ERA Training Video

START HERE

The IBC Team has created a brief video to assist PI's with getting started on an IBC disclosure in the ERA electronic system. It is highly recommended that all PI's view this video prior to beginning their disclosure. Click the Vimeo link below to be directed to the video. If you need additional training, please contact IBC@asu.edu.
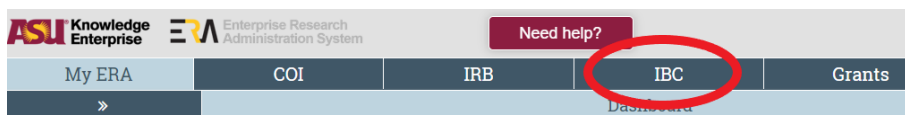
https://vimeo.com/504544396/93497abd43

Important Information About Occupational Health Requirements

Any PI who is conducting research with Bloodborne Pathogens or human materials will be subject to the OSHA Bloodborne Pathogens Standard. PI's are REQUIRED to ensure all lab members have completed a Hepatitis B Vaccination/Declination form that will be submitted to Employee Health. Your IBC disclosure will not be approved unless all lab members have completed and submitted this form. Please contact ASU Employee Health for additional information regarding lab specific Occ Health requirements.

Instructions for ERA Access and IBC Disclosure Submission

1. To access the IBC ERA system, navigate to http://era.oked.asu.edu/ If you cannot access the system, email IBC@asu.edu.

2. Click on the tab that says "IBC".

3. Click the "Create Safety Submission" box on the left side of the page.

IBC ERA Access Instructions for Primary Investigators Created By: Bree Prinzhorn, Compliance Coordinator, Office of Research Integrity and Assurance
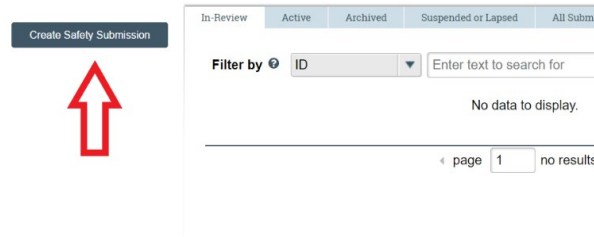
4. If you are planning to assign a PI Proxy (a lab manager or another member of the lab who can edit your disclosure/protocol and fill in information), you will need to first complete the "Biosafety Summary" Page and add the person who will be your proxy to the "Protocol Team Members" Page. Click "Save" and "Exit".

5. Once you are back on the main page, click the "Assign PI Proxy" tab on the left side of the page.

6. Assign your PI proxy. A PI Proxy should be a lab manager or a high level employee in the lab with a strong knowledge of the work that is being performed. Undergrads should not be assigned as a PI proxy. A notification should be sent to the assigned individual.

7. PI or PI Proxy will enter all materials and information into your IBC disclosure/protocol.

8. Once complete, the PI Proxy should inform the PI of disclosure completion and the PI should review the disclosure and click the "Submit" button on the main page of the disclosure/protocol. The PI is responsible for reviewing all information prior to submission.

9. Your disclosure/protocol will be sent to the IBC coordinator for review. You will be contacted by EHS through the ERA system for any edits that may be required.
10. If you have questions, please contact IBC@asu.edu.

Instructions on how to Create an Amendment or Continuing Review in ERA

1. To access the IBC ERA system, navigate to http://era.oked.asu.edu/ If you cannot access the system, email IBC@asu.edu.

2. Click on the tab that says "IBC".

3. Click the button that says "Create Amendment/CR".
4. If you are only completing an amendment, select the "Amendment" option. If you are creating a continuing review with no changes, select the "Continuing Review" button. If you are completing a continuing review and have changes to add, click the "Amendment/CR" button.

Amendment / Continuing Review

1. * **Type of Submission:**
   - Amendment
   - Amendment/CR
   - Continuing Review
   - Clear

ⓘ To change the PI, select "Other parts of the protocol." When changing team members, select both amendment types if team members must be added or removed as handlers of materials.

2. * **Amendment type:**
   - ☑ Protocol team member information
   - ☑ Other parts of the protocol

5. Determine the type of amendment you are submitting in question 2. Only select the options you will be amending in the disclosure.
6. Click the save and continue buttons to navigate to the next page.
7. Provide a clear introduction to your changes.
8. Click the save and continue buttons.
9. Make the necessary changes to your disclosure (if applicable) and click the finish button.
10. Hit the submit button on the main page of the disclosure with the flow chart.

How to Create a De Novo Submission (Renewal of your IBC disclosure)

1. Log into your IBC disclosure using the ERA system. Make sure you are logged into your my.asu.edu account. Navigate to your ERA dashboard at era.oked.asu.edu.
2. Navigate to the button titled "Create De Novo Submission". This button will be located under the "Edit Protocol" button, on the main page of your IBC disclosure that has the flow chart.
3. Read the statement and select "Yes" to indicate that you are ready to create this De Novo submission and click "Ok".
4. On the History tab, click the De Novo submission ID you just created to navigate to the submission workspace.
5. Proceed with any edits to the disclosure and click the "Submit" button on the main page of the disclosure with the flow chart. The information from your current disclosure will auto-populate in the De Novo submission. Please document any changes to your lab work, personnel, etc., prior to submitting your disclosure.

Please note, you will be assigned a new disclosure number for your De Novo submission. Do NOT change the numbers on the disclosure.

You will receive a series of automated reminders beginning three months prior to the expiration date of your current disclosure. Automated emails will provide you with a due date that is inaccurate. Please submit your disclosure by the due date our office provides to you, not the due date that is listed in the automated emails.

Your De Novo submission will require adequate time for review by the ASU Biosafety Team and the committee. Submissions are generally due 2-3 months prior to the expiration of the current disclosure, to allow time for review.

Additional Information

- In addition to entering your information into the ERA system, you will need to complete the following five documents in Word format and attach them at the end of your disclosure submission in the ERA system.
  ASU Needlestick Protocol Template (If applicable)
  Biological Exposure Medical Form (If applicable)
  Spill and Incident Guidelines
  Catalog of Organisms
  Lab Specific Biosafety Manual and SOP's
- All forms can be found on our website,
  http://researchintegrity.asu.edu/biosafety/forms
- A helpful tip for searching for materials in the ERA is to use the % symbol as a wildcard for searching. For example, rather than looking for pseudomonas, type in %pseudomonas.
- A helpful tip for searching for rooms in the ERA is to use the % symbol as a wildcard and to search by room number. For example, rather than looking for "Biodesign A Room 300", search for %300 and select the appropriate room from the populated list.

To add someone to the ERA System if they are not showing up:

- Need to have an ASU email and ASUrite ID

- Person being added will need to be logged into my.asu.edu account

- Person being added will create an account at era.oked.asu.edu/IRB

- The system will take approximately 15 minutes to update once it is completed

Troubleshooting Missing "Submit" Button

Both the PI and the assigned Proxies have the power to submit a protocol. Only the PI can assign their proxies. The steps to do so are as follows:

- User1 creates protocol and assigned User2 as PI. User1 is automatically added to the study team as the protocol creator.

- User2 (PI) logs in and executes the Assign PI Proxy activity to assign User1 as a Proxy.
- User1 (Proxy) or User2 (PI) now have access to the Submit activity