Title	File Transfer for Biorepositories
SOP Code	SOP107_012
Effective Date	04-Jan-2016

Site Approvals

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

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the steps required during the transfer of external files to and from the biorepository database, to preserve the integrity of transmitted data and the database and to ensure that participant privacy is protected.

2.0 SCOPE

This SOP is applicable to all data files that are part of the data set and which are transmitted from or to the biorepository database. This SOP is also applicable to those personnel responsible for the transmission, such as all the Data Management and Information Technology (IT) personnel

3.0 RESPONSIBILITIES

The biorepository Director, Data Management, and IT personnel (if applicable) are responsible for ensuring that the processes involved in all database file transfers, from or to the study database, meet all of the applicable regulatory and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained team members, but should remain the ultimate responsibility of the biorepository Director.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1. Treatment Coding and Blinding

5.1.1. Where necessary, maintain the blinding of the treatment coding in released datasets. This may mean removing the treatment codes or replacing the treatment codes with mock codes. Document the recoding and include notification of the re-coding/blinding with the transmitted file.

5.2. Data Security

5.2.1. Maintain appropriate authorizations for access to data to be transferred/ received.

5.2.2. Ensure that the receiving site is aware of privacy legislation regarding the use of linked data.

5.2.3. Encrypt files for transfer using local encryption methods and software. Files may also be transferred as password protected compressed archives or transferred directly using encrypted file transfer.

5.2.4. Ensure that the original data files that are to be received by the data centre and that are to be transferred into the database are write-protected and are included in the data archiving process.

5.2.5. Maintain a copy of all files of the originating database before they are transmitted externally. Ensure the copy is write-protected and is included in the data archiving process.

5.2.6. Use point-to-point file transfers or utilization of authorized “drop file” facilities, when available. File drop/exchange services, provided by many institutions, utilize file encryption and secure transmission. File transfer via an email message is a secondary option.

5.2.7. Always send passwords to the recipient of the data files in a separate transmission.

5.3. Documentation and Verification

5.3.1. Ensure that the data file is accompanied by documentation of the content and format.

- If applicable, use export/import functions for creating/reading transport files and ensure that the appropriate documentation is associated to the transport.

- The minimum information should include:
  - The column positions or delimiter
  - The column headings
  - The field formats for all columns
  - The field lengths for all columns

5.3.2. Verify the data conversion by comparing the transferred fields to original field specifications, in cases where transferred data are converted to a different format.

5.3.3. Provide/verify the number of observations (rows) and number of variables (columns) in the transferred file, when feasible.

5.3.4. Request documentation from the receiving site or provide documentation to the transmitting site, to ensure that the file was received and verified.

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, http://www.isber.org

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network,

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP107_01	01-Aug-2012	Original version
SOP107_01	04-Jan-2016	Purpose: clarification added. Updated references. Removed OTRN logo.