|  |  |  |
| --- | --- | --- |
|

|  |
| --- |
|  **TEMPLE UNIVERSITY** **Office of the Vice President for Research**  **Research Compliance** **Institutional Biosafety Committee**  |

  **BIOSAFETY REGISTRATION FORM** **for select clinical trial protocols** **that do NOT involve the use of recombinant DNA** *(for any research that involves collection, use and/or storage of human blood* *and other potentially infectious materials*)[**http://research.temple.edu/institutional-biosafety-forms-standard-operating-procedures**](http://research.temple.edu/institutional-biosafety-forms-standard-operating-procedures)Please complete the form. Follow all instructions. Email to: ibc@temple.edu IBC office: 215-707-9741 | COMMITTEE USE ONLY |
| IBC REGISTRATION #       |
| ASSOCIATED IRB#       |
| APPROVAL DATE      **EXPIRATION DATE**       |
| 1. PERSONNEL |
| 1a. PRINCIPAL INVESTIGATOR |
| 1. Name, Degree(s)

      | (2) Job Title       | (3) Office Phone       |  (4) Cell/pager      |
| (5) School/College/Center/Department and section (if applicable)      | (6) Fax:      |
| (7) Interoffice Address:      | (8) e-mail address       | (9) TU/TUHS ID#      |
| 1b. LIST ALL OTHER PERSONNEL DIRECTLY INVOLVED IN THIS PROJECT |
| NAME | PROJECT POSITION(S) | TUID # | PHONE |
| (1)       |        |       |       |
| (2)       |       |       |         |
| (3)       |        |       |       |
| (4)       |        |       |       |
| (5)       |         |       |       |
| (6)       |        |       |        |
| 2. GENERAL |
| 2a. FUNDING SOURCE (check only one) |
| [ ]  Funded internally with departmental funds. FOAPAL No:       [ ]  Funded externally by:       Grant contract No: Program officer (name, email):       |
| 2b. PROJECT TITLE |
|       |
| 2c. DOES THE RESEARCH INVOLVE~~S:~~ |
| Human Subjects Yes:       IRB #:       Approval Date:       | No:        |
| **Human Fetal Tissue Yes:       No:** HumanEmbryonic Stem Cells Yes:       No:        |
| 2d. MATERIAL TRANSFER AGREEMENT (MTA) |
| The protocol will be involved with MTA. Yes:       MTA number:       No:        |
| 2e. FLOW CYTOMETRY  |
| The protocol will be involved with flow cytometry. Yes       Please provide [hazard assessment form](https://medicine.temple.edu/research/facilities-and-services/flow-cytometry-core/forms-and-resources). No:       *If check yes, please include flow cytometry procedure at section 4.*  |

**3. EXPERIMENTAL AGENTS AND PROCEDURES**

|  |  |
| --- | --- |
| **3a.** | Are you using rDNA in this protocol?Yes:       No:      *If yes, please submit regular BRF form to IBC Office* |
| **3b**. List human tissue, diagnostic samples and/or other potentially infectious materials (OPIM): |
| Blood       | Unfixed Tissue       | Feces       | Urine       |
| Semen       | Vaginal Secretions       | Spinal Fluid       | Any Body Fluid Contaminated with Blood       |
|  |

|  |  |
| --- | --- |
| **3c.** | List the source of the human material (or confirm that the material will be collected only at Temple University Hospital) |
|  |

|  |  |
| --- | --- |
| **3d.** | Is human material tested for presence any bloodborne pathogens or SARS-CoV-2?Yes:       No:       |
| **3e**. Is the human material to be sent offsite for processing and/or analyzing? Yes:       No:       *If yes, provide the name(s) of the institution(s) and complete DOT required Shipping Dangerous Goods training provided by EHRS* |
|  |
| **3f**. Brief description of the experimental procedures and the purpose of the project *(limit the description of the purpose of the study to 3-4 sentences. For the procedures simply provide information regarding the basic laboratory work that will be carried out AT TEMPLE UNIVERSITY. For example, blood will be processed for the isolation of plasma; blood will be inoculated into tubes for the preservation of DNA; or urine will be aliquoted and stored at -80C for eventual shipment to the central processing laboratory)* |
|  |

|  |  |
| --- | --- |
| **3g.** | Frequency of human material processing:Daily       Weekly       Other       |

|  |  |
| --- | --- |
|  |  |

**4. RESEARCH LABORATORIES LOCATIONS**

*List agent, location (including another PI’s lab), what’s being done with the human material in that particular location, and your assessment of the necessary biological containment. Expand table as necessary.*

*(be sure to list where you STORE your human material)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| HUMAN BIOLOGICAL MATERIAL USED OR STORED *(human unfixed tissue, blood, feces, urine, semen, vaginal secretions, diagnostic samples or body fluid contaminated with blood)* | BUILDING and ROOM NUMBER | GENERAL TASKS PERFORMED WITH HUMAN BIOLOGICAL MATERIAL IN A PARTICULAR ROOM *(sample collection, centrifugation, sonication, pipetting, blending/mixing, dissection, storage, etc.)* | BIOSAFETY LEVEL *(based on risk assessment)* | BIOSAFETY CABINET (BSC) |
| *Type* | *Certification date* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**5. LAB PERSONNEL**

|  |
| --- |
| **5a.** List the individual(s) who are collecting human material |
|  |

|  |
| --- |
| **5b**. List the lab workers who are transporting human material between collection site(s) and research laboratories, and/or storage locations |
|  |

|  |
| --- |
| **5c.** List the lab workers who are processing and or analyzing human material |
|  |

|  |
| --- |
| **5d.** List the lab workers who are shipping or transporting human material |
|  |

**5e.** Safety training (dates should be provided for the PI and personnel listed above in section 1b) The records of the training can be retrieved from [TUeRA](https://era.temple.edu/tu_login/login.asp)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | AIRBORNE PATHOGENS  | BLOODBORNE PATHOGENS | BIOSAFETY  | **BIOHAZARDOUS WASTE** | SHIPPING OF DANGEROUS GOODS |
| (PI) |       |       |       |       |       |
| (1) |       |       |       |       |       |
| (2) |       |       |       |       |       |
| (3) |       |       |       |       |       |
| (4) |       |       |       |       |       |
| (5) |       |       |       |       |       |
| (6) |       |       |       |       |       |

**5f.** Occupational health requirement

|  |  |
| --- | --- |
| (1) | Are there any special groups of workers at risk of infection or disease from the use of the biohazard(s) (e.g. pregnant, immuno-compromised, allergic, etc.)? [ ]  Yes [ ]  NoIf yes, describe below.      |
| (2) | Are any special immunizations necessary for personnel involved in the research (e.g. Hepatitis B,Tetanus/Tdap, COVID-19 etc.)? [ ]  Yes [ ]  NoIf yes, describe below.       |
| (3) | Is there a need to monitor the health of personnel involved (e.g. testing)? [ ]  Yes [ ]  No If yes, describe. *Contact Employee/Occupational Health if you are uncertain.*      |
| 6. ASSURANCE |
| 6a. PRINCIPAL INVESTIGATOR |
| I certify the information provided in the *Biosafety Registration* form is complete and accurate and understand my responsibilities as noted in it. No changes will be made without advance approval form the Institutional Biosafety committee.I acknowledge my responsibility for the safe conduct of this research. I will inform all associated personnel of the nature and risks of this work, as well as necessary precautions and safe practices. I also agree to comply with the requirements for the shipment and transfer of human source materials.I further acknowledge my responsibility to ensure compliance with the following:(1) Work surfaces will be appropriately decontaminated at least daily and immediately after working with biohazardous materials.(2) All contaminated materials will be discarded appropriately according to Environmental Health & Radiation Safety (EHRS) guidelines (e.g. as Biohazard Waste).(3) EHRS and the Institutional Biosafety Committee will be immediately notified of all spills or incidents that may occur associated with this biosafety level 2 experiment.(4) In the event of an incident where there is a risk of infection or other consequences to incident, affected personnel will be counseled to seek appropriated medical attention. |
| SIGNATURE OF PRINCIPAL INVESTIGATOR | DATE |
| 6b. CO-INVESTIGATOR(S)I certify that I have reviewed this Biosafety Registration form and that the information provided in it is complete and accurate. |
| SIGNATURE OF CO- INVESTIGATOR  | DATE |
| SIGNATURE OF CO- INVESTIGATOR  | DATE |
| 6c. PI’S DEPARTMENT CHAIRPERSON, DEAN, OR DEAN’S DESIGNEEIn addition to endorsing the PI’s certification, if the experiments are supported primarily by department or university funds, I certify that I have reviewed the protocol and it is judged to be of scientific merit. |
| PRINT NAME      |
| SIGNATURE OF PI’S DEPARTMENT CHAIRPERSON, DEAN, OR DEAN’S DESIGNEE | DATE |