Biosafety Standard Operating Procedures – Non-human Primate Materials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator: | | | **Click or tap here to enter text.** | | | | | | | | IBC Protocol Number: | | | | **Click or tap here to enter text.** | | | |
|  | | |  | | | | | | | |  | | | |  | | | |
| 1.0 Non-Human Primate Materials: | | | | | | | | | | | |  | | | | | | |
| 1.1 a) Specify tissues - | Body fluids | | | | | | Blood & Blood products | | | | | | | Cell lines | | | | |
|  | Tissue (excluding brain tissue) | | | | | | | | | | | Brain tissue | | | | |  | |
| b) Describe the source(s) of this material (for each box checked above: | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| c) List all cell lines: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
| 1.2 Biosafety Level: | | BSL2 | | | | | | | | BSL2+ | | | | | | BSL3 | | |
|  | |  | | | | | | | | | | | | | | | | |
|  | | ***NOTE:*** *Unfixed samples of brain or spinal cord, as well as any other tissues* ***KNOWN*** *to contain human prions should be handled with extreme care in a BSL-2 facility utilizing BSL-3 practices* ***(BSL2+)****. Formaldehyde or formalin-fixed, glutaraldehyde-fixed and paraffin-embedded tissues, particularly of the brain, remain infectious for long periods, if not indefinitely.  Treatment with* ***95% formic acid*** *is necessary to render prions noninfectious.* | | | | | | | | | | | | | | | | |
| 1.3 a) What room will this material be stored in?  Click or tap here to enter text. | | | | | | | | b) What room will this material be used in?  Click or tap here to enter text. | | | | | | | | | | |
| 1.4 Describe the procedures used with EACH type of material and amount of material to be used per procedure: | | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
| 1.5 Procedures will (check all that apply & list EACH material beneath): | | | | | | Generate aerosols  Click or tap here to enter text. | | | | | | | Involve sharps  Click or tap here to enter text. | | | | | Inoculation of live animals  Click or tap here to enter text. |
|  | | | | | | Potential contaminate hands or clothing  Click or tap here to enter text. | | | | | | | Other (Please explanation)  Click or tap here to enter text. | | | | | |
| 1.6 How much tissue is expected to be present in the lab at any given point? Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | |
| 1.7 How frequently is tissue handled in the lab (e.g. daily, weekly)? Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| 2.0 Training Requirements: | | | | | | | | | | | | | | | | | | |
| 2.1 LSE Training: | | | | It is mandatory all lab personnel complete Laboratory Safety Essentials per HSC OP 75.01 TTUHSC Safety Programs and the IBC Bylaws, by checking “I Agree” you are confirming that all personnel handling non-human primate tissue have been appropriately trained in use of tissue and emergency procedures related to accidents and/or exposure events. | | | | | | | | | | | | | | |
|  | | | | I Agree | | | | |  | | | | |  | | | | |
| 2.2 Hepatitis B Vaccine: | | | | *It is the policy of TTUHSC to maintain a Health Program that conforms to the guidelines established by the CDC, recommendations of the Texas Department of State Health Services (DSHS), Texas Administrative Code (TAC) §96 – Bloodborne Pathogen Control, §97 – Communicable Diseases, and §99 – Occupational Diseases. The HSC OP 75.11, Health Surveillance Program for TTUHSC targets those who have contact with patients and/or human body fluids/tissues or those that work with animals or infectious materials in any laboratory through the LARC.* **Has the Hepatitis B vaccine been offered?** | | | | | | | | | | | | | | |
|  | | | | Yes | | | | |  | | | | |  | | | | |
|  | | | |  | | | | |  | | | | |  | | | | |
| 2.3 List any constraints on this material as they apply to personnel: | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| ***NOTE:*** *LSE training and universal precautions are required; Working with samples obtained from human subjects* ***requires CITI training.*** | | | | | | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | |
| 3.0 Risks associated with use of non-human primate materials: *Non-human primate tissues may contain adventitious viruses including, but not limited to, HBV, HCV, HIV, and CMV; as well as other human viral, bacterial, fungal, parasite, or prion pathogens, leading to a wide variety of symptoms such as hepatitis, mononucleosis-like symptoms, rash, and/or fever, depending on the agent. If risk is low, prions do not need to be addressed further; if risk is KNOWN or high, protocol* ***must******address prions.*** *If risk is moderate, protocol must address prions or explain why risk is mitigated by population of study.* ***Please see attachment on PRIONS for information.*** | | | | | | | | | |
| 3.1 Assess infectious prion risk for tissue/brain tissue: | | | KNOWN to contain infectious prions | | | | | HIGH (brain, spinal cord, nerves) | |
|  | | | MODERATE (lung, liver, kidney, spleen/lymph nodes, placenta) | | | | | LOW (tissues other than those listed under high or moderate risk) | |
|  | | | |  | | | |  | |
| 3.2 Have tissues been tested for specific agents? | | | | | | Yes | | No | |
| If YES, specify which agents: | | | Click or tap here to enter text. | | | | | | |
|  | | |  | | | | | | |
| 3.3 Discuss any additional risks associated with a particular type of tissue registered on this SOP including PRION risks if applicable: | | | | | | | | | |
|  | | | Click or tap here to enter text. | | | | | | |
| ***NOTE:*** *Formaldehyde or formalin-fixed, glutaraldehyde-fixed and paraffin-embedded tissues, particularly of the brain, remain infectious for long periods, if not indefinitely.  They should be handled cautiously as fresh materials from fixation through embedding, sectioning, staining and mounting on slides,* ***unless treated with 95% formic acid****. S****ee PRIONS for information in CDC biosafety publications.*** | | | | | | | | | |
|  | | | | | | | | | |
| 3.4 Describe any hazards to laboratory workers: | | | Click or tap here to enter text. | | | | | | |
| *(Risks generally include: ingestion, skin puncture, contact with mucous membranes [e.g., eyes, nose, mouth], contact with non-intact skin, exposure to aerosols generated during procedures)* | | | | | | | | | |
|  | | | | | | | | | |
| 3.5 Personal Protective Equipment: | | | List all PPE required to work with this chemical; if not applicable state N/A. | | | | | | |
|  | | | **Click or tap here to enter text.** | | | | | | |
|  | | | | | | | | | |
| 4.0 Administrative and Engineering Controls: | | | | | | | | | |
| 4.1 a) Describe processes or procedures **established by the PI** for the purpose of reducing personnel exposure: | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | |
| b) Describe any additional PPE: Click or tap here to enter text. | | | | | | | | | |
|  | | | | | | | | | |
| 4.2 Engineering Controls: | | List EACH material beneath the category. | | | | | | | |
| Containment: | Open Bench  Click or tap here to enter text. | | | | Fume Hood  Click or tap here to enter text. | | Draft Shielded Scale  Click or tap here to enter text. | | Other (list below) |
|  | List Other here: Click or tap here to enter text. | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | |
| 5.0 Animal Use: | | | YES  NO If used in animals identify risks related to use in animals | | | | | | | | |
| 5.1 | | A.  Sharps hazard | | | | B.  Aerosol hazard | C.  Hazards from animal waste, bedding, and/or cage handling | | | | D.  Physical hazard from animal/lesions on animals related to agent |
| 5.2 | | Describe means to mitigate hazards produced from section 5.1 for each non-human primate material: | | | | | | | | | |
|  | | Include any risk from presence of non-human primate materials present in animal’s blood, tissues, and/or organs. | | | | | | | | | |
|  | | 1. Sharps Hazard: Click or tap here to enter text. | | | | | | | | | |
|  | | 1. Aerosol Hazard: Click or tap here to enter text. | | | | | | | | | |
|  | | 1. Hazards from animal: Click or tap here to enter text. | | | | | | | | | |
|  | | 1. Physical Hazard: Click or tap here to enter text. | | | | | | | | | |
| 5.3 | | Describe any hazards to LARC Staff: | | | | | | | | | |
|  | | Click or tap here to enter text. | | | | | | | | | |
|  | | | | | | | | | | | |
| 6.0 Waste Disposal: Indicate what type of waste this agent will produce: | | | | | | | | | | | |
| Liquid | Solid | | | | Contaminated Reusable Item | | | Animal Tissue | Animal Carcass | Animal bedding/waste/cage | |
| Unused agent | | | | | | | | Only select the above if used in animals | | | |
|  | | | | | | | |  | | | |
| 6.1 Describe how you will dispose of each waste selected above for each non-human primate material: Please provide specific details regarding prions if at high risk. | | | | | | | | | | | |
| Liquid: | | | | Click or tap here to enter text. | | | | | | | |
| Solid: | | | | Click or tap here to enter text. | | | | | | | |
| Unused material: | | | | Click or tap here to enter text. | | | | | | | |
| Animal Waste: | | | | Click or tap here to enter text. | | | | | | | |
| (Specify for each type of animal waste) | | | |  | | | | | | | |

|  |  |  |
| --- | --- | --- |
|  |  | |
| 7.0 Accidental Cleanup Procedures: Describe methods to be used to address spills, including concentration and contact time of any cleaning or deactivating agents, spill kits and/or any other necessary supplies required for cleanup. | | |
|  | |  |
| Describe appropriate PPE during cleanup:  Click or tap here to enter text. | | |
|  | | |
| Describe procedure for spill cleanup:  Click or tap here to enter text. | | |
|  | |  |