Biosafety Standard Operating Procedures – Human Materials

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| Principal Investigator: | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | IBC Protocol Number: | | | | | Click or tap here to enter text. | | | | |
| 1.0 Human Materials: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
| 1.1 Specify tissues | | | Body fluids | | | | | | | | | | | Blood & Blood products | | | | | | | | | | Cell lines | | | | | |
|  | | | Tissue (excluding brain tissue) | | | | | | | | | | | | | | | | | | Brain tissue | | | | | | |  | |
| 1.2 Describe the source(s) of this material (for each box checked above: | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1.3 List all cell lines & source (s): Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.4 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* ***NaOH (Sodium Hydroxide)*** *is necessary to render prions noninfectious.* | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.5 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. | | | | | | | | | | | | | |
| 1.6 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.7 Procedures will (list EACH material per category): | | | | | | | | | | | | | 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 contaminates hands or clothing  Click or tap here to enter text. | | | | | | | | | Other (Please explanation)  Click or tap here to enter text. | | | | | | | |
| 1.8 How much human material is expected to be present in the lab at any given point?  Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1.9 How frequently is human material handled in the lab (e.g., daily, weekly)?  Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 human 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 | | | | | | | | | |  | | | | | |  | | | | | |
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| 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.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3.0 Risks associated with use of human materials: *Human 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.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3.1 Assess infections prion risk for EACH material: | | | | | | | KNOWN to contain infectious prions  Click or tap here to enter text. | | | | | | | | | | | | | | | | HIGH (brain, spinal cord, nerves)  Click or tap here to enter text. | | | | | | |
|  | | | | | | | MODERATE (lung, liver, kidney, spleen/lymph nodes, placenta)  Click or tap here to enter text. | | | | | | | | | | | | | | | | LOW (tissues other than those listed under high or moderate risk)  Click or tap here to enter text. | | | | | | |
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| 3.2 Have tissues been tested for specific agents? | | | | | | | | | | | | | | | Yes | | | | | | | | No | | | | | | |
|  | | | | | | | | | | | | | | |  | | | | | | | | Click or tap here to enter text. | | | | | | |
| If Yes, specify which agents: | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
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| 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.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3.4 Describe any hazards to laboratory workers (& LARC personnel): | | | | | | | 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;* ***for brain tissue include the risk of exposure to prions.****)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3.5 Personal Protective Equipment: | | | | | | | List all PPE required to work with this material; if not applicable state N/A. | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
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| 4.0 Administrative and Engineering Controls: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4.1 a) Describe processes or procedures **established by the PI** for the purpose of reducing personnel exposure; **if applicable, provide procedures to address potential prions in brain tissue**: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| b) Describe any additional PPE: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 4.2 Engineering Controls: | | | | | | List EACH material under the appropriate 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. | | | | | | Biological Safety Cabinet (BSC)  Click or tap here to enter text. | | | | | |
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| 5.0 Animal Use: | | | YES  NO If used in animals identify risks related to use in animals, list EACH material per category. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| List exclusions: | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.1 | A.  Sharps hazard  Click or tap here to enter text. | | | | | | | | | B.  Aerosol hazard  Click or tap here to enter text. | | | | | | | C.  Hazards from animal waste, bedding, and/or cage handling  Click or tap here to enter text. | | | | | | | | | D.  Physical hazard from animal/lesions on animals related to agent  Click or tap here to enter text. | | | |
| 5.2 | Describe means to mitigate hazards produced from section 5.1 for each human material: | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Include any risk from presence of human 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| 6.0 Waste Disposal: Indicate what type of waste EACH material will produce: | | | | | | | |
| Liquid  Click or tap here to enter text. | Solid  Click or tap here to enter text. | | | Contaminated Reusable Item  Click or tap here to enter text. | Animal Tissue  Click or tap here to enter text. | Animal Carcass  Click or tap here to enter text. | Animal bedding/waste/cage  Click or tap here to enter text. |
| Unused material | | | Sharps | | Only select the above if used in animals | | |
| Click or tap here to enter text. | | | Click or tap here to enter text. | |  | | |
| 6.1 Describe how you will dispose of each waste selected above for each human material; If applicable, please address precautions taken during cleanup for brain tissue: | | | | | | | |
| Liquid: | | Click or tap here to enter text. | | | | | |
| Solid: | | Click or tap here to enter text. | | | | | |
| Reusable Items: | | Click or tap here to enter text. | | | | | |
| Sharps: | | 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) | |  | | | | | |

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| 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. If applicable, please address brain tissue and necessary precautions. | | |
| Describe appropriate PPE during cleanup for EACH material:  Click or tap here to enter text. | | |
|  | | |
| Describe procedure for spill clean-up for EACH material:  Click or tap here to enter text. | | |
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