CTRNet Standard Operating Procedure Notification of Significant and Relevant Findings			
SOP Number:	02.007	Version:	e2.0
Supersedes:	2.1.007 e1.0	Category:	Participant Recruitment and Management

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	30-May-2012

1.0 PURPOSE

Biospecimens donated to the tumour biobank are intended for research studies. In most cases the research findings have no immediate clinical relevance to individual participants. Very rarely the research may yield data that might be relevant to the participant's immediate treatment, outcome, wellbeing or future health or have impact on their family. There are many social, ethical, and clinical considerations attached to the decision to make disclosure of research findings directly to the patient.

2.0 SCOPE

This standard operating procedure (SOP) covers the procedures for handling disclosure of significant and relevant research study findings to the tumour biobank participant.

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

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*
3.4 *CTRNet Standard Operating Procedure: SOP 02.005 Obtaining Informed Consent*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank personnel, clinical and research staff at the collection centres that are involved in decision making that might lead to disclosure of research findings. This may include the following personnel:

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank 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 Biobank Manager or Director	Coordinating notification with the consulting physician 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

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

7.0 PROCEDURES

The primary goal of the tumour biobank is to facilitate research that can advance the practice of oncology and preventative medicine. However, the biobanks are responsible for ensuring that patients' rights are upheld and this may lead to involvement in return of significant information.

7.1 Plan for Dealing with Significant and Relevant Findings

If a potential and significant finding comes to light as a result of donating biospecimens to a biobank, the biobank should have a clear plan to engage with relevant parties to consider a number of issues relevant to the process of return of research data, that will likely include REBs and clinicians.

7.2 Findings Review, Considerations and Consultation

Significant and relevant research findings should only be disclosed after careful consideration of the following:

a. Provincial laws and regulations
b. Whether or not individual results disclosure was covered by the consent process,
c. Confidence levels that the test/research results have been adequately validated and correctly interpreted,
d. The findings have significant implications for the participants health concerns and diagnosis,
e. A course of action or options to ameliorate or treat the participants health concerns are readily available,
f. The well being of the participant should take precedence over the interests of science and society,
g. Whether contact with the participant is feasible.

h. In the event that the participant cannot be contacted, the effects of disclosure on family members who may be affected by the information (such as in the case of genetic or hereditary research),
i. Complete confidentiality is maintained and that results are not disclosed to insurance agencies or employers.
j. The availability of both pre and post-disclosure counselling.
k. The advice of the REB that has been obtained.

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 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/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

8.6 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
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

8.7 American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. 2003. J Clin Oncol. 21(12):2397-2406.

8.8 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.

8.9 Genetics in Medicine. 2012 Apr; Volume14 (Issue 4): 478-83

Practical implementation issues and challenges for biobanks in the return of individual research results.

Bledsoe MJ, Grizzle WE, Clark BJ, Zeps N.
http://www.nature.com/gim/journal/v14/n4/full/gim201167a.html

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.007 e1.0	2008	JdSH	Original Document
2.1.007 e1.0	May 2012	CMG	Grammatical and formatting throughout Definitions removed Revision History moved to bottom Reference links updates Updated SOP references Section 1: Purpose, last two sentences deleted from the paragraph. Revised paragraph Section 4: minor additions to content Section 7.0: revised opening paragraph Section 7.1: Title changed, deleted points 1 & 2. Added new opening paragraph. Section 7.2: Removed the term “REB” from title, two bullet points added to content. Reference # 8.9 added.