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|  | **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 Drexel University’s Institutional Biosafety Committee (IBC) at any time. It will be reviewed by the IBC prior to its approval.* * *This form is not used to register a change in principal investigator (PI) responsible for IBC-approved research. To register a change in PI responsible for IBC-approved research, complete BIOSAFETY PROTOCOL APPLICATION - Change in Principal Investigator Amendment Form (Form G) which can be found on the Biosafety Website:* [*Biosafety | Office of Research & Innovation | Drexel University*](https://drexel.edu/research/compliance/environmental-health-safety/biosafety/) * *If you have questions about this form or the application process, please contact us by e-mail (*[*biosafety@drexel.edu*](mailto:biosafety@drexel.edu)*).* | |

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| 1. PROJECT AND INVESTIGATOR INFORMATION |
| Protocol Title (as it was approved) |
| Principal Investigator’s Name |

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| 2. REASON FOR FILING THIS FORM (check all that apply) |
| Adding or removing laboratory personnel from an IBC-approved protocol (complete section 3) |
| Making changes to an IBC-approved protocol (complete section 4) |
| Changing the laboratory location(s) associated with an IBC-approved protocol (complete section 5) |

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| 3. CHANGE OF PERSONNEL | | | | | | |
| In the following tables, provide the names of Drexel University personnel to be added to and/or removed from this study. All personnel must have completed BioRAFT-based laboratory safety training within the last 12 months. Please note that:   * When entering information in the “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” modules 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, laboratory personnel must go to <https://drexel.bioraft.com> and log in using their DrexelOne user ID and password. | | | | | | |
| *Name(s) of individual(s) to be added to the protocol* | | | | | | |
| *Name of laboratory personnel* | | *Title* | *Tasks to be performed* | *Date of BioRAFT training* | *rDNA Module Completed* | *Biohazard Material Shipping Module Completed* |
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|  | *Name of individuals removed from protocol* | | | *Reason for removing this individual* | | |
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| 4. 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 [biosafety@drexel.edu](mailto:biosafety@drexel.edu) who will direct your inquiry to the Biological Safety Officer and/or the IBC Chair as appropriate. |

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| 5. CHANGE IN LAB LOCATION | | |
| If the location(s) of laboratory facilities associated with this protocol have changed (or will change), indicate the new lab location(s), the reason for the change, and the effective date of the change. | | |
| Location (building, room #) | Reason for the change | Effective date of change |

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| 6. ADDITIONAL INFORMATION |
| Use this text field to provide any additional information pertinent to your work and this biosafety protocol form. |
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| 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 |
| Name of preparer (if prepared by someone other than the PI) | Position |

*SUBMISSION INSTRUCTIONS:*

*Once you have completed this form, convert the completed form directly to an Adobe PDF file and electronically sign the form using the E-signature feature of Adobe Acrobat. Alternatively, print the completed form, add your signature, and scan it to create an Adobe PDF file. . Send the completed form by e-mail as an attachment to* [*biosafety@drexel.edu*](mailto:biosafety@drexel.edu)*.*