DREXEL UNIVERSITY'S INSTITUTIONAL BIOSAFETY COMMITTEE

BIOSAFETY PROTOCOL APPLICATION

Human Specimens Registration Form (Form F)

Instructions

- ***Complete this form if performing laboratory analyses or experimentation involving human study participant specimens.***
- *This form is to be used for Institutional Biosafety Committee (IBC) registration of studies involving human specimens containing Risk Group 1 or 2 human pathogens, or specimens of unknown pathogen status.*
- *Investigations covered by this form will involve the collection, analysis, and/or experimental manipulation of sera, blood products, or other specimens (e.g., stool, urine, sputum and other secretions) derived from human subjects. However, formalin-preserved samples do not require registration.*
- *All activities of this nature performed in Drexel University research laboratories require registration with the IBC, as prescribed by the guidelines of the NIH Office of Biosafety Administration.*
- *In addition, registration is required for activities performed in those Drexel University clinical laboratories that are NOT accredited by the College of American Pathologists (CAP) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).* ***Note****: Tenet clinical labs and some private clinical pathology laboratories are CAP accredited. Therefore, studies involving the use of those laboratory facilities and resources for specimen collection and analyses do not require registration with the IBC.*
- *Submit this form (and any supporting documentation) to the Institutional Review Board (IRB) with your human subjects research protocol. IRB coordinators will forward this form to the IBC for review. Once this form has been reviewed and approved, you will receive an approval letter indicating the registration of these studies.*
- *More than one type of human specimen may be registered using the same form. For example, a study involving the collection of blood, urine, and sputum specimens from study participants could be registered using a single form.*
- *If you are performing experiments involving biohazardous materials or the generation and/or use of recombinant DNA (rDNA),* ***do not use this form****. In such cases, submit a full biosafety protocol application.*
- *If your study involves specimens known to contain Risk Group 3 or 4 organisms,* ***do not use this form****. Studies involving these organisms require a full biosafety protocol application. However, if specimens containing Risk Category 3 or 4 organisms are* ***only*** *being collected for analyses in a College of American Pathologists (CAP) accredited laboratory, this form will be sufficient to register your study with the IBC.*
- *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 INFORMATION		
Study Title (Must exactly match the grant title if externally funded)		Sponsor
Protocol Identifiers (provide all that apply)		
DUCOM IRB / WIRB #	UBSC 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. OTHER PERSONNEL		
a. Role (select one) ☐ Co-Principal Investigator ☐ Study Coordinator ☐ Alternate Contact		
Name		Degree
Department	*Phone Number*	
E-mail address		
b. Role (select one) ☐ Co-Principal Investigator ☐ Study Coordinator ☐ Alternate Contact		
Name		Degree
Department	*Phone Number*	
E-mail address		

4. SAFETY TRAINING

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 "Tasks to be Performed" 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-yyyy format.
- If the "Shipping Biological Materials" course was 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.)*

Name of investigator, student, or coordinator	*Tasks to be performed (e.g., sample collection, processing/shipping)*	*Date of BioRAFT training*	*Biohazard Material Shipping Training*
	PI		☐
			☐
			☐
			☐
			☐
			☐
			☐

5. 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.html#_Toc446948379). If you answered **No** to both questions 5a and 5b, select Not Applicable, since no Risk Group can be assigned.
Risk Category (select one): 1 ☐ *2 ☐ *3 ☐ *4 ☐ Not Applicable ☐ ***Note**: The IBC reserves the right to require a full biosafety protocol for studies involving Risk Group 2 agents. You can use this form for specimens containing Risk Group 3 or 4 organisms **only** if they are being collected solely for analyses in a College of American Pathologists (CAP) accredited laboratory.
e. Describe briefly 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

6. 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 (http://www.drexel.edu/facilities/healthSafety/labSafety/) and agree that my staff and I will abide by it. I understand that a site visit may be part of the approval process. If there are any changes to the protocol, I understand that it is my responsibility to notify the UBSC in writing. I also assure that:

- All personnel have received training regarding the specific study agent. Documentation of this training includes date of training, a training summary, the signature of trainee, and initials or signature of trainer.
- All significant or potential exposures to the study agent will be reported to the UBSC immediately.
- All employee injuries and/or exposures will be reported to the University through the University's Employee Incident Report Form.
- The Principal Investigator is responsible for rapidly communicating new information, a change in study personnel/staff, or data which strongly suggest that the anticipated safety or biohazard potential of the approved investigations 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
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.