CTRNet Standard Operating Procedure Obtaining Confidentiality Disclosure Agreements			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	28-May-2012

1.0 PURPOSE

Employees at CTRNet member biobanks have access to confidential information in the form of patient medical records. Medical information is protected under federal and provincial privacy laws and under the terms of the consent process. Furthermore, information may also be bound under non-disclosure or confidentiality agreements. Employees with access to this information may not disclose it.

2.0 SCOPE

This standard operating procedure (SOP) outlines a process that should be followed to ensure that employees keep all sensitive information confidential. The process covers information that is protected under privacy laws as well as information that may be protected because of an agreement between the tumour biobank and a third party.

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 1 Informed Consent*
3.2 *CTRNet Policy: POL 5 Records and Documentation*
3.3 *CTRNet Policy: POL 7 Material and Information Handling*
3.4 *CTRNet Policy: POL 4 Privacy and Security*

4.0 ROLES AND RESPONSIBILITIES

The policy applies to all personnel from CTRNet member biobanks that have access to sensitive and personal information.

Tumour Biobank Personnel	**Responsibility/Role**
All employees	Sign agreement
Tumour Biobank Director, Manager, or Principal Investigator.	Ensure that agreement is signed before personnel are given access to any patient or research information. Maintain record of completed Confidentiality Disclosure Agreement (CDA).

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms 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)
Confidentiality Disclosure Agreement (CDA)	

6.0 DEFINITIONS

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

7.0 PROCEDURES

These procedures outline steps that should be followed to ensure that employees who have access to confidential information sign a Confidentiality Disclosure Agreement (CDA) that addresses privacy issues. It is intended to protect the rights of the patient and researchers that share proprietary information in the process of transactions with the tumour biobank.

7.1 CDAs – Important Elements

CTRNet must require an employee to sign a Confidentiality Disclosure Agreement (CDA) in order to protect sensitive and personal information to which the employee may have access. The CDA should contain at least the following elements:

- Definition of confidential information
- Knowledge of the appropriate relevant policies *(POL 7-Material and Information Handling and POL 4-Privacy and Security*)
- Exclusions (if any) from confidential information
- Obligations of the employees
- Miscellaneous provisions if relevant

7.2 CDAs – Completion of Agreement

7.2.1 Request that all employees at the tumour biobank (that will have access to patient or research information) complete a CDA.
7.2.2 Obtain, in duplicate, a completed (signed, dated and witnessed by a supervisor) CDA prior to the employee being granted any access to sensitive information.
7.2.3 Ensure that a supervisor or manager has signed and dated the CDA.
7.2.4 Retain one copy of the signed and witnessed CDA in hardcopy for the tumour biobank records.
7.2.5 Provide the duplicate copy to the employee for their records.

Appendix A has a sample CDA that may be used. This is a recommended agreement and biobanks may modify it to meet the local privacy laws and requirements.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Declaration of Helsinki
http://www.wma.net/en/30publications/10policies/b3/index.html

8.2 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/

8.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

8.4 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

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

9.0 APPENDICES

9.1 Appendix A – Confidentiality Agreement for Employees

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
1.1.001 e1.0	Aug 2008	JdSH	Initial release
1.1.001 e1.0	May 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 1: Deleted last half of first sentence in paragraph; deleted first part of 3rd sentence; deleted 2nd paragraph • Section 7: Minor changes to the first paragraph. • 7.1: Added *Knowledge of the appropriate relevant policies*, deleted *Time periods.* • Updated reference links

CONFIDENTIALITY AGREEMENT FOR EMPLOYEES

I am aware that the CTRNet Member Tumour Biobank named below has policies and procedures regarding the privacy, confidentiality, and security of personal patient/donor information and that it must comply with the (relevant Provincial and Federal) Health Information Protection Act. I understand that it is my responsibility to be familiar with the requirements outlined in these policies and procedures and I have read the current version of these policies and procedures.

As an employee I understand that I will encounter information through various sources including, but not limited to, interoffice communications, data or software maintenance, electronic media, verbal interactions or medical records.

As an employee of the Tumour Biobank named below, I agree to observe and comply with all policies and procedures of the Tumour Biobank with respect to privacy, confidentiality, and security of patient information. I will keep all information confidential during and after my term of employment with the tumour biobank. Except when I am legally authorized or compelled to do so, I will not use or disclose personal patient information that comes to my knowledge or possession by reason of my employment with this Tumour Biobank.

As an employee of the CTRNet Member Tumour Biobank I may also have access to proprietary and confidential research information. I will not use or disclose research information that comes to my knowledge or possession by reason of my employment with this Tumour Biobank.

I also acknowledge that:

1. The logon and password assigned to me is unique and is non-transferable.
2. I will promptly notify my supervisor if I suspect that someone has gained unauthorized access to my Logon/password.
3. I am responsible for any information accessed or changed with the use of my Logon/password.
4. I am responsible for adhering to all CTRNet privacy and information security policies.
5. Accounts can be revoked or locked at any time without prior notice.

I understand that any breach of the policies and procedures, including misuse or inappropriate disclosure of patient information, may be just cause for the termination of my employment.

Employee name: (please print)

_____

_____ _____
Employee Signature Date (dd/mm/yy)

Tumour Biobank:_____

Witness (privacy officer/Tumour Biobank Manager): (please print)

_____

_____ _____
Witness Signature Date (dd/mm/yy)