

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.

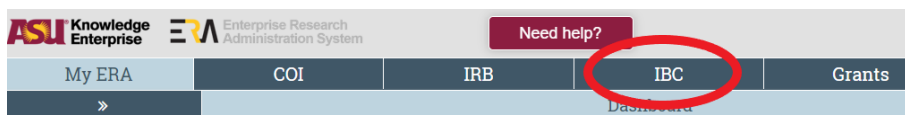
<https://vimeo.com/504544396/93497abd43>

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".



Welcome to Arizona State University's Enterprise Research Administration system (ERA).

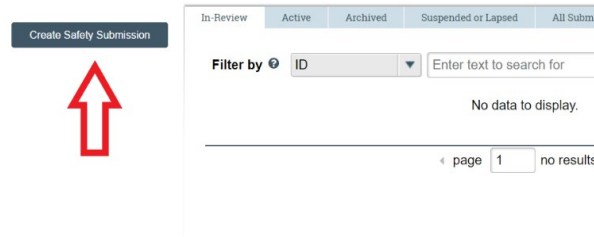
The ERA will provide an integrated platform for the administration of research and sponsored projects at ASU. Development, proposals, management of awards and integrity and assurance activities are managed in one system allowing for efficient and our investigators. ASU's ERA provides for streamlined business processes and reduces the effort required to manage our ext projects.

We look forward to continually improving our processes and systems. Please provide us with feedback at ERA@asu.edu.

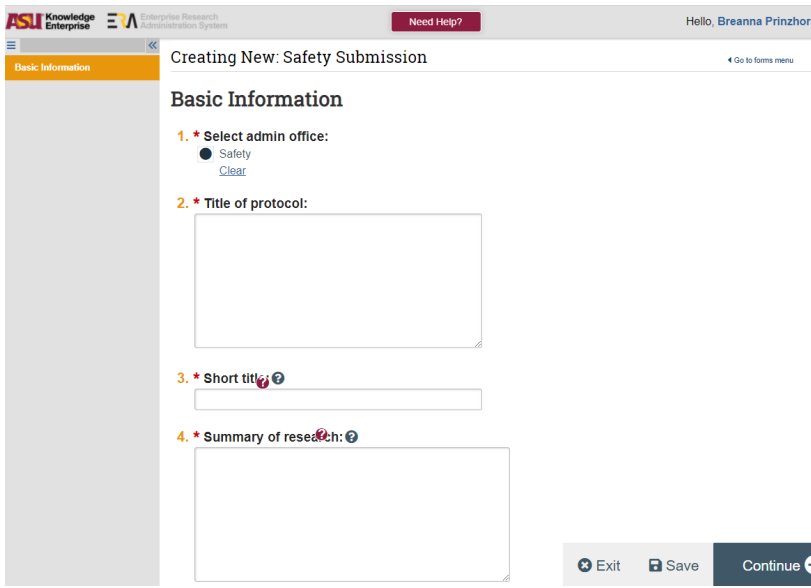
3. Click the "Create Safety Submission" box on the left side of the page.



Submissions



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”.



IBC ERA ACCESS INSTRUCTIONS FOR PRIMARY INVESTIGATORS

Editing: Test

Protocol Team Members

1. Identify each additional person involved in the design, conduct, or reporting of

Name	Roles	Additional Roles	Involved With Procedures	E-Mail	Phone
There are no items to display					

2. Team member training:

Filter by: First Name

First Name	Last Name	Training														
Breanna	Prinzhorn	<table border="1"> <thead> <tr> <th>Course</th> <th>Category</th> <th>Source</th> <th>Stage</th> <th>Stage Number</th> <th>Completion Date</th> <th>Expiration Date</th> </tr> </thead> <tbody> <tr> <td>ASU Biosafety</td> <td>ASU</td> <td>Required</td> <td></td> <td></td> <td>7/27/2020</td> <td>7/27/2021</td> </tr> </tbody> </table>	Course	Category	Source	Stage	Stage Number	Completion Date	Expiration Date	ASU Biosafety	ASU	Required			7/27/2020	7/27/2021
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ASU Biosafety	ASU	Required			7/27/2020	7/27/2021										

- Once you are back on the main page, click the “Assign PI Proxy” tab on the left side of the page.

Pre-Submission SPROTO20200000240

Test

Principal Investigator: Breanna Prinzhorn
 Specialist:
 Primary Contact:
 Admin office: Safety
 PI proxies: There are no items to display

Submission Type:
 Safety Review Type:
 Approval Date:
 Last day of continuing review period:
 Last day of de novo review period:

Next Steps

- Edit Protocol
- Printer Version
- Submit
- Assign PI Proxy**
- Assign Primary Contact
- Manage Guest List
- Manage Ancillary Reviews
- Inspection Information
- Add Comment
- Copy Submission
- Discard
- Manage Related IACUC Protocols
- Manage Related IRB Studies

Workflow: Pre-Submission → Specialist Review → Committee Review → Post-Review → Review Complete

History: Documents, Reviews, Contacts, Snapshots, Training, Follow-on Submissions, ...

Filter by: Activity

Activity	Author	Activity Date
Protocol Created	Prinzhorn, Breanna	10/30/2020 3:13 PM

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

IBC ERA ACCESS INSTRUCTIONS FOR PRIMARY INVESTIGATORS

The screenshot displays the IBC ERA system interface for a submission titled "Test Research" (SPROTO20210000003). The submission is in the "Pre-Submission" stage. Key details include: Principal Investigator: Breanna Prinzhorn; Submission Type: Initial P; Safety Review Type: Safety; and a note that there are no items to display for PI proxies. A workflow diagram shows the process from Pre-Submission through Specialist Review, Committee Review, Post-Review, and Review Complete. A red arrow points to the "Submit" button in the "Next Steps" section. The interface also features a filter section for "Activity" and "Author".

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".


The screenshot shows the ASU Knowledge Enterprise ERA system interface. The navigation menu includes tabs for "My ERA", "COI", "IRB", "IBC", and "Grants". The "IBC" tab is highlighted with a red circle. Below the navigation menu, there is a "Need help?" button and a welcome message: "Welcome to Arizona State University's Enterprise Research Administration system (ERA). The ERA will provide an integrated platform for the administration of research and sponsored projects at ASU. Development proposals, management of awards and integrity and assurance activities are managed in one system allowing for efficient and our investigators. ASU's ERA provides for streamlined business processes and reduces the effort required to manage our projects. We look forward to continually improving our processes and systems. Please provide us with feedback at ERA@asu.edu."


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 ASUwrite 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.

IBC ERA ACCESS INSTRUCTIONS FOR PRIMARY INVESTIGATORS

- 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