

Biosafety Submission Creation

This Quick Guide provides instructions for creating a new Biosafety submission.

Log into Click with your username and password; your My Inbox will display.

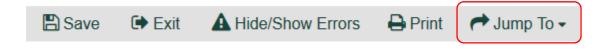
»	My Inbox	Site Administration	Facilities	IACUC	IRB	Safety	Settings
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Select Safety and then select Create Safety Submission.

	»	My Inbox	Site Administration	Facilities	IACUC	IRB	Safety	Settings	
	Su	bmissions Ir	ncidents Inspecti	ons Meeting	s Reports	Help Cente			
							Comp	onents 🌣 Properties 🕯	Permissions
S	ubr	nissions							
							Search	Search projects	Q
ſ	Creat	te Safety Submissio	n In-Review	Active Archi	ved Suspende	ed or Lapsed	All Submissions		

You will be presented with a series of SmartForm pages (page display based upon selections made). Provide a response to each required question within each page of the form; click the Continue button when you are ready to proceed to the next page. **Note:** A response is required for all questions marked with an asterisk (*).

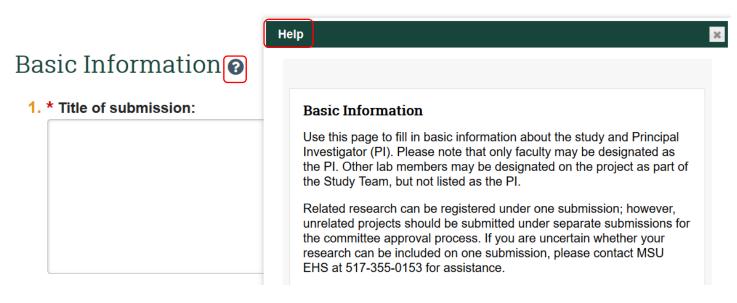
To navigate between the multiple pages, the Jump To drop down menu can be used when working within a submission. This menu will populate based upon the responses provided to the various questions.





Note: some questions have an associated question mark; click on the question mark to view more information about that question or form.

Basic Information 🛛 ←

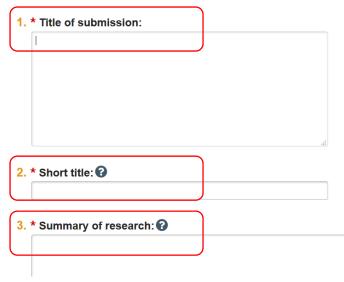


Basic Information:

The purpose of this page is to collect basic information. Provide a response to each of the questions.

• Questions 1-3: require text to be entered.

Basic Information





- Question 4: requires item selection. Select **Biosafety**.
 - 4. * Select appropriate safety review: 😮



• Question 5: search for or begin typing last name and select the **Principal Investigator**.

•••



Team Members:

This page defines the submission team members.

• Question 1: select Add to add a team member.

Team Members

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





A pop-up window will appear, begin typing or use the search to select the team member, optionally assign their research role, and click **OK**.

Add Study Team Member
1. * Select the submission team member:
2. Role in research: (check all that apply)
Co-Investigator
Biosafety User
Radiation User
Research Assistant
Lab Safety Representative
3. Job Title
* Required OK OK and Add Another Cancel

Note: the system will automatically pre-populate the Primary Job Title of the selected team member.

Note – Person Search: If you are having difficulty searching for and finding a team member, it may be necessary for that individual to first log into Click in order to populate their profile in Click. [Please contact EHS (517-355-0153) or the Click Help Desk (<u>clickhelpdesk@msu.edu</u> / 517-355-2000) for further assistance.]

 Question 2: If External (e.g., non-MSU researchers) team members, select the Add button. Attach files for each External team member. Form to add external member: <u>https://ehs.msu.edu/ assets/docs/bio/external-team-members_safety.docx</u>

2. External team member information:





- Question 3: The system will display the training information for each team member added, including the Principal Investigator.
 - 1. Identify each additional person involved in the design, conduct, or reporting of the research: 🕑

First Name Kristen	Last Bull	ard I	Biosafety R	Substance Shipping Refresher e Pathogen Refreshe		Date Completed 2/19/2018 2/19/2018 12/21/2017	
Update 3. Training	Christopher Colvin	Biosafe	ety User	Industrial Hygienist I	colvinch@msu.edu	+15173531281	
Update	Kristen Bullard	Biosafe	ety User	Industrial Hygienist I	pennerkr@msu.edu	+15173536710	
	Name	Roles	(Job Title	E-Mail	Phone	
+ Add	Name	Roles	(Job Title	E-Mail	Phone	

Funding Sources:

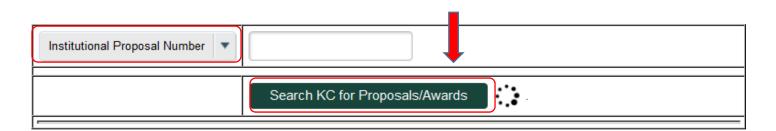
Funding source(s) are identified on this page.

- Question 1: select **Find Now** to select a funding source.
 - 1. Identify each organization supplying funding for the protocol

	Find Now							
1	Related Funding Sources:							
	PI First Name PI Last Name	Institutional Proposal Number	Award Number	Prime Sponsor Name	Sponsor Name	Project Title	Project Start Date	Co Investigator
	There are no items to display							

A pop-up window will appear; use the dropdown menu to search for and select the funding source. Select **Search KC for Proposals/Awards**.

Find Funding Source from KC







Select the funding source (radio button selection) and click **OK**. If more than one funding source applies, repeat the search and selection process.

• Question 2: select Add.

2. Identify the internal funding source details:

	······································	
	Description	
_	Start up Funds	
	+ Add	

- Question 2: select either the Yes or No radio button.
 - 2. * Will this submission result in patentable work, or potentially generate commercial revenue?

Biosafety Summary:

 Question 1: item selection displays additional SmartForm pages. (Example: selecting Tissues, Blood, or Body Fluids displays the Tissues, Blood, or Body Fluids and Biohazards SmartForm pages.)

Selecting Plant Pathogens displays the Transgenic Plants SmartForm page. If 'Other' is selected, a response (data entry) is required in Question 2.

Biosafety Summary

- 1. * Select any items involved in the submission: 🚱
 - Tissues, Blood, or Body Fluids
 - Primary Cells or Cell Lines
 - D Bacteria, Yeasts, Fungi, or Parasites
 - Viruses or Prions
 - Toxins, Agricultural Pathogens or Select Agents
 - Recombinant or Synthetic Nucleic Acids
 - Human Research Participants
 - Animals/Invertebrates (not covered on an IACUC protocol)
 - Genetically Modified Animals, Invertebrates, and Plants (including creating, testing, or using)
 - Plant Pathogens
 - Other
- 2. If other, describe items:



Tissues, Blood, or Body Fluids:

• Question 1: select Add.

MICHIGAN STATE

UNIVERSI

1. * List category, type, and source of all tissues, blood, and body fluids:

+ Add					
Category	Material	Biocontainment Level	Source	Туре	Used In Animals
There are no it	ems to display				

• Question 2: describe any tissues transplanted between species.

2.	Describe any tissues transplanted between species:	

• Question 3: Describe the quantity of tissues and volumes of fluids to be used.

3. Describe the quantity of tissues and volumes of fluids to be used:



Selecting the Add button displays the following pop-up SmartForm page:

d Biological Material Info	rmation	
1 Catanamu 0		
1. Category: 🚱		•
2. * Material: 😧		
3. * Biocontainm	ent level:	
O BSL-1		
O BSL-2		
O BSL-2+		
O BSL-3		
Clear		
4. * Describe the	use of the mate	rial: 😮
5. * Where are you	l obtaining the m	aterial from?
	, estanlig tie in	
	Leastion	
6. * Usage Room	Location.	
Usage Building	Location:	
eouge Building	Loouton	
7. If storage locati	on is different tha	an usage location, check here
8. Quantity:		
9. Handlers:		
There are no items	to display	
10. * Is material u	and in animala?	
O Yes O No	Clear	
11. * Is material u	sed in humane?	
O Yes O No		
12. * Is material re	combinant or o	(nthetic?
		minetic :
O Yes O No	Clear	

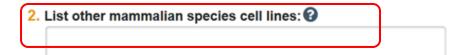


Human Primary Cells or Cell Lines:

- Question 1: select **Add**.
 - 1. * Identify the category and source of all primary cells or cell lines:

+ Add					
Category	Material	Biocontainment Level	Source	Туре	Used In Animals
There are no i	tems to display				

• Question 2: list other mammalian species cell lines.



• Question 3: list other non-mammalian species cell lines.

3. List other non-mammalian species cell lines: 🚱

• Question 4: identify cultures in volumes over 10 liters.



Selecting the Add button displays the 'Add Biological Material Information' pop-up SmartForm page (as previously displayed):





Bacteria, Yeasts, Fungi, or Parasites:

- Question 1: select **Add**.
- Question 2: describe other microorganisms.
 - 1. * Identify microorganisms by category, strain, and source:

	+ Add						
	Category	Material	Biocontainment Level	Strain	Source	Туре	Used In Animals
	There are no iter	ns to display					
2. [Describe other	microorgan	isms: 🕜				

Selecting the Add button displays the 'Add Biological Material Information' pop-up SmartForm page (as previously displayed):

Add Biological Material Information

Viruses or Prions:

- Question 1: select Add.
- Question 2: describe other viruses or prions.

1. * Identify	viruses or prions by strain and	source:				
+ Add						
Material	Biocontainment Level	Strain	Source	Туре	Used In Animals	Activities
There are	no items to display					
2. Describe	other viruses or prions: 🚱					
<u> </u>						

Clicking the Add button displays the 'Add Biological Material Information' pop-up SmartForm page (as previously displayed):

Add Biological Material Information



Toxins, Agricultural Pathogens, or Select Agents:

Note: clicking the link below titled "Select Agents and Toxins Exclusions" directs the user to the (CDC/USDA) Federal Select Agent Program website.

• Question 1: select Add.

List of Select Agents an					
1. * Identify s	elect agents or toxins by so	urce:			
+ Add					
Material	Biocontainment Level	USDA Classification	Source	Туре	Used In Animals
There are n	o items to display				

• Question 2: select appropriate radio button.

2.	Does th	<u>his sub</u>	mission	involve an	excluded	toxin,	agricultural	pathogen,	or agent?)
	O Yes	O No	<u>Clear</u>							

• Question 3: add and upload SOPs.

3.	Upload SOPs: 🕜	
	+ Add	
	Document Name	Date Modified
	There are no items to display	

Clicking the Add button displays the 'Add Biological Material Information' pop-up SmartForm page (as previously displayed):





Add Biological Material Information – Material Selection:

Note: when searching for biological material, if the item is not found in the displayed list, select **Other**.

Add Biological Material Info	ormation	
Add Biological Material Information	(i 🎴 https://clickqa.researchadmin. msu.edu /Safety-QA/sd/Com	monAdministration/Choos 🚥 👽 🏠 🗏
1. Category: 😧	Sciect Biological Agents	Clear Advanced
2. * Material: 🚱	Name	Туре
	Human Derived Blood and Blood Types O Non Human Derived Blood and Blood Types	Blood
3. * Biocontainment level: O BSL-1	O Other O Amniotic Fluid	Blood Body Fluid
O BSL-2 O BSL-2+	Cerebrospinal Fluid Other	Body Fluid
O BSL-3 <u>Clear</u>	O Pericardial Fluid	Body Fluid Body Fluid

Identify the material; provide a detailed summary describing the use of the material.

4. ³	Describe the use of the material: 🕜	

The 'other' material will be added to the biological agents list in a future update (as a selection item).



Biohazards:

In a tabular format, the system displays the items selected in the previous SmartForm pages.

Biohazards

1. Summary of each material, agent, toxin, or microorganism that will be used in this protocol:

Agent	BSL	Туре	Select Agent	Storage Building	Storage Room	Usage Building	Usage Room	Supplier Qty. Handlers E	CXRecombinan	Used in Animals	Used in Humans
Actinobacillus ureae	BSL-1	Bacteria	no	1855 PLACE-BUILDING 1801	1010-WS18	1855 PLACE-BUILDING 1801	1010-WS18	а	no	no	no
Saliva	BSL-1	Body Fluid	no	FEE HALL	317B	FEE HALL	317B		no	no	no
42-MG-BA	BSL-1	Cell Line	no	1855 PLACE-BUILDING 1801	1010-WS13	1855 PLACE-BUILDING 1801	1010-WS13		no	no	no
Adenovirus type 1	BSL-1	Virus	no	1855 PLACE-BUILDING 1801	1010-WS12	1855 PLACE-BUILDING 1801	1010-WS12		no	no	no
African Swine Fever	BSL-1	Virus	yes	1855 PLACE-BUILDING 1801	1010	1855 PLACE-BUILDING 1801	1010	a	no	no	no

2. Provide additional details on any materials, agents, toxins or microorganism indicated above: 🚱



Recombinant or Synthetic Nucleic Acids Usage:

Recombinant or Synthetic Nucleic Acids Usage

1. * Responsibilities as a Principal Investigator NIH brochure:

The NIH requires that every PI read, understand, and comply with this document when working with Recombinant DNA molecules. Have you read and understand your responsibilities as a PI, as outlined in Section IV-B-7-a through e of the NIH Guidelines? O Yes O No

2. * Does research with recombinant or synthetic nucleic acids involve the use of: (select all that apply)

Section III-A	Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation	
Section III-B	Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation	*
Section III-C	Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review (if applicable) Before Research Participant Enrollment	*
Section III-D	Experiments that Require Institutional Biosafety Committee Approval Before Initiation	•
Section III-E	Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation	
Section III-F	Exempt Experiments	•
	A deliberate release of genetically-modified (insertion of recombinant or synthetic nucleic acids) plants or animals into the environment	

A deliberate release of genetically-modified (insertion of recombinant or synthetic nucleic acids) plants or animals into the environment

Breeding of Transgenic Animals

Breeding rodents from one strain (propagation/colony maintenance)	BL1	Exempt (III-F-4)
Breeding rodents from one strain (propagation/colony maintenance)	BL2 or higher	III-D-4-b
Breeding rodents from two strains (generating new strain)	BL1	III-E-3
Breeding rodents from two strains (generating new strain)	BL2 or higher	III-D-4-b
Breeding of transgenic animals other than rodents	BL1	III-D-4
Breeding of transgenic animals other than rodents	BL2 or higher	III-D-4
Breeding of recombinant DNA modified arthropods	BL1	Exempt (III-F-4)
Breeding of recombinant DNA modified arthropods	BL2 or higher	III-D-4-b
Breeding of knockouts (propagation)	BL1	Exempt (III-F-4)
Breeding of knockouts (propagation)	BL2 or higher	III-D-4-b
Breeding of knockouts from two strains (generating new strain)	BL1	III-E-3
Breeding of knockouts from two strains (generating new strain)	BL2 or higher	III-D-4-b

3. Please describe your research objectives including (if question is not applicable to your research, please write N/A):

a. List how and why the recombinant gene inserts are to be used. Please mark all inserts with an asterisk that may pose a specific hazard or risk. Describe the potential hazards (i.e. oncogenes, inhibitory rNA molecules and off target effects):

b. List how and why the host/vector systems to be used in the research (e.g., bacterial expression plasmid closed in lab strains of E.coli, mammalian expression plasmid transfected into cell culture, replication-deficient adenovirus infecting mouse neurons):



Recombinant or Synthetic Nucleic Acids Usage: (continued)

- C. Will the research involve the use of antibiotic selection markers? O Yes O No
- d. Will the research involve the use of plants or animals? O Yes O No
- e. Describe in detail each viral vector to be used. Describe features of the viral vector, if any, that are intended to reduce the likelihood of a recombination event that would lead to a replication-competent vector (e.g., gene deletions, expression of packaging genes on multiple plasmids, self-inactivating long terminal repeats):

f. Describe the risks that would be associated with accidental human exposure to the viral vector, including the probability and consequences of (1) recombination events leading to restoration of a



replication-competent virus, (2) expression of the gene insert product, and (3) integration of the viral vector into the host genome leading to insertional mutagenesis:

2. * Does research with recombinant or synthetic nucleic acids involve the use of: (select all that apply)

Section III-A Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation

Section III-A Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation
 Section III-A-1-a The deliberate transfer of drug resistance into organisms that do not acquire them naturally. (Set by NIH (case by case))

Clicking the associated checkbox will also display the additional information:

2. * Does research with recombinant or synthetic nucleic acids involve the use of: (select all that apply)

Section III-A Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation Section III-A-1-a The deliberate transfer of drug resistance into organisms that do not acquire them naturally. (Set by NIH (case by case))



Recombinant or Synthetic Nucleic Acid Work Description:

1. * Select source(s) of recombinant system(s):

- Purchasing or obtaining a recombinant construct from another source
- Building a recombinant construct

If you are purchasing and building, please select both checkboxes.

2. * Recipient Organism – specify the type; include species, strain, cell line, or cultivar receiving the nucleic acid.

- 3. * Will you express a toxin or oncogene? O Yes O No <u>Clear</u>
- 4. * Will the vector host range be altered? O Yes O No Clear
- 5. * Will the project use infectious DNA/RNA viruses, defective DNA/RNA viruses, or phages in the presence of helper virus in a tissue culture system? O Yes O No Clear
- 6. * Are human or animal pathogens to be used as a host-vector system? O Yes O No <u>Clear</u>
- 7. * Are you using CRISPR or other new technologies not efficiently described in previous questions? O Yes O No <u>Clear</u>
- 8. * Deliberate release of recombinant DNA-modified plants, animals, or other organisms into the environment? O Yes O No <u>Clear</u>



Question 1: when selecting first check box, the system displays field to describe the construct being used.

1. * Select source(s) of recombinant system(s):

- Purchasing or obtaining a recombinant construct from another source
- Building a recombinant construct

+ Add	
Document Name	Date Modified
These are its set to display	

There are no items to display

If you are purchasing and building, please select both checkboxes.

Question 1: when selecting the second check box, the system displays the following:

1. * Select source(s) of recombinant system(s):

- Purchasing or obtaining a recombinant construct from another source
- Building a recombinant construct

If you are purchasing and building, please select both checkboxes.

- i. * Build recombinant system:
 - Host/Recipient
 - Vector/Plasmid
 - Donor/Insert

ii. * What approximate fraction (of the eukaryotic or eukaryotic viral source genome) is the insert?
 O < 1/2
 O >= 1/2

Clear

Both checkboxes may be selected.



Human Gene Transfer/Human Clinical Trial: Approval:

- Question 1: select Add to attach documents relevant to standard operating procedures.
- Question 2: select upload.

1. * Attach all relevant standard operating procedures: (SOPs)

+ Add	
Document Name	Date Modified
There are no items to display	

2. * Attach Investigator Brochure:

[None] 1 Upload



Animals and Arthropods:

1. For research not covered on an IACUC protocol:

i.	i. Identify the species to be used: 🕜								
	1								
	Common Name	Scientific Name	USDA	Species					
	Invertebrates	n/a	no						
ii. Identify the locations where animals are being housed or used:									
	Building	Room Date of Last Inspection	Next Inspection Deadline	Date of Scheduled Inspection					

3. Which of the following present exposure risks to the protocol team members or animal care personnel?

- Aerosols
- Animal bite/scratch
- Bedding
- Blood
- Contact with lesions on the animal
- Feces
- Mucous membrane contact with secretions or excretions
- Penetrating injury from contaminated caging
- Saliva
- Urine
- Other

Note: (Question 1i) Clicking the ellipsis allows for species selection:

Select One or More Species		
Filter by Common Name	•	Go Clear Advanced
	I 4 1-25 of 42 ►	
Common Name	▲ Scientific Name	USDA-Covered Species
Axolotl	Ambystoma mexicanum	no
Anole	Anolis	no
Frog	Anura	no
Arthropods	Arthropoda	no
Rat, Grass	Arvicanthis niloticus	yes



Note: (Question 1ii) Clicking the ellipsis allows for building/room selection, switching to advanced search to locate buildings and rooms.

Select One	e or More Facility I	Roor	m Projects			
Filter by	Building Name	•		Go	Clear	Basic
and	Room Number	•				

Genetically Modified Animals, Arthropods, and Plants:

• Questions 1 – 2: enter text descriptions.

- Questions 3–4: select appropriate radio button.
- Question 5: upload SOP documents, if applicable.

3. * If purchasing or receiving, what is the source of the DNA? (select all that apply)

- Human
 Plant
 Animal/Arthropod
 Microorganism
- 4. * Does this experiment use viruses?

OYes ONo <u>Clear</u>

5. Upload SOP documents here:

+ Add	
Document Name	Date Modified
There are no items to display	



Gene Transfer: Transgenic Strain:

Questions 1 - 3: enter descriptions and select appropriate radio button.

1	 	 	 	

2. Does this protocol involve the alteration of the germ line of the animal or arthropod?

3. How will the DNA be introduced?	

Gene Transfer: Virus:

Question 1: select appropriate radio buttons.

Commercially Purchased Animals/Invertebrates

1. *	Are you using commercially purchased (non-MSU) animals or invertebrates? • Yes O No Clear
	 a. * Do the experiments involve formation of rDNA molecules containing >= 1/2 of the genome of any eukaryotic viruses of the same family? O Yes O No <u>Clear</u>
	 b. * Do the experiments involve the use of infectious human, animal, or invertebrate viruses? O Yes O No <u>Clear</u>
	 C. * Do the experiments involve the use of a defective human, animal, or invertebrate virus in the presence of a helper virus? O Yes O No <u>Clear</u>



Transgenic Plants:

1. * Does your protocol involve the use of transgenic plants?

O Yes O No Clear

Risk Group and Containment Practices:

 * What is the highest risk group level of the biological agents and materials you will use in the proposed research? (If you are unsure about the risk group designation of an agent and/or material please refer to the <u>NIH Guidelines Appendix B</u>.)

0	RG-1
0	RG-2
0	RG-3
0	RG-4
	Clear

2. * What are the highest biosafety containment practices required for the research activities covered by this protocol? (If you are unsure about the required containment practices for your research activities refer to the BMBL or NIH links in each category below.)

(BMBL:			
	Biological Research Standards	Biological Research Involving Animals	Biological Research Involving Arthropods	
	O BSL-1	O ABSL-1	O ACL-1	
	O BSL-2	O ABSL-2	O ACL-1	
	O BSL-2+	O ABSL-2+	O ACL-2	
	O BSL-3	O ABSL-3	Clear	
	<u>Clear</u>	<u>Clear</u>	<u></u>	

<u>NIH Guidelines</u> *rDNA* or synthetic nucleic acids:

- <u>Appendix B</u> Lab Biosafety Levels
- <u>Appendix Q</u> Animal Biosafety Levels
- <u>Appendix P</u> Plant Biosafety Levels
- <u>Appendix K</u> Large-scale Biosafety Levels

Physical Containment	Research Involving Animals	Research Involving Plants	Large-scale Uses of Organisms
O BL-1	O BL1-N	O BL1-P	O BL1-LG
O BL-2	O BL2-N	O BL2-P	O BL2-LG
O BL-3	O BL3-N	O BL3-P	O BL3-LG
<u>Clear</u>	<u>Clear</u>	<u>Clear</u>	<u>Clear</u>



Exposure Assessment and Protective Equipment:

Questions 1 - 2: enter description and select appropriate radio button.

1. * Describe consequences of exp	osure or release of agents used to humans, animals, plants, and the environme	ent:
ι		
2. * Indicate the personal protective	equipment that will be used.	
	equipment and this be abea.	
Eye Protection		
Gloves		
Gowns		
D Twok Course		

- Tyvek Gowns
- Shoe Covers
- RespiratorsOther



Note: (Question 3) selecting Biosafety Cabinet, Autoclave, Eye wash facilities, and Other displays additional data fields. Example:

3.	الـ*	ndicate the engineering controls that will be used:
	~	Biosafety Cabinet
	\checkmark	Autoclave
		Centrifuge with aerosol containment (including sealed safety cups, safety buckets, or sealed rotors)
		HEPA inline filter for vacuum line
		Safety shielding
		Hand wash facilities
	~	Eye wash facilities
	~	Other
		N/A
-		

* If other, specify:			\searrow
* Biosafety cabinet number:			
* Biosafety cabinet room location:			
Biosafety cabinet building location:			
* Biosafety cabinet certification date (month and year):			
* Autoclave number:			
* Autoclave room location:]	
Autoclave building location:			
* Eyewash flush date:]		

4. * Indicate the sharps that will be used:

- Needles with safety feature
- Needles without safety feature
- Plastic Pasteur pipettes
- Glass Pasteur pipettes
- Scalpels with safety blade
- Scalpels without safety blade
- IV tubing with needle
- Hamilton syringes
- Razor blades
- Other
- N/A



Exposure Assessment and Protective Equipment: (continued)

5. * List disinfectants, concentration, and contact time:

	· · · · · · · · · · · · · · · · · · ·		
	Disinfectant	Concentration	Contact Time
There are no items to display			

Note: (Question 5) clicking the 'Add' button displays the following:

5. * List disinfectants, concentration, and contact time:

Disinfectant	Concentration	Contact Time	
•	I		×
+ Add			_

6. * Provide any vaccination recommendations or other medical advice that should be observed for personnel involved in this

research:			
\bigcirc	Hepatitis B		
	Influenza		
	Rabies		
	Other		
	N/A		



Dual Use Research of Concern:

Dual Use Research of Concern (DURC) is life science research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel or national security. For a full discussion of this topic, consult the NSABB website.

1. * Is your research reasonably anticipated to fall under DURC based on current understanding?

O Yes O No Clear

Note: selecting 'Yes' displays the following:

1. * Is your research reasonably anticipated to fall under DURC based on current understanding?

Yes O No <u>Clear</u>

- Enhances the harmful consequences of the agent or toxin

- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
- Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions, or facilitates the agent or toxin's ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin

a. * Comment on aspects of your research with potential for dual use:



Environmental Release Controls:

Questions 1 – 3: select appropriate radio buttons.

1. * How will biohazardous waste be managed for disposal?

Waste Type	Disposal Method
Solid	Autoclaved
Solid	Picked up by EHS
Solid	Other
Liquid	Autoclaved prior to sewer
Liquid	Chemical treatment prior to sewer
Liquid	Picked up by EHS
Liquid	Other
Sharps	Sharps container - Red
Sharps	Pharmaceutical sharps - Black
Sharps	Chemotherapeutic (antineoplastic) sharps - Yellow
Sharps	Other
Tissue	Stored in refrigerator or freezer until picked up by EHS
Tissue	Other
Blood	Tubes are emptied and collected in separate waste container with appropriate label; then picked up by EHS
Blood	Other
N/A	N/A

Questions 1 – 3: select appropriate radio buttons.

2. * Do you agree to the following? O Yes O No Clear

• to follow the biological material spill response procedure outlined during training and as specified on the procedure card within the biological spill kit, and

• to make sure all personnel are aware of the procedure and expected to adhere to it?

3. * Do you have a spill kit? O Yes O No Clear



Biosafety Additional Information:

Questions 1 – 3: select appropriate radio buttons.

1. * Does this research involve shipment or receipt of materials that require an import or interstate transport permit (i.e. CDC import permit, USDA APHIS import permit, USDA APHIS interstate transport permit)?
 O Yes O No Clear

For self-transport of regulated or hazardous biological materials between MSU labs, facilities or non-MSU facilities, please use the Packaging, Containment, Absorbent and Labeling (PCAL) system. https://ehs.msu.edu/lab-clinic/shipping/pcal.html

- 2. * Will you be transporting biological materials or genetically modified materials between lab and other MSU facilities?
- 3. * Will you be transporting biological materials or genetically modified materials between MSU and non-MSU facilities?
- 4. * Does this research involve human subjects? O Yes O No Clear
- 5. * Does this research involve the use of live vertebrate animals? O Yes O No Clear
- 6. * Will this project require a field release registration?

7. * How will exposure incidents be managed by research personnel?

- A agree to follow the exposure incident response procedures located in the MSU Biosafety Manual and the MSU Exposure Control Plan. All personnel will be made aware of the procedure and be expected to adhere to it as it related to this project.
- O This research is being conducted at Grand Rapids Research Complex (GRRC). I agree to follow MSU exposure incident response procedures located in the MSU Biosafety Manual and the MSU Exposure Control Plan and report to security.

O This research is not being conducted at any MSU facility.

O Additional exposure response procedures will be used due to the nature of the proposed research (i.e. BSL-3).

Clear

Note: Question 1 'Yes' radio button selection – page display:

1. * Does this research involve shipment or receipt of materials that require an import or interstate transport permit (i.e. CDC import permit, USDA APHIS import permit, USDA APHIS interstate transport permit)?

Yes ONo <u>Clear</u>

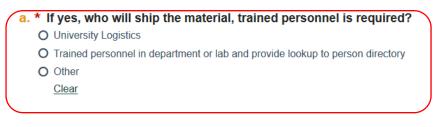
a. * Additionally, all materials must be shipped according to International Air Transportation Authority (IATA) regulations. For shipment of any recombinant DNA materials, you must contact the Biosafety Team at EHS for permit and shipping assistance. Provide the permitting agency and permit number:



Biosafety Additional Information:

Note: Questions 3-6 'Yes' radio button selection – page display:

3. * Will you be transporting biological materials or genetically modified materials between MSU and non-MSU facilities?
Yes O No <u>Clear</u>



4. * Does this research involve human subjects?

• Yes • No <u>Clear</u>

a. Related IRB Protocol(s):							
	+ Add						
	Study ID	Title	PI	Status	Coordinator	Last Date of Approval	
	There are no items to c	lisplay					

5. * Does this research involve the use of live vertebrate animals?

• Yes • No <u>Clear</u>

a. Related IACUC Protocol(s):								
	+ Add							
	Protocol ID	Title	PI	Status	Coordinator	Species	Last Day of Triennial Approval Period	
	There are no item	ns to display	1				,)

6. * Will this project require a field release registration?

• Yes O No Clear

a.	* If yes, upload permit:		
	+ Add		
	Document Name	Date Modified	
	There are no items to display		



Supporting Documents:

Question 1: click the **Add** button to attach or upload documents relevant to the submission (e.g., waste, spill, and/or decontamination management plans, SOPs – documents that will aid in the review of the submission).

1. Attach additional supporting documents: 😮

+ Add	
Document Name	Date Modified
There are no items to display	

Click the **Finish** button.



Note:

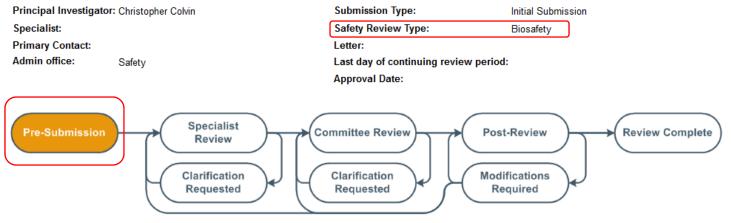
- Selecting Finish will not submit the application; the Submit action on the application workspace still needs to be performed.
- Selecting Finish will exit the SmartForm and return you to the application workspace.
- You can also select Exit to exit the SmartForm and return to the application workspace.



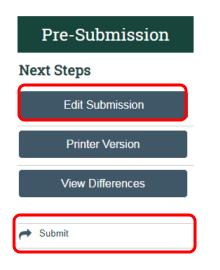
Submission Workspace:

SAFETY0000018

25 July 2018 Biosafety Submission - Demo



The submission may still be edited by the Principal Investigator/applicant or select 'Submit' on the left side menu (application workspace).



Note:

- The Submit action will display on the application workspace only to the PI.
- The **Submit** action is not displayed to team members on the application workspace.



Review the Investigator's Assurance.



Investigator's Assurance

Biosafety:

- I attest that the information contained in the Huron Click submission is accurate and complete.
- I agree to comply with the requirements pertaining to the possession, use, transfer and disposal of all
 regulated biohazardous materials in accordance with all applicable Federal, State and local regulations as
 well as MSU policies and procedures.
- I attest that prior to the onset of research described in this submission, all persons involved shall have site specific safety training that covers the use and disposal of all research materials.
- For my laboratory and any other research locations owned by MSU that I conduct research in, I hereby adopt the MSU EHS Safety Manuals (Biosafety, Bloodborne Exposure Control Plan, Chemical Hygiene, MSU Hazardous waste, MSU Biohazardous Waste, etc.) as the principal safety reference material <u>in</u> <u>combination with site specific safety operating procedures that must be developed by me for the research</u> conducted by myself, lab members and visitors. In addition, for locations not owned by MSU, I will follow the protocols provided by the leased or borrowed space as long as they are not in conflict with MSU policies and procedures.
- Due to Federal, State and Local reporting requirements, I will report any theft, loss, release or exposure to
 any biological research materials <u>immediately</u> to the MSU Biosafety Officer at (517) 355-0153. After
 hours and weekends, will go to the EHS Pager who will contact the Biosafety Officer or designate.
- I understand my responsibilities with regards to laboratory safety and security and certify that the submissions as approved by the IBC are good for the time period established (3 years) and that I will submit an annual assurance document as required by the NIH and MSU.

Click the checkbox indicating statement agreement, add applicable comments and supporting documentation, and click the OK button.

If you have finished filling out your application, click "OK". Afterwards you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

If you are not ready to submit your application. click Cancel

* I agree with the above statement: \Box							
1. Comments:	1. Comments:						
2. Supporting documents:							
+ Add							
Document Name	Date Modified						
There are no items to display							

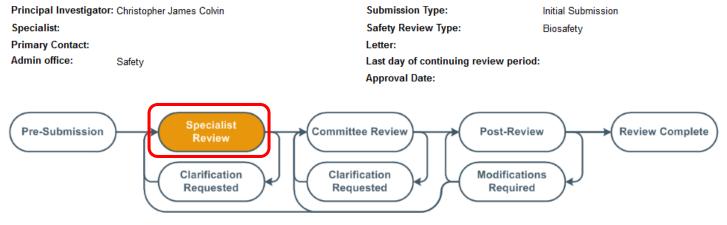




The application has now been submitted to the Biosafety office for review.

SAFETY0000018

Demo - Biosafety Submission



Note:

- The application is now in the Specialist Review state.
- The application is not editable in the Specialist Review state.

