Step by Step Process
Research Projects Using an External IRB

First, have all documents reviewed and approved by your DNP Project/Dissertation Chair (PhD and Dual Degree students) and Alice Pasvogel in the Office of Research & Scholarship (apasv@email.arizona.edu). This includes:

- IRB Protocol for Projects Using External IRBs. The form can be found at https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index. The new forms are Word documents. The fillable PDFs will be accepted through Friday November 12, 2021 but this must be the Application for Human Research dated December 2019. As always, recommend going to the website and downloading the current version of the form.
- Recruitment material
- Consent document (A template for a Disclosure form is available on the College of Nursing website https://www.nursing.arizona.edu/resources/research-human-subjects-templates)
- Data collection instruments (surveys, questionnaires, interview/focus group questions, etc.)
- Copy of the IRB approval document from the external site.

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

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

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

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 study at another site and you have IRB approval at that site, select Multi-site. The University of Arizona is considered a site since you are a University of Arizona student.
- Will an external IRB act as the IRB of record for this study? Select ‘Yes’
- Lead principal investigator: Select the principal investigator responsible for the entire conduct of the study. This is the PI at the external site. If this is you, select your name from the list. If this not you but is someone at the external site, leave this blank.
- Local principal investigator: This is you. Select your name from the menu.
- Is the local PI a student or medical school resident investigator? Check ‘Yes’. Your Chair (what the IRB calls Advisor) will need to be listed as a Advisor and Co-Principal Investigator.
- Attach the protocol: Please note the new forms are now called ‘IRB Protocol for’. It is this form that you attach here, IRB Protocol for Projects Using External IRBs (or the Application for Human Research if within the timeframe when it will be accepted).

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.

**Basic Local Site Information**

Briefly describe the activities the UA site will perform. Enter “None” if all activities will be performed at the external site. Enter “All” in this section if the UA will conduct everything as described in the IRB protocol document.

**External IRB**

Select the IRB of Record from the list and indicate the external study ID if applicable. If you cannot locate the IRB of Record, contact the IRB.
**Study Funding Sources**
If you have funding for your project, enter the information. If you have no funding, click Continue and move to the next page.

**Additional Local Funding Sources**
Only update this page if the University of Arizona is receiving additional funding beyond the scope of the study’s funding.

**Local Study Team Members**
List all your committee members. Remember that your Dissertation/DNP Project Chair must be listed as Advisor and Co-Principal Investigator (Co-PI). All other committee members should be listed as Advisor. 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’

**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.

**Study Site Documents**
Here is where you will attach all your study documents:
- **Consent forms**: Attach your consent document, disclosure form or consent form. Click ‘+ Add’ and attach the document(s)
- **Recruitment material**: Attach all recruitment material, for example recruitment email, recruitment flyer, recruitment script. Click ‘+ Add’ and attach the document(s)
- **Other attachments**: This is all other documents, for example surveys, questionnaires, interview/focus group questions, educational material, educational presentation or outline of what will be included in the presentation, site authorization letter, Advisor attestation, Attestation for Scientific Review and Department Review. The Advisor Attestation is required. A form for this is available or your Chair can send you an email that can be added. Alice Pasvogel will provide 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

   ![Add button]

   Document | Category | Date Modified | Document History
   --- | --- | --- | ---
   None
   There are no items to display

2. **Recruitment materials**:
   - Add all material to be seen or heard by subjects, including ads

   ![Add button]

   Document | Category | Date Modified | Document History
   --- | --- | --- | ---
   None
   There are no items to display

3. **Other attachments**:

   ![Add button]

   Document | Category | Date Modified | Document History
   --- | --- | --- | ---
   None
   There are no items to display
Local Site Documents
Attach all your study documents here as well:

- **Consent forms**: Attach your consent document, disclosure form or consent form. Click ‘+ Add’ and attach the document(s)
- **Recruitment material**: Attach all recruitment material, for example recruitment email, recruitment flyer, recruitment script. Click ‘+ Add’ and attach the document(s)
- **Other attachments**: This is all other documents, for example surveys, questionnaires, interview/focus group questions, educational material, educational presentation or outline of what will be included in the presentation, site authorization letter, Advisor attestation, Attestation for Scientific Review and Department Review. The Advisor Attestation is required. A form for this is available or your Chair can send you an email that can be added. Alice Pasvogel will provide the Attestation for Scientific Review and Department Review. Click ‘+ Add’ and attach the documents.

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.

- **Assign PI Proxy**. Add your Dissertation/DNP Project Chair as PI Proxy. This is required by the IRB.
• **Training Records** (coming soon). 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.

Please send an email to Alice Pasvogel (apasy@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.

Once you receive notification from Alice Pasvogel 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, the next thing 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.

Submissions reviewed by an external IRB are found on the External IRB tab