Frequently Asked Questions

Q: Where do I find human subjects forms?

Q: Once I complete the form, what are the next steps for submitting in eIRB?
A: Send the completed form and all supporting documents to Alice Pasvogel in the Office of Research & Scholarship (apasv@email.arizona.edu). Once the form and all supporting documents have been reviewed by Alice Pasvogel, and for students by your DNP Project/Dissertation Chair, complete the smart form in eIRB (https://uaccess.arizona.edu). Before you submit it, there are a couple of things to add. **Add a Primary Contact.** Add Alice Pasvogel as a Primary Contact so she can review the form to make sure everything is correct. **Add PI Proxy.** For students, add your DNP Project/Dissertation Chair as PI Proxy. This is required by the IRB. Send an email to Alice Pasvogel (apasv@email.arizona.edu) and include the study number (STUDY000000011) in the email. Once she has reviewed the form, she will let you know that 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/eirb-information). Step by step processes for submitting in eIRB are available on the College of Nursing website (https://www.nursing.arizona.edu/resources/faqs-helpful-hints-tips-completing-forms).

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 from the other institution, complete the IRB Protocol for Projects Using External IRBs. This form can be found on the Human Subjects Protection Program website https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index. Once you have completed the form, follow the steps outlined above for submitting in eIRB.

Q: Is additional documentation needed from the other institution?
A: Check to see if the institution 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 at the other institution, complete the IRB Protocol for Determination of Human Research. If your project was approved as research at the other institution, 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@email.arizona.edu) follow the steps outlined above for submitting in eIRB.

Q: I will be doing my quality improvement project at a Banner facility. Are there additional steps?
A: 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. Submit a copy of the completed Banner RDC Project Review Application and all supporting documents to Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu) for review. You will be notified of any concerns or recommended revision. 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. Submit a copy of the approval letter to Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu). Review by the University of Arizona IRB is not needed.

Q: Where can I find a template for a consent document?
A: Consent templates can be found at 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: 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: Attestation for Advisor/Co-PI (student projects), Scientific Review (research projects) and Department Review (research projects) is needed. How do I get these?
A: The Attestation forms are available on the Human Subjects Protection Program 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/Co-PI attestation and Alice Pasvogel will provide the Attestation for Scientific Review and Department Review after she has reviewed your human subjects documents. The attestations will need to be uploaded in eIRB (upload as ‘institutional approval’ in Other attachments in Local Site Documents).

Q: Where do I find additional information about a specific topic?
A: Guidance is available at 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 to get approval?
A: On average, it takes 1-2 months to get IRB approval/determination. This may increase depending on when you submit the forms and how quickly you respond to requests for revision/clarification.

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 for storage is 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 a modification in eIRB (https://uaccess.arizona.edu). Please read the guidance regarding when a modification is required. If you have questions, please contact the University of Arizona IRB (VPR-IRB@email.arizona.edu) or Alice Pasvogel, Office of Research & Scholarship (apasv@email.arizona.edu). Include the project title and study number in the email.

Q: I have questions. Whom should I ask?
A: For students, your Committee Chair should be able to answer your questions. Another resource is Alice Pasvogel, 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 (COI) 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. Please make sure you and all those included as Local Study Team Members 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 a University of Arizona Health Care Component (HCC) as part of their job responsibilities must complete HIPAA Essentials 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.