Institutional Biosafety Committee – ERA – Frequently Asked Questions

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This document is designed to answer frequently asked questions for the IBC ERA system. Below, you will find answers to some of the most common questions we receive for IBC submissions. If you have additional questions, please reach out to our office by contacting <u>IBC@asu.edu</u>.

How do I create a new IBC submission?

To create an IBC submission in the ERA system, you will need to log into my.asu.edu, then navigate to era.oked.asu.edu. Once you are on the ERA home page, click the IBC tab and click the "Create Safety Submission" button on the left side of the screen. Our office has also developed a brief tutorial video to guide you through the steps for submitting an IBC disclosure. We recommend watching the video in full, prior to starting your submission. A link to the video can be <u>found here</u>.

One of my lab members isn't showing up when I try to enter their name. What should I do?

If a lab member is not showing up in the ERA system, they will need to add themselves using the steps outlined below. Once the lab member has added themself, the PI should be able to add the lab member to the submission after about 15 minutes.

- 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

I cannot find a material on the materials list. How should I enter the material?

If you are entering a material that is not showing up on the list, try to search for the material using the % symbol as a wildcard. For example, if you are searching for E. coli, you would type in %coli and choose the appropriate strain from the dropdown menu. If you still cannot locate the material, type in %other and choose the "other" category. You will then have the opportunity to enter the name and details for the material.

I finished my submission. Is there anything else I need to do?

Once you finish your submission, you will need to click the "submit" button on the main page of the disclosure that contains the flow chart. The "submit" button can be found on the left side of the screen, under the "edit protocol" button.

What forms should I add to the "Supporting Documents" page?

When you receive instructions from our office on how to submit an IBC disclosure, we will provide you with five additional forms that need to be completed. These forms can also be found on our



website, <u>linked here</u>. The forms you will need to include are listed below. Please note, if a form does not apply to your lab, such as the needlestick protocol, there is no need to fill it out.

- Lab Specific Biosafety Manual (Required for all labs, case by case for BSL1 Exempt Labs)
- Spill and Exposure Incident and Response Guidelines (Required for all labs)
- Biological Waste Handling Procedures (Required for all labs)
- ASU Needlestick Protocol (Required for labs using needles)
- Catalog of Organisms (Optional for labs who have a large amount of materials)

How can I make a change to my IBC disclosure?

To make a change to your disclosure, you will need to log into your current disclosure and click the "Create Amendment/CR" button. Select the option for "Amendment" and identify if you have protocol team member changes or changes to other parts of the protocol. Proceed with the prompts and record your changes, then hit the "Submit" button on the main page of the disclosure with the flow chart.

What is a Continuing Review?

A Continuing Review, formerly called an Annual Review, is a short submission that is required for every lab, regardless of biosafety level, on an annual basis. Continuing Reviews are submitted directly in the ERA system, during the approval month listed on your disclosure. You will be provided with automated reminder emails from the system when you have a Continuing Review due. Our office will also send a reminder email when you have a Continuing Review due. To submit a Continuing Review, log into your disclosure and click the "Create Amendment/CR" button. Select the Continuing Review option if there are no changes to your disclosure and follow the prompts to finish and submit. Select the Amendment/CR button if you are submitting a Continuing Review and have changes to record. Follow the prompts to finish and submit.

Why is the automated reminder saying my CR is due at the end of the month, but the email from ORIA is saying my CR is due sooner?

The ERA system records the last day of Continuing Review as the last day of the month. This means the Continuing Review must be approved by the last day of the month. We ask that Continuing Reviews be submitted sooner, to allow adequate time for review and IBC Chair approval.

What is a De Novo Review?

A De Novo Review, formerly called a renewal, is required for BSL 1 labs every five years and BSL 2 or 3 labs every three years. This is a full renewal of the disclosure. A De Novo Review should be submitted at least two months prior to the expiration date listed on your current disclosure. You will be provided with automated reminder emails from the system when you have a De Novo Review due. Our office will also send a reminder email when you have a De Novo Review due. To submit a De Novo Review, follow the steps outlined below.



- Log into your current IBC disclosure.
- Navigate to the button titled "Create De Novo Submission". This button will be located on the left side of the screen under the "Edit Protocol" button.
- Read the statement and select "yes" to indicate you are ready to create the De Novo submission and click "ok".
- On the history tab, click the De Novo submission ID you just created to navigate to the new submission workspace. You may need to refresh the page a few times before seeing the new submission number.
- The new submission is a copy of your old disclosure. Proceed with any edits to the disclosure and click the "Submit" button on the main page of the disclosure with the flow chart.

Do I need to change any of the numbers that show up in the title section of my Continuing Review, Amendments, or De Novo Review?

We ask that you do NOT change numbers in the title section of any submission.

I have started my submission but I'm still having trouble. Who can I contact?

Please send all inquiries to <u>IBC@asu.edu</u>. A member of our team will respond as quickly as possible. Most of the questions we see can be answered quickly through email. We also offer Zoom meetings to assist with IBC submissions, but we ask that you thoroughly read all instructions and watch the informational video prior to requesting a Zoom meeting.

What happens after I submit my disclosure, amendment, or CR?

Once our office receives your submission, it will be routed to the appropriate reviewers. This may include administrative members in our office, the Biosafety Team, members of the IBC, or the IBC Chair. For additional information on the specific review process for your disclosure, please contact <u>IBC@asu.edu</u>. Amendments or Continuing Reviews that do not have changes to the biosafety level generally require Biosafety review and Chair review only. BSL 1 disclosures that are exempt from the NIH Guidelines generally require Biosafety review and Chair review only. BSL 2 disclosures that are exempt from the NIH Guidelines generally require Biosafety review and Designated Review by a single member of our committee. Disclosures of any biosafety level that are not exempt from the NIH Guidelines require full committee review at one of our monthly IBC meetings. A schedule of IBC meetings and submission deadlines can be <u>found here</u>.