CTRNet Biobanking Policy			
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Approved By:	CTRNet College of Advisors
	Per: Dr. Peter Watson

1.0 INTRODUCTION AND PURPOSE

The Canadian Tissue Repository Network's (CTRNet) primary focus is biobanking and biobanks in the context of health research. Biobanks are defined by CTRNet as encompassing all types of research collections irrespective of size or type. These collections arise through the process of biobanking in the course of pursuing basic research projects, translational research studies, clinical studies and trials, as well as when creating a collection to support future health research.

Biobanks benefit from good governance and standardisation. These features are best achieved by adoption of known external standards and delineation of internal principles and processes through policies, standard operating protocols (SOPs), guides and forms. CTRNet has developed a standard for quality biobanking that is outlined in a set of Required Operational Practices (ROPs) covering all aspects of biobanking. CTRNet has also developed a set of policies and SOPs for biobanks to use as templates for their own internal use. Since the development of the CTRNet policies (version 2011) the implementation of the CTRNet ROPs has led to some redundancy.

This integrated policy has therefore been developed to update and supersede the original set of policies. This CTRNet biobank policy is organized by sections that conform to existing CTRNet ROP topic headings and reflect and link to the individual standards relevant to the activity of biobanking. This CTRNet biobank policy also highlights the key elements that should be considered in the development of individual biobank policies and should reflect both the biobank itself and comply with the host institution. This policy can be used as it stands with links to the ROPs or as a template for a biobank to draw upon to develop policies in individual areas for their biobank.

2.0 POLICIES SECTIONS

2.1 Governance

- To ensure that the biobank will be governed by the overarching principles of transparency and accountability, the biobank will have a clearly defined purpose/mission (i.e., primary focus of research it supports).

- Compliance with the laws, codes, and agency and institutional requirements is required. These include:
  - Canadian (federal and provincial) legislation and regulations governing the collection use, dissemination, retention and destruction of human biospecimens and associated data for research purposes.

  - Canadian professional codes of conduct where these overlap with stakeholders' activities (e.g., medical licensing bodies and societies).
  - Research Ethics Board (REB) approval (certification/accreditation of the biobank by an external body may be beneficial for this review process).
  - Requirements from funding agencies/organizations/foundations and host institutions may also be delineated and comprise additional external accountability factors (e.g. annual reporting, creation of advisory boards) that should be incorporated into the internal governance of the biobank.

- The biobank should have a defined organizational structure including a description of leadership, management and operations and oversight access process.

- The biobank may choose to also include a public/participant advisory role, an ethics advisory role and/or a scientific advisory role in its governance structure.

- During the creation of a biobank, development of a business or scientific plan is essential. This plan may overlap with current provincial requirements, such as Quebec's Management Framework. The plan should include:
  - Mission, vision, goals of the biobank
  - Current need and status of local biobanking
  - Ethical issues associated with the biobank
  - How the biobank will evaluate its performance
  - Financial and sustainability plan including cost recovery if applicable
  - Legacy plan

For more information, please see ROP 1, Ethics, ROP 4, Governance and ROP 5, Access and Release.

2.2 Informed Consent

- The collection and use of biospecimens and clinical data for research must be undertaken with voluntary and informed consent of competent participants using an REB approved informed consent form. Any revision of this form or support material presented to the participant should receive REB approval in advance of use.

- In some circumstances a waiver of the requirement for obtaining consent can be granted when permitted by law. This can only be granted by the institutional REB on behalf of the participants where certain criteria including the physical and privacy risk to the participant is very low and the feasibility of contacting the participants for specific study consent is poor.

- In the case of minors or participants lacking decision-making capacity, consent must be obtained from an authorized third party (i.e. legally acceptable representative).

- Informed consent requires the participant to hold decision-making capacity to understand the consent in its entirety. Consent must be performed in a private and appropriate space and participants should be given appropriate time to consider the consent form such that they are making a truly informed decision.

- Participants must be able to withdraw their consent and this must not affect their standard of medical care.

- Unless otherwise approved by a REB, consent must be obtained in a written form or via verifiable electronic means.

- Personnel obtaining informed consent must be fully trained, qualified and be knowledgeable about the biobank.

For more information, please see ROP 1, Ethics and ROP 3, Informed Consent.

2.3 Ethics

- Research involving human biospecimens and associated data must conform to all institutional policies and ethical norms as delineated in the Canadian "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans."

- Approval of the biobank will be obtained from the institutional REB (or applicable REB).

- The REB approval should include approval of processes for maintaining confidentiality of participants, risk associated with the participation, custodianship of biospecimens and governance. It should also include any plans for:

    - Live cell biobanking
    - The sharing of genomic and clinical data
    - Commercialization
    - Determination of intellectual property
    - Return of research findings

For more information, please see ROP 1, Ethics and ROP 2, Privacy and Security.

2.4 Education and Training

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

- Education and 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.

- Education and training should include regulatory requirements for the biobank, best practices and standards for biobanking, privacy and security, biospecimen and data handling, processing, storage, equipment monitoring and safety procedures.

- Training and the work space should be designed to mitigate risks of injury and damage from biological, chemical, physical, electrical and fire hazards.

- Up to date biobank SOPs should be accessible at all times for dedicated staff.

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

For more information, please see ROP 7, Education and Training.

2.5 Privacy and Security

- The privacy of participants must be protected at all times and throughout every step of the biobanking pathway. The public and participants should have confidence that biobanks and researchers will use and handle biospecimens and clinical data with confidentiality.
- The biobank should ensure that participants are informed about the biospecimens and clinical data that will be collected and the associated privacy risks.
- It is important to ensure that sensitive participant information is used ethically and optimally for the research to benefit health and knowledge.
- The biobank should consider accountability for biospecimens and clinical data that are collected and ensure all appropriate safeguards are in place.
- The biobank must ensure that physical security measures are in place to protect the biospecimens that are stored.

For more information, please see ROP 1, Ethics, ROP 2, Privacy and Security, ROP 3, Informed Consent, ROP 4, Governance, ROP 5, Access and Release and ROP 8, Data Systems and Record Management.

2.6 Records and Documentation

- The use of biospecimens and clinical data is critical for medical research. Clear, accurate and complete records are essential. As custodians of biospecimens and associated data, biobanks are responsible for keeping accurate records.
- Biobanks must ensure that records and documentation reflect what has been approved by the REB.
- Records and documentation should be findable and retained in a secure environment. Electronic records should be backed-up regularly.
- Audits of records and documentation should be conducted as appropriate, (e.g. annually), as required by regulatory bodies or upon release of biospecimens.
- Biobanks must have procedures for participant withdrawal or to receive and respond to complaints or inquiries about its policies and practices relating to the handling of personal information.
- Any deviation to the regular procedures should be documented.

For more information, please see ROP 2, Privacy and Security, ROP 3, Consent, ROP 5, Access and Release, ROP 7, Education and Training, ROP 8, Data Systems and Record Management and ROP 12, Facility Design and Security.

2.7 Access and Release

- Access should be granted only after review by an established scientific review process. The

appropriate quantity of biospecimens and the extent of data needed to answer the research question should be determined.

- Biobanks should develop a standardized material access and release process to ensure that the use of biospecimens and associated data is transparent and equitable. It is recommended that biobanks develop an evaluation criterion which should be applied to all requests.

- Biobanks may need to develop a cost recovery model for access to biospecimens and associated data.

- Biobanks should only release material and associated data to research studies that have REB approval for their planned research.

- Biobanks should ensure the use of a Material Transfer Agreement (MTA) or Data Transfer Agreement (DTA), as appropriate to transfer biospecimens and/or information to any outside organization or individual. The use of a specific MTA or DTA for academic and commercial collaborators may be warranted.

- Biobanks should include a statement within their MTA's or DTA's regarding researcher responsibility for continued participant confidentiality.

For more information, please see ROP 1, Ethics, ROP 2, Privacy and Security, ROP 4, Governance, ROP 5, Access and Release, ROP 9, Biospecimens Collection and Processing and ROP 10, Biospecimen Collection & Retrieval.

2.8 Material and Data Handling

- The biobank must ensure that biospecimens are only collected and shared for research as per the informed consent form.

- The biobank must ensure that biospecimens are only collected in health care settings once all clinical needs have been met and approval has been obtained.

- When biospecimens collected by the biobank are potentially traceable to the participant, (e.g. coded), the biobank should develop a plan to respond to requests to access biobank biospecimens for clinical purposes.

- The biobank should handle biospecimens and data in accordance with the FAIR (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) principles. These principles have been developed to enhance data sharing and reuse and encapsulate a set of features and characteristics that promote the action and capacity to share resources.

- The biobank should consider the optimal processing and storage conditions for biospecimens such that they have the maximum utility.

- Quality assurance and regular audits should be conducted to ensure the integrity and quality of the collection is maintained.

For more information, please see ROP 2, Privacy and Security, ROP 6, Quality Management System and Process Improvement, ROP 8, Data Systems and Record Management, ROP 9, Biospecimens Collection and Processing, ROP 10, Biospecimen Collection & Retrieval, ROP 12,

Facility Design and Security and ROP 13, Safety and Waste Disposal.

2.9 Emergency Preparedness

- The biobank should develop an emergency preparedness plan to establish emergency responses for any natural disaster, pandemic or other disaster.
- The plan should be developed taking into consideration the type of disaster that could occur given the geographical location of the biobank and should include contact information for all appropriate staff and professionals.
- All staff should be trained in regard to the emergency plan.
- The biobank should ensure that all critical equipment has a back-up plan as required.

For more information, please see ROP 11, Storage Equipment and ROP 12, Facility Design and Security.

3.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Quebec Management Framework https://publications.msss.gouv.qc.ca/msss/document-000408/
- Canadian Federal Personal Information Protection and Electronic Documents Act. https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/pipeda_brief/
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- Declaration of Helsinki. https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
- FAIR principles. https://www.go-fair.org/fair-principles/
- ISBER Best Practices for Repositories. Collection, Storage, Retrieval and Distribution of Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). http://www.isber.org
- NCI Best Practices for Biospecimen Resources. NCI-NIH Office of Biorepositories and Biospecimen Research. https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf
- Quebec's Act respecting access to documents held by public bodies and the protection of personal information. http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/A_2_1/A2_1_A.html
- 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.
- https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

4.0 APPENDICES

None.

5.0 REVISION HISTORY

Policy version	Author	Summary of Revisions
V1_6 June 2024	TT	New policy format.