CTRNet Standard Operating Procedure Data Transmission to CTRNet Catalogue			
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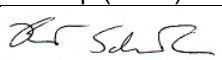
Supersedes:	3.1.003 e1.0	Category:	Records Management and Documentation

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter 	31-May-2012

1.0 PURPOSE

Tumour biobanks are intended to manage the safekeeping of clinical data and other sample associated data in their custody. When data transmission is required, it is important to ensure that no data is lost or modified, and that participant's privacy is protected

2.0 SCOPE

This standard operating procedure (SOP) outlines general elements and features that should be in place in order to share data electronically.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 4 Privacy and Security*
3.2 *CTRNet Policy: POL 7 Material and Information Handling*
3.3 *CTRNet Standard Operating Procedure: SOP 03.001 Information Access Control*

4.0 ROLES AND RESPONSIBILITIES

The SOP applies to personnel from CTRNet member biobanks that are responsible for the database system and for the transmission of data stored on the system.

Tumour Biobank Personnel	**Responsibility/Role**
Biobank Director	Provides guidance to IT on scheduling of export. Ensures export of de-identified data to CTRNet is approved by local Research Ethics Boards (REBs).
Information Technology (IT) Staff	Establishes and schedules data export process, monitors submission status, reviews process logs for errors.
Technical staff	Validate data integrity and ensure that data is de-identified.

5.0 MATERIALS, EQUIPMENT AND FORMS

Items listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	Materials and Equipment (Site Specific)
Internet connection	
Electronic Transfer Protocol	
Access to the Tumour Biobank Application	

6.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/glossary

7.0 PROCEDURES

The facility should employ fundamental systems to ensure that data transmitted to member biobanks is complete, free of corruption and protected from interception. At no time should personal identifiers be included in the export file.

7.1 Data Transmission – General Description Process

7.1.1 If using ATiM:

a. Using the built in tools generate the CSV export file.

b. Validate the file, ensuring that data integrity is maintained and that all participants are de-identified.

c. Send CSV file to CTRNet as per established electronic transfer protocol.

d. Ensure confirmation of data submission.

7.1.2 For other Tumour Biobank Applications:

Local IT staff develops submission scripts based on CTRNet CSV. All subsequent steps are identical to Section 7.1.1.

7.2 Data Transmission – Frequency

7.2.1 Generate and submit a data file to CTRNet as required. (CTRNet recommends monthly).

Biobanks may submit more or less frequently depending on the rate of new sample accrual and sample use for research.

7.3 Data Transmission – Audit and Validation

7.3.1 CTRNet tracks all submissions to the national catalogue. Attributes include:

a. Date/Time of submission

b. Biobank ID and province

c. Submission number

d. Version

e. Status (Record error, invalid file, success)

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

8.2 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).
http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories

8.3 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
8.1.003 e1.0	2008	JdSH	Original document
8.1.003 e1.0	May 2012	CMG	• Section 1, Purpose: revised • Section 2, Scope: revised • Section 4, Roles & Responsibilities: revised • Section 7.1:revised • Grammatical and formatting changes throughout • Definitions removed • Revision History moved to bottom • Reference links updated • Updated SOP references • Deleted “that Data is Free from corruption of Recovered Data Security Systems for Fire” from the 7.3 title.