

Step by Step Process Projects Using Publicly Available Data or De-identified Research Data

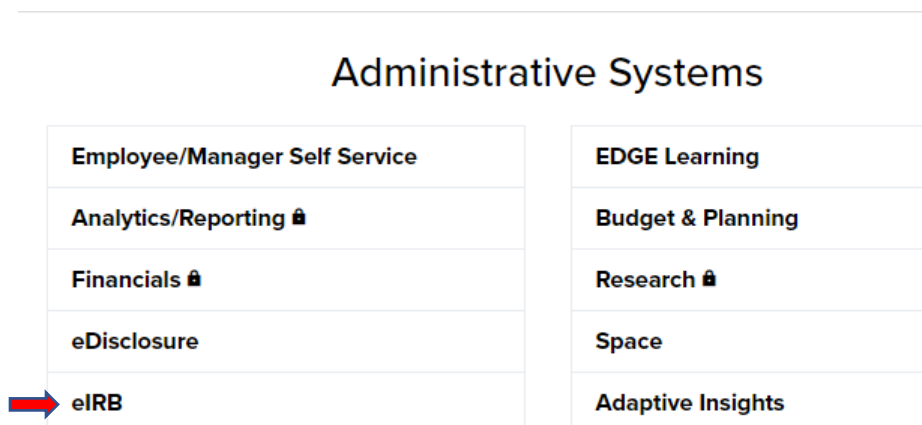
For students, have all documents reviewed and approved by your Dissertation/DNP Project Chair. Send all documents to Alice Pasvogel in the Office of Research & Scholarship (apasv@arizona.edu) for review. This includes:

- IRB Protocol for Determination of Human Research (Word document available 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.
- List of data elements to be received/obtained
- Permission (letter or email) to use de-identified research data, if applicable
- Consent document(s) from parent study if using de-identified research data

Now that the 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.

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

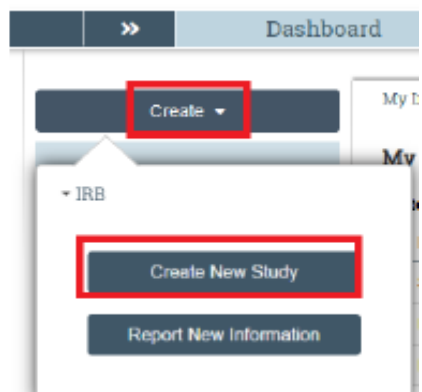
Click on eIRB. Log in using your UANet ID and Password.



You should be on your Dashboard.



From 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 in the Smart Form 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? If 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? This will be 'No'. If an external IRB will be the IRB of record, please see the process for projects using external IRBs.
- 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 your IRB Protocol for Determination of Human Research form. 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.

Local Study Team Members

For students, list all your committee members. Your Dissertation/DNP Project Chair should be listed as Advisor and Co-Investigator (Co-I); your committee members should be listed as Co-Investigator (Co-I). Click '+ Add' and select from the list. Remember to indicate if those listed will be consenting participants. Since the project involves analysis of publicly available or de-identified research data, this will be 'No'.

Study Scope

Answer all the questions.

Local Research Locations

List 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 project documents:

- Consent forms: Attach the consent document(s) from the parent study if using de-identified research data. Click '+ Add' and attach the document(s).
- Recruitment material: You will probably not have recruitment material.
- Other attachments: This is all other documents, for example list of data elements, permission to use the data, if applicable, and Advisor Attestation (students). The Advisor Attestation is required for students. Alice Pasvogel will ask you Chair for this and send you a copy. 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.


Pre-Submission


Last updated: 11/2/2020 4:11 PM


Next Steps

Edit Study

Printer Version

 [Submit](#)

 [Assign Primary Contact](#)

 [Assign PI Proxy](#)

- **Assign PI Proxy.** For students, add your Dissertation/DNP Project Chair as PI Proxy. This is required by the IRB. Your Dissertation/DNP 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.


Pre-Submission


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Next Steps


Edit Study

Printer Version

 [Submit](#)

 [Assign Primary Contact](#)

 [Assign PI Proxy](#)

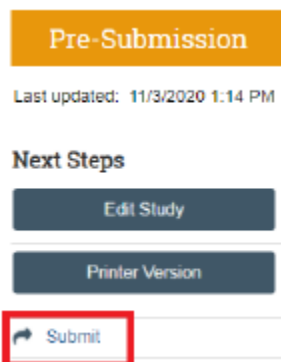
 [Manage Ancillary Reviews](#)

- **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, then they have not completed any required training.



Please send an email to Alice Pasvogel (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 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 Determination letter is available to download.