Step by Step Process
Research Projects Using an External IRB

First, have all documents reviewed and approved by your DNP Project/Dissertation Chair (DNP, 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. As always, recommend going to the website and downloading the current version of the form.
  - In the form you will be asked for a Short Title. Please include as it is required in eIRB.
- 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 in 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)
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 list.
- 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 Advisor and Co-Principal Investigator.
- Attach the protocol: Click ‘+ Add’ and attach the IRB Protocol for Projects Using External IRBs.

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 no funding, click Continue and move to the next page. If you have funding for your project, select the project’s external funder(s) from the drop-down menu of Institutional Proposals or Awards. Internal funding should be identified in the IRB Protocol document.
**Important:** The selected funding information directly impacts COI disclosures. If your project is receiving external funding but you cannot locate the funder, contact the IRB prior to submitting the project. If your project is funded, refer to correspondence from Sponsored Projects or UAHS Research Administration regarding your Institutional Proposal and/or Award Number.

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 DNP Project/Dissertation 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’. If you have an External Team Member, attach a copy of their CITI training report or a copy of an equivalent training. You can also upload a document that has their name, role on the project, and their CITI training completion date.

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(s), disclosure form(s) or consent form(s). 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, copy of the IRB approval document from the external site, Advisor Attestation, 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 provide the Attestation for Scientific Review and Department Review. Click ‘+ Add’ and attach the documents.
Local Site Documents
Attach all your study documents here as well:

- **Consent forms**: Attach your consent document(s), disclosure form(s) or consent form(s). 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, copy of the IRB approval document from the external site, Advisor Attestation, 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 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. Please send an email to Alice Pasvogel (apasv@email.arizona.edu) and include the study number (STUDY000000011) in the email. Once Alice Pasvogel has reviewed the form, she will let you know that it is ready to submit.
• **Assign PI Proxy.** Add your Dissertation/DNP Project Chair as PI Proxy. This is required by the IRB. Your Project 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** (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 (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.

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.
### Submissions

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