CTRNet Policy Biobank Planning			
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Approved By:	CTRNet Management Group (CMG)	27-March-2014
	Per: Brent Schacter	27-March-2014

1.0 INTRODUCTION

Human biospecimens are essential for translational cancer research. Collections of stored and well-annotated biospecimens and their derivatives represent considerable investment of time and resources and in many cases they are irreplaceable. As custodians of these valuable materials, biobanks have a responsibility to strive for public confidence, standardization of processes, enabling high quality research, and financial stability and sustainability.

Biobank planning is a valuable activity for new and existing biobanks to review their objectives and practices. It also serves to create a formal document that can be used as a reference for the existence of the biobank and as a communication tool for various stakeholders. CTRNet member banks are expected to employ sound business practices to maximize their ability to secure adequate funding to maintain the biobank, in accordance with the biobank's overall mission.

2.0 DEFINITIONS

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

3.0 PURPOSE

The Canadian Tumour Repository Network (CTRNet) is committed to enhancing biobanking capacity within Canada. One important element of this biobanking capacity is financial security of new and existing Canadian biobanks. The purpose of this CTRNet policy is to outline the general business planning principles for biobanks to consider in order to become sustainable entities.

4.0 SCOPE

This policy applies to the major business planning considerations that are applicable to biobanks. The way in which the individual biobank puts these policies into operation should be scaled in relation to the biobank's size of operations and should be adapted so that they are appropriate to the mission and goals of the biobank and are in accordance with institutional policies.

5.0 RESPONSIBILITY

Principal Investigators of CTRNet member biobanks are responsible for ensuring that sound business practices are used and the following principles should be used as a guide.

6.0 POLICIES

6.1 Develop and maintain a biobank plan that defines the biobank's overall goals and guiding principles. The biobank plan should include the following components:

6.1.1 Description of the vision, goals and objectives of the biobank;
6.1.2 Description of the need and current status of biobanking practices on the site;
6.1.3 Summary of ethical issues in the milieu specific to the biobank and issues relating to public confidence and public relations;
6.1.4 How the biobank will evaluate its success at meeting its objectives, developed in collaboration with all necessary stakeholders (e.g., milestones; metrics such as the number of cases collected and released); and

6.2 Develop a financial plan and sustainability strategy including a budget estimate of the anticipated revenues and operating expenses.

6.2.1 On a regular basis (e.g., annually) a review should be conducted of both the estimated costs and anticipated revenues to ensure they remain current and accurate.
6.2.2 Work processes should be regularly reviewed to identify any potential cost savings measures (e.g., alternate source for lab consumables; more efficient workflows). NB – prior to implementing any change to a standardized procedure, it is important to test and verify that the proposed change will not create an undesirable effect).
6.2.3 Any upgrades to aging equipment or redevelopment of infrastructure should be anticipated and included in the budget.

6.3 Establish and document any planned cost recovery mechanisms and obtain approval/endorsement from all necessary stakeholders.

6.3.1 On a regular basis (e.g., annually) a review should be conducted of the cost recovery processes.

6.4 Develop a legacy plan in the case that the biobank is discontinued.

6.4.1 Should it become necessary to cull the collection through destruction or transfer of the biospecimens/data, document the plan for the culling process and obtain the necessary approvals prior to enacting it, including all applicable governing bodies (e.g., the governing Research Ethics Board).
6.4.2 All records pertaining to the destruction or transfer of biospecimens/data should be stored under the same terms and conditions for other archival records of the biobank.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

7.1 ISBER Best Practices for Repositories 2012. Collection, Storage, Retrieval and Distribution of Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). http://www.isber.org

7.2 NCI Best Practices for Biospecimen Resources 2011. NCI-NIH Office of Biorepositories and Biospecimen Research.

7.3 OECD Guidelines on Human Biobanks and Research Databases 2009. OECD.

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 9 e1.0	27-Mar-2014	RB	Original document