

## Step by Step Process Single-Site Research Projects

For students, have all documents reviewed and approved by your DNP Project/Dissertation Chair. Send all documents to Alice Pasvogel in the Office of Research & Scholarship ([apasv@arizona.edu](mailto:apasv@arizona.edu)) for review. This includes:

- IRB Protocol for Human Subjects Research or if your project involves the review of records only, the IRB Protocol for Human Subjects Research - Retrospective Data Review. These forms can be found at <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index>. Recommend going to the website and downloading the current version of the form.
- Recruitment material
  - Remember that all recruitment material must include the IRB required statement. It may be shortened, but the main concept must remain: 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.
- Consent document(s) (consent templates can be found at <https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates>)
- Data collection instruments (surveys, questionnaires, interview/focus group questions, etc.)
- Site Authorization letter, if applicable (a template for a Site Authorization letter is available on the College of Nursing website <https://www.nursing.arizona.edu/resources/research-human-subjects-templates>).

Now that all documents have been reviewed, you are ready to submit to the IRB through eIRB. For students, Alice Pasvogel will ask your Chair for the Advisor Attestation and send you a copy. Alice Pasvogel will send the Attestation for Scientific Review and Department Review.

Go to UAccess (<https://uaccess.arizona.edu>).

Click on eIRB. Log in using your UANet ID and Password.

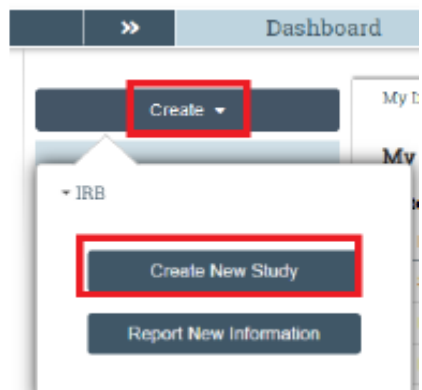
### Administrative Systems

Employee/Manager Self Service	EDGE Learning
Analytics/Reporting	Budget & Planning
Financials	Research
eDisclosure	Space
eIRB	Adaptive Insights

You should be on your Dashboard.



On the list on the left side of the screen, click **'Create'** then from the drop-down list select **'Create New Study'**.



You will now be on the **Basic Study Information** page.

A couple of things on this page:

- **Please Note:** fields marked with a red asterisk (\*) are required fields.
- What kind of study is this? Single-site or Multi-site study? Since you are doing your project at only one site, select Single-site.
- Will an external IRB act as the IRB of record for this study? Select 'No'
- Local principal investigator – this is you; your name should be prefilled.
- Is the local PI a student or medical school resident investigator? For students, check 'Yes'.
- Attach the protocol: Click '+ Add' and attach the IRB Protocol form, either the IRB Protocol for Human Subjects Research or the IRB Protocol for Human Subjects Research - Retrospective Data Review. This is the only document that should be attached here.

On the bottom right, click 'Continue'. This will save the form and move you to the next page. If there are any errors on the page, they will be shown and must be corrected before you can move to the next page.



### Study Funding Sources

If you have no funding, click Continue and move to the next page. If your study is funded, select the study's external funder(s) from the drop-down menu of Institutional Proposals or Awards. Internal funding should be identified in the IRB protocol form.

**Important:** If your study is receiving external funding but you cannot locate the funder, contact the IRB prior to submitting the study. If your study is funded, refer to correspondence from Sponsored Projects or UAHS Research Administration regarding your Institutional Proposal and/or Award Number.

### Local Study Team Members

For students, list all your committee members. Your DNP Project/Dissertation Chair should be listed as Advisor and Co-Investigator (Co-I); your committee members should be listed Co-Investigator (Co-I). Click '+ Add' and select from the list. Remember to indicate if that individual will be consenting participants. For your committee members, generally this will be 'No'.

If you have an External Team Member, attach a copy of their CITI training report or a copy of an equivalent training.

### Study Scope

Answer all the questions.

### Local Research Locations

From the list, select the location(s) where your project will take place. If it is not included on the list, you can add the site.

### Local Site Documents

Here is where you will attach your study documents:

- Consent forms: Attach your consent document(s), for example your disclosure form(s), consent form(s) and/or assent form(s). Click '+ Add' and attach the document(s). Only attach consent documents here.
- Recruitment material: Attach all recruitment material, for example recruitment email, recruitment flyer, recruitment script. Click '+ Add' and attach the document(s). Only attach recruitment material here.
- Other attachments: This is all other documents, for example surveys, questionnaires, interview/focus group questions, site authorization letter, PI CV, Appendices, Advisor Attestation (students), Attestation for Scientific Review and Department Review. For students, the Advisor Attestation is required. Alice Pasvogel will ask your Chair for the Advisor Attestation and send you a copy. Alice Pasvogel will send you the Attestation for Scientific Review and Department Review. Click '+ Add' and attach the documents.

#### 1. Consent forms: (include an HHS-approved sample consent document, if applicable) ?

Document	Category	Date Modified	Document History
There are no items to display			

#### 2. Recruitment materials: (add all material to be seen or heard by subjects, including ads) ?

Document	Category	Date Modified	Document History
There are no items to display			

#### 3. Other attachments:

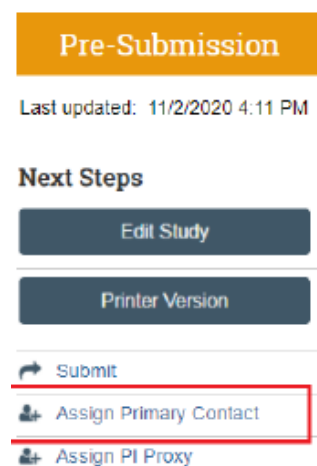
Document	Category	Date Modified	Document History
There are no items to display			

At the bottom of the page click **Finish**.

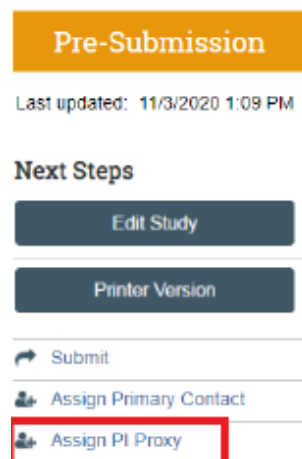


You have completed the form, but it has not been submitted to the IRB for review. It will be listed on the Workflow Map as **'Pre-Submission'**. Before you submit it, there are a couple of other things to add. From the list on the left side of the screen:

- **Assign Primary Contact.** You will be listed as Primary Contact. Please change this to Alice Pasvogel so she can review the form to make sure everything is correct. 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, add your DNP Project/Dissertation Chair as PI Proxy. This is required by the IRB. Your Chair must be listed as a Local Study Team Member as only those listed as Local Study Team Members can be assigned as PI Proxy.



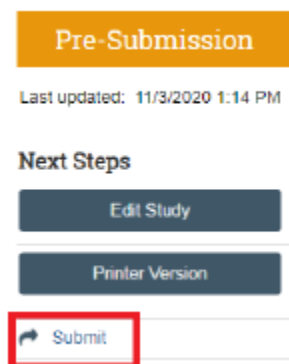
- **Training Records** Check the training dates for all personnel listed as Local Study Team Members to make sure training is current prior to submitting to the IRB. Training records will appear in a new window. For each person, the Curriculum, Completion Date, and Expiration Date will appear. If nothing appears next to a person's name, they have not completed any required

training. Please note that training for personnel must be current before the IRB can approve the submission.

#### Next Steps



Please send an email to Alice Pasvogel ([apasv@arizona.edu](mailto:apasv@arizona.edu)) and include the study number (STUDY00003151) in the email. Once she has reviewed the form, she will let you know when it is ready to submit. Once you receive notification that the form is ready to submit, submit the form in eIRB. From the list on the left side of the screen, click **Submit**.



- ✓ If there are errors in the smart form, they will appear and must be addressed before you can submit the form.
- ✓ If there are no errors, next will be your attestation. Read the information presented and click 'OK'.

On the Workflow Map you should now see that your project is in '**Pre-Review**'. You will hear from the IRB if clarification is requested or when the review is complete and the Approval letter is available to download. Look under the Documents tab for stamped consent document(s).

**Conflict of Interest (COI) Research Certification and How to Complete It**

All investigators and study personnel need to complete a research certification for each study they are involved with before IRB approval is granted. Please note that these study specific Research Certifications are in addition to the annual COI Disclosure Certification.

Study specific Research Certifications are generated on a project-by-project basis, and to complete them, investigators need to:

- Log into eDisclosure (<https://uaccess.arizona.edu>)
- From the Dashboard, locate the “My Inbox” tab to view a list of their outstanding Research Certifications. They can locate the project title by clicking the Research Certification.

COI Resources:

Instructions for completing the research related COI certification can be found at

[https://research.arizona.edu/sites/default/files/data/Submitting%20a%20Research%20Certification\\_1.pdf](https://research.arizona.edu/sites/default/files/data/Submitting%20a%20Research%20Certification_1.pdf)

Email [coi@arizona.edu](mailto:coi@arizona.edu) with questions about the COI process and requirements.