BC CHILDREN'S HOSPITAL BIOBANK

Title	Governance
Policy number	POL 8
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

Biospecimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetic insights, there has been a significant increase in the demand for properly prepared and clinically annotated biospecimens that yield valuable insights into the mechanisms and pathways of human disease. Research on biospecimens has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of biospecimens in basic and translational research. These guidelines have been applied to issues related to collection, storage, transfer and disposal of biospecimens and associated patient data.

2.0 PURPOSE

The BC Children's Hospital BioBank (BCCHB) is committed to the highest standards and practices in the collection and storage of biospecimens for research purposes. The purpose of this BCCHB policy is to outline general principles that can be applied in developing and implementing good governance for biobanks to ensure that the interests of the patient and all other stakeholders are safeguarded.

3.0 SCOPE

This policy applies to the governance of the BCCHB.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

- BCCHB Policy: POL 4 Privacy and Security
- BCCHB SOP: MTR 003-01 Material Request and Release

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Governance Policy (POL 008 v.2.0).

5.0 RESPONSIBILITY

This policy applies to BCCHB staff and members of the BCCHB governance committees and those involved in all aspects of the biobank program.

6.0 POLICY STATEMENTS

The following principles will guide the BCCHB in establishing good governance mechanisms.

Declaration of Purpose
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) and operational scope and this will be made publicly available.

External Governance and Accountability
Compliance with the laws, codes, and agency and institutional requirements that exist in Canada is required. These external governance elements include:

- Canadian 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).
- Biobanks that provide human biospecimens and associated data for research purposes must undergo ethics review and approval by a research ethics board (REB). Certification and/or accreditation of the biobank by an external body may be beneficial for this review process.
- Other 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.

Internal Governance and Accountability
An organizational structure should be clearly defined to encompass at a minimum the following roles and elements: leadership, management of operations, and contact and access processes. An organizational structure, including identification of individual(s) who will perform these roles, may be influenced by external stakeholders (such as the institution in the case of large biobanks) and approval will normally be part of ethics review and approval.

The internal governance structure is presented in **APPENDIX 1**, and the roles and responsibilities of each committee and subcommittee of the BCCHB are described below. Sample issues/questions for each committee/subcommittee are outlined in **APPENDIX 2.**

Each committee will operate with clear terms of reference including mandate and guiding principles relevant to each group. Each member will be asked to sign their acceptance of these terms.

BC Children's Hospital BioBank (BCCHB) Oversight Committee (BOC) is responsible for all of the operations of the BioBank, including its set up and long term operations. It acts as the liaison with the PHSA, BCCH, BCWH, CFRI, WHRI, BCMHARI and UBC. In addition, it has a close working relationship with the Research Ethics Board (REB) and includes members with specific biobanking expertise. The BOC provides regular updates to its funders, in particular Mining for Miracles through the BCCH Foundation. An important component of the BCCHB is external communications and public relations; therefore, an External and Public Members at Large ad hoc Committee will be established.

External Public Members at Large Ad Hoc Committee is formed ad hoc when required by the BOC with members at large who can either be brought together to provide direction and advise on specific public issues or alternatively its members may be consulted on an individual basis.

C&W Research Ethics Board (REB) works very closely with the BCCHB and advises from an ethical stand point but it is part of the BCCHB governance structure.

BioBank Executive Committee (BEC) will direct management and operations of the BCCHB; it will strategize and direct allocation of resources. The BEC will be responsible for all financial aspects such as budget, use of funds, annual planning, budget review and long term sustainability. Further, the BEC will oversee access to biospecimen processes including overseeing and directing subcommittee structure. This committee is accountable to the BOC.

Biospecimen Advisory Committee (BAC) is responsible for providing input into issues that directly and indirectly affect the type and amount of biospecimen and clinical data collected by the BCCHB. This committee is accountable to the BEC.

Scientific Access Subcommittees (SAS) are responsible for assessing the scientific merit of research applications. These committees are accountable to the BAC. The BCCHB will utilize two types of SAS.

1. For Principle Investigator (PI) driven research: PI's will approach the BCCHB with a request for biospecimen collection, storage and potentially, other BCCHB services. The PI will have to fill out an application form if he/she wishes to access the biospecimens. Any release of biospecimens from the BCCHB will include a review by a SAS, which will be composed of BCCHB representatives AND representatives from the relevant PI's laboratory such that the number of PI representatives outweighs the number of BCCHB representatives by one. This will allow for input from BioBanking experts while the PI will remain in charge of his/her biospecimens. After completion of the research study, any leftover biospecimens may be donated to the BCCHB if participants have consented to participation in the BCCHB. Review of each specific application and votes will be documented for future reference.

2. For ongoing BCCHB collections: Any researcher wishing to access biospecimens from the BCCHB collected for general use will have to undergo an application procedure which will include a review by a SAS. Composition of these SAS's may include 4-5 individuals including the Director of the BCCHB or a delegate, a clinician, scientist and pathologist. These committees will be assembled on an ad hoc basis, at the time of biospecimen applications. Reviewers will be invited according to their area of expertise so that experts with no conflict of interest but within the scope of the application can make recommendations accordingly. The peer reviewers that are

selected will be chosen by the BAC. Review of each specific application and votes will be documented for future reference.

7.0 REFERENCES

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4. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html

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16. Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.

17. Canadian Tumour Repository Network (CTRNet) Policy POL 008 e2.0. Governance

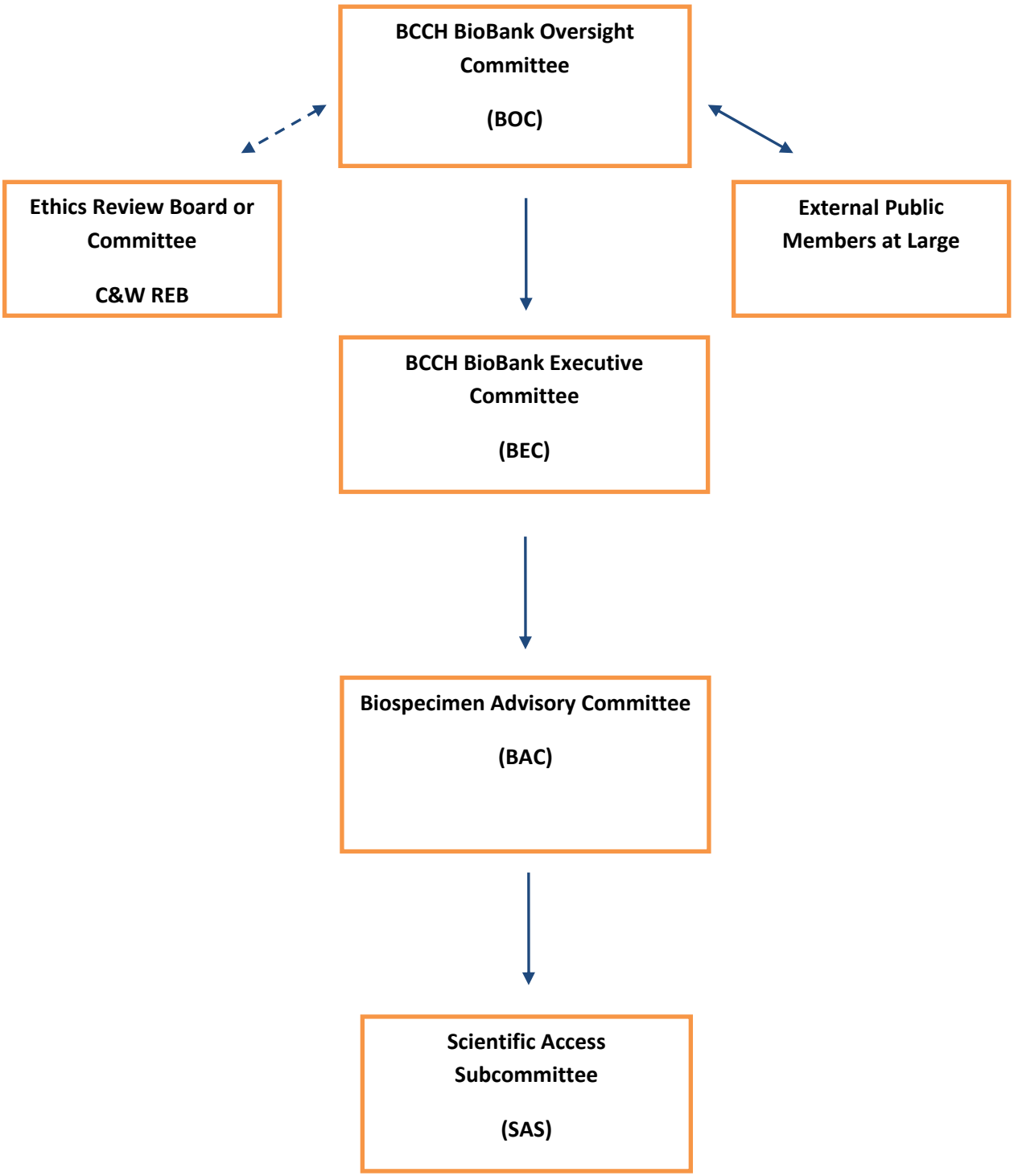
8.0 REVISION HISTORY

BCCHB Policy – Governance				
Policy Code -Version No.	**Date Revised**	**Approved By**		**Summary of Revisions**
		Print Name	**Signature**	
POL 8				Original version

9.0 APPENDICES

Appendix 1.

BC Children's Hospital BioBank (BCCHB)
Governance Structure



Appendix 2: Sample issues/questions for proposed BCCHB committees

BC Children's Hospital BioBank (BCCHB) Oversight Committee (BOC):

- Issues of long term/renewal of funding
- Privacy
- Patient and Public engagement
- Large scope issues related to Biobank set-up
    - Large equipment purchase
    - Overarching issues in space allocation/attainment
- Provide general guidance points

External Public Members at Large Ad Hoc Committee:

- Advise on specific public issues including:
    - Those that may pertain to current events in biobanking/translational research
    - Deliberative democracy or other public engagement activities
- Members may be consulted on an individual basis

Biobank Executive Committee (BEC):

- Allocation of resources:
    - Personnel
    - Funding
    - Infrastructure
- Issues of access to biospecimens
- Issues regarding biobank participation
        - Groups that may want to be involved representing
            - retrospective collections
                - "We collected pediatric brain samples FFPE blocks for 10 years and would like them to be a part of the Biobank"
            - prospective projects
                - "We want to collect 50 blood biospecimens from a rare disease group. Will you collect and store them for us?"
                - "We are collecting 50 biospecimens that we will consent. Will you process and store them for us? We will want all biospecimens for our research project."
    - Issues relating to PI driven research and the adoption of such biospecimens into the BCCHB.
- How to attribute costs to biospecimens:
    - Retrospective vs prospective collections
- Equipment purchase
- Grants and other funding resources

Issues related to:

- Finance
    - Annual budget
        - Annual planning
    - Use of funds
    - Budget review/modification
    - Revenue generation
- Matters on daily operation

- Hiring/firing personnel

Biospecimen Advisory Committee (BAC):

o Issues regarding biospecimen collection:
  - Quantity of biospecimen collected
  - Type of biospecimen being collected

"Given that we have $x allotted for the year 2014-2015, and our operating costs are y, we will be able to collect 'z' number of biospecimens of a certain type."

o Provide direct and indirect advice on issues related to biospecimen access including:
  - Quantity of biospecimen requested
  - Type of biospecimen being requested

o Issues of cost associated with biospecimen release at a project level

o Issues regarding biobank network opportunities

Scientific Access Subcommittees (SAS):

- Issues regarding the scientific merit of research applications with input from the BAC with consideration of:
  - Biospecimen type requested
  - Volume of biospecimens being requested
  - Proposed research protocol
- Further enrichment of the Biobank
- Enrichment of the scientific literature and community