RISe application form- Questions specific to Biobanks

Legend

Grey Highlighted questions appear depending on previous answer(s).

Guidance notes, click on icon to jump to guidance note

4.C. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

* **4.7.A. Creation of a Research Registry (Data) or Biobank**

Does this study involve the creation of a research registry (data) or biobank for future use in other research?

○ Yes ○ No

4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research registry or biobank? [Note if the creation of the database/ registry or biobank is part of a bigger project also included in this application, you must answer "no" below.]

○ Yes ○ No

Please note that Page C will only appear if Box 4.7A is marked as “Yes”

C. Creation of a Research Registry or Biobank

***C.0** Please select Application type:

○ Biobank (Biospecimen +Data) ○ Data registry

* **C.1.** What is the scope and purpose of the research registry or biobank?

* **C.2.** What are the anticipated public and scientific benefits of the research registry or biobank?

C.3. Over what period of time will data and/or biospecimens be collected?

C.3B Does this registry/ biobank focus on the analysis of biological material or data originating from Indigenous peoples, communities, or organizations?

○Yes ○No

C.3.B.1 Please note that additional provisos will be issued regarding research conducted on biological material and or data originating from Indigenous peoples or distinct communities.

C.4.A. Sources
Please name/list information source(s) are you accessing?

C.4.B. Provide specific details about the source(s), i.e., type of health records, location etc.
b) Please describe how permission to access this information, and to collect and use this information, will be obtained.
Note: A data collection form must be attached to Box 9.8.A.

C.4.C. What are the sources of your biospecimens? Check all that apply.

☐	Direct from live individuals (procedure conducted for research purposes) Select biospecimen source: If "Other" or multiple sources will be used, specify them here:
☐	Indirect from live individuals (procedure conducted for clinical purposes and leftover biospecimens collected for research) Select biospecimen source: If "Other" or multiple sources will be used, specify them here:
☐	Post mortem biospecimen collection Select biospecimen source: If "Other" or multiple sources will be used, specify them here:

C.4.D. Provide a detailed description of the method of recruitment. Include, where applicable:
a) who will contact prospective participants;
b) by what means will recruitment be done (e.g., public posting, in-person, letter of initial contact etc.);
c) how will prospective participants be identified;
d) all applicable site-specific information;

e) attach letters of initial contact or other recruitment materials (i.e., posters, phone/email scripts) to page 9.

C.5.A. Confidentiality

Are you collecting personally identifying information/will the biospecimens or data be linked to personally identifiable information?

○Yes ○No

C.5.B. Indicate the type of personally identifying information you will be collecting that will be linked to the biospecimens.

b) Include a justification for its inclusion in the registry / biobank and/or retention of the link.

C.5.C. Elaborate further how long data will remain identifiable / biospecimens will be linked (i.e., When, if ever, will it be de-identified?).

b) Justify why data / biospecimens need to remain identifiable, if this is the case.

C.5.D. List the individuals (who are not already listed on page 1 of the application) who will have access to personally identifying information at any stage in the data collection or review/abstraction of the data/analysis of the specimens including those who will have access to master lists of keys linking identifiable participants to research data/biospecimens.

Add

Name	Degree	Affiliation	Role on project	Email

C.6.A. Consent

Will participants consent to be included in the registry or biobank?

○Yes ○No

C.6.B. Specify who will explain the consent form and invite participants to be included in the registry / biobank. Include details of where consent will be obtained and under what circumstances (e.g., in-

person, online consent, phone, etc). If participants will not have capacity to consent, please click blue ? icon for additional questions.

C.7. If you do not plan to obtain individual participant informed consent, please explain how all waiver of consent criteria are met. CLICK on blue question mark. Please address each criterion individually. Include the corresponding letter (a, b, c, d, e, f) before each answer

C.8.A. Participant access to data/biospecimen and withdrawal

Will individual participants have the right to access their data/biospecimen, or right to amend or withdraw their information?

○Yes ○No

C.8.B. Provide details of the process for accessing and/or withdrawing data/biospecimens, including what data/biospecimens can be withdrawn.

* **C.9.** What is the entity or who is the person that will have custodianship of the research registry/ biobank?

* **C.10.** Where will the data/biospecimens be kept?

* **C.11.** What steps will be taken to ensure the security of the data and/or biospecimens?

* **C.12.** Please describe the risks associated with the possible disclosure of the data. Include any foreseeable circumstances where disclosure of identifying data may be required by law.

* **C.13.A. Data and/or Biospecimen Transfer to Other Institutions**

Will data be sent outside of the institution?
○Yes ○No

C.13.A.1.

Please
a) Explain why it is necessary to send the data outside of the institution;
b) indicate what data will be sent;
c) where the data will be sent (list institution & location);
d) who the data will be sent to;
e) how the data will be transferred (faxed, emailed, couriered, encrypted electronic transfer etc.); and
f) where the data will be stored.

C.13.B. Will biospecimens be sent outside of the institution?
○Yes ○No

C.13.B.1.
Please
a) Explain why it is necessary to send the biospecimens outside of the institution;
b) indicate what biospecimens will be sent;
c) where the biospecimens will be sent (list institution & country);
d) who the biospecimens will be sent to;
e) how the biospecimens will be transferred; and
f) where the biospecimens will be stored.

C.13.C. Will there be a data transfer/material transfer agreement?
○Yes ○No

* **C.14.A. Data Linking**

Do you plan to link all or some of the data and/or the biospecimens to another data source?
○Yes ○No

C.14.B. Identify the data set, how the linkage will occur, and provide a list of data items in the other database. Also, identify what personal information will be used to link the databases and how confidentiality regarding this shared information will be preserved.

C.14.C. Please clarify if consent will be obtained for the linkage:

* **C.15.A. Data/ Biospecimen Retention**

How long are you planning to keep the data/biospecimens?

C.15.B. If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens.

* **C.16. Access to Registry/ Biobank**

C.16.A. Provide a full description of the data/biospecimen stewardship process, including whether the registry/ biobank will have formalized standard operating procedures.

C.16.B. Please clarify who will have access to use the registry/ biobank for future research and how access will be granted.

C.16.C.1. Is your biobank / registered in the CTRNet Biobank Certification Program?

☒ Yes. If yes, please provide your registration record: _____

☐ No. If no, please go to https://biobanking.org/canreg to get information about the program.

C.16.C.2. This biobank does not need to register because it is not currently a requirement of my institution. ☐

* **C.17.** Describe any potential commercial uses for the data/biospecimens, including any disclaimers concerning participant remuneration for such use.

*C.18. How do you plan on updating registry/biobank participants with important information/updates such as types of research, governance, and operations?

Guidance Notes in Application

Box	Guidance Notes
	Page 4C Clinical Study Review Type (Q4.7)
4.7A	This does **NOT** apply to: i) a database that will be created for the sole purpose of routine data analysis of a project. ii) instances where the industry sponsor will be the custodian of data or biospecimen for future research. iii) secondary use of existing data or biospecimen which have already been collected clinically or under a previous research project that you plan to re-analyze for a different purpose. This applies to situations where the registry/biobank team is creating a registry of data or biobank that is specifically intended to be accessed by the researcher and/or other researchers for future use over an extended period of time. **Definitions:** **Registries** are repositories that collect and store information about humans specifically for use in subsequent research. The information may or may not include personally identifying information, clinical files, clinical test results, x-rays, MRIs, information about race, age, or place of origin, etc., that is collected retrospectively or prospectively. **Biobanks** (also known as biorepositories) An organized collection of searchable human biological materials stored for one or more specific or future unspecified research purposes. It may also include associated information about individuals from whom biological materials were collected. Registries and biobank can be of any size. Please note that once your application has been approved, then this box cannot be revised via an amendment.

Box	Guidance Notes
	Page C. Creation of a Registry or biobank
C.0	Select “Biobank” if you will be collecting and storing biospecimens and data. Select “Data registry” if you will be collecting and storing data only, this may include imaging (MRI, X-Ray) and medical chart/record data. Some institutions may request that a Privacy Impact Assessment (PIA) be completed when creating a research database or registry. Consult your hospital or institutional privacy office for more information.
C.1	Scope and purpose– what kind of research will be supported, types of biospecimen/data that will be collected, services offered, design of the biobank/registry, target enrollment.
C.3	Include a clear date range of the collection period. If collection will be indefinite, clearly indicate that data and/ or biospecimen will be collected indefinitely or until the participant withdraws, if applicable.
C.3.B	Click here for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities as well such as for eg, the Deaf community. Please see Article 9.19 to 9.22 regarding Collection of Human biological materials involving First Nations, Inuit and/or Métis People
C.4.C	Biospecimens - human biological materials which include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.
C.5.A	**Personally identifying information** is any information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g. name, SIN, PHN, date of birth, address, or unique personal characteristic etc.
C.5.B	For databases or registries, a data collection form should be attached to Box 9.8.A.
C.5.C	**Anonymized data** are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low to very low.
C.5.D	Include the name, degree, affiliation, role on the project, and email address of **ALL** individuals who have access to personally identifying information.
C.6A	Attach a copy of the consent form to Box 9.2.
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Box	Guidance Notes
C.6B	If participant will not have capacity to consent, please include the following information: A. Provide details of the nature of the incapacity (for instance, young age, mental or physical condition). B. How capacity to consent will be evaluated. Please see here C. Who will consent on their behalf? D. Will they be able to give assent to participate? E. If yes, explain how assent will be sought.
C.7	Please see below for the different types of waivers. Along with links to the appropriate TCPS 2 articles. Include the corresponding letter (A, B, C, D, E, etc.) before each answer. **For Retrospective (pre-existing) data collection** refer to Article 5.5A; click here Address criteria (a) to (f) individually. **For Retrospective (pre-existing) biospecimens** refer to Article 12.3A click here. Address criteria (a) to (f) individually. **For Prospective data collection**, please refer to Article 3.7A please click here. Address criteria (a) to (e) individually. If a researcher satisfies all of the applicable conditions the REB may approve the research without requiring consent from the individuals.
C.8	TCPS Article 3.1: If a participant withdraws consent, the participant can also request the withdrawal of their data or biospecimens *TCPS Article 12.2: The process for requesting withdrawal of Biospecimens shall be clearly explained, along with an explanation of the conditions under with researchers would NOT be able to remove a participant's data from the project (information already derived from the biospecimens and aggregated cannot be withdrawn, or anonymized data)
C.9	A **data/biobank custodian** is an entity or person who is responsible for overseeing the management and use of the data/biobank, including the main rules governing use of the database/ biobank, the process by which access requests will be reviewed, and the organization to whom the researcher is accountable for the proper management of the data/biospecimens.
C.10	Biospecimens/data will be stored in facilities overseen by the institution under the supervision of the <PI, department x and name of institution>.
C.11	Reference procedural measures, technical measures, and physical measures planned for the protection of data. If a coding procedure is being used, describe the procedure in detail in this box.
C.13A	Note that if this changes in the future an amendment must be submitted before data are transferred.
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Box	Guidance Notes
C.13.B	Note that if this changes in the future an amendment must be submitted before biospecimens are transferred.
C.13.C	Material/data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached to Box 9.9 after initial approval via an amendment
C.14.A	Note that if this changes in the future an amendment must be submitted before data/ biospecimens are linked.
C.16.B	Reference who will have access to the database in the future and under what circumstances, what will happen if an individual data custodian leaves the institution, where the ongoing database will be stored or maintained, and what security measures will be in place. UBC's REBs encourage researchers who are creating biobank to consider certification of their biobank with the 1. Canadian Tumour Repository Network (CTRNet) Biobank Certification Program 2. or accreditation with the College of American Pathologists (CAP) biobank Accreditation Program or 3. The international biobanking standard - ISO 20387:2018 - https://www.iso.org/standard/67888.html
C.18	Researchers have an ongoing duty to provide participants and REBs with all information relevant to the participants' ongoing consent to participate in the research. The biobank/registry may choose to provide participants with access to information within a reasonable timeframe via a website or newsletter.
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