Title	Destruction of Human Specimen Material
SOP Code	SOP202_01
Effective Date	01-Sep-2012

Site Approvals

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

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the dispose of human biological material that is eliminated from the repository collection. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

There are situations such as inadequate consent, revoked consent, specimen contamination, or storage equipment failure where it becomes necessary to dispose of human biological material. Under these conditions, all unprocessed material must be destroyed or disposed under conditions that incorporate safety considerations and respect the rights of the participant from whom the material was derived.

3.0 RESPONSIBILITIES

This SOP applies to clinical research 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 Destruction of Human Biological Specimens

5.1.1 Note: Refer to institutional safety procedures for handling human biological (i.e., biohazardous) material.

5.1.2 Confirm destruction of specific specimens with the qualified investigator prior to disposal.

5.1.3 Retrieve specimens from storage facility.

5.1.4 Confirm the identity of the specimens in the inventory system, and on the specimen label.

5.1.5 Remove all labels. For labels that cannot be removed, obliterate any information, including alphanumeric information and barcodes (if possible).

5.1.6 Dispose of specimens in the appropriate biohazardous waste container, as per institutional procedure.

5.1.7 Record specimen(s) disposal in the inventory system.

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. Cell Preservation Technology 6(1), 3-58, 2008 http://www.isber.org/Pubs/BestPractices2008.pdf

CTRNET Standard Operating Procedures, Canadian Tumour Repository Network, http://www.ctrnet.ca/operating-procedures

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP202_01	01-Sep-2012	Original version