

2019 Biosafety Program Permit and Facility Certification Guide

umanitoba.ca/biosafety

Biosafety.program@umanitoba.ca



2019 New Biosafety Program Permit

As of January 2019, we have combined the BPAC and biosafety permit processes and are implementing the biosafety program permit.

What is a biosafety program permit?

- A biosafety program permit documents a PI's facilities, personnel, equipment and scope of research. The scope of research will be reviewed by the institutional biological safety advisory committee. The review complies with our HPTA licensure requirement of conducting risk assessments on research and is required for the release of Grant and Contract funds for U of M researchers whose project involves work with Risk Group 1-3 biological agents.
- The biosafety program permit will be administered through a questionnaire in the Environmental Health and Safety Assistant (EHSA) Database.

What information does a biosafety program permit include?

- The questionnaire will request information regarding the following:
 - Principal Investigator (Permit-holder) and Alternate contact information
 - Personnel, Facilities and Equipment
 - Site specific training, operating and waste procedures in use
 - Description of the scope of research including objectives, plan and potential hazards
 - Adding and amending grants/contracts (for new funds only, not retroactive)

Facility Certification

From the information provided above, the biosafety program permit will be assigned one of four levels of containment depending on the risk group and containment level requirements for the biological agents intended for use.



CL1/Clinical	CL2 (Unregulated)	CL-2R (Regulated)	CL-2R + RG3
<ul style="list-style-type: none"> • Work with RG1 biological agents • Providing clinical services • Collecting clinical samples from patients or participants 	<ul style="list-style-type: none"> • Work with samples which are not known to be pathogenic • May be contaminated with pathogens • Blood, body fluid, tissues, cell cultures etc. 	<ul style="list-style-type: none"> • <u>Controlled activities</u> • Human and Terrestrial animal pathogens and toxins • Risk group and containment level 2 	<ul style="list-style-type: none"> • <u>Controlled activities</u> • Narrow range of Risk group 3 containment level 2 pathogens

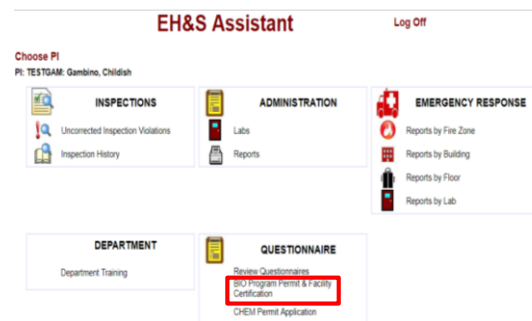
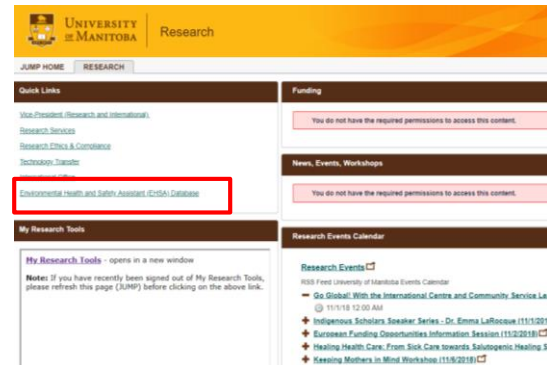
What's different with the biosafety program permit?

- The previous biosafety permit and biosafety project approval certificates (BPAC) processes are now integrated into one. Whether you are adding new personnel to your lab or need to release new research funds, the program permit is designed to include all changes to your bio-agent use lab.
- As well, submissions (BPACs) to release grant/contract funds for each project will no longer be required. As the biosafety program permit will approve a researcher's entire scope of work, any new funds can be released without committee review if the scope of the project falls within their approved research program. If the project includes new biological agents or procedures, it may need to be reviewed by the BSAC committee as an amendment to your program's research scope.
- *Note: The process for external applicants requiring the release of funds will not change.*

Use this guide to assist in filling out the new questionnaire

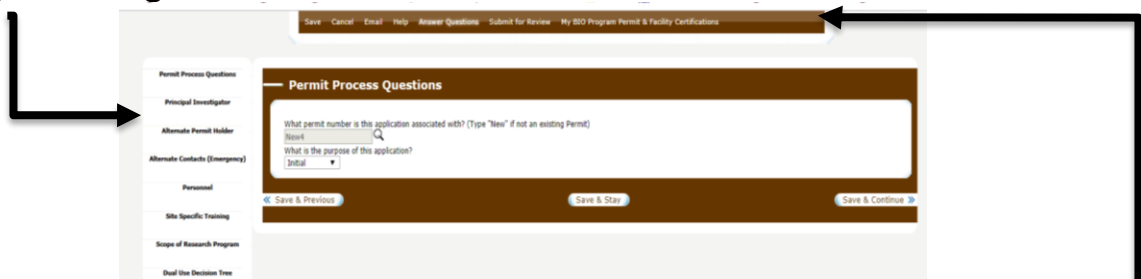
Login to the Environmental Health and Safety Assistant (EHSA) Database to Access the new Questionnaire

- For New Users
 - Contact us at biosafety.program@umanitoba.ca
- For Existing Users
 - Login to EHSA through the University of Manitoba's JUMP portal (umanitoba.ca/jump)
 - Under the Research tab, click on the link to the Environmental Health and Safety Database under the Quick Links Menu
 - Under the Questionnaire Menu, click on BIO Program Permit and Facility Certification to access the new questionnaire
 - Allow the sections for the questionnaire to load (page should refresh and sections will appear)

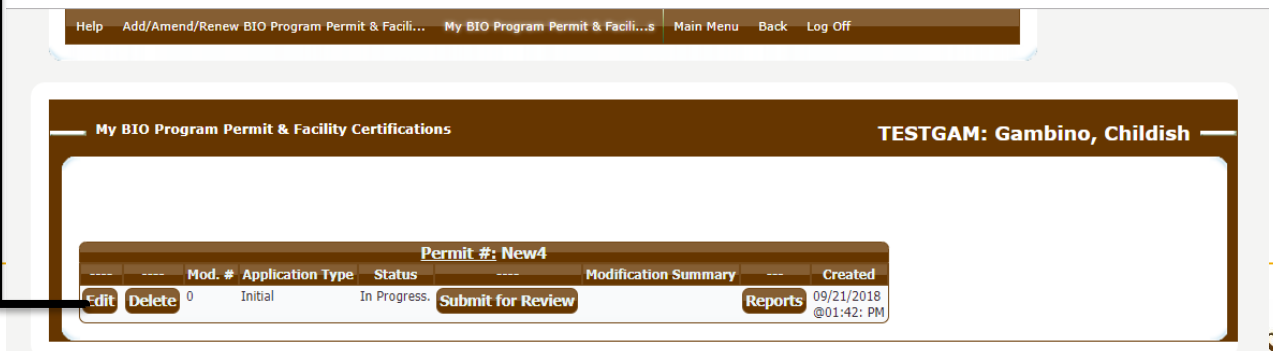


Notes

- **** The server can be slow and time out, for sections that require extensive writing, please write your answers in a word document and copy it into the questionnaire****
- There are 19 sections to complete. You can save your submission at any time by clicking the “Save & Stay” button at the bottom of each section. You can navigate to any section by clicking on the section name on the left hand side menu.



- Required fields will be highlighted in red if not completed once saved
- To exit out of the questionnaire, click on the “My Bio Program Permit....” in the menu at the top of the screen
- Your submission will be saved as a draft and is located in your dashboard. To edit an existing draft, click on edit



****If at any time your browser is slow to load the page, in the browser, Stop loading the page (X in Google Chrome or Firefox) then hit the back button****

- Green checkmarks will appear next to the section on the left hand menu when all questions have been answered.
- If required questions are missing, a red number will appear instead.

Permit Process Questions

- In this section your biosafety permit number will populate as “new” in the permit number field automatically. If you currently hold a biosafety permit, we will link this application to your existing number and going forward your permit number will be in this field.
- Please indicate the purpose of the application using the drop down menu
 - Existing Permit-holders : Select Amendment
 - New Permit-holders: Select Initial

The screenshot shows a web application interface for 'Permit Process Questions'. At the top, a navigation bar includes links for 'Save', 'Cancel', 'Email', 'Help', 'Answer Questions', 'Submit for Review', and 'My BIO Program Permit & Facility Certifications'. On the left, a sidebar menu lists various sections: 'Permit Process Questions' (highlighted), 'Principal Investigator', 'Alternate Permit Holder', 'Alternate Contacts (Emergency)', 'Personnel', 'Site Specific Training', 'Scope of Research Program', 'Dual Use Decision Tree', and 'Facilities'. The main content area is titled 'Permit Process Questions' and contains two input fields: 'What permit number is this application associated with? (Type "New" if not an existing Permit)' with a text input containing 'New4' and a search icon, and 'What is the purpose of this application?' with a dropdown menu showing 'Initial'. At the bottom of the form, there are three buttons: 'Save & Previous', 'Save & Stay', and 'Save & Continue'.

Principal Investigator

- If not already populated, please fill in the requested fields.
- Emergency contact number should be a number that you can be reached outside of office hours. We will not share this number on postings or signage.

Save Cancel Email Help Answer Questions Submit for Review My BIO Program Permit & Facility Certifications

Permit Process Questions

Principal Investigator

Alternate Permit Holder

Alternate Contacts (Emergency)

Personnel

Site Specific Training

Scope of Research Program

Dual Use Decision Tree

Facilities

Procedures in Use

Program-Specific Safe Work Procedures

Safety Equipment

Medical Surveillance

Emergency Response

Decontamination, Sterilization and Waste Disposal

Adding Grants and Contracts

Amending Awarded Grants and Contracts

Principal Investigator

Principal Investigator - Contact Information
Please complete all fields and update any incorrect/out of date information.

Principal Investigator / Responsible Biological Agent Owner Contact Info

Last Name:
Gambino

First Name:
Childish

UM Staff/Employee ID Number:
55555

UMNetID (JumpID):
gambch

Department:
School of Art

Office Location:
123 Georgia

Office Phone Number:
(204) 555-555

Lab Phone Number:
(204) 555-555

Email Address:
donaldglover@atlanta.com

PI Emergency Phone Number:
(204) 555-5555

Save & Previous Save & Stay Save & Continue >>

Alternate Permit Holder

- As noted, use this section to identify an alternate permit-holder
- This person must hold a faculty position. They will not have access to your permit information unless you are not present to oversee your lab operations for >30 days and a responsible authority is required.

Save Cancel Email Help Answer Questions Submit for Review My BIO Program Permit & Facility Certifications

- ✓ Permit Process Questions
- ✓ Principal Investigator
- Alternate Permit Holder**
- Alternate Contacts (Emergency)
- Personnel
- Site Specific Training
- Scope of Research Program
- Dual Use Decision Tree
- Facilities
- Procedures in Use

Alternate Permit Holder

In the event that you, the permit-holder, will be away from your lab for an extended period of time (>30days) please indicate a faculty member who is familiar with your scope of work that would be able to oversee your laboratory operations and permit responsibilities.

Complete/update all fields.

Alt Permit Holder Last Name:

Alt Permit Holder First Name:

Alt Permit Holder Phone Number:

Alt Permit Holder's Email Address:

← Save & Previous
Save & Stay
Save & Continue →

Alternate Contact (Emergency)

- In the event of an emergency and we are not able to reach you, use this section to identify someone who would know the day-to-day activities of what is happening in your lab.
- This person can be staff or students in your lab
- Their personal number will not be shared publically
- Both the permit holder and this identified alternate will be added to our mailing list

Save Cancel Email Help Answer Questions Submit for Review My BIO Program Permit & Facility Certifications

Permit Process Questions
 Principal Investigator
 Alternate Permit Holder
Alternate Contacts (Emergency)
 Personnel
 Site Specific Training
 Scope of Research Program
 Dual Use Decision Tree
 Facilities
 Procedures in Use
 Program-Specific Safe Work Procedures
 Safety Equipment

Alternate Contacts (Emergency)

Emergency Contact Information
 Person to contact in case of an emergency (someone who knows the day-to-day activities of the lab)
 Please answer all questions and update/correct information as needed

Last Name:

First Name:

Emergency Contact's Office Location:

Alternate's Office Phone:

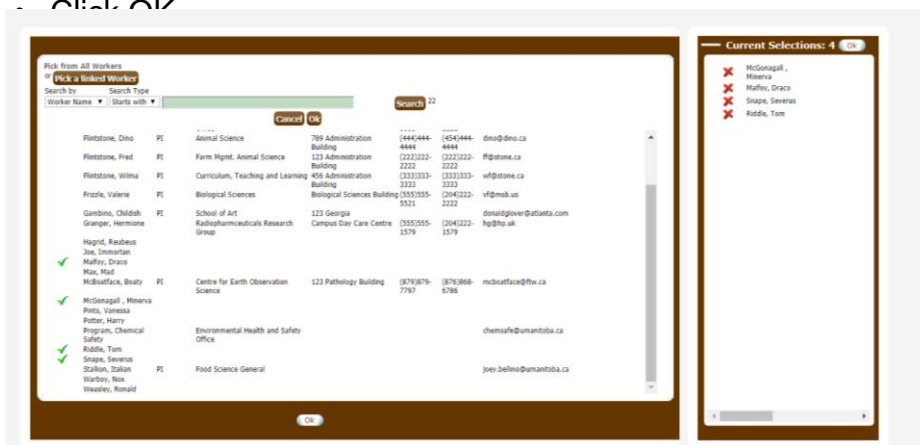
Emergency Contact Email:

Emergency Contact's Emergency (after hours) Number:

Both the permit holder and their indicated alternates will be added to the BioSafety Information distribution email list.

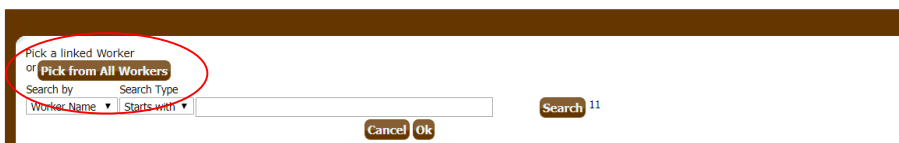
Personnel

- List all personnel who will be working with biological agents in your lab.
- For existing permit-holders, your current personnel list should appear prepopulated into this section if not
 - Click on the Add+ button
 - The resulting screen will show the people already attached to your permit, click on their names. Their names will populate in the right “Current Selections” Menu
 - Click OK



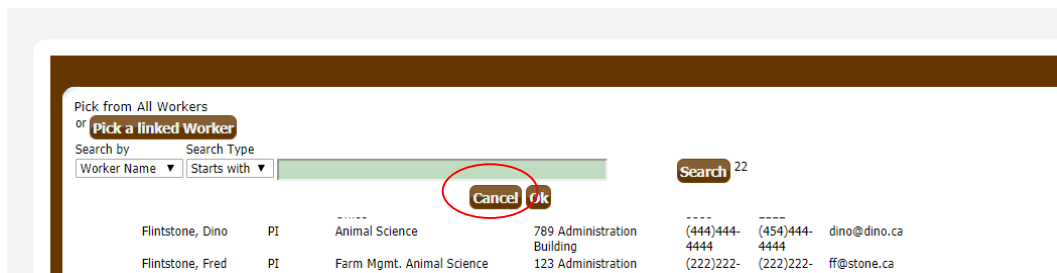
– To add personnel not on your permit:

- Click on Pick from All Workers button and search by last name.
- Click on the person’s name to add them – the list of added names will populate in the right menu.
- Click OK

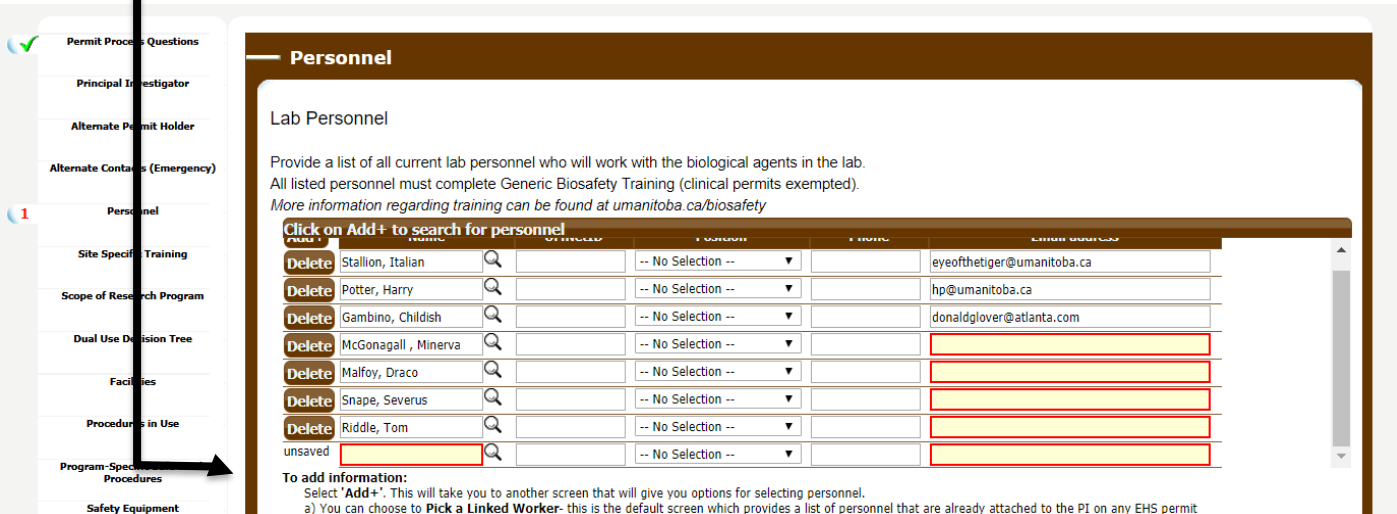


- See next page on how to add personnel who cannot be found in database

To add a person who cannot be found in the database, click Cancel



The previous screen will load with an extra line where you can manually enter their information



Scope of Research Program

- Use lay terms for this section when describing your research program - DO NOT copy the section from grant submissions.

Research objectives:

- In this section, describe your research program in lay terms and LIST specific objectives. Do not include biological agents in this section

For example:

The scope of my research is to identify key proteins and pathways involved in wound healing through accomplishing the following objectives:

1. *Replicate in vivo (wound) environments in vitro.*
2. *Establish knockout Animal model of key proteins identified in Objective 1*
3. *Demonstrate utility of model in objective 1 for clinical applications*

Scope of Research Program Continued

- Research Plan

- In this section indicate how the objectives described in the previous question will be met. Include types of biological agents but NOT by strain (ie indicate that if cells lines are human/animal or established/primary, bacterial/viral genus and species name) Ensure that all these agents are listed as ACTIVE in your inventory.
- For example:
 1. *Replicate in vivo (wound) environments in vitro.*

We will be using established human and animal fibroblast cell lines initially for standardization. Cells will then be cultured on matrices comprised of different biomaterials consisting of different concentrations of collagen and fibronectin. The resulting stiffness of these matrices will be reflective of in vivo environments (soft as fat, hard as bone). We plan to conduct time-lapse experiments where live cells will be visualized by confocal microscopy to determine morphological differences during live cellular growth and extension processes. Cells will also be lysed to determine protein/DNA concentrations or fixed for immunological studies.
 2. *Establish knockout Animal model of key proteins identified in Objective 1*

Through objective 1, we will identify key proteins involved in wound-healing pathways in vitro. We will procure knock-out mice and using primary fibroblasts, will use our standardized system to study these affected pathways.
 3. *Demonstrate utility of model in objective 1 for clinical applications*

Once we have identified key pathways and proteins in objective 1 and have standardized our in vitro environments, we will isolate primary fibroblasts from patient samples. These samples will be provided by a clinical collaborator (external to UM). As described, we will culture these cells and using microscopy, PCR and immunological studies will determine robustness of our system.

Scope of Research Program Continued

- Potential Hazards

- In this section indicate potential hazards posed by the biological agents you are using. Describe these hazards as if no protective measures are in place.

For example:

*Lab staff working with primary cells will be immunized for Hep A/B
To the best of my knowledge no other potential hazards are posed by the biological agents used my scope of work.*

- Core service provider

- If you are providing services to collaborators whether paid/unpaid (such as microscopy, flow cytometry, sample processing etc.) indicate YES and describe the service you are providing

Dual Use Decision Tree

- We are required to assess research for dual use potential. The University of Manitoba has produced [this Standard](#) to identify research that would be considered Dual Use. If your research IS NOT considered dual use potential, select NO
- If it does, select yes and answer the subsequent questions.

Facilities

- Similar to the Personnel question, add all rooms where biological agents will be used AND stored.

Facilities

Facilities

List all rooms and storage locations for biologicals that will be used:

Add+	Building	Lab/Room	Lab Use	Declared Containment Level
Delete	Agriculture Building	100	<input type="checkbox"/> Active Manipulation Space <input type="checkbox"/> Bio Storage	-- No Selection --
Delete	Agriculture Building	103	<input type="checkbox"/> Active Manipulation Space <input type="checkbox"/> Bio Storage	-- No Selection --

To add Room Locations:
 Select 'Add+' This will take you to another screen that will give you options for selecting labs/rooms.
 a) You can choose to **Pick a Linked Lab** - this is the default screen which displays a list of current rooms/labs associated with any of your permits. -OR-
 b) You can select the **Pick from All Labs** tab to see and select from the complete EHSA list of labs.
 For both of these options, when you select a location from a list it displays on the right side of the screen. You can select and delete multiple entries before choosing 'OK' to move the final list to your application

If you can't find your room on any list:
 - Check the Note at the bottom and review your location on the U of M floor plans or Select Cancel. This takes you back to this screen where you can type in your information in the new row.

To Edit the Room Locations List:
 -Any entry marked as 'unsaved' can be deleted by selecting the 'Cancel' button (found at the top of the web-page). Cancelling will delete ALL unsaved entries.
 -If the entry has been saved, select the Delete button for all locations that need to be changed and then select 'Save and Stay'.

Note: Our building lists are based on current Physical Plant maps which can be found on the U of M website.

Save & Previous Save & Stay Save & Continue

Procedures in Use

- Select yes or no to the procedures under the culturing, homogenization and general procedures table
- If you identify the location as both the BSC and Benchtop, identify in the memo box which agents are being used in which location.

Site Specific Training

- EHS provides generic biosafety training however permit-holders are responsible for providing training that is specific to the biohazards in the lab.
- A template for what should be included in a site-specific training document can be found [here](#) (on page 3)
- Click on the “upload site specific training doc” button to upload your training document (see next page)

Save Cancel Email Help Answer Questions Submit for Review My BIO Program Permit & Facility Certifications

Permit Process Questions

Principal Investigator

Alternate Permit Holder

Alternate Contacts (Emergency)

Personnel

Site Specific Training

Scope of Research Program

Dual Use Decision Tree

Site Specific Training

The University of Manitoba provides Generic Biosafety Training for all users working with biological agents, however permit holders are required to provide training specific to the biological agents being used in their program of research (ie site-specific training). We recommend that this training be reviewed annually to ensure information is accurate and that personnel are refreshed when this training is updated. A template of site-specific training can be found on our website (umanitoba.ca/biosafety) under the Biosafety Training Hub.

Upload a synopsis/template of your site-specific training.

Upload Site specific training doc

Review period (eg annually, monthly etc)

Date of last redraft:

<< Save & Previous Save & Stay Save & Continue >>

Decontamination, Sterilization and Waste Disposal

- Click on the Add+ button to attach the autoclave you will be using to dispose of your biowaste. Note: you can search by building/lab or “show all” if you are unsure of the autoclave's serial number by changing the option in the Search By drop down menu.
- Select the autoclaves and click OK when done

Pick an Autoclave

Search by: **Serial Number** Search Type: Starts with

Search ¹

Cancel Ok

Serial Number	Building	Lab	Manufacturer	Model
AUTOTEST	Agricultural and Civil Engineering	104A	Amisco	xyz

Ok

Decontamination, Sterilization and Waste Disposal Continued

- Indicate in the comment box how often validation of the autoclaves is performed
- Decontamination procedures:
 - Indicate how each type of biowaste is decontaminated by selecting yes/no. If your answer is No indicate in the comment section why No was selected.
 - NOTE: Sharps waste includes pipette tips!
 - For Chemical Sterilization: use the comment box to indicate any notes to be reviewed.

Program Specific Safe Work Procedures

- Click on the “add a document” button to upload safe work procedures that are used in your lab.

Safety Equipment

- BSC table
 - Similar to the Facilities and Personnel question, click on the Add+ button and search for BSCs by serial number
- Other Equipment Section
 - Select all equipment that apply and indicate any that are not listed
- PPE Table
 - Select all PPE that are used for each identified event. Use the comment box to indicate any notes to be reviewed.

Medical Surveillance

- Indicate how personnel working with human blood and body fluids are protected against Hep B.
- NOTE: Do not submit records of immunization.

Emergency Response

- Answer the following questions regarding emergency response
- Click on the “Upload PEP” button to upload specific post-exposure procedures that are used in your lab.
- See Section 7 on instructions on how to upload documents.

Adding Grants and Contracts

This section is replacing our current BPAC system. If you are awarded new funds that require biosafety approval to be released, this is where you add these new funds and submit for approval.

- **NOTE:** These are for NEW funds, do not add funds that have already received biosafety approval!
- Click on the Add+ button to add a new row for each fund and fill the respective columns
- SAVE & STAY after filling out each row

Collaborators/Co-investigators and Service Providers:

- Indicate internal collaborators for an attached fund (should be in UMP# pull down menu if you saved after adding your fund in the previous table)
- **NOTE:** Collaborators who are identified here and have a UM Biosafety Program Permit will need to login into their own Program Permit and attach this fund to their Program Permit as well.

Approval for Fund Release

All initial program permits will be reviewed by the institutional biosafety advisory committee on a monthly basis. Researchers working with biological agents will need to submit a program permit even if no funds are associated with the program permit. The committee will review your application to approve your research program's scope of work

If the attached fund fits within your approved scope, the BSO and Chair can approve the release of these funds without committee review.

If the attached fund includes new procedures, biological agents or any other modifications that changes your risk assessment, the amendments will need to undergo committee review

Amending Awarded Grants and Contracts

If your scope of work has changed from the initial approval, use this section to declare these changes if they are tied to a specific fund.

- Changes include
 - new biological agents
 - New procedures
 - New collaborators
- NOTE: if these modifications affect other projects, amend your program's scope of work in the Scope of Research Program Section

Self Inspection

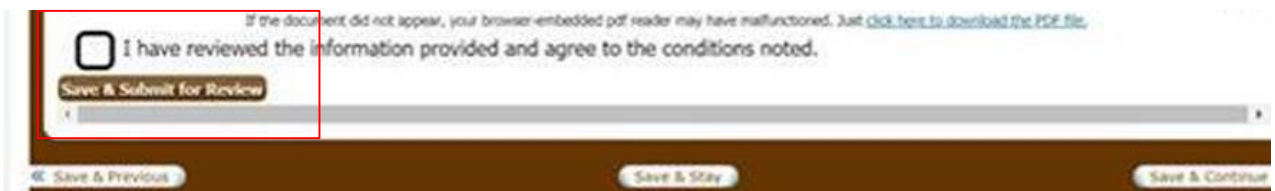
- To confirm if spaces are being used for biological use/storage, we request that a self-inspection report be uploaded to your program permit.
- We will contact you in advance when your self-inspection report is due.

Assurances Section

This page will indicate the conditions that are required for the permit-holder.

A preview of your report will be at the bottom of the conditions.

Select the box to indicate you agree to the conditions and hit the Save and Submit for Review button to submit your application.



If the document did not appear, your browser-embedded pdf reader may have malfunctioned. Just [click here](#) to download the PDF file.

I have reviewed the information provided and agree to the conditions noted.

Save & Submit for Review

Save & Previous Save & Stay Save & Continue

