CTRNet Standard Operating Procedure Database Backup Systems			
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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. CTRNet has policies regarding security safeguards to protect data and personal information stored in its database against failure, loss and damage. Failure may occur due to user error (modifying or destroying the data on its own or through a user choice), media failure (failure of equipment such hard drive) or a catastrophic event such as a fire, flood, power outage, virus, or deliberate hacking. The backup process must ensure the database can be completely and accurately recovered. CTRNet recommends biobanks strive to ensure data can be fully recovered on a daily basis. The aim is to limit data loss to no more than one day.

2.0 SCOPE

This standard operating procedure (SOP) outlines general elements and features that should be in place to ensure that information stored in a database can be recovered accurately, completely and in a timely manner.

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*

4.0 ROLES AND RESPONSIBILITIES

The policy applies to personnel from CTRNet member biobanks that are responsible for the database system and the safekeeping of sample and participant related information.

Tumour Biobank Personnel	**Responsibility/Role**
Information Technology (IT) Staff	Conducts backup/restores database according to specific biobank plan.
Tumour Biobank Director, Manager, or Principal Investigator.	Participates in development of biobank backup and recovery plan. Outlines recovery expectations.
Tumour Biobank management	Ensures adequate backup systems are in place

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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)
Database back up system	
Removable backup media	
Offsite storage location	

6.0 DEFINITIONS

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

7.0 PROCEDURES

The facility must employ backup systems to protect the data stored on the database from damage and loss. In the case of user error, media failure or catastrophic events, the system should ideally be able to recover the information to or near the point before failure occurred. There should also be confidence that the information is complete and free of corruption.

7.1 Database Backup – General Description of Process

7.1.1 Each biobank should develop a backup strategy based on:

- Database size
- Backup media available
- Database Management System (DBMS) used
- Recovery requirements (Acceptable data loss)
- Error detection. Undiscovered problems with data integrity that may require recovery from one or more older archive sets to locate and correct the problem.

7.1.2 Upon development of an acceptable backup plan, IT staff at the biobank should implement and monitor regular backups.

7.1.3 Send regular backup copies to offsite storage in case of fire, flood, earthquake or other “Acts of God” which may destroy on-site archives.

7.1.4 Test data recovery at specific intervals as specified in the backup/recovery plan and record results. Test both individual records and full database recovery. Be sure to test offsite archival sets as well.

7.2 Database Backup – Routine Process

7.2.1 Routine steps will depend on the media used. Ideally, the backup system should be automated and not require daily user intervention (manual changing of backup tapes for instance) to reduce chance of error.

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7.2.2 Perform validation to ensure the nightly backup completed successfully. Investigate any failed backups and resolve with the highest priority.

7.3 Database Backup - Frequency

7.3.1 Frequency is dependent on the recovery needs of the biobank. As a guideline the database should be backed up nightly. In the event of catastrophic hardware failure, at most one day of data entry or changes may be lost.

7.3.2 The maintenance of a standard archive set using current IT protocols is recommended.

7.3.3 Offsite Storage

a. CTRNet recommends (at minimum) monthly copies be sent offsite, weekly is preferred.

b. Where offsite storage is maintained, the service provider must be authorized by the host institution to handle sensitive data.

7.4 Database Backup – Recovery Plan

Base the biobank recovery plan on acceptable data loss. The ability to recover data may also depend on the system hardware and DBMS used.

7.5 Database Backup – Audit and Validation of Recovered Data

7.5.1 Develop a test plan to ensure backups are readable and store valid data.

7.5.2 Perform tests for full database recovery as well as individual record retrieval on a quarterly basis.

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

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10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
3.1.002 e1.0	2008	JdSH	Original document.
3.1.002 e1.0	May 2012	CMG	• Grammatical and formatting changes throughout • Definitions removed • Revision History moved to bottom • Reference Links updated • Updated SOP references

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