Human Subjects
Frequently Asked Questions

Q: Where do I find the IRB Protocol forms?
A: IRB Protocol forms can be found on the Human Subjects Protection Program (IRB) website **https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index**. There are four (4) forms for new projects: IRB Protocol for Determination of Human Research, IRB Protocol for Human Subjects Research, IRB Protocol for Human Subjects Research – Retrospective Data Review, and IRB Protocol for Projects Using External IRBs.

Q: Once I complete the form, what are the next steps for submitting to the University of Arizona IRB through eIRB?
A: Send the completed IRB Protocol form and all supporting documents to Alice Pasvogel in the Office of Research & Scholarship (**apasv@arizona.edu**) for review. Once the form and all supporting documents have been reviewed by Alice Pasvogel, complete the smart form in eIRB (**https://uaccess.arizona.edu**) and upload all the documents. Before you submit it, there are a couple of things to add. **Assign Primary Contact**. Assign Alice Pasvogel as Primary Contact so she can review the form to make sure everything is correct. You will be listed as Primary Contact. Please change this to Alice Pasvogel so she can review the form. As Principal Investigator you will receive all communication regarding the project; changing Primary Contact to Alice Pasvogel will not change this. **Assign PI Proxy.** For students, assign your DNP Project/Dissertation Chair as PI Proxy. This is required by the University of Arizona IRB. Send an email to Alice Pasvogel (**apasv@arizona.edu**) and include the study number (STUDY00004151) in the email. Once she has reviewed the smart form, she will let you know when it is ready to submit. Submit the form in eIRB. Additional information about eIRB is available on the IRB website **https://research.arizona.edu/compliance/human-subjects-protection-program**. Step by step processes for submitting in eIRB are available on the College of Nursing website **https://www.nursing.arizona.edu/resources/eirb-submission-processes**.

Q: I am doing my research project at another institution. Do I need to get IRB approval at both institutions?
A: It depends on the IRB approval status from the other institution. If your project was approved with Expedited status or full committee approval at the other institution, complete the IRB Protocol for Projects Using External IRBs. In this case, the other institution will be the IRB of record. If your project was approved with Exempt status at the other institution, complete the 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. IRB Protocol forms can be found on the Human Subjects Protection Program (IRB) website **https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index**. Once the form has been reviewed in the Office of Research & Scholarship by Alice Pasvogel (**apasv@arizona.edu**), follow the steps outlined above for submitting to the University of Arizona IRB through eIRB.

Q: Is additional documentation needed from the other institution?
A: If the other institution will be the IRB of record, check to see if it is a member of SMART IRB. Access to SMART IRB allows research investigators or their designee to submit requests for IRB reliance. If the institution is not a member of SMART IRB, a Reliance Agreement will be needed. This form can be found at **https://research.arizona.edu/compliance/human-subjects-protection-program/single-irb-research-and-forms**.

Q: I received IRB determination/approval at another institution for my quality improvement project, is the IRB Protocol for Determination of Human Research the appropriate form to complete?
A: If your project was approved as quality improvement (Not Human Research) at the other institution, complete the IRB Protocol for Determination of Human Research. If your project was approved as research at the other institution with Exempt status, complete the IRB Protocol for Human Subjects Research. If your project was approved as research at the other institution with Expedited status or full committee approval, complete the IRB Protocol for Projects Using External IRBs to cede IRB oversight to the other institution (see information above). Once the form has been reviewed in the Office of Research & Scholarship by Alice Pasvogel (**apasv@arizona.edu**) follow the steps outlined above for submitting to the University of Arizona IRB through eIRB.

Q: Where can I find a template for a consent form?
A: Consent templates can be found on the Human Subjects Protection Program (IRB) website **https://research.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: A template for a Disclosure form for quality improvement projects can be found on the College of Nursing website **https://www.nursing.arizona.edu/resources/research-human-subjects-templates**. For research studies, use the consent template from the Human Subjects Protection Program (IRB) website, remove the signature line, and modify as instructed in the form.

Q: Advisor Attestation (student projects), Attestation for Scientific Review (research projects) and/or Attestation for Department Review (research projects) is needed. How do I get these?
A: Attestation forms are available on the Human Subjects Protection Program (IRB) website (**https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index**) or an email will be accepted. For students, your DNP Project/Dissertation Chair will provide the Advisor Attestation. Alice Pasvogel will ask your Chair for the Advisor Attestation and send you a copy. Alice Pasvogel will provide the Attestation for Scientific Review and Department Review (research projects) after she has reviewed your human subjects documents. In eIRB, upload the attestation(s) in Local Site Documents, Other attachments with the category 'institutional approval'.

Q: Where can I find additional information about a specific topic?
A: Guidance is available on the Human Subjects Protection Program (IRB) website **https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers**. Information is also available on the College of Nursing website **https://www.nursing.arizona.edu/resources/research**.

Q: How long does it take for review and approval?
A: In the College of Nursing, allow one week for review; Alice Pasvogel will respond within 1-2 working days. At the University of Arizona IRB, please allow 4-6 weeks. On average, please allow 1-2 months for IRB approval/determination. This may increase depending on when you submit the forms and how quickly you respond to requests for revision/clarification.

Q: I received an email about Research Certification, what is this for? I already completed Conflict of Interest Disclosure of Significant Financial Interests.
A: All investigators and study personnel need to complete a research certification for each research study they are involved with before IRB approval is granted. This is in addition to the annual Conflict of Interest Disclosure Certification.

Q: How do I complete the Research Certification?
A: To complete the Research Certification, 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.
- Locate the project title by clicking the Research Certification.
- Once you have completed the certification, the "Save" button in eDisclosure means you want to save your progress to return later. The "Submit" button means you want to send your certification to OROI for review. If you select Submit and the status of your certification does not change to "Administrative Review" or "No Review Required", your certification has not been submitted. From the list on the left side of the screen, select “Submit Changes” or “Submit Disclosure”.

Q: Where are signed consent documents (consent forms, assent forms, PHI authorization forms) stored?
A: Signed consent documents must be stored at the University of Arizona. Consent documents signed online should be stored in an approved secure location such as REDCap. For paper copy of the consent documents with a physical signature, one option for storage is the Office of Research & Scholarship, College of Nursing room 410.

Q: How long should signed consent documents be stored?
A: Per University of Arizona policy, signed consent documents must be stored at least 6 years after the conclusion of the study or if the study involves children, at least 6 years after the youngest child reaches 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 a modification in eIRB (**https://uaccess.arizona.edu**). Please read the guidance on the University of Arizona IRB website for exempt and minimal risk research regarding when a modification is needed (**https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers**). If your project was approved with expedited status or full committee approval, all changes must be approved by the IRB. A modification will need to be submitted in eIRB. If you have questions, please contact the University of Arizona IRB (**VPR-IRB@email.arizona.edu**) or Alice Pasvogel, Office of Research & Scholarship (**apasv@arizona.edu**). Include the project title and study number in the email.

Q: I have questions. Whom should I ask?
A: For students, your DNP Project/Dissertation Chair should be able to answer your questions. Another resource is Alice Pasvogel, Office of Research & Scholarship (**apasv@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 human subjects training, Conflict of Interest (COI) training and financial disclosure, and HIPAA Training Certification. Information about required training and links to the training is available on the College of Nursing website **https://www.nursing.arizona.edu/resources/training**.

Human Subjects Training – Human Subjects Training is required for all Investigators, Faculty, Staff, and Students conducting research with human subjects at the University of Arizona. There are two CITI Training options for Investigators to choose from depending on the type of research they will be conducting: Social & Behavioral Research BASIC Course or Biomedical Research BASIC Course. Training must be appropriate for the study design. For all studies conducting FDA regulated research or projects accessing medical records, complete the Biomedical Research Investigators BASIC Course. For non-FDA regulated studies and projects not accessing medical records, complete either the Biomedical or the Social & Behavioral human subjects research training course. Both training courses include the Native American Research Module, which is required training for all University of Arizona researchers.
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 any modules required by the University of Arizona.

Conflict of Interest Training and Disclosure - Conflict of Interest (COI) Training and Disclosure of Significant Financial Interests 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.

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 PHI and/or perform work and/or research in a University of Arizona Health Care Component as part of their job responsibilities must complete HIPAA Annual Certification training in Edge Learning within thirty (30) days of joining University of Arizona and annually thereafter. You will receive an email forty-five (45) days prior to expiration of your HIPAA certificate notifying you that will need to recertify.

Additional Training that may be required:
GCP for Clinical Trials with Investigational Drugs and Medical Devices Certification - Completion of the Collaborative Institutional Training Initiative (CITI) course on Good Clinical Practice for Clinical Trials involving Investigational Drugs and Medical Devices is mandatory for non-MD/DO PIs overseeing clinical trials.

Clinical Research Coordinator Foundations - All research coordinators listed on protocols overseen by non-MD/DOs supervising clinical trials must complete the Clinical Research Coordinator CITI training course.