

FREQUENTLY ASKED QUESTIONS

University of Michigan Institutional Biosafety Committee

TABLE OF CONTENTS

IBC REGISTRATION: WHO NEEDS AN IBC APPLICATION, WHAT FOR, AND WHY?

1. What type of work requires IBC approval?	3
2. What is “exempt” work?	3
3. Do I need to register for PCR work?	3
4. I am not working with recombinant DNA. Do I still need an IBC application?	4
5. Do I need different IBC applications for different work?	4
6. Who can be the Principal Investigator on an IBC application?	4
7. What are my responsibilities as a Principal Investigator?	5
8. Can I use another investigator’s IBC application if we share a lab space?	6
9. The PI on our application is leaving UM, but the lab will still be active temporarily. What do we do?	6
10. Do I need an IBC application for work involving potentially hazardous biological substances that is performed in my colleague’s lab?	6
11. Do I need an IBC application if a Managed Core is doing work for me?	6
12. Do Managed Cores need IBC applications?	6
13. Who should be listed as the PI for a Managed Core IBC application?	7
14. I am an external investigator outside the University of Michigan. Do I need to submit anything to the IBC in order to utilize the services of the Vector Core?	7

SUBMITTING AN IBC APPLICATION

15. What are the different types of submissions?	7
16. When should I submit an amendment?	7
17. When should I submit a renewal?	8
18. What is the deadline for submitting an IBC application?	8
19. How do I submit an IBC application?	8
20. Can I submit an IBC application for my PI?	8

21. I have been sharing an IBC application with another investigator, but now want to have an application of my own. Can you duplicate our current IBC application for me?	8
22. What is the process for submitting an IBC application for work done at BSL3 or ABSL3?	9
23. What is the process for submitting a human gene transfer study?.....	9
24. Can we use a centralized IBC provider for our human gene therapy study?	9
25. Who can I contact with questions?	9

NAVIGATING THE IBC APPLICATION

26. Where can I find information about what research I currently have approval for?	10
27. What types of information can I find in my Approved Application Summary?	10
28. How do I withdraw an IBC application/amendment?	12
29. How do I update lab personnel without having to submit an amendment?	12
30. What if the name of the lab personnel I want to add to my application is not available?	12
31. What if the building or room number that I want to add to my application is not available?	13

EHS-RELATED QUESTIONS

32. What is the difference between Biosafety Level 1 and Biosafety Level 2?	14
33. Do I need to have a Biosafety Inspection before my IBC application is approved?.....	15
34. How do I resolve the corrective actions identified during my Biosafety Inspections?	15

ANIMAL-RELATED QUESTIONS

35. What types of animal derived substances require an IBC application?	15
36. How does my IBC application relate to my IACUC animal protocol?	15
37. How do I add the administration of a biological substance to animals to my application?	16
38. Do my animals require ABSL2 containment housing?	18

IBC REGISTRATION: WHO NEEDS AN IBC APPLICATION, WHAT FOR, AND WHY?

1 What type of work requires IBC approval?

Any U-M investigator planning a research project that involves recombinant DNA (rDNA) or synthetic nucleic acid (SNA) molecules must submit an application for Institutional Biosafety Committee (IBC) review and approval *before* initiating the work. U-M investigators must also register their work with other potentially hazardous biological substances.

IBC approval is required for work with:

- Recombinant DNA & SNA (including exempt work and human gene transfer)
- Infectious agents (e.g., viruses, bacteria, parasites, fungi, prions)
- Biological toxins
- Human-derived materials
- Animal-derived materials from:
 - Non-human primates
 - Ruminants
 - Swine
 - Chickens or other fowl
 - Any wild vertebrate animals
- Administration of the above substances to animals
- Creation, purchase, or other acquisition of vertebrate or invertebrate transgenic animals
- federally regulated Select Agents, experiments with Dual Research of Concern potential, and research requiring BSL3 containment

If you have any questions regarding whether you may need IBC approval, please email IBC staff at IBCstaff@umich.edu.

2 What is “exempt” work?

Section III-F of the NIH Guidelines set forth eight categories of research that are exempt from the requirements of the NIH Guidelines; however, the University of Michigan still requires that Principal Investigators register these categories of work with the IBC by submitting an IBC application.

3 Do I need to register for PCR work?

You need to register the work with the IBC if you are cloning the PCR product prior to sequencing. The direct sequencing of PCR products does not need to be registered with the IBC - as long as there is no cloning involved.

4 I am not working with recombinant DNA. Do I still need an IBC application?

Yes, if your work involves:

- Infectious agents (e.g., viruses, bacteria, parasites, fungi, prions)
- Biological toxins
- Human-derived materials
- Animal-derived materials from:
 - Non-human primates
 - Ruminants
 - Swine
 - Chickens or other fowl
 - Any wild vertebrate animals
- Administration of the above substances to animals

5 Do I need different IBC applications for different work?

No. PIs can only have one IBC application. This application covers all their laboratory's research with biohazards. The exceptions to this rule are BSL3 work and human gene transfer studies. To learn more about these processes, please see "[***What is the process for submitting an IBC application for work done at BSL3?***](#)" and "[***What is the process for submitting a human gene transfer study?***](#)".

6 Who can be the Principal Investigator on an IBC application?

The principal investigator on an IBC application must be either tenure-track faculty (Instructor through Professor), or research faculty (Research Investigator through Research Professor). Exceptions to this requirement may be approved on a case-by-case basis.

Another faculty member may be designated as a co-principal investigator on the application. A co-principal investigator must also be either tenure-track or research faculty and should be able to assume responsibility for the work covered by the application if the principal investigator is unavailable. Co-principal investigators must accept their role on the IBC application. Exceptions to this requirement may be approved on a case-by-case basis.

The principal investigator may designate individuals with editing rights on their application, however, the principal investigator is responsible for the content and must be the one to submit the application in [eRRM](#).

7

What are my responsibilities as a Principal Investigator?

Principal investigators or project directors at U-M are responsible for:

- Adhering to and promoting applicable biosafety procedures, including:
 - Ensuring the use of proper microbiological practices and laboratory techniques at the approved biosafety level;
 - Ensuring that everyone working in your lab is aware of the potential biosafety risks associated with the research they are undertaking and of any protective measures (such as vaccines or special PPE) that can reduce these risks;
 - Ensuring that everyone working in the lab is aware of the potential symptoms caused by exposure/infection;
 - Providing all lab personnel listed in the IBC application with copies of the procedures describing potential biohazards and appropriate precautions, including an updated [Biosafety Manual](#) and Chemical Hygiene Plan;
 - Providing all lab personnel listed in the IBC application with documented formal and informal instruction and training in the practices and techniques required to ensure safety and for dealing with accidental spills, personnel contamination, and other laboratory accidents;
 - If working at BSL2, downloading and compiling a BSL2 Biosafety Manual for use by lab personnel;
 - If working at BSL2, scheduling and completing an annual BSL2 laboratory inspection with U-M Environment, Health & Safety (see the [EHS Inspection Checklist](#) for details); and
 - If working at BSL2, establishing policies and procedures to limit access to BSL2 biohazardous materials to only those individuals who are listed on the application, who have been advised on the potential hazards, and who meet specific entry requirements (e.g., immunizations, training)
- Fulfilling any additional PI/PD responsibilities as detailed in Section IV-B-7 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Complying with the requirements pertaining to the possession, use, transfer, and disposal of all regulated biologically hazardous materials in accordance with all applicable federal, state, and local laws and regulations, and UM policies and procedures
- Being familiar with the CDC/NIH publication, "[Biosafety in Microbiological and Biomedical Laboratories](#)," including specific sections that apply to the PIs work
- Abiding by the reporting requirements and submitting a report to the IBC, Biological Safety Officer, and other appropriate authorities for activities that may include, but are not limited to, the following:
 - Any accident that results in exposure to infectious agents, biological toxins, or recombinant DNA, or which presents a danger of environmental contamination, or
 - All spills of biohazardous materials outside of physical containment equipment (e.g., outside of a biosafety cabinet, outside of centrifuge)

8 Can I use another investigator's IBC application if we share a lab space?

If Principal Investigators are working with the same materials and sharing staff, they may also share an IBC application. In this case, one investigator should be named the Principal Investigator on the IBC application and the other should be listed as the Co-PI.

9 The PI on our application is leaving UM, but the lab will still be active temporarily. What do we do?

If the principal investigator leaves U-M for a position elsewhere or for retirement and laboratory members are still working on projects covered by the IBC application, a person must be designated who meets the requirements of principal investigator and who is available to serve in an oversight capacity in the lab for the duration of time while those projects are being completed. This change is made as an amendment to the IBC application, and the committee will approve the change at a meeting.

10 Do I need an IBC application for work involving potentially hazardous biological substances that is performed in my colleague's lab?

If you are having work performed in another investigator's lab, you are responsible for ensuring that it is occurring in a laboratory that is registered with the IBC for that type of work and that it is conducted by individuals who have received training for the work they are performing.

11 Do I need an IBC application if a Managed Core is doing work for me?

If a PI will be providing biological substances subject to IBC approval to a managed core, or a managed core will be providing a PI with biological substances for use in their own laboratory, then the PI must obtain IBC approval.

12 Do Managed Cores need IBC applications?

Yes, managed research cores that handle biological substances subject to IBC approval must complete an IBC application regarding the work that occurs in the core with those biological substances. For more information, see [Policy on IBC Applications for Managed Cores Serving Researchers at U-M](#).

13**Who should be listed as the PI for a Managed Core IBC application?**

IBC applications for managed cores should be completed under the name of the staff person who serves as the manager of the core.

The faculty member serving as director of the core should be listed as a Co-PI. This will allow the faculty member to maintain a separate IBC application for their own research.

14**I am an external investigator outside the University of Michigan. Do I need to submit anything to the IBC in order to utilize the services of the Vector Core?**

No. External investigators are no longer required to submit a registration application for this purpose.

SUBMITTING AN IBC APPLICATION

15**What are the different types of submissions?**

The IBC application process includes submissions of:

- An initial application to obtain IBC approval for a three-year period.
- Amendment(s) to obtain approval for changes to the research.
- Renewal(s) to extend IBC approval for ongoing work for another three-year approval period.

16**When should I submit an amendment?**

You must amend your approved IBC application in the [eResearch Regulatory Management](#) (eRRM) system if you are adding or changing:

- genes studied or host/vector systems used in your rDNA work
- infectious agents or biological toxins
- work with substances from humans or certain vertebrate animals
- transgenic animal work or transgenic plant work
- administration of biological substances to animals
- administration of biological substances to plants
- anything else that may have an impact on the biosafety level of the work being performed
- BSL2 laboratory space

17 When should I submit a renewal?

An approved IBC application is valid for three years. Amendments submitted within the 90-day period leading up to expiration are considered renewals. We recommend that you submit your renewal at least 60 days before the expiration date. Amendments (i.e., applications submitted outside of the 90-day renewal window) have no impact on the expiration date of a registration.

18 What is the deadline for submitting an IBC application?

The IBC meets monthly on the third Friday of each month. The deadline for submissions to be considered at these meetings is generally the last Friday of the previous month. Please visit our [website](#) for more information.

19 How do I submit an IBC application?

1. Log into the [eResearch Regulatory Management](#) (eRRM) system with your unqname and UMICH password.
2. Initiate your application.
3. When finished and ready to submit, click "Submit" or "Submit Changes" from the Activities menu on the left-hand side of the page.

For more detailed instructions, please review [this document](#) from ITS.

Note: If you do not see the state of your application change to "IBC Staff Review," you have not submitted your application.

20 Can I submit an IBC application for my PI?

No. Your PI is responsible for submitting the IBC Application. If your PI has given you edit rights to the application, you may fill out various portions of the application, then move it to the "Ready to Submit Inbox" to indicate to your PI that the application is ready for their review.

21 I have been sharing an IBC application with another investigator, but now want to have an application of my own. Can you duplicate our current IBC application for me?

Unfortunately, IBC applications cannot be duplicated at this time.

22 What is the process for submitting an IBC application for work done at BSL3 or ABSL3?

Applications for research in the BSL3 Biocontainment Facility or the ABSL3 Biocontainment Facility are submitted through a process separate from that used for BSL1 and BSL2 work. To learn more about how to submit an IBC application for BSL3 or ABSL3 work, please contact IBC staff at IBCstaff@umich.edu.

23 What is the process for submitting a human gene transfer study?

The IBC serves as an Ancillary Committee to the IRB for these types of studies, so the way you submit an application for a Human Gene Transfer clinical trial is through the IRB application itself. There is a question in the IRB application that asks about whether it is a gene transfer study. When answered yes, the gene transfer section of the application opens for completion, and when the IRB application is submitted the IBC is notified. If the IBC reviewers have any questions or comments about the application or the other included materials, these are directed to the study team during this review process. The total turnaround time from submission to IBC meeting varies depending on when the application is submitted, but the average is around 30 days.

24 Can we use a centralized IBC provider for our human gene therapy study?

No, U-M does not employ a centralized IBC provider for human gene transfer studies.

25 Who can I contact with questions?

For general questions, please email IBCstaff@umich.edu. For questions about a specific IBC Application, you can use IBCstaff@umich.edu or contact IBC staff directly:

Alicia Trombley

Phone: (734) 615-9637

Email: atrombl@umich.edu

Provides support to Principal Investigators with last names beginning: A - L

Jen Harley

Phone: (734) 936-1236

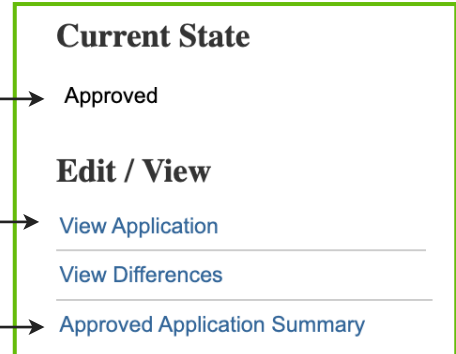
Email: jenhar@umich.edu

Provides support to Principal Investigators with last names beginning: M - Z

NAVIGATING THE IBC APPLICATION

26 Where can I find information about what research I currently have approval for?

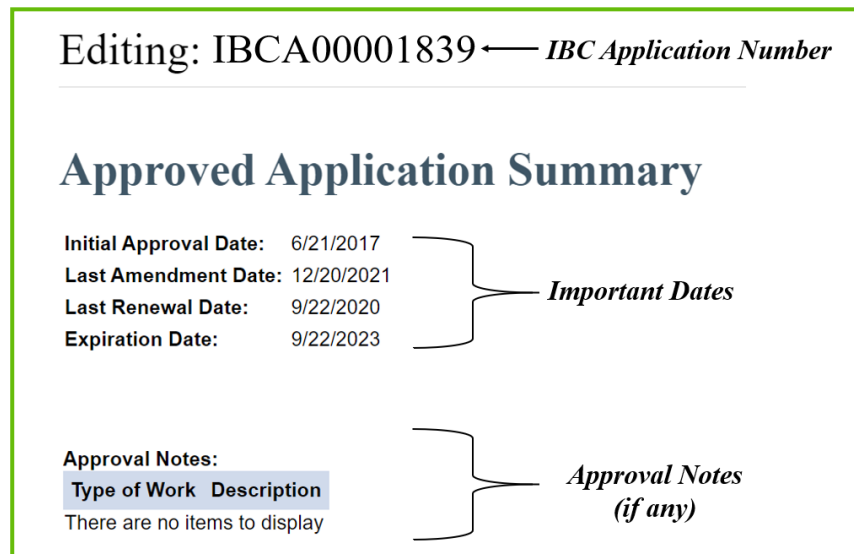
- Open your application workspace and confirm that the current state of your application is **Approved**.
- To view your entire approved application, select **View Application**.
- To view a summary of your approved work, select **Approved Application Summary**.



The screenshot shows a sidebar menu with three sections: 'Current State' with 'Approved', 'Edit / View' with 'View Application' and 'View Differences', and 'Approved Application Summary'.

27 What types of information can I find in my Approved Application Summary?

At the top of your Approved Application Summary, you will find your IBC Application Number, Important Dates (Initial Approval Date, Last Amendment Date, and Expiration Date), and Approval Notes from the IBC Committee (e.g., conditions of your approval).



The screenshot shows the 'Approved Application Summary' page. At the top, it says 'Editing: IBCA00001839' with an arrow pointing to 'IBC Application Number'. Below this is the title 'Approved Application Summary'. Underneath, there are four dates: 'Initial Approval Date: 6/21/2017', 'Last Amendment Date: 12/20/2021', 'Last Renewal Date: 9/22/2020', and 'Expiration Date: 9/22/2023'. A bracket groups these four dates as 'Important Dates'. Below the dates is the 'Approval Notes' section, which has a table header with 'Type of Work' and 'Description', and a message that says 'There are no items to display'. A bracket groups this section as 'Approval Notes (if any)'.

The NIH Guidelines specify the biosafety practices and containment principles for constructing and handling: (1) recombinant nucleic acid molecules, (2) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (3) cells, organisms, and viruses containing such molecules.

(question continues on next page)

You can view which sections of the NIH Guidelines apply to your research by going to the Recombinant DNA or Synthetic Nucleic Acids section of your Approved Application Summary.

• **Recombinant DNA or Synthetic Nucleic Acids:**

- **NIH Guidelines Applicable to Your Research**

NIH rDNA/SNA Guideline Categories you selected	Approvals Required
rDNA/SNA work in one or more of the following NIH Guidelines exempt categories: Section III-F-1; Section III-F-2; Section III-F-3; Section III-F-4; Section III-F-5; Section III-F-6, Appendices A-I through A-VI; Section III-F-7.	EXEMPT CATEGORY: IBC Registration required. You may begin this work upon confirmation of the successful submission of your IBC application. Perform at BL1 containment.
rDNA/SNA work in one or more of the following NIH Guidelines exempt categories under Section III-F-8: rDNA or SNA molecules in tissue culture; <i>Escherichia coli</i> K-12 Host-Vector Systems; <i>Saccharomyces</i> Host-Vector Systems; <i>Kluyveromyces</i> Host-Vector Systems; <i>Bacillus subtilis</i> or <i>Bacillus licheniformis</i> Host-Vector Systems; Extrachromosomal Elements of Gram Positive Organisms.	EXEMPT CATEGORY: IBC Registration required. You may begin this work upon confirmation of the successful submission of your IBC application. Perform at BL1 containment.
The introduction of rDNA molecules or synthetic nucleic acid molecules into Risk Group 2 agents. (Section III-D-1-a)	BEFORE INITIATION: IBC approval required. Additional approvals may also be necessary.
Experiments in which DNA from Risk Group 2 or Risk Group 3 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes. (Section III-D-2-a)	BEFORE INITIATION: IBC approval required. Additional approvals may also be necessary.

As you scroll through your Approved Application Summary, you will see: (1) which biological hazards you are approved to work with, and what biosafety levels they must be handled at; (2) which animal species you are approved to work with, whether they are transgenic or immunodeficient, and the required animal containment level; (3) which biological hazards you are approved to administer to animals, the approved routes of administration, and the required animal containment level.

For example: In this application, the PI is approved to work with human cadavers or body parts at BSL2.

◦ **Human-derived Substances**

Substance Type	Known Infectious Agents in Sample	Administered to Animals	Biosafety Level
<input checked="" type="checkbox"/> Human cadavers or body parts	No	Yes	BSL2

For example: In this application, the PI is approved to work with transgenic mice housed at ABSL1.


◦ **Animal Species**

Species	Rodent, Non-Rodent Vertebrate, or Invertebrate	Any immunodeficient	Transgenic Animal Containment Level	Administration of other recombinant or non-recombinant substances
<input checked="" type="checkbox"/> Mouse, Laboratory	Rodent	No	ABSL1	Yes

(question continues on next page)

For example: In this application, the PI is approved to administer human cadavers or body parts to mice through an oral route of administration at ABSL2 for the duration of the experiment.

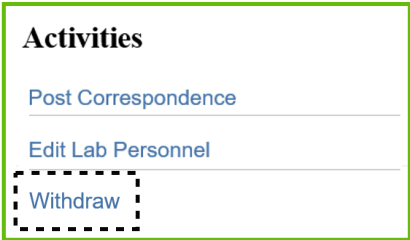
◦ **Substances Administered to Animals**

Species	Rodent, Vertebrate Non-Rodent, or Invertebrate	Biological Substance Administered	Route(s) of Administration	Animal Containment Level(s)
 View Mouse, Laboratory	Rodent	Human cadavers or body parts	Orally	ABSL2 for duration of experiment

28

How do I withdraw an IBC application/amendment?

To withdraw an IBC application or amendment, go to the activities panel and select “Withdraw.” Please note that this action is permanent. If you have any questions about withdrawing an IBC application or amendment, please contact IBC staff at IBCstaff@umich.edu.

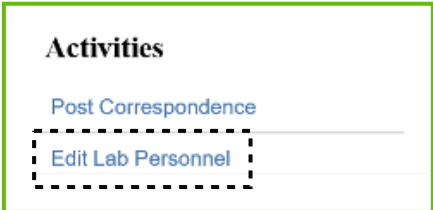


29

How do I update lab personnel without having to submit an amendment?

To update lab personnel:

1. Log into eRRM and navigate to the main page of your application.
2. Select “Edit Lab Personnel” under the “Activities” header.
3. Update your lab personnel as needed.



30

What if the name of the lab personnel I want to add to my application is not available?

If you cannot find the individual by searching for their name or username, you may need to create a new user account for them. Do this by selecting “Add” in the Lab Personnel section, then clicking the “Create New User Account” link.

(question continues on next page)

Editing: IBCA00001839

Go to forms menu Print

IBC Application Overview

IBC Application Overview

Lab Personnel and Lab Spaces

Types of Potentially Hazardous Biological Materials

1. NIH Guidelines for Research Involving rDNA/SNA Molecules

1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Lab Personnel: Please ADD information as applicable for:

- Co-Principal Investigators
- Persons working in a lab where biosafety level 2 (BSL2) research is conducted (including graduate and undergraduate students)
- Others who need to view and/or edit this registration (e.g. lab manager or administrative staff)
- **Managed Research Cores:** The faculty director of the core should be listed as "Co-Principal Investigator."

+ Add

Name	Role	Username/Email	Edit Rights
------	------	----------------	-------------

Add IBC_Personnel

Add/Edit Personnel:

Name:

Function with respect to lab:

Allow person to edit application?

Yes No [Clear](#)

Note: If the user is not in the system, you may [Create A New User Account...](#)

31 What if the building or room number that I want to add to my application is not available?

If you cannot find a certain building or room number, search for "Other" and select that from the drop-down list.

Note: The IBC application uses the formal building name (for example, BSRB is Taubman Biomedical Science Research Building).

Select Building:

If you cannot find a certain building, search for "Other" and select that building. An additional field will display to allow you to describe the space being used.

other

Building Name

Other work conducted in this lab (Select all that apply):

BSL1

BSL2

BSL3

EHS-RELATED QUESTIONS

32

What is the difference between Biosafety Level 1 and Biosafety Level 2?

The table below gives a general comparison of BSL1 vs BSL2 requirements. Please see the UM [Biosafety Manual](#) or contact EHS for additional information.

Biosafety Level	Agents Used	Facility Requirements	Special Practices
BSL1	Non-infectious agents	<ul style="list-style-type: none"> • Doors for access control • Screens on windows that open to the exterior • Non-fabric chairs and furniture easily cleanable • Sink required • Eyewash station readily available in the lab 	None
BSL2	<p>Infectious spread via blood or oral/fecal transmission</p> <p>Includes human blood and cell lines, toxins, venom, materials from Non-human primates</p>	<p>All BSL1 requirements, plus:</p> <ul style="list-style-type: none"> • Door(s) should be self-closing and lockable • Vacuum lines protected • Autoclave available or approved alternative decontamination method • Laboratories should be under negative pressure or must be neutral pressure 	<p>All BSL1 requirements, plus:</p> <ul style="list-style-type: none"> • Controlled access • Proficiency in SMPs & techniques • Medical surveillance as appropriate and offered available immunizations • BSCs or other containment device used for aerosol generating procedures • Lab equipment is routinely decontaminated • Method of decontamination for lab waste • Incidents/exposures to infectious materials are reported and evaluated

33

Do I need to have a Biosafety Inspection before my IBC application is approved?

Yes, if you are proposing work for BSL2 containment. In order for the IBC to issue approval for work at BSL2 containment, you must have had a satisfactory biohazard inspection by U-M Environment, Health & Safety (EHS) for that work within the past 12 months (including the resolution of any corrective action items). You can find a BSL2 inspection checklist from EHS [here](#).

To schedule a Biosafety Inspection, please contact EHS at 734-647-1143 or BioSafetyInspections@umich.edu.

34

How do I resolve the corrective actions identified during my Biosafety Inspections?

Please make sure you follow [these](#) directions for closing out Biosafety Inspections. If you have any questions, please contact EHS at 734-647-1143 or BioSafetyInspections@umich.edu.

ANIMAL-RELATED QUESTIONS

35

What types of animal derived substances require an IBC application?

IBC approval is required for work with animal-derived tissues, fluids, or cells from:

- Non-human primates
- Ruminants
- Swine
- Chickens or other fowl
- Any wild vertebrate animals

36

How does my IBC application relate to my IACUC animal protocol?

Before the IACUC approves the use of certain biohazards in animals, approval by the IBC is required. Animal users must provide the required information needed to conduct the risk assessment (e.g., the nature of the hazard and the route of administration) through a submission to the IBC.

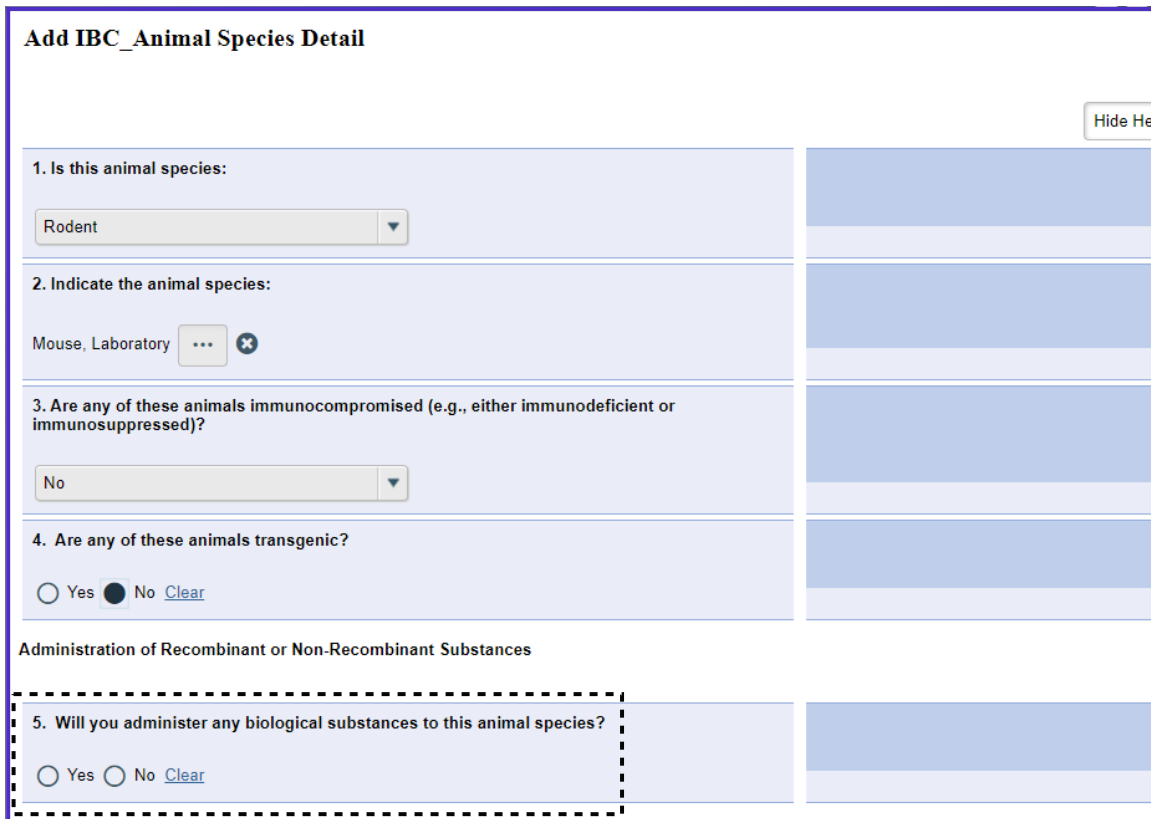
Failure to receive IBC approval may result in a delay in the approval of an IACUC protocol.

How do I add the administration of a biological substance to animals to my application?

1. Go to Section 6 (*Research Involving Animals*).
2. Select “Add” in question 6.1 to add the species you will be working with.



3. Fill out species detail questions, being sure to answer YES to question 5 (“Will you administer any biological substances this species?”).



(question continues on next page)

4. If you plan on administering cells modified with rDNA/SNA to this species (e.g., rDNA-modified human cells, rDNA-modified animal cells, rDNA-modified bacteria), answer YES to question 6, then select the type(s) of cells you will be administering.

6. Will you administer cells modified with rDNA/SNA to this animal?

Yes No [Clear](#)

6.1 What type(s) of cells modified with rDNA/SNA will be administered to this animal? (SELECT ALL THAT APPLY)

Primary human cells (rDNA modified)

Non-primary human cells (rDNA modified)

Animal cells (rDNA modified)

RG2 bacteria (rDNA modified)

RG1 bacteria (rDNA modified)

Other RG2 cells (rDNA modified)

Other RG1 cells (rDNA modified)

5. If you plan on directly administering any vectors, vectorless systems, or non-recombinant biological substances to this species, answer YES to question 7, then check the box(es) of each biological substance.

7. Will you administer any vectors or non-recombinant biological substances to this animal species?

Yes No [Clear](#)

7.1 Please identify which, if any, of the substances below will be administered directly to this animal species. The list below is derived from selections made earlier in your application.
(If you are using one of the recombinant vectors listed below to modify cells that will be administered to these animals, and not administering that vector directly, do not select that vector here. Instead, respond yes to question 6 above.)

Vectorless System(s)

Human cadavers or body parts

6. Select OK, then fill out this section in the same manner for any additional species you plan on working with.

(question continues on next page)

- If you do not see a box for a substance you plan to administer, revisit the section of the application where you gave specific details about that biological substance. Double check that you have indicated you will administer this biological substance to animals. In the example below, the PI has indicated in Section 3-7 (*Retrovirus Vectors*) that they will administer retrovirus vectors directly to animals.

3-7.7 Will any of these vectors or vector constructs be administered to whole animals, either directly or via transfected cells?

Yes No [Clear](#)

Note: You must complete the Animal Section. For work with vertebrates, IACUC approval is required before initiation.

3-7.7.1 Please indicate which you will perform (Select all that apply):



- Direct administration of this vector to animals
- Cells transfected/transduced with this vector will be administered to animals

- Continue to Section 6-1 (*Administration of Recombinant or Non-Recombinant Biological Substances to Animals*).
- Select UPDATE in question 6-1.1 to give additional details about your planned experiments.

6-1. Administration of Recombinant or Non-Recombinant Biological Substances to Animals

Displayed below are the animals you indicated will be administered recombinant or non-recombinant biological substances. To update or change which species/biological substance combinations display, please return to the Research Involving Animals page then update the species information.

6-1.1 Please use 'Update' to answer required questions about each biological substance administered to a species.

	Species	Rodent, Vertebrate Non-Rodent, or Invertebrate	Biological Substance Administered	Route(s) of Administration	Animal Containment Level(s)
 	Mouse, Laboratory	Rodent	Retrovirus Vector(s)		

38

Do my animals require ABSL2 containment housing?

Please consult [this table](#) to determine what animal biosafety level is appropriate for your animals.