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|  | DREXEL UNIVERSITY’S INSTITUTIONAL BIOSAFETY COMMITTEE  **PERIODIC REPORT FORM** |

*Please type all responses. Handwritten responses will be returned to the applicant.*

**PROJECT DETAILS**

**PROJECT INFORMATION**

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| *Project Title (must exactly match grant title if externally funded)* | | | *Sponsor:* |
| *Protocol Number:* | | *Project Number:* | |
| *Initial Approval Date* | *Annual Review Date* | | *Expiration Date* |

**INVESTIGATOR PROFILE**

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| *Principal Investigator:* | *Lab Location:* |

**STUDY STATUS**

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| *Indicate whether your study is:*  *a.*   *Ongoing b.*  *Completed c.*  *Discontinued d.*  *Otherwise ended.* |

**DISPOSITION OF MATERIALS**

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| *If you checked b, c, or d above, then describe the disposition of the biohazardous material:* |

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| **Section I – Biohazard**  ***Please note: all four questions in this section must be answered.*** |
| *1. Are any pathogens in use on this protocol?*  *Yes*  *No*  *If yes, list:* |
| *2. Are any human/primate tissues or body fluids in use?*  *Yes*  *No*  *If yes, list:* |
| *3. Are chemical carcinogens or cytotoxic agents in use on this protocol?*  *Yes*  *No*  *If yes, list:* |
| *4. Are recombinant or synthetic DNA technologies used on this protocol?*  *Yes*  *No*  *If yes, list the rDNA in use and the risk group(s):* |

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| **Section II – Online Safety Training**  **Complete this section** | | | |
| *In the following table, provide the names of Drexel University personnel involved in this study (including the Principal Investigator) and their last date of safety training. 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.* * *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*](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.)* | | | |
| *Personnel* | *Date of BioRAFT Training* | *rDNA Course Completed* | *Biohazard Material Shipping Course Completed* |
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| **Section III – General Questions**  **Complete this section** | | | | | |
| *1. Is there a biological safety cabinet (i.e., tissue culture hood, laminar flow hood) available for use in the laboratory?* | | | | Yes  No  N/A | |
| *Date of last certification* |  | | | | |
| *The biological safety cabinet is used with (check all that apply):* | | | Biologicals  Toxic Chemicals  Radioactive materials | | |
| *2. Is there a chemical fume hood available for use in the laboratory?* | | | | Yes  No  N/A | |
| *Date of last certification* |  | | | | |
| *The chemical fume hood is used with (check all that apply):* | | Biologicals  Toxic Chemicals  Radioactive materials | | | |
| *3. Have you changed location where the work is being performed?* | | | | | Yes  No |
| *If yes, describe.* | | | | | |

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| **Section IV – rDNA, Pathogenic Organisms or Human/Primate Samples**  **(If any of these are used on this protocol, complete this section)** | | |
| *1. Have there been any significant changes in the use of agents listed in the next column?* | a. Hosts  Yes  No  b. Vectors (i.e., plasmids)  Yes  No  c. Cells  Yes  No  d. Tissue  Yes  No  e. Pathogens  Yes  No  f. Recombinant DNA  Yes  No | |
| *If your answer is “yes” to any of (a) to (e) above, describe changes that have been made:* | | |
| *If your answer is “yes’ to (f) above, please complete the Recombinant DNA Registration Addendum (Form B).* | | |
| *2. Are there any special groups of workers in your laboratory at risk of infection or disease from the use of this biohazardous material; e.g. pregnant, immunocompromised, allergic, etc.?* | | Yes  No |
| *Comments:* | | |
| *3a. Is health surveillance of laboratory workers necessary?*  *3a. If yes, is this being performed?* | | Yes  No  Yes  No |
| *Comments:* | | |
| *4. Are there any problems with decontamination or disposal of biohazardous wastes?* | | Yes  No |
| *Comments:* | | |
| *5. Are there any questions or problems or accidents with respect to general laboratory procedures for biohazard containment?* | | Yes  No |
| *Comment:* | | |
| *6. Are all personnel knowledgeable of the emergency plan in the event of spills as outlined in the Lab Safety Manual?* | | Yes  No |
| *Comment:* | | |
| *7. Are adequate spill cleanup materials available?* | | Yes  No |
| *Comment:* | | |
| *8. Have you informed all personnel performing the research of the hazards involved in the research?* | | Yes  No |
| *Comment:* | | |
| *9. Are personnel aware what to do if injured or exposed?* | | Yes  No |
| *Comment:* | | |
| *10a. Are human materials involved?*  *10b. If yes, are Universal Precautions understood and used by all affected personnel?* | | Yes  No  Yes  No |
| *Comment:* | | |

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| **Section V – Chemical Carcinogens and Cytotoxic Agents**  **(If any of these are used on this protocol, complete this section)** | | |
| *1. Have there been any changes in the use of chemical carcinogens and cytotoxic drugs?* | Yes  No | |
| *If Yes, describe:* | | |
| *2. Have you informed all laboratory personnel of the risks associated with these agents?* | Yes  No | |
| *Comment:* | | |
| *3. Is the approved amount of hazardous material in the laboratory appropriate for the nature and length of pertinent experiments?* | Yes  No | |
| *Comment:* | | |
| *4. Are the approved precautions appropriate for the hazardous material understood and in practice by affected laboratory personnel?* | Yes  No | |
| *Comment:* | | |
| *5. Are there any questions or problems with disposal or decontamination of materials?* | Yes  No | |
| *Comment:* | | |
| *6. Are you using any of the Select Agents? (*[*Link to Select Agent list*](https://www.selectagents.gov/SelectAgentsandToxinsList.html)*)* | Yes  No | |
| *Comment:* | | |
| *6. Can your research be considered Dual Use Research of Concern (DURC)? (*[*Link to Policy for Institutional DURC Oversight*](http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) *– see page 9 of PDF.)* | | Yes  No |
| *Comment:* | | |
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| **Section IV – Biohazardous Agents in Animals**  **(If protocol includes administering a biohazard to animals, complete this section)** | |
| *1. Have there been any changes in the use of hazardous agents in animals?* | Yes  No |
| *If Yes, describe:* | |
| 2a. Are laboratory personnel aware of the prophylactic or protective procedures or devices needed for working with hazardous agents in animals?  *2b. Are these in active use?* | Yes  No  Yes  No |
| *Comment:* | |
| *3. Are there any questions or problems with disposal or decontamination of animal materials or animal related materials?* | Yes  No |
| *If yes, describe:* | |
| *4a Are there any special procedures required after an accidental direct exposure?*  *4b. If so, have you informed personnel about these and are they readily available?* | Yes  No  Yes  No |
| *Comment:* | |
| *5. Have animal care personnel been trained in hazards associated with this agent(s)?* | Yes  No |
| *Comment:* | |
| *6. Have there been any laboratory accidents involving biohazardous agents?* | Yes  No |
| *If yes, describe each incident below and state whether it was reported:* | |

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| **Certification of 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 certifies that the principal investigator affirms that this research and the actions of all project personnel involved in conducting the study will conform with the IBC approved protocol and the provisions of the [NIH Guidelines for Research Involving Recombinant DNA](http://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf), the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories Manual](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf), the [Federal Select Agent Program Rule](https://www.selectagents.gov/SelectAgentsandToxinsList.html), and all associated university policies and procedures. | | |
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| *Name of the Principal Investigator (typed):* |  |  |
|  |  |  |
| *Signature:* |  |  |
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| *Date:* |  |  |
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*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*](mailto:biosafety@drexel.edu)*.*