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New Study Creation in ERA

Step 1: Access the ERA system by going to the IRB website: [https://era.oked.asu.edu/](https://era.oked.asu.edu/)

Step 2: Click “IRB”→Click “Create New Study”

![ASU Knowledge Enterprise Development](image)

Step 3: Proceed through the questions in the application form. Templates for protocol and consent forms are provided throughout the electronic application, complete and upload copies in the proper sections. Proceed through the entire application, clicking “Continue” after answering questions on each page.

The following are the questions you will be asked to complete:

**Basic Information**

- The software will automatically guide you through the process of completing the application forms based on the information you enter.
- All required fields must be filled in.
Step 4: After clicking “Finish” on the final page, you will be brought back to the application workspace. Click “Submit” from the column on the left.

If you are not the PI, you will not see the Submit button. Only the PI can submit an application. Once created, the PI should see the application in their inbox (following directions 1-2 in Step 2 above). Click on the blue link, then submit as shown below.

- If you wish to review, click “Printer Version” or “Edit Study” click continue when done.
- To submit, click “Submit” from the My Current Actions list on the left.

Step 5: You will know the application has successfully been submitted when the dark blue circle moves from the “Pre-Submission” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.
Responding to Clarifications Requested in ERA

**Step 1:** You can access the new system by going to the IRB website: http://researchintegrity.asu.edu/humans.

**Step 2:**
- Click IRB (#1)
- Click IRB records (#2)
- Click “In Review” (#3)
- **Click on the title under the heading “Name” (#4)**

**This will show you All Active application (applications in-progress) for you are designated as a team member on, not just those where you are PI.**
Step 3: Click “Submit Changes”.  
If you are not the PI, you will not see the Submit button. Only the PI can submit an application or response.

Step 4: You will know the changes have successfully been submitted when the dark blue circle moves from the “Clarifications Requested” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.
Preparing & Submitting an IRB Modification

Step 1: You can access the new system by going to the IRB website: https://era.oked.asu.edu/

Step 2: Click IRB (#1) ➔ Click IRB records (#2) ➔ Click “Active” (#3) ➔ Click on the title under the heading “Name” (#4)

**This will show you All Active Studies you are designated as a team member on, not just those where you are PI (Expiration dates are shown, if no expiration date is listed, it is an exempt study)**
**Step 3:** For a Modification, Continuing Review, or to Close a study, click “Create Modification/CR”

**Step 4:** Proceed through the questions on the application. Upload any relevant documents where indicated in the application.

**Step 5:** Once complete, you will be brought back to the modification workspace. Click “Submit Modification/CR” from the column on the left.

If you are not the PI, you will not see the Submit button. Only the PI can submit an application. Once the application is created, the PI should see it in their inbox (following directions 1-2 in Step 2 above). Click on the blue link for the modification then submit as shown below.
Step 6: You will know the application has successfully been submitted when the dark blue circle moves from the “Pre-Submission” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.

Preparing & Submitting an IRB Continuation

Step 1: You can access the new system by going to the IRB website: https://era.oked.asu.edu/

Step 2: Click IRB (#1) → Click IRB records (#2) → Click “Active” (#3) ** → Click on the title under the heading “Name” (#4)
**This will show you All Active Studies you are designated as a team member on, not just those where you are PI (Expiration dates are shown, if no expiration date is listed, it is an exempt study)

Step 3: For a Modification, Continuing Review, or to Close a study, click “Create Modification/CR”

Step 4: Proceed through the questions on the application. Upload any relevant documents where indicated in the application. Click “Continue” after completing each page and click “Finish” on the last page.
Step 5: Once complete, you will be brought back to the modification workspace. Click “Submit Modification/CR” from the column on the left. If you are not the PI, you will not see the Submit button. Only the PI can submit an application. Once the application is created, the PI should see it in their inbox (following directions 1-2 in Step 2 above). Click on the blue link for the modification then submit as shown below.

Step 6: You will know the continuation has successfully been submitted when the dark blue circle moves from the “Pre-Submission” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.
Preparation & Submitting an IRB Study Closure

**Step 1:** You can access the new system by going to the IRB website: [https://era.oked.asu.edu/](https://era.oked.asu.edu/)

**Step 2:** Click IRB (#1) → Click IRB records (#2) → Click “Active” (#3) **→** Click on the title under the heading “Name” (#4)

**This will show you All Active Studies you are designated as a team member on, not just those where you are PI (Expiration dates are shown, if no expiration date is listed, it is an exempt study)**

**Step 3:** For a Modification, Continuing Review, or to Close a study, click “Create Modification/CR”
**Step 4:** For study closure, select “Continuing Review”. Proceed through the questions on the first page of the application, click “Continue” on the right to proceed.

**Step 5:** On the second page of the continuing review/close-out application, all of the top four milestones listed (shown below) must be marked to close the study. Continue through the application, then click “Continue”.

**Step 6:** When complete, you will be brought back to the project workspace, click ‘Submit’ on the left to send to IRB for review.
If you are not the PI, you will not see the Submit button. Only the PI can submit an application. Once the application is created, the PI should see the application in their inbox (following directions 1-2 in Step 2 above). Click on the blue link, then submit as shown below.

**Step 7:** You will know the close-out has successfully been submitted when the dark blue circle moves from the “Pre-Submission” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.

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**Adding Students to IRB New Study Application**

**Step 1:** Access the ERA System: [https://era.oked.asu.edu/IRB/](https://era.oked.asu.edu/IRB/)

**Step 2:** Access your existing application for your new study (steps 1-4 in picture below)
Step 3: Click “Edit Study”

Step 4: Easily jump to the correct page to add students by clicking small arrow in “Jump To:” Box
Step 5: Add students by ASUrite ID

Step 6: Click “Continue” to save. To Exit, click Exit at the top or click “Continue”/“Finish” through the remainder of the application, and clicking “Finish” on the final page which will bring you to the application workspace.

Step 7: Click “Submit” from the actions on the left. Only the PI can submit for IRB review, if you are not the PI, you will not see the submit button, and should notify the PI the application is ready for review/submission.
Accessing IRB Stamped/Approved Documents

Step 1: Open the study using steps 1-4 below.

Step 2: Click on the Documents tab, click on the document under the “Final” column. Documents in Final column are ones that have been approved by the IRB.
Step 3: The IRB approval watermark is located at the bottom of the documents approved by the IRB requiring IRB approval stamps.

External IRB

For studies in which ASU is the IRB of record a study must be submitted in ERA IRB. The study should consist of the approved protocol at the other institution, approval notice and IRB affiliation agreement. Investigators should also fill out the Local Contextual review form describing ASU’s role in the study.

- The external IRB application form.
- Affiliation agreement with the other institution.
- Consent forms
- HIPAA Authorization Form (when appropriate)
- Recruitment materials
- Investigator’s Brochure
- Research protocol
- Questionnaires, surveys, interview questions
- Verification of Training

There are some cases where ASU has a master agreement such as the University of Arizona and Northern Arizona University. The IRB Administrator should be contacted with questions. The Institutional Official or IRB Administrator signs the affiliation agreement. Once the review is done external IRB is confirmed in ERA.

There are studies in which ASU is the IRB of record. The PI should include this request as part of the original study or through a modification. The assigned study coordinator works with the Institutional Official to review the affiliation agreement. This form is signed by the Institutional Official or designee at both institutions. The signed request is sent back to the research team and included as part of the study record so that it is clear that the other individual(s) are covered as part of an affiliation agreement. Where ASU is the IRB of record we use the standard OHRP IRB template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html