CTRNet Standard Operating Procedure Handling Participant (Donor) Complaints			
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Subject:	Handling Participant (Donor) Complaints	Category	Administration

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
1.1.001 e1.0	09 Jan 08	JdSH	Initial version

1.0 PURPOSE

Voluntary participation of patients will influence the success of the banking program. Participants must be assured that their interests and privacy is of primary importance to the management and employees of the bank. 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

The SOP covers handling of participant complaints. This SOP covers steps that should be followed when complaints are received formally or informally from participants in the tumour bank program. These steps may be adopted as is, or modified by specific CTRNet member repositories 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

1. CTRNet Policy: POL 001.001 Informed Consent.
2. CTRNet Policy: POL 002.001 Ethics
3. CTRNet Policy: POL 004.001 Privacy and Security

4.0 ROLES AND RESPONSIBILITY

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

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

5.0 MATERIAL, 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	

6.0 DEFINITIONS

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a subject's identity.

Informed and Voluntary Consent: A process by which a subject voluntarily confirms his or her willingness to participate in the tumour repository program, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Participant: An individual (patient or healthy volunteer, if applicable) who participates in the Tumour Repository Program. The terms patient, participant, subject and potential donor may be used interchangeably.

Complaint: A grievance expressed formally or informally if the participant feels that the tumour bank has inappropriately collected, used or disclosed personal or medical information or in any way violated the terms of the Informed Consent Form.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term ‘bank’ and ‘repository’ is used interchangeably.

7.0 PROCEDURES

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

7.1 GENERAL CONSIDERATIONS

1. 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

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

2. The tumour bank staff should try to resolve the complaint at the time it is received.

3. If complaints/concerns are not easily resolved by staff, or if the staff feels uncomfortable addressing the complaint refer the complaint to the Director of the tumour bank.

4. Only if the individual lodging the complaint requests a formal independent review, refer the complaint to the REB.

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

    - Encourage the participant to submit the complaint in writing (using a form such as the one included in Appendix 1),
    - Speak to the person or representative lodging the complaint to confirm the basis of the complaint,
    - Collect additional information,
    - Write a letter to the participant acknowledging the receipt of the complaint. This acknowledgement should include an explanation of the procedure for reviewing complaints,
    - Conduct an investigation if warranted,
    - Produce a report outlining the findings of the investigation and the recommendations,
    - Write a letter to the individual summarizing the resolution and/or summary of the complaint review.
    - Inform relevant authorities if there has been a breach of privacy.

7.3 DOCUMENTATION OF THE COMPLAINT HANDLING PROCESS

1. Document the complaint.

2. Document the results of the complaint investigation/review.

3. Document any communications with the participant.

4. Document the resolution and recommendations.

5. Document any changes to inventory after the resolution of the complaint

7.4 COMPLAINT REVIEW

1. Periodically (such as annually) review complaints that have been received.

2. Make necessary modifications to procedures to ensure that the incident precipitating the complaint does not recur in the future.

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. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. 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
4. Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm
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

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

APPENDIX 1

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 Repository 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 repository has inappropriately collected my personal /clinical information
The repository has inappropriately disclosed my personal /clinical information
The repository has inappropriately used my personal /clinical information
The repository 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 repository)

Signature: Date:

POST REVIEW (to be completed by Tumour Bank)

Immediate actions taken:

Tumour Bank Director's findings and comments: