**Hazardous Agents Form and Study Safety Plan**

**(For each class of hazardous agent complete a separate form)**

**Note:** one form may be used for multiple hazardous agents only if they are in the same class of material (i.e. where all information on the form would be identical for each agent other than its name). An example of a class of similar agents might be a list of several human cell lines to be injected into mice where the dose and hazard remains identical for each cell line.

**1. General Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Number |   | Amendment Number |  |
| Principal Investigator |  |
| Hazardous Agent(s) |  | Handling State (e.g. liquid, solid, etc.) |  |

**2. Please check the appropriate Biosafety Level (BSL) Animal Biosafety Level (ABSL), and Risk Assessment Group for the listed agent(s).** Currently this institution does not support levels 3 & 4 for any of these categories. See appendix A for definitions of levels.

BSL: [ ]  1 [ ]  2 [ ]  2+

ABSL: [ ]  1 [ ]  2 [ ]  2+

Risk Assessment: [ ]  1 [ ]  2 [ ]  2+

**3. Identify and Describe Use of Agent Type and *Class***

* Biohazardous materials: *injection of cell lines, infectious agents (bacteria, fungi, parasites, prions, rickettsias, viruses, etc), recombinant DNA, etc.*
	+ **NOTE: Recombinant DNA: PI must also complete Section 13 A. (Recombinant DNA Use) in the Animal Use Protocol Form.**
	+ **NOTE:** All **cells and cell lines used for implantation should be tested for infectious agents prior to the start of the work as per the guidelines of the Institutional Biosafety Committee (IBC).** A validated test result from an independent agency should be submitted to IACUC. PCR tests are now considered the best and most inexpensive way to screen cell lines for potential contamination. SEE APPENDIX B FOR SCREENING INFORMATION.
* Chemical hazardous materials: *carcinogens, allergens, corrosives, irritants, neurotoxins, teratogens, etc.*
* Physical hazards: *lasers, X-ray machines, radioisotopes, etc.*

Click here to enter text.

#### Species:

#### Dose (Volume):

#### Route:

#### Needle Size:

#### Duration and Frequency:

Are there **potential** risks to humans? **[ ]**  No **[ ]**  Yes

(If YES, complete below)

#### Method of exposure:

#### Signs/Symptoms:

#### Treatment:

#### Protection:

### Are there risks to other animals (zoonotic) in the room or animal facility? [ ]  No [ ]  Yes

### (If YES, complete below)

#### Method of exposure:

#### Signs:

#### Treatment:

#### Protection:

1. **List and Describe the responsibility of personnel handling/exposed to the material**

|  |  |
| --- | --- |
| **Name(s)** | **Responsibility** (example formulation, injecting, disposal) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. Describe any required special handling of the material *in vitro* (prior to *in vivo* administration to the animal) (e.g. location of fume hood, location of BSL-1 or BSL-2 cell culture incubators and centrifuges, location of biosafety cabinet, presence of lab ventilation, etc.):

Click here to enter text.

1. Describe any required special handling of the animals, bedding, feces, urine, or carcasses following administration of the material to the animals. Note: animals injected with non-human cell lines (and their bedding and carcasses) must be handled with BSL-1 precautions. Animals injected with human cell lines (and their bedding and carcasses) must be handled with BSL-2 precautions. For animals injected with any cell lines, their bedding and carcasses must be disposed in Stericycle biohazardous waste boxes. State whether any of these special handling situations apply to your work:

Click here to enter text.

1. Describe any special personnel training or monitoring needed (e.g. biosafety training by the biosafety officer, radiation safety training by the radiation safety officer, radiation monitoring badge to monitor received doses, etc.):

Click here to enter text.

1. Describe emergency procedures in case of personnel exposure (e.g. inhalation, adsorption, injection, ingestion):

Click here to enter text.

1. Describe decontamination procedure(s) that will be used in the event of a spill [e.g. for a chemical spill contact EHS, EHS@wpi.edu; for a biological spill, contact the Biosafety Officer (BSO) (currently Paula Moravek, pmoravek@wpi.edu) or IBC Chair (currently David Adams dadams@wpi.edu); for a spill involving radioisotopes, contact the radiation safety officer (RSO) (currently David Adams dadams@wpi.edu); for a spill requiring medical intervention, call Campus Police at 508-831-5555). In addition to the specialists mentioned above, for any spill the vivarium operations manager (VOM) is also contacted].

Click here to enter text.

1. Describe method of disposal of (spilled) material:

Click here to enter text.

1. List any PPE that is required in addition to the “standard” PPE (standard PPE includes disposable gloves, lab coat, and eye protection) (special PPE might include: special gloves to prevent bites and scratches, lead apron to protect personnel against radiation, coveralls, bouffant cap, respirator, etc.):

Click here to enter text.

1. Describe any additional precautions:

Click here to enter text.

|  |
| --- |
| **FOR IBC CHAIR/RADIATION SAFETY OFFICER USE ONLY** |
| *For Chair IBC use only***[ ]**  N/A**[ ]**  No **[ ]**  Yes Expedited IBC Chair Review and IBC Notification.**[ ]**  No **[ ]**  Yes Does this require full IBC Review? If yes, IBC approval date:*For Radiation Safety Officer use only***[ ]**  N/A**[ ]**  No **[ ]**  Yes Expedited RSO Review and Radiation Safety Committee Notification.**[ ]**  No **[ ]**  Yes Does this require full Radiation Safety Committee Review? If yes, approval date: |

1. **PI and EHS Rep/Biosafety/Radiation Safety Officer Reviewer Approval**

It is the PI’s responsibility to assure that all individuals participating in these studies have been properly trained and notified and comprehend the *Study Safety Plan*. The PI’s signature acknowledges their responsibility to assure that each person involved is taught correct procedures for handling the test material and to monitor its use for the duration of the study.

Signature below indicates that the *Study Safety Plan* is acceptable and will be followed:

Signature of Principal Investigator Date

Signature ofEHS Rep/Biosafety/Radiation Safety Officer Date

Appendix A

**Biosafety Levels (BSL)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **BSL** | **Agents** | **Practices** | **Safety Equipment****(Primary Barriers)** | **Facilities****(Secondary Barriers)** |
| **1** | Not known to consistently cause disease in healthy adults  | Standard Microbiological Practices | None required | Open bench top sink required  |
| **2** | Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure  | BSL-1 practice plus: * Limited access
* Biohazard warning signs
* “Sharps” precautions
* Biosafety manual defining any needed waste decontamination or medical surveillance policies
 | Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves, and face protection as needed | BSL-1 plus: * Autoclave available
 |
| **3** | Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences | BSL-2 practice plus: * Controlled access
* Decontamination of all waste
* Decontamination of lab clothing before laundering
* Baseline serum
 | Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPE: protective lab clothing, gloves, and respiratory protection as needed | BSL-2 plus: * Physical separation from access corridors
* Self-closing, double-door access
* Exhausted air not recirculated
* Negative airflow into laboratory
 |
| **4** | Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission  | BSL-3 practice plus: * Clothing change before entering
* Shower on exit
* All material decontaminated on exit from facility
 | Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit | BSL-3 plus: * Separate building or isolated zone
* Dedicated supply and exhaust, vacuum, and decon systems
* Other requirements outlined in the BMBL text
 |

\* *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*

**Animal Biosafety Levels (ABSL)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ABSL** | **Agents** | **Practices** | **Safety Equipment (Primary Barriers)** | **Facilities (Secondary Barriers)** |
| **1** | Not known to cause human infection  | Standard animal care and management practices, including appropriate medical surveillance programs | As required for normal care of each species. | Standard animal facility * No recirculation of exhaust air
* Directional air flow recommended
* Hand washing sink recommended
 |
| **2** | Of moderate risk that cause human disease by ingestion or percutaneous or mucosal exposure  | ABSL-1 practices plus: * Limited access
* Biohazard warning signs
* Sharps precautions
* Biosafety manual
* Decontamination of all infectious wastes and of animal cages prior to washing
 | ABSL-1 equipment plus primary barriers: containment equipment appropriate for animal species; PPES: laboratory coats, gloves, face and respiratory protection as needed. | ABSL-1 facility plus: * Autoclave available
* Hand washing sink available in the animal room.
* Mechanical cage washer used
 |
| **3** | Cause serious and potentially lethal infections and have known potential for aerosol transmission | ABSL-2 practices plus: * Controlled access
* Decontamination of clothing before laundering
* Cages decontaminated before bedding removed
* Disinfectant foot bath as needed
 | ABSL-2 equipment plus: Containment equipment for housing animals and cage dumping activities Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPEs: appropriate respiratory protection  | ABSL-2 facility plus: * Physical separation from access corridors
* Self-closing, double-door access
* Sealed penetrations
* Sealed windows
* Autoclave available in facility
 |
| **4** | Non-indigenous (exotic) agents that pose high individual risk of life-threatening disease for which there is no available vaccine or treatment  | ABSL-3 practices plus: * Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting
* All wastes are decontaminated before removal from the facility
 | ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial containment equipment in combination with full body, air-supplied positive-pressure personnel suit) used for all procedures and activities | ABSL-3 facility plus: * Separate building or isolated zone
* Dedicated supply and exhaust, vacuum and decontamination systems
* Other requirements outlined in the text
 |

\**Biosafety in Microbiological and Biomedical Laboratories (BMBL)*

**Risk Classification Criteria for National Institute for Health (NIH)**

**Risk Group 1 (RG1)** - Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community. Examples: E. coli K12 and derivatives, Saccharomyces cerevisiae, Bacillus subtilis, Lactobacillus.

**Risk Group 2 (RG2)** - Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community. Examples: E. coli K12 and derivatives, Saccharomyces cerevisiae, Bacillus subtilis, Lactobacillus.

**Risk Group 3 (RG3)** - Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community. Currently not supported at this institution. Examples: HIV (WT), SARS virus, Yersinia pestis, Hantavirus, West Nile virus.

**Risk Group 4 (RG4)**- Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community. Currently not supported at this institution. Examples: Ebola virus, Marburg virus, Lassa fever virus.

**Appendix B**

**Cell Line Screening Tests Required by WPI Vivarium**

**(Charles River Labs, or Equivalent)**

<https://www.criver.com/products-services/research-models-services/animal-health-surveillance/cell-lineresearch-biologics-screening?region=3601>

**1) Human Cell Lines:** An acceptable test is: Charles River **Human HEP/HIV Clear Panel** ($248): HBV, HCV, HIV-1, HIV-2, and Mycoplasma.

**2) Mouse Cell Lines:** An acceptable test is Charles River **Mouse Essential Clear Panel**: Hantavirus, LCMV, LDV, MAV-1, MHV, MNV, Mouse parovirus, Mousepox, MRV, POLY, REO, SEND, TMEV, Vesivirus, Mycoplasma.

Charles River Research Animal Diagnostic Services (CR-RADS), 261 Ballardvale Street, Receiving Dock, Building 22, Wilmington, MA 01887



