

 **Institutional Biosafety Committee**

**BIOSAFETY REGISTRATION FORM:**

**For Collection of Human Blood, Blood Products, Bodily Fluids, and Tissue**

(For registration of human tissue collections being done on campus. NOT for the use/processing of collected specimens)

Administered by:

UNE Office of Research Integrity

Pickus 106

11 Hills Beach Road

Biddeford, ME 04005

 ***If you have any questions or need assistance with the UNE IBC process, please contact the IBC directly at*** ***ibc@une.edu******, or via phone at 207-602-2117.***

**Instructions**

Please complete this application for an initial submission to the IBC if you plan on using any human tissue or bodily fluid as, a part of your research, teaching, or testing activities at UNE. DO NOT leave any questions blank in required sections. If you currently have an IBC protocol on file and need to make changes to that protocol or submit the required annual review, please submit the **Modification/Annual Review/Completion Form.**

**Important Information**

**Training of Principal Investigators & Research Personnel**: All principal investigators, co-investigators, and any/all research personnel must complete the required CITI OSHA Blood Borne Pathogen Training. Please provide a copy of your completion certificate along with this application.

**Investigators**: The [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) state that the Principal Investigator of an IBC project is responsible:

* For ensuring that the laboratory staff are appropriately trained (*Section IV-B-1-h*);
* For full compliance of the conduct of the IBC research (*Section IV-B-7*); and
* For the supervision of safety performance by laboratory staff (*Section IV-B-7*).

Please note that correspondence from the IBC will be directed to the Principal Investigator as the recognized individual responsible for the research, and not to co-investigators or other lab personnel. However, a co-investigator may be listed as the alternate contact if preferred.

**IF you intend to process the collected materials on campus, in any way, you must complete a protocol and submit to the IBC.** This form is intended for registration of human tissue collections being done on campus.

***If you have any questions or need assistance with the UNE IBC process, please contact the IBC directly at*** ***ibc@une.edu******, or via phone at 207-602-2117.***

**Application Form**

1) Complete and submit the application via email attachment to the IBC at ibc@une.edu.

2) Attach Blackboard Certificates of Completion for each individual listed on the protocol submission.

Please fill in the appropriate information if this application is being submitted in conjunction with an IACUC, IRB, or RSC application. If the application is pending, list the date submitted:

IACUC Application (animal subjects) Yes [ ]  Protocol #\*:  Date Submitted:

IRB Application (human subjects) Yes [ ]  Protocol #\*:       Date Submitted:

RSC Application (radioactive materials) Yes [ ]  Protocol #\*:       Date Submitted:

\*Please fill in N/A if no protocol # has been assigned

***NOTE****: As long as an existing or pending IACUC application covers work to be performed, animals may be ordered once the UNE IBC has confirmed receipt of your IBC Application; you do not need an official approval letter prior to ordering these animals. However, you may not receive animals at the institution until you have an approval/exemption letter from both the IACUC and IBC for the work to be performed.*

1. Title of Project:

2. Contact Information:

Name of Principal Investigator (PI):

Phone #:

Email Address:

Campus Mailing Address:

Project Campus Location:

Name of Co-Principal Investigator (co-PI):

Phone #:

Email Address:

Campus Email Address:

Is Co-PI from outside institution? Yes [ ]  No[ ]

Project Start Date:       Project End Date:

3. Is this project funded? Yes [ ]  (list funding source below) No[ ]

4. List all personnel involved in the project and their respective roles in the research\*

|  |  |  |
| --- | --- | --- |
| Student/ PI(s) Name, or Individuals Authorized to Conduct Procedures 🡫 | Procedure(s) to be performed  | Training received |
|       |       |       |
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*\*Please attach CITI Certificates of Completion for all investigators and personnel listed above.*

5. The proposed protocol involves (check all that apply):

 [ ]  Human Blood

 [ ]  Saliva

 [ ]  Urine

 [ ]  Tissue

 [ ]  Other (Specify)

6. A consult with the University Biosafety Officer, Ronnie Souza, is required, please provide date of consult:

7. Will the sample be previously collected or actively collected as a part of this project?

Previously Collected [ ]  Where?

Actively Collected [ ]

8. If the sample will be actively collected, who will be collecting the sample?

 [ ]  Phlebotomist [ ]  Nurse [ ]  MD

IF other, please explain:

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|       |

9. If blood will be collected, how will it be collected?

 [ ]  Vacutainer [ ]  Butterfly [ ]  Fingerstick

10. Where will samples be stored?

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11. How will you transport the samples from collection site to storage site?

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12. How long will the samples be stored:

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13. Do you inactivate the material prior to other laboratory manipulations? [ ]  Yes [ ]  No

 Methods used: [ ]  Heat [ ]  Chemical [ ]  Radiation [ ]  Other:

14. Do you concentrate the material prior to other laboratory manipulation? [ ]  Yes [ ]  No

 Methods used: [ ]  Centrifuge [ ]  Filtration [ ]  Precipitation [ ]  Other:

 15. Will you be conducting laboratory manipulations with this material? [ ]  Yes [ ]  No

 If no, please list facility that will be receiving the materials for laboratory manipulations:

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16. Are you using standard precautions used for BSL2 work? [ ]  Yes [ ]  No\*

 *\* If* ***NO****, please explain why you are not and what precautions used for BSL2 work.*

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17. How will you dispose of the samples?

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18. Please list and/or describe all current training (beyond completion of required IBC CITI training) relevant to the proposed work that will support IBC approval of research activities with the materials described. Specifically, identify trainings such as Chemical Hygiene, BloodBorne Pathogens, general laboratory safety, relevant IACUC trainings, etc.

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| **19.** Provide facilities information for ALL locations, including the facility used for work with human tissue/fluid samples: \*Work at the BSL2 level or higher requires the approval of EH & S. |
|  | **Location #1** | **Location #2** | **Location #3** |
| **Building & Room #** |  |       |       |
| **Describe procedures for this location** |  |       |       |
| **Provide approved biosafety level** |  |       |       |

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| 20. Please check all of the personal protective clothing & equipment to be used by personnel in the above facilities:  |
| [ ]  Eye/face protection [ ]  Head cover[ ]  Show covers[ ]  Gloves[ ]  Double gloves | [ ]  Lab coat[ ]  Tyveks/disposable gowns[ ]  Surgical scrubs[ ]  Automatic pipettors [ ]  Safety centrifuge/blender/grinder | [ ]  N95 particulate respirator\*[ ]  PAPR (HEPA) respirator\*[ ]  Other (please indicate):       |

\* Use of respirators requires fit testing through EH&S. Please contact them to schedule an appointment.

**Assurance Page**

I agree to conduct this research in accordance with the compliance policies of the University of New England Institutional Biosafety Committee, including all requisite training of students, staff, and other professionals participating in this research.

1. I have consulted **Section IV-B-7** of the[*NIH Guidelines*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) describing the responsibilities of the Principal Investigator and hereby agree to comply fully with all provisions of the [*NIH Guidelines*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html).
2. I understand I am responsible for assuring that my research facilities are in compliance with local, state and federal environmental laws and regulations.
3. I understand that I am responsible for the proper conduct of any research by laboratory personnel that are directly related to this protocol application
4. I understand that all changes in the research protocol or research participants must be reported to the IBC Office.
5. The information within this application is accurate to the best of my knowledge.
6. I understand that yearly reporting is required for continuing approved research on all non-exempt protocols.
7. I understand that all non-exempt protocols must be resubmitted for committee review after a term of three years.

**It is the Principal Investigator’s responsibility to ensure that all personnel involved in this study are appropriately trained, and are provided the equipment necessary to perform at the designated biosafety containment level.**

**NOTE**: EHS in conjunction with IBC reserves the right to conduct inspections of research facilities at any time.

Principal Investigator’s name typed:

Principal Investigator’s signature

**1) Complete and submit the application via email attachment to the IBC at** **ibc@une.edu****.**

**2) Attach CITI Certificates of Completion for each individual listed on the protocol submission.**

**3) Provide a scanned or pdf file of the signed Assurance page with original signatures to the IBC at** **ibc@une.com****.**