|  |
| --- |
| **EHSS Use Only** |
| **Protocol Number** |  |
| **Biosafety Level** |  |
| **IBC Review Required** | **Yes** [ ]  **No** [ ]  |
| **Date Approved** |  |
| **Approved By** |  |
| **Renewal Date** |  |

INSTRUCTIONS: Complete the gray fields below. Advance to the next field by using the mouse or the arrows in the keypad (up, down, left, or right). Avoid using “Tab” throughout this document.

**Biohazardous Material Use Amendment Form**

This form is designed to assist Principal Investigators (PIs) with modifications to their Institutional Biosafety Committee (IBC) approved protocols. The IBC may request that the PI submit a new application for approval dependent upon the proposed modification(s). No work involving proposed modification(s) may begin until the PI receives approval from the IBC.

**Protocol Title:**

**Current IBC Protocol Number:**

**Date:**

**Section 1. Contact Information**

|  |  |
| --- | --- |
| **Principal Investigator**  |  |
| **Department** |  |
| **Email** |  |
| **Phone** |  |
| If an individual is completing this application on behalf of the Principal Investigator, complete the information below. |
| **Name** |  |
| **Role/Title** |  |
| **Email** |  |

**Section 2. Amendment Purpose**

1. Which of the following are applicable to this protocol?

|  |  |
| --- | --- |
|  [ ]  | ADDITION OF |
| [ ]  | Lab Personnel |
| [ ]  | Work, Storage, or Analysis Location(s) |
| [ ]  | Biohazardous Material |
| [ ]  | Procedure |

|  |  |
| --- | --- |
| [ ]  | OTHER |
| [ ]  | Other:  |

**Section 3. Protocol Modifications**

1. **Thoroughly describe the proposed modification(s) to be applied to the protocol. Provide sufficient information to determine if this modification(s) changes the hazard potential of the current IBC approved protocol.**

**Section 4. Rationale**

1. **Provide a rationale for the proposed modification(s). If adding biohazardous materials, describe why new material(s) was chosen and why it must be used.**

# **Section 5. Addition of Lab Personnel [ ]  Not Applicable**

1. Provide a list of lab personnel added to this amendment.

|  |  |  |
| --- | --- | --- |
| Name | SUID | Role |
|       |       |  |
|       |       |  |
|       |       |  |

Note: To add more rows, click in the cell that is farthest to the right in the bottom row, a small plus (+) symbol will appear. Click on the plus (+) at the bottom right corner of the table to add an additional row. Repeat steps as necessary.

2. The laboratory will implement the following procedures to ensure laboratory personnel are trained prior to working with biohazardous materials (select all that apply):

[ ]  Initial EHSS [biosafety training](https://its-forms.syr.edu/frevvo/web/tn/SUFS/u/356b3aac-4b02-456e-9751-952ba64d7f48/app/_uujYAGwwEeWxmM5q6-jqow/formtype/_58HMcNujEeic_sT0ysp2EQ/popupform?_gl=1*12jyil9*_ga*MjAxNDk0MzA1OS4xNjQ4NDgzNzM3*_ga_QT13NN6N9S*MTY5NDU0MTg2Ny4zNjQuMS4xNjk0NTQxOTk2LjUyLjAuMA..) will be completed by all lab personnel prior to working with biohazardous materials.

[ ]  EHSS biosafety refresher training will be completed on an annual basis by all lab personnel working with biohazardous materials.

[ ]  The PI will provide in-lab training on the SOP(s) associated with this protocol to all lab personnel working with biohazardous materials.

# **Section 6. Addition of Work, Storage, or Analysis Locations [ ]  Not Applicable**

1. Provide the locations (building and room number) for the following: primary work location, biosafety cabinet location, storage, and analysis for the type of biohazardous materials used.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Room Use  | Building(s) and Room Number(s) | Type of Biohazardous Materials Used | Additional Biohazardous Materials Used | **EHSS USE ONLY****Biosafety Level** |
| Primary Work Location(s) |       |  |  |  |
| Biosafety Cabinet Location(s) |       |  |  |  |
| Storage Area(s) |       |  |  |  |
| Analysis Room(s) |       |  |  |  |
|       |       |  |  |  |

Note:

(1) To add more rows, click in the cell that is farthest to the right in the bottom row, a small plus (+) symbol will appear. Click on the plus (+) at the bottom right corner of the table to add an additional row. Repeat steps as necessary.

(2) An additional document may be included at the end of this protocol as an Excel spreadsheet, a floor plan, a map, etc. to describe where all biohazardous materials are used, stored, and/or analyzed, if preferred.

# **Section 7. Addition of Biohazardous Materials [ ]  Not Applicable**

1. Which of the following are applicable to this amendment?

|  |  |
| --- | --- |
| [ ]  | Recombinant or synthetic nucleic acid molecules  |
| [ ]  | Microorganisms (bacteria, parasites, fungi, live virus, etc.) |
| [ ]  | Established cell lines, primary cells, or stem cells  |
| [ ]  | Non-human derived materials (fluids, tissues, organs, bones, etc.) |
| [ ]  | Human derived materials (fluids, tissues, organs, bones, etc.) |

2. **Biohazardous Material Information.** Provide the information associated with each material(s) added to this protocol.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type and Source of Material | Name of Strain or Cell Line | Manufacturer(Vendor/Collaborator) and Product Number | Biosafety Level | Largest Scale and Units (anticipated) |
| EXAMPLE: Bacterial strain | *Escherichia coli*BL21(DE3) | ThermoFisher Scientific, C600003 | BSL-1 | 500 mL |
|       |       |       |  |       |
|       |       |       |  |       |

Note: To add more rows, click in the cell that is farthest to the right in the bottom row, a small plus (+) symbol will appear. Click on the plus (+) at the bottom right corner of the table to add an additional row. Repeat steps as necessary.

**3. Induced Pluripotent Stem Cell (iPSC) Activities.** **[ ]  Not Applicable**

3.1 Which of the following are applicable to this protocol?

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| [ ]  | [ ]  | *In vitro* culturing, passaging, differentiation, and storage  |
| [ ]  | [ ]  | *In vitro* organoid research |
| [ ]  | [ ]  | Modelling specific stages of embryonic development (i.e. amnion formation, neural tube development, development of primordial germ cells, placental structures, 2D or 3D models of gastrulation or post-gastrulation events) |
| [ ]  | [ ]  | Modelling continuous processes of embryonic development (i.e. any sequence of events leading to the creation of the primitive streak) |
| [ ]  | [ ]  | Generating iPSC lines |
| [ ]  | [ ]  | Banking or distributing iPSC lines or embryos |
| [ ]  | [ ]  | *In vitro* culturing and/or creation of intact human embryo(s) |
| [ ]  | [ ]  | In vitro gametogenesis without fertilization  |
| [ ]  | [ ]  | Introducing iPSCs into animals and/or humans |

**4. Human Embryonic Stem Cells (hESC).**  **[ ]  Not Applicable**

4.1. List the NIH Registry Number.

4.2 If any restrictions are identified by the NIH and/or Provider, specify:

**4.3. Human Embryonic Stem Cell (hESC) Source.**

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| [ ]  | [ ]  | hESCs to be obtained are registered with the NIH |
| [ ]  | [ ]  | hESCs to be obtained from a reputable, domestic cell bank/repository |

**4.4. Human Embryonic Stem Cell (hESC) Activities.**

4.4.1 Which of the following are applicable to this protocol?

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| [ ]  | [ ]  | *In vitro* culturing, passaging, differentiation, and storage  |
| [ ]  | [ ]  | *In vitro* organoid research |
| [ ]  | [ ]  | Modelling specific stages of embryonic development (i.e. amnion formation, neural tube development, development of primordial germ cells, placental structures, 2D or 3D models of gastrulation or post-gastrulation events) |
| [ ]  | [ ]  | Modelling continuous processes of embryonic development (i.e. any sequence of events leading to the creation of the primitive streak) |
| [ ]  | [ ]  | Conducting NIH or Provider restricted activities |
| [ ]  | [ ]  | Generating hESC lines |
| [ ]  | [ ]  | Banking or distributing hESC lines or embryos |
| [ ]  | [ ]  | *In vitro* culturing and/or creation of intact human embryo(s) |
| [ ]  | [ ]  | Procurement of gametes, blastocysts, embryos, or cells for hESC generation |
| [ ]  | [ ]  | In vitro gametogenesis without fertilization  |
| [ ]  | [ ]  | Introducing hESCs into animals and/or humans |

**Section 8. Signature**

EHSS will review this application and contact the Principal Investigator with comments or concerns.

I confirm that all information provided in this document are true and complete to the best of my knowledge.

Signature of Principal Investigator:

Date:

Send all completed protocols to ehss@syr.edu

# **Section 9. Terms and Conditions of Approval**

|  |
| --- |
| **EHSS/IBC Comments:** |
|  |

*Updated July 2025*