

## PI/Lab Team – IBC Application

The IBC Application has replaced the IBC Registration. This reference document provides an overview of the IBC Application and the functionality within it.

The IBC Application has six high-level sections:

- Overview
- Lab Personnel and Space
- Types of Work (i.e. recombinant DNA/SNA, non-recombinant infectious agents/biological toxins, human- or animal-derived substances, federally regulated Select Agents/Toxins)
- Risk Mitigation
- Dual Use of Concern
- Finish Application

All questions that display are required. Depending on the response to questions, conditionally related sections and questions may appear (see **E** below). These sub-sections and sub-questions provide the IBC, OSEH, and associated compliance offices (e.g. UCUCA) with the detail about the research and biosafety precautions needed to protect the PI, lab personnel, campus, and the community.

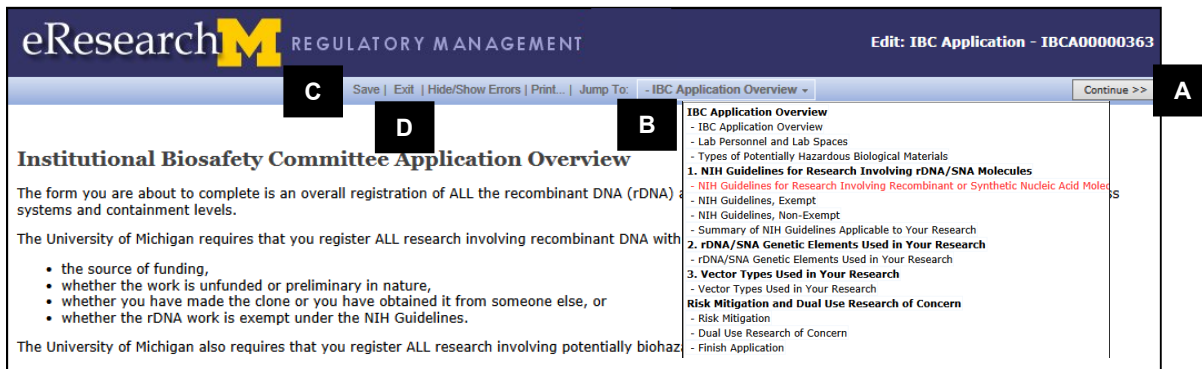
### Important Information

- For an overview of the conditional content sections, see [IBC Application Smartform Path](#)
- IBC Applications have a naming convention of **Last Name, First Name – IBC Application (IBCA000001234)**.
- Your previous IBC Registration (i.e. “legacy” registration) has a naming convention of *IBC Registration for First Name Last Name* (IBC000001234). Legacy registrations are available for viewing.

**Tip:** You can copy & paste text answers from your legacy registration into your new IBC application.

## IBC Application – Navigation Tools

Navigation tools display at the top and bottom of each application page.



- A.** Click **Continue** to save your answers and go to the next section in the application.
- B.** Click a section in the **Jump To** down-down menu to go to that section. This navigation tool is most often used to return to a previously completed section of the application to make changes; or when amending an approved application.
- C.** Click **Save** to save your data entry in the application. Save will not advance you to the next section.
- D.** Click **Exit** to close the IBC Application and go back to the workspace.  
**Note:** When closing an incomplete application, *always* click **Save** prior to clicking **Exit** to save your work for a later date.

## IBC Application – Question Formats

Many of the questions in the IBC Application have a Yes/No format, but you will also see text entry fields. Yes answers may trigger conditional detail sections and sets of questions. The conditional functionality allows you to answer only those questions that are relevant to the type of work you will do with biohazards.

### Example: Answer Triggers Additional Sections

The screenshot shows the eResearchM Regulatory Management interface for editing an IBC Application (ID: IBCA00000016). The main section is titled "Types of Potentially Hazardous Biological Materials" and asks the user to indicate the types of biological materials used in their laboratory. There are three main categories with radio button options for "Yes" or "No" and a "Clear" link:

- Recombinant DNA or Synthetic Nucleic Acids:**  Yes  No [Clear](#)
- Infectious Agents (non-recombinant) or Biological Toxins (non-recombinant):**  Yes  No [Clear](#)
- Human-derived blood or body substances, cells, or cell lines OR Animal-derived blood or body substances, cells, or cell lines:**  Yes  No [Clear](#)

A note below the second category states: "Note: Indicate Animal-derived ONLY if from non-human primates, ruminants, swine, chickens or other fowl, or any wild vertebrate animal." A third category, "HHS and USDA Select Agents or Toxins (federally regulated)", also has "Yes/No/Clear" options.

An inset window titled "Types of Potentially Hazardous Biological Materials" provides an "IBC Application Overview" with a list of sections:

- IBC Application Overview
- Lab Personnel and Lab Spaces
- **Types of Potentially Hazardous Biological Materials**
- 1. NIH Guidelines for Research Involving rDNA/SNA Molecules**
  - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
  - NIH Guidelines, Exempt
  - NIH Guidelines, Non-Exempt
  - NIH Guidelines, Animals
  - NIH Guidelines, Plants
  - Summary of NIH Guidelines Applicable to Your Research
- 2. rDNA/SNA Genetic Elements Used in Your Research**
  - rDNA/SNA Genetic Elements Used in Your Research
  - Random Genomic Fragments and DNA/RNA Libraries
  - Cloned or Targeted Genes

**E.** Depending on the response to questions, additional sections may be required. For example, if you select **Yes** to **Recombinant DNA** as a type of work, sub-sections 1-3 (e.g. 1. NIH Guidelines) and related question-sets (e.g. NIH Guidelines Exempt) become available. Clicking **Continue** takes you to the first conditional sub-section.

**Note:** The **Jump To** menu will update to display the conditional sections and questions.

**Example: Question-set**

Questions with an **Add** button allow you to enter multiple sets of answers (as applicable).

- F. Click **Add** to open the initial question-set.
- G. After completing all answers in the initial question-set, click (as applicable):

**OK** – if you have only one answer-set, or after entering the final answer-set.

**OK and Add Another** – to enter an additional set of answers.

**Note:** You may need to scroll right to see these buttons on your screen.

*You must click **OK** to save data and close the answer-set. Then, click **Continue** to go to the next application section.*

**Table Views**

There are two types of table views in the IBC Application:

- Question-set table summaries (editable)
- Conditional section table summaries (viewable).

**Example: Question-Set Summary**

	Name	Fragment or Library	Type of Fragment or Library	From What Organism	From What Tissue	From What Cell Line	
H	name1	Fragment	Random Genomic DNA	organism	tissue	cell	Delete
J	name2	Fragment	Random Genomic DNA	organism2	tissue2	cell2	Delete
I	name3	Fragment	Random Genomic DNA	organism3	tissue3	cell3	Delete

- H. A row-complete indicator (green checkmark in a circle) displays for a set of answered questions.
- I. A warning symbol displays if one or more questions have not been answered or are incomplete within an answer-set.
- J. Click **Update** to edit an answer-set.
- K. Click **Delete** to remove an answer-set.

**Example: Conditional Section Summary**

**3-12. Summary of Recombinant Constructs**

Please review the information in this table and check for completeness. If you use vector/gene combinations not shown here, please return to the applicable section to add them.

Vector	Type or Tropism Variant	Gene Name	Cell growth, division or apoptosis	Toxicity of Gene	Biosafety Level
Plasmid	E. coli K-12 lab strain	test1	--	--	BSL1
		test2	--	--	BSL2
Plasmid	Bacillus subtilis or Bacillus licheniformis				
Plasmid	Agrobacterium				
Cosmid	E. coli K-12 lab strain	test1	--	--	BSL1
		test2	--	--	BSL2
Phage	E. coli K-12 lab strain				
YAC	E. coli K-12 lab strain				
Other Non-Viral Vector	E. coli K-12 lab strain				
Adenovirus	Type 1				
Retrovirus	MoLV				
Adeno-Associated Virus	AAV1				
Other Viral Vector	Other viral vector type				

**L**

Save | Exit | Hide/Show Errors | Print... | Jump To: - Summary of Recombinant Constructs - Continue >>

L. A summary page may display at the end of a section for you to review answers and check for completeness. To update an answer, use the **Jump To** menu to return to a previous page.

**Error Notifications**

In addition to the warning symbol that may display in a question-set summary table (see I above), the IBC Application also displays error information in the following ways:

**Page-level Error Validation**

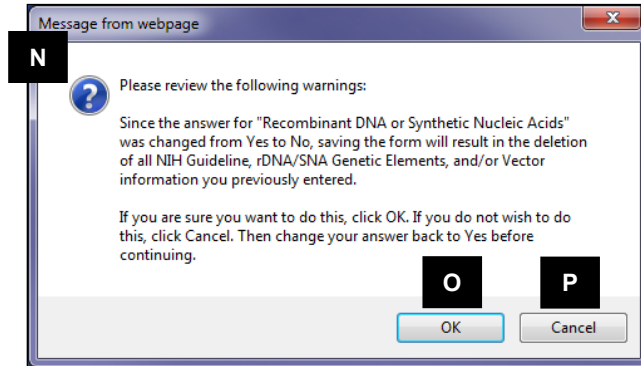
**M** Could not update the IBC Application due to one or more errors:  
Validation Failed: You must indicate at least one type for the genes you'll be using in your research.

**2. rDNA/SNA Genetic Elements Used in Your Research**

**2.1 Research Goals for Your Work with Recombinant or Synthetic Nucleic Acid Molecules**  
Please explain in lay terms how your planned experiments involve recombinant DNA (rDNA) or synthetic nucleic acid (SNA) molecules. Your explanation should provide the IBC reviewers with a complete picture of your work with rDNA or SNA, and how using these techniques contribute to your work. Indicate the types of vectors to be used, and whether different types of recombinant or synthetic nucleic acid molecules will be used together or independently. Include descriptions of human, animal, and plant models to be used.

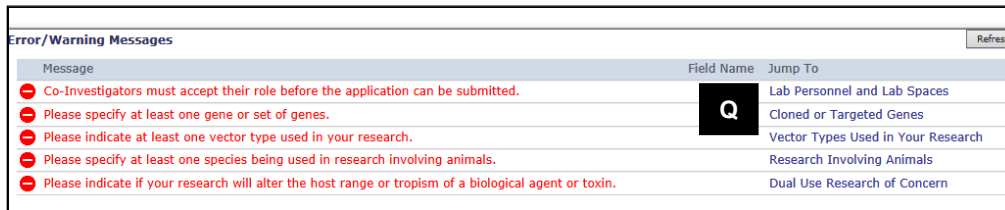
M. A few application pages contain page-level validation that requires you to answer a question before you can continue to the next application page. In these cases, then the error message displays near the top of the page.

### Change Previous Answer Warning Message



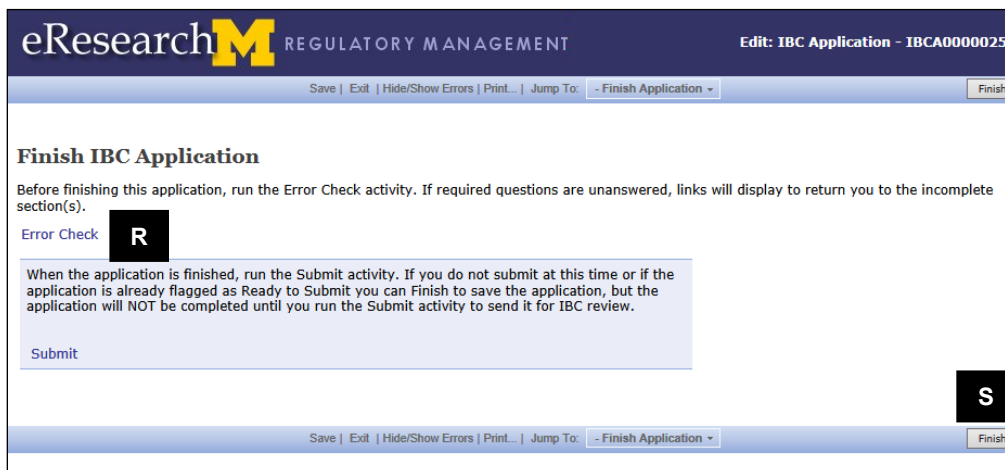
- N. A warning message displays if you change a previously saved answer to a question (e.g. from yes to no) that will cause conditional sections and questions located elsewhere in the application to be deleted.
- O. Click **OK** to *change* your answer and *delete* previously entered information.
- P. Click **Cancel** to prevent the deletion from happening, then change your answer back or Exit without saving changes.

### Hide/Show Errors



- Q. Click **Hide/Show Errors** on the page navigation bar (not shown here) to check the application for errors or incomplete answers. The results display in a list in a split window at the bottom of the application. Use the **Jump To** link to go to the indicated page, section, or question-set to update the application and fix the error.

### Finishing the IBC Application



- R. Always click **Error Check** prior to finishing the application to validate that data entry is complete. Error Check displays the same results table as Hide/Show Errors (see Q above), but in a separate window.
- S. Click **Finish** to indicate all data entry is complete and return to the Application workspace.

**Note:** Clicking Finish does not submit the IBC application. Only the PI can submit the Application for review. For more information, see [Submitting an IBC Application](#).