CTRNet Standard Operating Procedure Notification of Significant and Relevant Findings			
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Subject:	Notification of Significant and Relevant Findings	Category	Participant Recruitment and Management

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
2.1.006	2008	JdSH	Initial document.

1.0 PURPOSE

Tissue donated to the tumour bank is intended for research studies. Sometimes the research may yield significant data that could be relevant to the participant's treatment, outcome, well-being or future health. Some provinces require that patients be informed of such findings. However, there are many social and ethical considerations attached to disclosure of research findings directly to the patient. Communication needs to be handled in a sensitive, professional and secure manner. This SOP is intended to outline basic steps that need to be followed if such a situation arises.

2.0 SCOPE

The SOP covers the procedures for handling disclosure of significant and relevant research study findings to the tumour bank participant.

These steps may be adopted as is, or modified by specific CTRNet member repositories at their collection sites to allow for the incorporation of site-specific details, local laws and regulations, conditions and REB requirements.

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. CTRNet SOP # 2.1.005: Obtaining Informed Consent

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel, clinical and research staff at the collection centres that are involved in decision making as well as disclosure of research findings. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank or Research Principal Investigator	Analyzing research data and determining if the data is significant and relevant	
REB	Reviewing research data and determining if the data is significant or relevant. Deciding if and how the notification will occur.	
Tumour bank Director and Consulting Physician	Coordinating notification in a sensitive, timely and confidential manner.	

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)**
Current ethical guidelines	
Relevant Provincial legislation	
Research Findings	

6.0 DEFINITIONS

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

Consent Form: A consent form is a written document that explains the tumour bank program to the participants. If they agree to participate this document is signed by the participants and must contain information/statements to ensure that subjects are fully informed about the program.

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.

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.

Significant and Relevant Findings: Research results which have been confirmed and validated and that have significant implications for healthcare, prevention or treatment options for the individual participant or general population.

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

The primary goal of the tumour repositories is to facilitate research that can advance the practice of oncology and preventative medicine. However, the repositories are responsible for ensuring that patients rights are upheld and that significant information is ethically disclosed and disseminated.

7.1 Confirmation of Significant and Relevant Findings

1. The Principal Investigator on the study should scientifically validate, confirm the findings and ensure that the findings are relevant to a particular tissue sample.

2. Once confirmed, the Principal Investigator should inform the Tumour Bank Director of the findings.

7.2 Findings review, considerations and consultation with the REB

1. The REB should reflect on the fact that disclosure of research results to participants represents an exceptional circumstance. Significant and relevant research finding should only be disclosed after careful consideration by the REB of the following points:

- Provincial laws and regulations requiring that research results be disclosed,
- Whether or not individual results disclosure was covered by consent process,
- Confidence levels that the test/research results have been adequately validated and correctly interpreted,
- The findings have significant implications for the participants health concerns and diagnosis,
- A course of action or options to ameliorate or treat the participants health concerns are readily available,
- The well being of the participant should take precedence over the interests of science and society,
- Disclosure of information that cannot be interpreted clinically, is premature,
- The effects of disclosure on family members who may be affected by the information (such as in the case of genetic or hereditary research),
- Complete confidentiality is maintained and that results are not leaked to insurance agencies or employers, and
- The availability of both pre and post-disclosure counselling.

2. The decision to notify a participant should be reviewed by the REB on a case-by-case basis.

3. REB approval must be obtained before notifying a participant.

7.3 Notification of participant

1. Assign a member of the clinical team to disclose findings (Family Physician or Primary Physician).

2. Notification should be conducted in-person.

3. Notification should adhere to clinical standards, including confidentiality.

4. Make sure adequate pre and post-disclosure counselling is available to participants and family.

5. If non-clinical investigators are responsible for disclosing findings (this practice should be avoided), then they should be trained in making clinical referrals, suggesting treatment options and trained in appropriate counselling techniques.

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. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html
4. 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
5. USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. http://www.fda.gov/oc/gcp/default.htm or www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
6. 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
7. American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. 2003. J Clin Oncol. 21(12):2397-2406.

8. Sharp, Helen M. and Robert Orr, 2004. When “Minimal Risk” Research Yields Clinically-Significant Data, Maybe the Risks Aren’t So Minimal. The American Journal of Bioethics 4(2): 32-36.

9.0 APPENDICES

None

