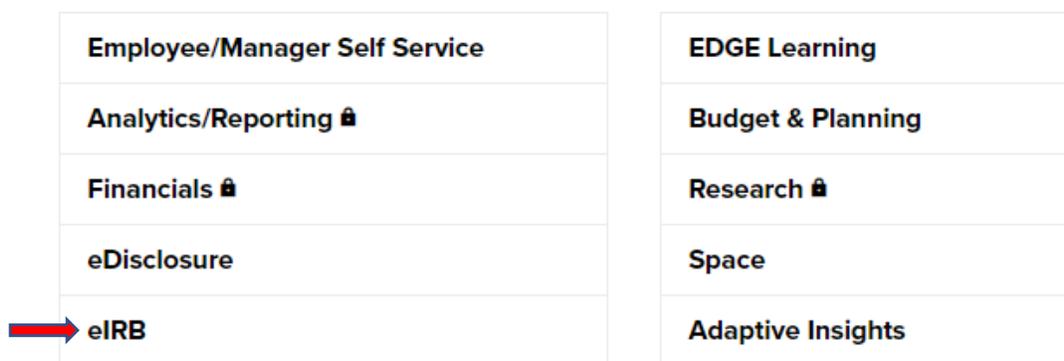


Step by Step Submission Process Research Projects Using an External IRB

Once all 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. Alice Pasvogel will send the Attestation for Scientific Review and Department Review if needed.

Go to UAccess (<https://uaccess.arizona.edu>) and click on eIRB. Log in using your UANet ID and Password.

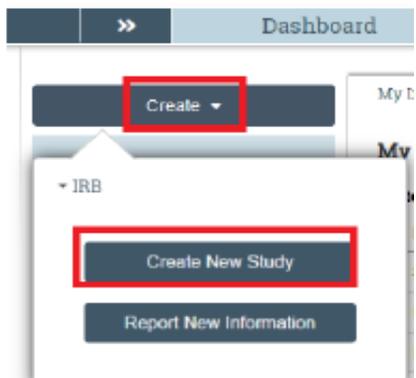
Administrative Systems



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 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? 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 PI at this site.
- 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? For students, check 'Yes'.
- Attach the protocol: Click '+ Add' and attach the IRB Protocol for Projects Using External IRBs. The IRB Protocol form must be in Word format. 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.



Basic Local Site Information

Briefly describe the activities the University of Arizona site will perform; provide a brief description of activities the University of Arizona PI will perform for the study. Enter "All" if the University of Arizona site will conduct all activities as described in the IRB protocol document. Otherwise enter the activities that will take place at the University of Arizona site.

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. If the funding is at the external site, leave this blank.

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 study. If your project is funded, refer to correspondence from Sponsored Projects or Research Administration regarding the 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

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 as 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. Do not include information about team members at other sites involved in the multi-site study.

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-Related Documents

Use this page only for template documents provided by the external site (sIRB). All documents with University of Arizona specific language should be uploaded under the **Local Site Documents** page.

If you are attaching documents, click '+ Add' and attach the document(s) to the appropriate section.

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

+ Add

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) ?

+ Add

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

3. **Other attachments:**

+ Add

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

Local Site Documents

Attach documents with University of Arizona specific language here.

- **Consent forms:** Attach your consent document(s), for example disclosure form(s), consent form(s) and/or assent form(s). Click '+ Add' and attach the document(s). The consent document(s) must be in Word format. 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, copy of the IRB approval document from the external site, PI CV, Appendices, Advisor Attestation (students), Attestation for Scientific Review and Department Review if needed. 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 if needed. Click '+ Add' and attach the documents.

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

[+ Add](#)

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) ?

[+ Add](#)

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

3. Other attachments:

[+ Add](#)

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 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

Last updated: 11/3/2020 1:09 PM

Next Steps

[Edit Study](#)
[Printer Version](#)
[Submit](#)
[Assign Primary Contact](#)
[Assign PI Proxy](#)
[Manage Ancillary Reviews](#)

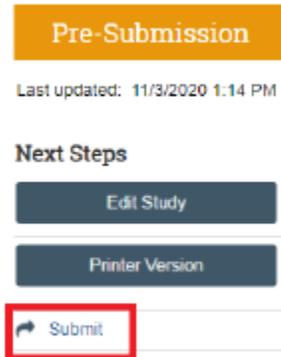
- **Training Records** Check the training dates for all personnel listed as Local Study Team Members to make sure training is current prior to submitting to the IRB. Training records will appear in a new window. For each person, the Curriculum, Completion Date, and Expiration Date will appear. If nothing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

Next Steps

[View Study](#)
[Printer Version](#)
[Create Modification/CR](#)
[Report New Information](#)
[Assign Primary Contact](#)
[Assign PI Proxy](#)
[Manage Ancillary Reviews](#)
[Manage Guest List](#)
[Add Related Grant](#)
[Add Comment](#)
[Copy Submission](#)
[Training Records](#)

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**.



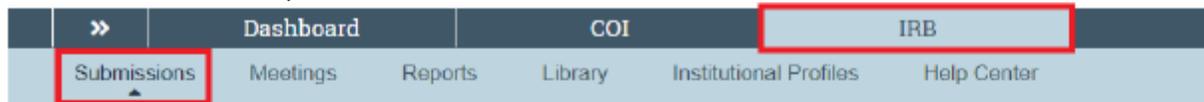
- ✓ If there are errors in the smart form, they will appear and must be addressed before you can submit the form.
- ✓ If there are no errors, the next thing will be your attestation. Read the information presented and click 'OK'.

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.

After all revisions have been submitted and reviewed, the UArizona IRB must confirm reliance on the external IRB (sIRB). If reliance is confirmed, the site enters the '**Pending sIRB Review**' state.

- The PI will be asked to submit documentation of sIRB approval.
- Use the '**Add Comment**' to attach the sIRB approval letter. In the Comment, under 'Who should receive an email notification' select 'IRB Coordinator'. Press **OK** to add the comment.
- Once sIRB Review is confirmed, the study will move through the remaining steps until the submission is in a '**Review Complete**' state. Once the study is in the Review Complete state, the UArizona IRB process is complete.

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



Submissions

