|  |  |
| --- | --- |
|  | **DREXEL UNIVERSITY’S INSTITUTIONAL BIOSAFETY COMMITTEE****BIOSAFETY PROTOCOL APPLICATION****Low-Risk Human Specimens Review Form (Form F)** |
| ***Instructions**** *Complete this form and submit it (and any supporting documentation) to the Institutional Review Board (IRB) with your human subjects research protocol. The IRB analyst will forward this form to the IBC for review. Once this form has been reviewed by the IBC, you will receive an IBC exemption letter indicating the review of these studies has been completed and does not require IBC oversight. If the IBC review determines that IBC oversight is required, a determination notification will be sent with instructions on how to submit a full biosafety protocol application for full committee review.*
* *More than one type of human specimen may be reviewed using the same form. For example, a study involving the collection of blood, urine, and sputum specimens from study participants could be reviewed using a single form.*
* *If you have questions about this form or the application process, please contact us by e-mail (**biosafety@drexel.edu**).*
 |

|  |
| --- |
| 1. PROJECT INFORMATION |
| Study Title (Must exactly match the grant title if externally funded)      | Sponsor      |
| Protocol Identifiers (provide all that apply) |
|  IRB / WIRB #      | IBC Protocol #      | IACUC Protocol #      |

|  |
| --- |
| 2. INVESTIGATOR PROFILE |
| Principal Investigator Name      | Degree      |
| Department       | *Location of Lab(s)*      |
| College or School      |
| Phone Number      | Fax Number      | Pager or Cell Number      |
| E-mail address      |

|  |
| --- |
| 3. SAFETY TRAINING |
| Safety training, as it relates to the study, should be completed in accordance with The Office of Research and Innovation (ORI) eligibility and training requirements (e.g. ORI101-PROCEDURES FOR RESEARCH BLOOD DRAWS for eligibility and training requirements to draw blood.) and Environmental Health and Radiation Safety (EHRS) training requirements (e.g. BioRAFT Laboratory Safety Training). The IBC does not require the assessment of training for low-risk research that involves the collection of human specimens unless it is determined that the study requires IBC registration and review from the full committee. |

|  |
| --- |
| 4. STUDY INFORMATION |
| Answer the following questions about studies involving laboratory analyses or experimentation involving specimens collected from human study participants. |
| a. Describe the specimens to be collected from study participants.  |
|       |
| b. Will the specimens be collected from study participants known or demonstrated to be infected with human pathogens? If your answer is **Yes**, list the pathogen(s). **Note**: All human specimens must be handled using Standard Precautions regardless of the participant pathogen status. | [ ]  Yes [ ]  No |
|       |
| c. Will the specimens be tested after collection for the presence of selected human pathogens? If your answer is **Yes**, list the pathogens to be detected. **Note**: All human specimens must be handled using Standard Precautions regardless of the pathogen testing results. | [ ]  Yes [ ]  No |
|       |
| d. If you answered **Yes** to either question 5b or 5c above, indicate the Risk Groups(s) of the pathogen(s). Human etiologic agents are classified by Risk Group in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (https://osp.od.nih.gov/wp-content/uploads/NIH\_Guidelines.pdf). If you answered **No** to both questions 5a and 5b, select Not Applicable, since no Risk Group can be assigned. |
|  Risk Category (select all that apply): 1 [ ]  \*2 [ ]  Not Applicable [ ]  **\*Note**: The IBC reserves the right to require a full biosafety protocol for studies involving Risk Group 2 agents.  |
| e. Briefly describe the types of analyses or experiments that will be completed with each human-derived specimen. Include the aims of the experiments/analysis. All specimens **must** be handled at Biosafety Level 2. |
|       |
| f. Will Drexel University laboratories be used for specimen analyses or any other laboratory-based aspect of the study (e.g., centrifugation, shipping, analytical procedures)? If your answer is **Yes**, please indicate the locations (building, room number) where this work will be performed. | [ ]  Yes [ ]  No |
|       |

|  |
| --- |
| 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
 |
| * By signing below, I certify that I have read the [Drexel University Laboratory Safety Manual](https://drexel.edu/~/media/Files/facilities/pdf/DU%20-%20Lab%20Safety%20Manual%20-%20112817.ashx?la=en) and agree that my staff and I will abide by it. If there are any changes to the information described above, I understand that it is my responsibility to notify the IBC biosafety@drexel.edu in writing for next steps. I also assure that:
* All personnel have received training regarding the specific study material(s), and it is appropriately documented. All significant or potential exposures to the study material(s) and/or employee injuries will be reported to Drexel University’s Biosafety Officer (BSO), Jon Chase, via email immediately. jc52@drexel.edu or by phone 215-895-5919.
* The Principal Investigator is responsible for rapidly communicating new information to the IBC biosafety@drexel.edu, which strongly suggest that the anticipated safety or biohazard potential of the exempt investigations described above diverge significantly from what was originally anticipated.
* 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:*

*Submit this form (and any supporting documentation) to the Institutional Review Board (IRB) with your human subjects research protocol. IRB analysts will forward this form to the IBC for review. Once this form has been reviewed by the IBC, you will receive an IBC exemption letter indicating the review of these studies has been completed and does not require IBC oversight. If the IBC review determines that IBC oversight is required, a determination notification will be sent with instructions on how to submit a full biosafety protocol application for full committee review.*