





Standard Operating Procedure Ontario Tumour Bank Privacy Policy			
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Subject:	Ontario Tumour Bank Privacy Policy		

Written By:		Project Director	11June09
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Approved By:		Director	11June09
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## 1.0 PURPOSE/BACKGROUND

Adequate knowledge of the Ontario Tumour Bank (OTB) privacy policy is essential to patient safety, program compliance, data integrity and overall quality assurance of the program. Tumour Bank personnel must understand their responsibilities in relation to privacy.

## 2.0 SCOPE

The OICR has a privacy policy that applies to the entire organization. This standard operating procedure (SOP) is an extension of that policy and specifies the particular privacy requirements of the OTB. Tumour Bank personnel at the collection sites are also subject to the privacy policies of the hospital where they are employed.

## 3.0 RELATED SOPS AND FORMS

- AD102 - Responsibilities of Tumour Bank Personnel at Collection Centre Sites
- AD106 - Responsibilities of Tumour Bank Personnel at the Administrative Centre
- TB301 - Patient Recruitment into Tumour Bank Program
- TB302 - Informed Consent Process
- TB311 - Physical Security of Facilities at Collection Centre Sites
- TB314 - Physical Security of Facilities at Administrative Centre

## **4.0 RESPONSIBILITY**

The Principal Investigator (PI)/OTB Director is responsible for the Tumour Bank staff training with respect to privacy. This SOP applies to:

- ❑ Principal Investigator (PI)
- ❑ Project Director
- ❑ Tumour Bank Analyst
- ❑ Client Coordinator
- ❑ Administrative Assistant
- ❑ Clinical Research Coordinators at collection centre sites
- ❑ Pathologist's Assistants at collection centre sites
- ❑ Principal Investigators at collection centre sites

## **5.0 DEFINITIONS**

See Glossary of Terms.

## **6.0 PROCEDURES**

All Tumour Bank personnel must be qualified by education, training and experience to perform their duties, and being educated in matters of privacy is fundamental to the OTB's operations.

### **Overview**

The OTB program is a critical resource for enabling oncology researchers to develop new diagnostic and prognostic tools, as well as contributing to the identification of targets and treatments for new drug therapies. The program will allow cancer researchers to apply for, and to access blood and tumour tissue samples, and the accompanying clinical data through a centralized process at the OTB. The OTB program as a repository for this significant collection of cancer tissues and data, coordinates the collection, storage, analysis, annotation, and distribution of blood and tumour samples obtained from consenting Ontario patients (i.e., donors) at participating collection centres.

All requests to access blood and tumour tissue samples must be approved by the Chair of the Ontario Cancer Research Ethics Board (OCREB), even if a researcher has ethics board approval from their home institution. To learn what types of blood, tumour tissue samples and accompanying clinical data are available in the program, researchers from both the public and the commercial sectors can access a user-friendly website that allows them to browse the grouped, anonymized inventory of blood and tissue samples in real-time.

The OTB program uses customized software (TissueMetrix) to receive “data feeds” from participating collection centres (which are hospitals and therefore Health Information Custodians or HICs) to its central database. In order to link the OTB central database with Cancer Care Ontario’s data holdings for the Annotated Tumour Project (ATP), all data are de-identified except for the patient’s partial date of birth (year and month) and Surgical Pathology Number (SPN) that are transmitted by the HICs to the OTB central database. The ATP database is hosted by Cancer Care Ontario (CCO) (Toronto, Ontario). CCO is a Section 45 Prescribed Entity under PHIPA and is responsible for safeguards to protect the privacy of PHI stored in the databases under its authority, including the OTB’s Annotated Tumour Project (ATP) database. The ATP supplies de-identified data to OICR for research purposes.

## **Activities**

The OTB coordinates the collection, storage, analysis, annotation and distribution of blood and tumour samples from consenting patients in Ontario. Through these activities, the OTB enables the advancement of cancer research.

The ten principles of privacy are outlined below.

### **6.1. Accountability**

The Program designate for Privacy is the OTB Project Director.

All HIC employees who work on the OTB at their collection sites are required to act in compliance with their hospital privacy policies which are in accordance to PHIPA and the OTB and relevant OICR privacy policies.

All OTB employees working within the OICR are responsible for complying with the OICR and OTB Privacy and Confidentiality Policies, and receive training in privacy and confidentiality and the management of PHI, and are bound by a signed Confidentiality Agreement that is a condition of employment.

### **6.2. Identifying Purpose**

Potential tissue donors will be informed of the purposes for collecting personal health information and the potential uses of their donated biospecimens through an informed consent process to be administered by the OTB collection centres. The purpose of sample and data collection is to learn more about cancer, and potentially to address other research questions through the use of the data and tissue for genetic research. The biospecimen samples collected and their associated de-identified data may be utilized by both academic and industry researchers and may result in inventions or discoveries that could provide a foundation for new products, diagnostics, and/or therapeutic agents. Individuals who obtain consent from potential tissue donors do so under the Privacy Policies of the HICs, OTB and OICR, all in accordance with PHIPA.

### 6.3. Consent

It is OTB policy that express consent be given by the individual donor, and not by their substitute decision maker or next of kin. Additionally, the OTB does not seek consent from individuals who are under 18 years of age.

A general description of potential uses of samples and data is provided to donors in the consent form. The use of all OTB biological samples in research projects is under the oversight of the Chair of the Ontario Cancer Research Ethics Board (OCREB), to ensure that the prescribed uses are consistent with those for which consent has been given and received ethics approval to ensure the protection of the donors.

For the purposes of obtaining free and informed consent, OICR shall provide potential donors with the following information:

- The purpose of the OTB program;
- The amount of blood to be collected and mention that tissue remaining from a biopsy or surgery will also be collected;
- That personal data are to be collected from hospital medical records;
- The manner in which the samples and the data will be acquired;
- The potential uses for the samples and the data;
- The limits on the use, disclosure, and retention of the samples and the data;
- The safeguards to protect the donor's privacy and confidentiality;
- The identifying information that will be attached to specific blood and tissue samples and the potential traceability;
- The known risks associated with the OTB program including the risks to privacy for the donor;
- The donor's right to obtain information concerning the use of their tissue and data; and
- The process for obtaining information and/or for lodging a complaint with the OTB program.

A donor may revoke her/his consent at any time. Requests to revoke consent are preferred to be in writing and addressed to the designated HIC that initially received consent. If the donor does not wish to revoke consent by writing, they may contact the HIC contact provided on the consent form to revoke consent. The opt-out process including steps taken by OTB to purge samples and data is described in section 6.6 of TM302 (Informed Consent Process).

In the event that samples from a donor that has revoked consent have been distributed to a researcher, the de-identified data that accompanied that sample(s) may be used for the approved research. The limitations to withdrawal of consent will be set out in the consent form.

## **6.4. Limiting Collection of Data**

The OTB has developed policies and processes to ensure that there are restrictions on the use of blood, tissue, and related data collected.

The collection of blood, tissues, and related data, at each HIC has been approved by each HIC's REB, whose mandate is to ensure that patients' (donors') rights are protected during participation in the research study.

Generally, PHI is collected directly from the donor's medical record at the HIC where their samples were banked. However, in cases where PHI is disclosed to a third party for the purpose of linking to additional information, the OTB will ensure that REB approval has been obtained at each HIC to do so, that the Informed Consent is changed to reflect this procedural change, and that there is a Memorandum of Understanding in place with the third party to ensure that there are adequate security measures in place for the protection of the PHI. In the instance of the Annotated Tumour Project (ATP), where PHI will be collected from Cancer Care Ontario, the OTB has undertaken all of the aforementioned steps.

## **6.5. Limiting Use, Disclosure and Retention**

The OTB will disclose or transfer biological samples and/or data only to researchers whose studies have been approved by the Chair of the Ontario Cancer Research Ethics Board (OCREB). OTB hospital site staff will not disclose any additional information to researchers who have received biological samples and/or data. Any requests by researchers for additional information will be managed by the OTB administration office.

All personal health information collected by the OTB is used only for the research purposes outlined in the REB-approved research proposals prepared in accordance with PHIPA and for purposes of improving the provision of health care related to cancer patients.

PHI is retained/securely archived as is required for clinical research projects and as per all applicable guidelines and regulations.

The OICR has developed guidelines and implemented procedures required for the secure retention of PHI. PHI that is no longer required to fulfill the identified purposes will be securely destroyed or erased after the agreed-upon retention period has been met. The OICR has developed guidelines and implemented procedures to govern the secure destruction of PHI such that the reconstruction of the PHI is not reasonably foreseeable in the circumstances.

### **6.5.1. Data Linkage to External Data Sets**

Any linkages to data outside the OTB database will be completed only when approval is sought and received from each of the collection centre REBs. The OTB will develop an

agreement with the custodian of the external data set that specifies the conditions and restrictions, relating to the use, security, disclosure, return, destruction and/or disposal of the data.

All linked data sets will be subject to the OICR policies and procedures governing the use and disclosure of PHI.

### 6.5.2. Annotated Tumour Project with Cancer Care Ontario

Fundamental to the Annotated Tumour Project is OTB's link to CCO's data holdings to fully annotate information regarding a biological sample. This project has been undertaken after REB approval for this process by each of the participating HICs was obtained, and after donors were provided with this new information through various mechanisms (information posted on hospital, OTB, and CCO websites, posters in hospitals) and with the opportunity to opt-out of the program after learning of the link to CCO's data holdings. Donors also were reminded that they are free to stop their participation in the OTB project at any time now or in the future.

In order to link the OTB database with CCO's data holdings for the ATP database, the patient's partial date of birth (year and month) and Surgical Pathology Number (SPN) are transmitted by the HICs to the OTB database. Encryption software is used to ensure that the PHI transmitted by the HICs to the OTB database is not available or identifiable to the OICR, to the OTB staff and/or any external researchers. CCO performs the data linkage using the partial DOB and SPN fields. The linked information in the ATP database (a CCO data holding) is accessible only to seconded data analysts (i.e., an OTB employee who is seconded to CCO for the purposes of this linkage), and to researchers in a de-identified form.

Researchers who submit a request for samples from the OTB will be provided with associated de-identified sample data from the OTB and/or from the ATP database after approval from the Chair of OCREB.

The OICR has a Memorandum of Understanding with CCO which owns and manages the ATP. Under this agreement, CCO has the requisite physical, administrative, and technical systems to safeguard the information. Access to the ATP database is controlled and regulated through a secondment agreement of an employee to CCO, and is via a CCO-owned and maintained computing system.

## 6.6. Accuracy: Requesting Correction to Personal Information

If donors to the OTB program wish to request corrections to their personal information, they must do so by contacting the HIC at which they donated their biospecimens.

## 6.7. Safeguards: Safeguards for Personal Information

### 6.7.1. Physical safeguards

The HICs are governed by their own policies regarding physical safeguards for the collection and retention of PHI.

The OTB follows OICR procedures on physical safeguards.

### 6.7.2. Administrative safeguards

The HICs are governed by their own policies regarding administrative safeguards.

The OTB follows OICR procedures on administrative safeguards.

### 6.7.3. Technological safeguards

The HICs are governed by their own policies regarding technology safeguards.

The OTB follows OICR procedures on technology safeguards.

In addition, the following technology safeguards are in place:

#### ***Physical deployment of TissueMetrix across the Ontario Tumour Bank***

TissueMetrix is a client-server system implemented with an Oracle relational database management system. This is a distributed database scenario wherein each collection site has a TissueMetrix system implemented with its own database, residing on a dedicated server within the hospital's server environment. The central database receives data updated from each of the collection sites over a virtual private network (VPN) provided by Ontario's eHealth Ontario (formerly Smart Systems for Health Agency) network infrastructure.

#### Physical access and user authentication

- At each collection site, TissueMetrix is installed on 2-3 workstations dedicated to OTB personnel. To access TissueMetrix, users are first required to login to the workstation using their Local Area Network User ID/password, and then login to the TissueMetrix desktop application using a separate user ID and password. Only users with an authenticated user ID/password are allowed access to TissueMetrix and able to connect to the database. OTB personnel at the collection sites are granted access to the TissueMetrix database as per DM508 ( Electronic Access at Administrative Centre).

- Access to the database server requires a user ID/password and is restricted to server administrators. Access to the Oracle RDBMS requires a separate user ID/password and is restricted to database administrators.

#### Automated Timeout

- The TissueMetrix application is set to timeout after a specific period of inactivity, to prevent unauthorized access to data stored via a workstation that has been left unattended.

#### Audit Logs

- **Login Audit Log** – TissueMetrix records an audit log of all successful connections made to the database.
- **Data Modification Audit Log** – TissueMetrix records a history of all modifications made to field values (actions audited include creating, editing, deleting, and signing records).

#### Restricted User Functionality

- Individual accounts are set up with selected privileges depending on the user's role, which protects information from being viewed, created, modified or deleted by unauthorized users.

#### Digital Signatures

- Data transmitted from the collection sites to the central database are digitally signed so that, upon receipt, the central database can verify that the data originated at a valid collection site and was entered and signed by a registered system user. This provides a mechanism to verify that data stored in the central database has not been altered manually since its registration.

#### Access to the OICR central database and ATP database

- OICR staff who have access to the OTB central database and/or ATP database (as CCO seconded employees) do not have access to any patient identifying fields. The OTB analyst and Client Coordinator provide data to researchers. Since these roles only have access to de-identified data, no identifying information can be accessed by researchers.

## **6.8. Openness**

Information about the OTB and the OICR and their policies and practices as related to the management and protection of PHI is available on our web site: [www.oicr.on.ca](http://www.oicr.on.ca).

## **6.9. Individual Access to Personal Information**

All requests regarding personal health information must be made to the HIC where informed consent was obtained from the donor.

## **6.10. Challenging Compliance**

All challenges to compliance with the principles in this privacy policy may be made c/o the VP Operations at OICR (see below). All complaints and/or inquiries will be addressed in a timely manner.

For more information about the privacy protection practices of the OTB, please contact:

**Ontario Tumour Bank  
c/o OICR**

Attn: Sugy Kodeeswaran, Project Director (or Designate)  
MaRS Centre, South Tower  
101 College Street, Suite 800  
Toronto, Ontario  
M5G 0A3  
Phone: 416-673-6639

For more information about the privacy protection practices of the OICR, please see the OICR's website at [www.oicr.on.ca](http://www.oicr.on.ca) or contact:

**Ontario Institute for Cancer Research**

Attn: Jane van Alphen, Vice President Operations  
Ontario Institute for Cancer Research  
MaRS Centre, South Tower  
101 College Street, Suite 800  
Toronto, Ontario  
M5G 0A3  
Phone: 416-673-6643

For more information about the privacy protection practices of the CCO, please see CCO's website at <http://cancercare.on.ca/about/who/privacy/> or contact:

**CCO Privacy Office  
Cancer Care Ontario**

620 University Avenue, 15<sup>th</sup> floor  
Toronto, Ontario  
Canada  
M5G 2L7  
[privacyoffice@cancercare.on.ca](mailto:privacyoffice@cancercare.on.ca)

Questions, concerns and complaints may be addressed to the Information and Privacy Commissioner/Ontario:

**Information and Privacy commissioner/Ontario**

2 Bloor Street East

Suite 1400

Toronto, Ontario

M4W 1A8

Web: [www.ipc.on.ca](http://www.ipc.on.ca)

Telephone: 416.326.3333

Long Distance: 1.800.387.0073 (within Ontario)

**7.0 REFERENCES**

1. The Personal Information Protection and Electronic Documents Act (PIPEDA)
2. Ontario's Personal Health Information Protection Act, 2004 (PHIPA)
3. OICR's Privacy Policy

**8.0 SOP HISTORY**

SOP Number	Date Issued	Summary of Revisions
AD104.001	May 13, 2009	Original
AD104.002	June 11, 2009	Minor edits to document based on comments from Shelley Birenbaum, additional information added to contacts in Section 6.10.