CTRNet Standard Operating Procedure Obtaining Confidentiality Disclosure Agreements			
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Subject:	Obtaining Confidentiality Disclosure Agreements	Category	Administration

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
1.1.001 e1.0			

1.0 PURPOSE

Employees at CTRNet member repositories have access to confidential information in the form of patient medical records, research plans for public and private institutions and research results (that if made public) could adversely impact the patient. Medical information is protected under federal and provincial privacy laws and under the terms of the consent process. Employees with access to this information may not disclose it. Further, research-client information may also be bound under non-disclosure or confidentiality agreements.

The purpose of this procedure is to outline a process where employees sign a Confidentiality Disclosure Agreement (CDA) in order to protect the sensitive information that they have access to.

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 bank and a third party.

3.0 REFERENCE TO OTHER CTRNet SOPS or POLICIES

1. Obtaining Informed ConsentCTRNet Policy: POL 005.001
2. Records and Documentation
3. CTRNet Policy: POL 007.001 Material and Information Handling Policy
4. CTRNet Policy: POL 004.001 Privacy and Security

4.0 ROLES AND RESPONSIBILITY

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

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
All employees	Sign agreement	
Tumour bank Director or Manager	Ensure that agreement is signed before personnel are given access to any patient or research information. Maintain record of completed CDA.	

5.0 MATERIALS, REAGENTS 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)**
CDA	

6.0 DEFINITIONS

Confidentiality A principle emergent from a relationship in which something about individual, information or material has been shared (with some degree of loss of privacy) in confidence.

Confidentiality Disclosure Agreements (CDAs): confidentiality agreements are contracts intended to protect information considered to be proprietary or confidential. Employees involved in executing a CDA promise not to divulge sensitive or protected information disclosed/accessed during employment.

Personal information: All information about individuals, living or dead. This includes written and electronic records and information obtained from samples.

Privacy: The state or condition of limited access to an individual and/or to information about that individual.

7.0 PROCEDURES

These procedures outline steps that should be followed to ensure that employees who have access to confidential information sign a non-disclosure agreement to keep this private. It is intended to protect the rights of the patient and the rights of researchers that share proprietary information in the process of transactions with the tumour bank.

7.1 CDAs – Important elements

CTRNet must require an employee to sign a confidentiality disclosure agreement in order to protect sensitive and personal information that the employee may have access to. The CDA should contain at least the following elements:

- Definition of confidential information
- Exclusions (if any) from confidential information
- Obligations of the employees
- Time periods (period of employment)
- Miscellaneous provisions if relevant

7.2 CDAs – Completion of agreement

1. Request that all employees at the tumour bank (that will have access to patient or research information) complete a CDA.
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.

3. Ensure that by a supervisor or manager has signed and dated the CDA.
4. Retain one copy of the signed and witnessed CDA in hardcopy for the tumour bank records.
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 banks may modify it to meet the local privacy laws and requirements.

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. 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
3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
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
5. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

Appendix A. CONFIDENTIALITY AGREEMENT FOR EMPLOYEES

I am aware that the CTRNet Member Tumour Repository 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 Repository named below, I agree to observe and comply with all policies and procedures of the Tumour Repository 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 repository. 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 Repository.

As an employee of the CTRNet Member Tumour Repository 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 Repository.

I also acknowledge that:

- The logon and password assigned to me is unique and is non-transferable.
- I will promptly notify my supervisor if I suspect that someone has gained unauthorized access to my Logon / password.
- I am responsible for any information accessed or changed with the use of my Logon /password.
- I am responsible for adhering to all CTRNet privacy and information security policies.
- 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
Repository:_____

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

_____

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