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| Title | Biohazardous Material Waste Management |
| SOP Code | SOP003_02 |
| Effective Date | 04-Jan-2016 |

Site Approvals

| Name and Title (typed or printed) | Signature | Date dd/Mon/yyyy |
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1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines processes that must be followed in order to dispose of biohazardous waste in a manner compliant to safety regulations and ensure contamination risks are minimized.

2.0 SCOPE

All biospecimens whether fixed, fresh, frozen, or paraffin embedded should be considered biohazardous and treated with universal precautions. The purpose of this document is to minimize the risk biohazardous material poses to the environment and to personnel during disposal. Procedures should ensure adherence to Canadian, provincial, and institutional guidelines.

3.0 RESPONSIBILITIES

This SOP applies to clinical research and biorepository personnel involved in biospecimen management. Roles and responsibilities may vary at specific sites.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Human Anatomical Waste

5.1.1 Place all human anatomical waste and materials that have come into contact with such waste into a bag that is clearly labeled with the universal biohazard symbol.

5.1.2 Decontaminate biohazardous waste before disposal to a landfill site.

5.1.3 Decontaminate by heat sterilization (autoclaving) and take to the institutional designated area for pick-up and disposal.

5.1.4 Destruction of Frozen Tissue:

Retrieve samples from storage unit. Leave samples in storage vials or cryomolds. Place samples in the autoclavable biohazard bag.

Ensure that bag containing waste is incinerated or disposed of by a company with a license to do so. Record that the sample has been discarded to ensure the inventory systems are up to date.

5.1.5 Optional: Biohazardous waste that has not been decontaminated can be picked-up by an established waste disposal company for disposal. This may require that the facility obtains a special ministerial permit granting approval for generation and disposal of waste by this procedure.

5.2 Biohazardous Liquids (Human Blood and Body Fluids Waste)

5.2.1 Dispose of blood and liquid biohazardous waste generated during specimen processing by pouring the waste into a leak proof container containing freshly prepared 10 % chlorine bleach solution or other suitable chemical disinfectant.

5.2.2 Destruction of Blood Samples in a tube.

Retrieve blood samples from storage unit. Dispose of tubes in the biohazardous waste bag for incineration or adequate disposal as per institutional procedure. Update inventory systems by recording that the sample has been discarded .

5.2.4 Avoid the creation of aerosols or spills during this process.

5.3 Sharps

- 5.3.1 Do not recap needles,.
- 5.3.2 Dispose of all sharps waste into a readily available, CSA-approved puncture-resistant container, labelled with the biohazard symbol.
- 5.3.3 Decontaminate sharps containers (preferably by incineration or autoclaving), and dispose of in accordance with institutional, national, and provincial guidelines.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD.
<http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. 3rd Edition 2012, <http://www.isber.org>

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network,

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------|----------------|--|
| SOP003_01 | 01-Aug-2012 | Original version |
| SOP003_02 | 04-Jan-2016 | 5.14: Added instructions for frozen tissue destruction. 5.2.2: Added instructions for destruction of blood samples in a tube. Updated references. Removed OTRN logo. |
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