



DREXEL UNIVERSITY'S INSTITUTIONAL BIOSAFETY COMMITTEE
BIOSAFETY PROTOCOL APPLICATION
Protocol Amendment Form (Form E)

Instructions

- Complete this form at any time to (i) provide information on new personnel to be added to an approved and active biosafety protocol, (ii) indicate personnel who are no longer involved in the project, (iii) indicate a change to the project that deviates from the approved protocol, or (iv) record a change in the location of laboratory facilities.
- This form can be filed with the Drexel University's Institutional Biosafety Committee (IBC) at any time. It will be reviewed by the IBC prior to its approval.
- If you have questions about this form or the application process, please contact us by phone (215-762-7147) or e-mail (biosafety@drexel.edu).

1. PROJECT AND INVESTIGATOR INFORMATION

Protocol Title (as it was approved)

Principal Investigator's Name

2. CHANGE OF PERSONNEL

Do you wish to add new personnel to or remove personnel from the approved protocol? If your answer is **Yes**, please complete this section.

☐ Yes ☐ No

In the following table, provide the names of Drexel University personnel involved in this study (including the Principal Investigator). All personnel must have completed BioRAFT-based laboratory safety training within the last 12 months. Please note that:

- Because the PI is responsible for all biosafety aspects of the project, the PI must complete all relevant laboratory training.
- When entering information in the "Role and tasks" column, be specific as to the major tasks to be performed. For example, a project involving the collection of patient blood samples for cytokine analysis might include "blood collection," "sample processing," and "ELISAs" as tasks.
- The training completion date should be entered in the mm-dd-yy format.
- If the "Shipping Biological Materials" and/or "Recombinant DNA Materials" courses were completed through BioRAFT within the last 12 months, check the appropriate box(es) for each person listed in the table.

To complete laboratory safety training, go to <https://drexel.bioraft.com> and log in using your DrexelOne user ID and password. *(Please note: If you are using MS Word on a PC, you will likely need to copy the link directly into your web browser. This is a MS Word issue with no work-around.)*

<i>Name of investigator, student, or coordinator</i>	<i>Role and tasks to be performed</i>	<i>Date of BioRAFT training</i>	<i>rDNA Course Completed</i>	<i>Biohazard Material Shipping Course Completed</i>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
<i>Name of individuals removed from protocol</i>		<i>Reason for removing this individual</i>		
		Select one		
		Select one		

	Select one
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3. CHANGES TO THE APPROVED PROTOCOL

If you are:

- i. changing or adding a new rDNA molecule, complete the Recombinant DNA Registration Addendum (Form B) and submit with this amendment request;
- ii. changing or adding a chemical carcinogen/mutagen or cytotoxic agent, complete the Hazardous Substance Addendum (Form C) and submit with this amendment request;
- iii. changing or adding the use in animals, complete the Animal Use Addendum (Form D);
- iv. changing or adding a pathogen, complete Section 6 Question a. and Section 7 of the General Biohazard Form (Form A) and submit with this amendment request.

This form may be used for minor protocol changes (e.g., addition of similar pathogens or closely related toxins for which no changes to precautions are necessary, minor procedure changes) which do not:

- i. put any special group of workers (e.g., pregnant, allergic) at greater risk
- ii. require changes to preventive medical services
- iii. require changes to any special post-exposure prophylaxis or medical management
- iii. change decontamination procedures (unless the amendment is to change decontamination procedures)
- iv. add the use of animals
- v. increase the risk group level, laboratory biosafety level, or animal biosafety level

Describe the changes:

Note: The IBC may ask for an addendum form to be completed or a new protocol to be submitted depending on the extent of the proposed changes. For guidance, contact the IBC Coordinator at 215-762-7147 who will direct your inquiry to the Biological Safety Officer, IBC Chair, and/or the Director of Regulatory Compliance as appropriate.

4. CHANGE IN LAB LOCATION

Has there been a change in the location of laboratory facilities associated with this protocol?
If your answer is **Yes**, indicate the new lab location, the reason for the change, and the effective date of the change.

☐ Yes ☐ No

Location (building, room #)	Reason for the change Select one	Effective date of change
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5. ADDITIONAL INFORMATION

Use this text field to provide any additional information pertinent to your work and this biosafety protocol form.

CERTIFICATION BY THE PRINCIPAL INVESTIGATOR

I affirm that, to the best of my knowledge, the information I have provided is complete and accurate. I understand my responsibilities as noted in this form. No changes will be made without prior approval of the Institutional Biosafety Committee.

Signature of Principal Investigator	Date
Signature of Co-Principal Investigator (if applicable)	Date
Name of preparer (if prepared by someone other than the PI)	Position

Once you have completed, printed, and signed this form, scan it and create an Adobe PDF file. Alternatively, convert the completed form directly to an Adobe PDF file and electronically sign the form using the E-signature feature of Adobe Acrobat. Send the completed form by e-mail as an attachment to biosafety@drexel.edu.