

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.

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

A De Novo Submission is required every three or five years, depending on the biosafety level of your disclosure. A De Novo Submission is NOT the same thing as a continuing review, which is required annually. Only submit a De Novo Review if you have received a reminder stating it is due.

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.

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