Blood Draw/Fluid Collection Protocol

|  |  |
| --- | --- |
| IRBNet Number: | Click here to enter text. |
| Previous IRBNet Number (If applicable): | Click here to enter text. |

# 1: PRINCIPAL INVESTIGATOR INFORMATION

## 1.1. Principal Investigator Information

Principal Investigator: Click here to enter text.

Position/Title: Click here to enter text.

Department/College: Click here to enter text.

Office/Cell Phone #: Click here to enter text.

Email Address: Email address

Credentials: Click here to enter text.

Protocol Title: (for this proposal) Click here to enter text.

Will this project be funded by a grant, contract, or any pending grants or contracts? [ ]  Yes [ ]  No

If yes, please include funding information.

[ ] Internal Funding (provide funding source/grant #): Click here to enter text.

[ ] External Funding (provide funding source/grant #):Click here to enter text.

Please provide the name of your DU Project Administrator in Sponsored Programs:

Click here to enter text.

[ ] Grant Title: (if different from IBC protocol) Click here to enter text.

[ ] Grant Principal Investigator: (if different from protocol)Click here to enter text.

Is this project under review by the IRB?

[ ]  YES, there is an associated IRB protocol. List IRBNet number. Click here to enter text.

[ ]  NO, this research does not require IRB review/approval.

## 1.2. Biological Materials Checklist

1.2.1. Check all that apply to proposed work:

[ ] Sharps

[ ] Human blood, tissue, or bodily fluid.

[ ] Radioactive materials.

[ ] Shipping of biological materials.

[ ] Aerosol generating procedures

[ ] Import/Export to/from US

## 1.3. Research Location(s)

Please list the research activities, building, room number, and the biosafety level for that space and research activity.

### Table 1.3.A. Research Activities

To add additional research activities, click on the **+** at the end of each box.

| RESEARCH ACTIVITIES | BUILDING | ROOM | SHARED ROOM? (YES/NO) | BIOSAFETY LEVEL AND CERTIFICATION DATE |
| --- | --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | Click here to enter text. |

## 1.4. Blood/Fluid Storage

List locations of biological safety equipment (biosafety cabinet, autoclave). Include most recent certification date for biosafety cabinets.

### Table1.4.A. Blood/Fluid Storage

To add additional locations, click on the **+** at the end of the box.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| BUILDING | ROOM | FREEZER | REFRIGERATOR | INCUBATOR | OTHER |
| Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | [ ] Yes [ ]  No | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | [ ] Yes [ ]  No | [ ] Yes [ ]  No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | [ ] Yes [ ]  No | [ ] Yes [ ]  No | [ ] Yes [ ]  No | Click here to enter text. |

### Table 1.4.B. Biological Safety Cabinets

|  |  |  |  |
| --- | --- | --- | --- |
| BIOLOGICAL SAFETY EQUIPMENT USED | BUILDING ROOM | MOST RECENT CERTIFICATION DATE | SERIAL NUMBER |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |       |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |       |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |       |

# 2: Outline of Protocols

## 2.1. Outline of Protocols

2.1.1. Outline the biohazard control plan for biohazardous work.

* Briefly describe the general types of experimental procedures that will be performed.
* Address the potential sources of risk to personnel (aerosol generation, needle sticks, etc.) and/or the environment, and how these risks will be managed.
* Address the potential risks to participants (hematoma, fainting, etc.)
	+ Provide information about who to call and where to go if an adverse reaction were to occur
* Describe safety devices that will be used (e.g. biosafety cabinets, hand washing facilities, puncture resistant sharps containers, etc.)
* Include decontamination/disinfection processes.
* Include plans for disposing of materials.

Click here to enter text.

2.3.2. List any materials of human or mammalian origin (blood, tissues, fluids, etc.)

* Indicate whether each material is certified pathogen free.

Click here to enter text.

# 3: PERSONNEL AND TRAINING

3.1. Please list the PI and other personnel who will be handling blood/fluid.

### Table 3.1.A. Training

To add additional people, click on the **+** at the end of each box.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| NAME | PHONE # | EMAIL ADDRESS | CREDENTIALS | COMPLETED TRAINING | ROLE IN PROJECT |
| Click here to enter text. |       | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |       | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |       | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |       | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. |       | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

3.2. Briefly describe the training plan for lab members who lack experience in handling biological materials below. Include who will lead the training as well as the practices and techniques that will be taught.

Click here to enter text.

3.3. Attach copy of phlebotomist certification and proof of insurance to the IRBNet package.

* If your phlebotomist is a DU Faculty, Staff, or Graduate Student please contact risk@du.edu about coverage through DU’s insurance policy.

# 4. PROCEDURES FOR LABORATORY SAFETY AND EXPERIMENTAL PROCEDURES

## 4.1. Laboratory PPE

I understand University policy requires that PPE must be worn when working with laboratory hazards (chemical, biological, and radioactive materials).

Protocols must also comply with all requirements listed in: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>

At the minimum, this must include:

* Laboratory coats (or other protective clothing such as aprons, scrubs, coveralls, etc.)
* Safety goggles or glasses
* Gloves resistant to the material used
* Appropriate footwear (closed at the heel and toe)

Sandals must not be worn with working in the laboratory. Other protective equipment, such as splash goggles, face shields, aprons, thermal or cut-resistant gloves, hearing protection or respirators, must be worn when conditions dictate.

In a class situation, student shall purchase or obtain the necessary and approved PPE designated by the department or instructor responsible for the course. Students must be trained in the proper usage and care of the PPE.

## 4.2. Special Precautions

Please outline the PPE that will be used and any special precautions, in addition to the PPE and the regulatory guideline requirements, which may be employed in the laboratory for safety and waste handling.

Click here to enter text.

# 5: SENDING OR RECEIVING BIOLOGICAL SAMPLES

If you will be sending or receiving biological samples, please contact the IP/Tech Transfer Office at: 1-4230 or [techtransfer@du.edu](file:///%5C%5Cshares.du.edu%5CDivisions%5CFinancial%20Services-Controller%5CORSP%5CResearch%20Integrity%20%26%20Education%5CIBC-%20Biosafety%20Committee%5CIBC%20Forms%5CIBC%20Main%20Application%5CArchive%5Ctechtransfer%40du.edu). Anyone shipping hazardous materials outside of DU must complete **Shipping and Transport of Regulated Biological Materials (ID: 73305) on the CITI portal.**

Packaging/Marking/Labeling Instructions:

* <https://pe.usps.com/text/pub52/pub52apxc_024.htm>
* <http://www.fedex.com/us/packaging/guides/Clinical_fxcom.pdf>
* <https://www.ups.com/us/en/help-center/packaging-and-supplies/special-care-shipments/hazardous-materials/biological-substances.page>

Will you be:

[ ]  RECEIVING samples from outside of DU? Choose an item.

[ ]  SENDING samples outside of DU? Choose an item.

If either box is selected, please list how the materials will be sent/received.

Click here to enter text.

## 5.1.

What outside organization(s) will be sending or receiving samples?

Click here to enter text.

## 5.2.

What are the samples that will be sent or received?

Click here to enter text.

# 6: PRINCIPAL INVESTIGATOR AGREEMENT

A checked box indicates agreement by the PI for the statement checked.

[ ]  **IBC EDUCATION:** I confirm that all individuals working on this protocol have completed the required CITI Complete Biosafety Training and maintain valid (within 4 years) certification.

[ ]  **EH&S EDUCATION**: I confirm that all individuals working on this protocol have completed the required DU Environmental Health and Safety Laboratory Safety Training.

[ ]  **Occupational Health and Safety:** I confirm that all individuals listed on this protocol as working with biological hazards have completed the **[Occupational Health Review Form](https://www.du.edu/orsp/research-compliance/biosafety/forms-templates.html)** or will be required to do so before being permitted to begin work in the lab.

[ ]  **CONTAINMENT BREACH**: I will immediately report any biological hazard spills to the DU Chemical & Hazardous Materials Manager in EHS and document spills in my Annual Report to the IBC.

[ ]  **AMENDMENTS:** I will submit an amended application and receive IBC approval prior to instituting any changes in the biological materials used in the project as described in the approved application or adding new research personnel.

[ ]  **TRAINING:** I will keep written and organized documentation of training sessions in my lab and make this documentation available to the IBC during periodic inspections and/or audits. For BSL2 and above, I (or a designated lab member) will train project personnel involved in work using biological hazards above BSL1.

[ ]  **CONTINUING REVIEW:** I will complete an annual Post Approval Monitoring (PAM) meeting with the IBC Administrator each year during the first, second, third and fourth year anniversary month of the date of approval.

[ ]  **FINAL REPORT:** I will notify the IBC when the study is complete either by completing a Final Report Form when the work is complete or at the five-year anniversary from the date of approval, whichever comes first.

[ ]  I authorize individuals listed on this application to conduct procedures involving biological materials and I accept responsibility for their oversight in the conduct of this proposal.