CTRNet Standard Operating Procedure Handling Participant (Donor) Complaints			
SOP Number:	01.004	Version:	e2.0
Supersedes:	1.1.004 e1.0	Category:	Administration

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	28-May-2012

1.0 PURPOSE

Voluntary participation of patients will influence the success of the biobanking program. Participants must be assured that their interests and privacy is of primary importance to the management and employees of the biobank. If participants have any reason to believe that their rights or interests have been violated, a procedure must be in place to deal with their complaints.

2.0 SCOPE

This standard operating procedure (SOP) covers steps that should be followed when complaints are received formally or informally from participants in the tumour biobank program. These steps may be adopted as is, or modified by specific CTRNet member biobanks to allow for differences in local and provincial laws and regulations protecting patient rights and privacy of information.

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 2 Ethics*
3.3 *CTRNet Policy: POL 4 Privacy and Security*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank personnel and clinical staff at the collection centres that are involved in handling participant complaints. This may include the following personnel:

Tumour Biobank Personnel	**Responsibility/Role**
Clinical Research Coordinator (CRC)/Biobank Nurse/ Tumour Biobank Manager	Has knowledge of relevant CTRNet policies, accepts and handles complaints
Oncology Physicians (Surgeons/Oncologists) at the Cancer Centre/Hospital or their designates, Principal Investigators, Tumour Biobank Director	Has knowledge of relevant CTRNet policies, accepts and handles complaints. Initiates investigation of complaint.
Research Ethics Board (REB) Members	Reviews complaint and investigation of complaint. Recommends or ensures that ethical resolution is achieved.

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)
CTRNet Complaint Form*	

* See Appendix A

6.0 DEFINITIONS

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

7.0 PROCEDURES

Procedures are intended to formalize a process for effective and timely resolution of concerns or complaints directed at the Tumour Biobank. They are also designed to ensure that the biobank complies with CTRNet's ethical and privacy policies.

7.1 General Considerations

Optimally, complaints should be handled:

- In a timely manner,
- In a manner responsive to participant concerns,
- With quality and thoroughness,
- By a neutral individual trained to handle and investigate complaints,
- With fairness; and
- With flexibility.

7.2 Handling of Complaints

7.2.1 Assure the participant that the tumour biobank is serious about handling all complaints and that there is a procedure in place to deal with it.

7.2.2 The tumour biobank staff should try to resolve the complaint at the time it is received.

7.2.3 If staff does not easily resolve complaints/concerns or if the staff feels uncomfortable addressing the complaint refer the complaint to the Director of the Tumour Biobank.

7.2.4 Only if the individual lodging the complaint requests a formal independent review, refer the complaint to the appropriate institutional body: this could include a patient ombudsman and/or the REB.

7.2.5 For complaints that escalate beyond point of service, it may be required that any or all of the following steps be completed:

a. Encourage the participant to submit the complaint in writing (using a form such as the one included in Appendix A),
b. Speak to the person or representative lodging the complaint to confirm the basis of the complaint,
c. Collect additional information,
d. Write a letter to the participant acknowledging the receipt of the complaint. This acknowledgement should include an explanation of the procedure for reviewing complaints,
e. Conduct an investigation if warranted,
f. Produce a report outlining the findings of the investigation and the recommendations,
g. Write a letter to the individual summarizing the resolution and/or summary of the complaint review.
h. Inform relevant authorities if there has been a breach of privacy.

7.3 Documentation of the Complaint Handling Process

7.3.1 Document the complaint.

7.3.2 Document the results of the complaint investigation/review.

7.3.3 Document any communications with the participant.

7.3.4 Document the resolution and recommendations.

7.3.5 Document any changes to inventory after the resolution of the complaint

7.4 Complaint Review

If appropriate, make necessary modifications to procedures and/or policies to ensure that the incident precipitating the complaint does not recur in the future.

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 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
http://www.ich.org/products/guidelines.html

8.4 Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent.
http://www.hhs.gov/ohrp/policy/ictips.html

8.5 Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004;144:229-34.

8.6 Complaints, SOP #: TTR-12, B.C. Cancer Agency, Draft version 4, Oct. 30, 2003

9.0 APPENDICES

9.1 Appendix A – CTRNet Complaint Form

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
1.1.004 e1.0	Aug 2008	JdSH	Initial release
1.1.004 e1.0	Feb 2012	CMG	• Grammatical and formatting updates throughout. • Removed the definitions • Revision History moved to bottom • Reference Links Updates • Updated SOP references • Section 7.2 (#4): added "…refer the complaint to the appropriate institutional body; this could include a patient ombudsman and/or the REB" • Section 7.4 (#1): deleted "Periodically (such as annually) review complaints that have been received." (#2): reworded the sentence.

CTRNet COMPLAINT FORM

YOUR INFORMATION:

Mr. Mrs. Ms. Miss

Given Name: _____

Surname: _____

Address: _____

TEL: _____

E-mail*: _____

*I consent to being contacted at this e-mail address or through that of my representative on my behalf. I acknowledge that sending e-mail over the Internet is not secure, in that it can be intercepted and/or manipulated and retransmitted.

REPRESENTATIVE INFORMATION: (complete only if you will be represented)

I authorize the following person to act on my behalf and to receive any personal information pertaining to me, as necessary to investigate this complaint

Mr. Mrs. Ms. Miss

Given Name: _____

Surname: _____

Address: _____

TEL: _____

E-mail*: _____

COMPLAINT

Name of Biobank or collection site that this complaint relates to: _____

Details of Complaint:

I have reason to believe that one or more of the following has occurred:

- The biobank has inappropriately collected my personal /clinical information
- The biobank has inappropriately disclosed my personal /clinical information
- The biobank has inappropriately used my personal /clinical information
- The biobank has inappropriately disposed of my personal /clinical information
- Other - Please Specify.

RESOLUTION OF COMPLAINT

Please describe how the complaint could be resolved:

Where to send this form:

Please mail this completed form to:
(Add name and contact information of responsible individual at collection site or biobank)

Signature: _____ Date: _____

POST REVIEW (to be completed by Tumour Biobank)

Immediate actions taken:

Tumour Biobank Director's findings and comments: