Réseau de recherche sur le cancer du FRSQ

Réseau de recherche sur le cancer Policy

Education and Training

Policy Number:	POL 03	Category:	Policy
Supercedes:		Effective date	
Subject:	Education et Training		

BRIEF INTRODUCTION TO POLICY

Adequate knowledge of the tumour repository program processes, related regulations and guidelines is essential to safeguarding the interests of the patient, achieving program goals, maintaining program compliance, data and tissue integrity and overall quality assurance at the repositories that are members of Reseau de recherche sur le cancer du FRSQ (RRCancer) Personnel must understand the responsibilities of the repositories as the "custodians" of Human Biological Materials (HBMs) for research purposes and be appropriately qualified by education, training and experience to perform his or her task in an efficient, professional and ethical manner.

1.0 PURPOSE

The RRCancer is committed to high ethical standards and practices in the collection and storage of human tissue for research purposes. The purpose of this RRCancer policy is to outline general principles that can be used in most situations to ensure that personnel working at member repositories are adequately educated and trained to perform their tasks.

2.0 SCOPE

The policy describes recommendations for areas and material that should be the focus of any educational or training process to ensure that ethical and operational standards are maintained at RRCancer.

3.0 RESPONSIBILITY

This policy applies to RRCancer members and to personnel involved in all aspects of the tissue repository program. The Principle Investigator (PI) is ultimately responsible for the tumour repository-specific staff training, as well as ensuring that he/she has adequately-trained staff to carry out the processes of the program. The clinical and technical tumour repository personnel have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their relevant duties.

4.0 DEFINITIONS

Compliance: The state of conformity of a regulated party or a product with a legislative or regulatory requirement or a recognized standard.

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.

Human Biological Material: All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.

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.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the Tumour Bank Program is performed and the data are generated, documented (recorded), and reported in compliance with applicable policies, procedures and regulatory requirement(s) if any.

5.0 POLICIES

Learning is a dynamic process. All tumour repository staff should be qualified by education, training and experience to assume their responsibility for the proper conduct of the program.

- It is optimal that all those involved in the tumor repository program have necessary skills and knowledge and a clear understanding of the processes and policies that define the running of a compliant, efficient and successful program

- It is important that the personnel have a clear understanding of their role within the organization and have access to the appropriate level of information to support their decisions and actions.

- Training should be provided for staff who are new and have not previously received such training and for experienced staff who need to keep current with new developments, new methods, updated equipment or software and evolving regulatory requirements.

- Training should be designed to meet the needs of the staff working at the collection, storage and central sites if applicable. The scope, detail and content of the training should reflect the particular responsibilities of each site or individual.

- Training should be designed to include general issues such as:

    - The moral and ethical issues associated with the use of HBMs in research
    - Regulatory requirements that should be complied with
    - Best practices for record keeping and reporting
    - Security regarding issues of privacy and confidentiality
    - Tissue and Information release (material release)
    - Material Handling (tissue and information processing and storage)

- Training should be designed to include **site-specific** issues that may include:

    - Facility security and procedures
    - Occupational health and safety
    - Technical procedures and processes relevant to operations at the site (eg. deriving HBM products such as DNA, RNA, protein and tissue microarrays)
    - Maintaining records, updating inventories and databases

- Repositories should implement procedures by which they can assess and evaluate whether or not the personnel have achieved the learning outcomes of the training component.

- Tools used for training such as set of policies or standard operating procedures (SOPs) should be updated in a timely manner so as to accurately reflect current practice.

- Staff should be encouraged to keep current in their area of expertise. This could include attending relevant seminars, conferences, continuing education courses and keeping professional certification updated.

6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 03.01	04.11.2005	Original
POL 03.02		Brief description of revision. Sections of SOP affected.

7.0 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. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf