workforce members who work with or around protected health information (PHI) complete annual HIPAA training. All members of the University of Arizona workforce and students who access protected health information (PHI) and/or perform work and/or research in an University of Arizona Health Care Component (HCC) as part of their job responsibilities must complete HIPAA Essentials training in UAccess Learning within thirty (30) days of joining University of Arizona and annually thereafter. You will receive an email notification forty-five (45) days prior to expiration of your HIPAA certificate notifying you that will need to recertify.