CTRNet Standard Operating Procedure Database Transmission to CTRNet Database			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
6.1.002	2008	JdSH	1st Release.

1.0 PURPOSE

Tumour banks or repositories are intended to manage the safekeeping of clinical data and other sample associated data in their custody. When data transmission is required, it must be done in a manner that protects the participant's privacy and ensures that none of the data is modified or lost.

2.0 SCOPE

This standard operating procedure (SOP) outlines general elements and features that should be in place to ensure that information transmission is done in a manner that safeguards data integrity and protects the participant's privacy and security.

3.0 REFERENCE TO OTHER POLICIES AND SOPS

1. CTRNet Policy: POL 004.001 Privacy and Security
2. CTRNet Policy: POL 007.001 Material and Information Handling Policy
3. CTRNet SOP: 3.1.001 Information Access Control

4.0 RESPONSIBILITY

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

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Information Technology (IT) Staff	Schedules data export, monitors submission status, reviews process logs for errors. Corrects when needed.	
Bank Manager/Coordinator Bank Director	Provides guidance to IT on scheduling of export	
Tumour Bank management	Ensures export of de-identified data to CTRNet is approved by local R.E.B.	

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)**
Broadband Internet connection	
Secure File Transfer Protocol	
Access to the Tumour Bank Application	

6.0 DEFINITIONS

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.

Tumour Bank Application: Software and hardware system needed to annotate, track and distribute biospecimens stored within the biorepository

Data Transmission: Sending of XML submission file to CTRNet for processing. May require download of process log to view results for any errors in submission.

ATiM: Open source application framework provided by CTRNet to help banks manage Inventory (LIMS Module) and capture clinical annotation.

XML Schema Definition (XSD): Is an instance of an Extensible Markup language (XML) schema written in the XML Schema language. An XSD defines a type of XML document in terms of constraints upon what elements and attributes may appear, their relationship to each other, what types of data may be in them, and other things. It can be used with validation software in order to ascertain whether a particular XML document is of that type, and to produce a Post-Schema Validation Infoset.

Secure File Transfer Protocol (SFTP): The language used for file transfer from computer to computer across the internet. With SFTP both the commands and data are encrypted.

7.0 PROCEDURES

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

7.1 Data Transmission - General Description of Process

2. If using ATiM
   - Using the built in tools (TBD) set a submission time for upload
   - Test connection to CTRNet SFTP site
   - System will automatically generate and upload submission file via SFTP
   - Retrieve process logs and review for submission errors
3. For other Tumour Bank Applications
   - Local IT staff develops submission scripts based on CTRNet XSD document.
   - Schedule script execution based on frequency recommended by CTRNet or Bank Manager.
   - Retrieve process logs and review for submission errors.

7.3 Data Transmission – Frequency

1. Generate and submit a data file to CTRNet as required. (CTRNet recommends monthly).
   - Banks may submit more or less frequently depending on the rate of new sample accrual and sample use for research

7.4 Data Transmission – Audit and Validation that data is free of corruption of Recovered Data Security Systems for Fire

1. CTRNet tracks all submissions to the national catalogue. Attributes include:
    - Date/Time of submission
    - Bank ID and province
    - Submission number
    - Version
    - Status (Record error, invalid file, success)
2. Track every submission action (delete, sync, insert) in an audit table in case of logical errors with submission elements.

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Tri-Council Policy Statement; 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, August 1998. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
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
3. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

9.0 APPENDICES

None