Analysis of Biospecimen and related data-Page M

When filling the application, guidance notes only appear when the blue question mark bubble is clicked; it will appear in a separate pop-up.

Boxes 4.9A and 4.9B will appear if Boxes 4.7A and 4.8A are marked as "No"

Application Question	Guidance notes
Please click here for video explaining the next two questions **4.9.A.** Is this study exclusively analyzing previously collected biospecimen and data related to the biospecimens? ☐Yes ☐No	**Box 4.9A** Examples of studies that can use this truncated form: • Research on pre-existing biospecimens (for e.g., samples from the hospital Pathology Dept) • Research using biospecimens obtained from a dedicated biobank. • Research conducting new analyses on biospecimens collected in a different research study. • Cadaveric studies Please note that once your application has been approved, then this box cannot be revised via an amendment.
4.9.B. Are BC researchers, in this application, only conducting biospecimen analysis, with all participant recruitment occurring outside of BC? ☐Yes ☐No	**Box 4.9B** -Prospective study wherein BC researchers are only involved in sample analysis. For e.g., A study is enrolling in Montreal and Paris only. Biospecimens are transferred to BC researchers for analysis. No enrollment in BC. This study would answer "Yes" to this question. Please note that once your application has been approved, then this box cannot be revised via an amendment.

Please note that Page M will only appear depending on how Boxes 4.9 are answered.

M. Analysis of Biospecimens

Application Question **Shaded=**show depending on response to previous question	Guidance notes
For a tutorial on how to complete this form please see this video here * M.1. Summarize the research proposal using the following headings 1) Purpose 2) Hypothesis 3) Justification 4) Objectives 5) Specimen Analysis (tests performed-including any whole genome sequencing) Text box * M.2. Describe what permissions have been obtained or are required to access the biospecimens. Text box * M.3.A. Please describe what types of biospecimens will be used (types include: tissue site, normal or disease category, and preservation format). Text box M.3.B. Are biospecimens needed for clinical care, such as for standard of care diagnostic purposes? ☐Yes ☐No	**Box M.1** Please summarize study details, this would be similar to a Journal Abstract. The Protocol would contain more details regarding the study. **Box M.2** Biospecimens under the custody of health authorities require Institutional/Operational approval. Contact the health authority for more details. Please ensure that the access and use of biospecimens is permitted under privacy law and that the organization or department with custody and control of the information is aware of this use and access and has either approved it or explain the status of that approval. **Box M.3A** Biospecimens can include: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, fecal matter and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.

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* M.4. Please provide: a) Number of individuals for which samples will be obtained b) Total Volume of each specimen (e.g., 50 individuals - 20ml total blood and 10ml total CSF collected per individual): c) If samples are from the Pathology Dept, list full date range of samples to be included (e.g., Samples from Jan 1, 2000-Jan 1, 2020): Text box	
* M.5.A. Please clarify: a) What data will be collected/ provided along with the samples? b) How is this data obtained? c) What analysis will be performed with the data provided? Text box	**Box M.5A** Include participant data that will be provided along with the samples, for e.g., age, sex, disease type, date of specimen collection. Note that data, such as medical records, under the custody of health authorities require Institutional/Operational approval. Contact the health authority for more details.
* M.5.B. Do researchers plan to link the data obtained from the biospecimens to any other data (including personal health or research data of the individual)? ☐Yes ☐No	
M.6. Consent * M.6.A. Was consent obtained from participants for the use of biospecimens? ☐Yes ☐No	**Box M.6** If applicable, please ensure to include the study application number of the associated study or biobank in Boxes 4.3A and 4.3B Attach previously used consent form template to Box 9.9.
M.6.B. If yes, please explain the consenting process and the relevant details of what the participants consented to. Attach template consent form in Box 9.9. Text box	

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Waiver of Consent - Biospecimens Box M.6.A Indicates that consent was not obtained for the use of biospecimens. As institutional policy indicates that biospecimens shall not be considered anonymous (unless the BC REB determines otherwise) please complete the following waiver criteria.	**Waiver of Consent:** As per UBC policy LR9 "Genetic material shall not be considered Anonymous unless a BC REB determines otherwise". As such, if consent was not obtained for the proposed research, waiver criteria must be meet. Note that this will be determined by the REB.
* M.6.1. Explain why access to identifiable biospecimen is essential to the research Text box	**Box M.6.1** Researcher must address all the waiver conditions listed in Boxes 6.1-6.6, for the REB to consider approving the research without requiring consent from the individuals from whom the biological materials were collected. Please see TCPS2 Article 12.3A
M.6.2. Explain how the use of identifiable biospecimen without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the biospecimen relates Text box	
* M.6.3. Explain what measures will researchers will take to protect the privacy of individuals, and to safeguard the identifiable information Text box	
* M.6.4. Explain how researchers will comply with any known preferences previously expressed by individuals about any use of their biospecimens Text box	
* M.6.5. **Justify** how it is impossible or impracticable to seek consent from individuals to whom the biospecimen relates (***Please click** on blue question mark) Text box	**Box M.6.5** Impracticable – Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Please provide a justification as to why it is impracticable or impossible to consent.
* M.6.6. Explain how researchers have obtained any other necessary permission for the use of biospecimen for **research purposes**. Text box	

Application Question **Shaded=**show depending on response to previous question	Guidance notes
* M.7. Will researchers who are listed in this application have access to personal identifiers? ☐Yes ☐No M.7.A. Please indicate a) What personally identifying information will researchers have access to when conducting the study? b) Who will have access to the identifiable data? c) If a masterlist (key linking names and study IDs) is kept, clarify when this will be deleted. Text box * M.7.B. Will personal identifiers be retained as a part of the dataset? a) If yes, list which personal identifiers will be included: b) Include a justification of why personal identifiers will be retained. Text box **Waiver of consent - Data** Box M.6.A Indicates that consent was not obtained and researchers will have access to **identifiable information** (e.g., names or medical record) as indicated in box M.7. Please complete the following waiver: * M.7.1. Please explain why access and use of identifiable information is essential to the research: Text box	**Box M.7** Mark "Yes" if listed researchers will be the ones that pull records/charts/ or review records to retrieve the biospecimens. Mark "No" if researchers will be provided with de-identified data Only (i.e. personal identifiers are removed from the dataset provided by another party) 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, pathology accession number, or unique personal characteristic etc. **Box M.7.1** Consent was not obtained for the use of identifiable information. Researchers must address all the waiver conditions listed in Boxes 7.1-7.6, for the REB to consider approving the research without requiring consent from the individuals from whom the information relates. Please see TCPS2 Article 5.5A https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html#5a

Application Question **Shaded=**show depending on response to previous question	Guidance notes
* M.7.2. Explain how the use of the identifiable information without the individuals' consent is unlikely to adversely affect the welfare of the individuals to whom the information relates Text box	
* M.7.3. Explain how researchers will take appropriate measures to protect the privacy of individuals and safeguard the identifiable information. Text box	
* M.7.4. Explain how researchers will comply with any known preferences previously expressed by individuals about any use of their information. Text box	
* M.7.5. **Justify** why it is impossible or impracticable to seek consent from individuals to whom the information relates Text box	**Box 7.5** Impracticable – Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it **does not** mean mere inconvenience. Please provide a justification as to why it is impracticable or impossible to consent.
* M.7.6. Explain how researchers have obtained any other necessary permissions for the use of the information for **research purposes.** Text box	
* M.8. Does this study focus on analysis of biological material originating from Indigenous peoples? ☐Yes ☐No	**Box M.8** Secondary use of human biological materials identifiable as originating from a specific First Nations, Inuit or Métis community, or a segment of the Indigenous community at large, is addressed in Articles 9.20 to 9.22. Please see http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter9-chapitre9.html#20

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M.8.1 Please note that additional provisos will be issued regarding research conducted on biological material originating from Indigenous peoples.	
* M.9. Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on biospecimen labels and data collection forms. Text box	**Box M.9** REBs require the use of a unique study code. Information is considered de-identified if the following conditions are met: 1. the unique study code is not derived from or related to the information about the individual (i.e., name, SIN, PHN, hospital number, DOB, address, or unique characteristic); 2. the unique study code could not be translated to identify the individual, and; 3. the investigator or their institution do not currently or in the future use OR disclose the unique study code for other purposes OR disclose the mechanism for re-identification. Refer to TCPS2(2018), Article 5.3 for more information on safeguarding participant information.
* M.10. Please Explain: a) Who will have access to the biospecimens, data/data derived from the biospecimens at each stage of processing and analysis? b) Indicate whether a list of the names of current and past study team members and their delegated tasks will be maintained in the study file. c) If a list will not be maintained, please explain. Text box	
* M.11. Please describe for the biospecimens: a) What will happen to the biospecimens at the end of the study? b) Where and how long the biospecimens will be stored/retained? c) When and how the biospecimen will be destroyed ? Text box	
* M.12. Future use of biospecimen a) What plans are there for future use of the biospecimen? b) Who will have access to the biospecimen in the future and for what purpose? c) How and by whom will access be determined? Text box	**Box M.12** Please note that future use of biospecimen may require a separate ethics application. Please consult your REB regarding future use.

Application Question **Shaded=**show depending on response to previous question	Guidance notes
* M.13. Data Storage a) Describe how participant data or data derived from the biospecimens will be stored (e.g., computerized files, hard copy, other). b) Please provide the details on how any digital data will be stored. (e.g., an encrypted, password protected computer, storage device, or hospital network server) c) Clarify if the storage device/computer/cabinet is a personally-owned or provided by an organization Text box	**Box M.13** Study documents must be kept in a secure locked location/filing cabinet. Computer files should be password protected and encrypted, and data should not be stored or downloaded onto an unsecured computer or a portable laptop.
* M.14.A. Please describe for the participant data or data derived from the biospecimens a) What will happen to the data at the end of the study? b) How long the study data will be retained? c) How the data will be destroyed? Text box	**Box M.14.A** Please include the following information: Final disposition/storage of all research-related study documents. According to UBC Policy SC6, study **data** should be kept for a minimum of 5 years after publication Final disposition of any electronic data. The procedure that will be followed in response to additional requests for access to the study data (after the study has been completed and analyzed).
* M.14.B. Please clarify the researchers' plan for handling results and findings, including clinically relevant information and incidental findings Text box	**Box M.14.B** Material incidental findings: Researchers should refer to the guidance in TCPS2 2018 here, which addresses material incidental findings.

Application Question **Shaded=**show depending on response to previous question	Guidance notes
* M.15.Future Use of data a) What plans are there for future use of the data? b) Who will have access to the data in the future and for what purpose? c) How and by whom will access be determined? Text box	**Box M.15** Please note that future use of data may require a separate ethics application. Please consult your REB regarding future use.
* M.16. Will biospecimens or the related data be transferred out of the BC study site(s) OR received by the BC study site(s)? ☐Yes ☐No	**Box M.16** Please indicate the type of biospecimens/data to be transferred and in what form it will be in when transferred. If biospecimens/data are transferred out of BC sites and biospecimens/data will be received by BC sites, please complete sub-questions twice. 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 after initial approval via an amendment. Note that if this changes in the future an amendment must be submitted before biospecimen/data are transferred.
* M.17. Stem Cell Research- Does this research fall within the categories of pluripotent stem cell research that need to be submitted to the CIHR Stem Cell Oversight Committee (SCOC)? ☐Yes ☐No	**Box M.17** Click here for information on human pluripotent stem cell research. Certain types of research involving the use of human pluripotent stem cells conducted under the auspices of institutions receiving Tri-Council funding are required to apply to the CIHR SCOC for approval

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M.18. Clarify if the following documentation is needed for the research (select all that apply). **Please attach** the following if applicable, to Box 9.9 as reference	**Box M.18** Please attach these documentations for the previously collected biospecimen. Note that in some instances when biospecimens were collected over a period of time, there may be more than one applicable document in each category. Consent form, if applicable, should be from when the biospecimens were originally collected. Do not create an example or potential new consent form. 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 after initial approval via an amendment. Data collection forms includes variables that are provided along the biospecimen, such as: sex, date of collection and disease type. A data collection form should also be attached if data will be extracted from medical records.

☐	Purchase agreement
☐	Previous Consent form(s) used (when biospecimens were originally collected)
☐	Data collection forms: provided with the samples OR extracted from records (Attach to box 9.8A).
☐	Certificate of Ethics approval(s) (obtained for initial biospecimen collection)
☐	Material transfer agreement