Guidance Document HREB Secondary Use Application

Please complete ALL fields below ACCURATELY. The information provided will be used for invoicing by the Health Research Ethics Authority for industry sponsored research. By completing below, you understand and agree that payment is due upon review by the HREB for services rendered and is not contingent upon securing approval by the HREB or executing a contract with the PI and/or Institution. Payment is expected within 60 days of the invoice date. To Note: If a Sponsor has outstanding review fees, any subsequent applications WILL NOT be reviewed by the HREB until full payment is received.

Tab 1: Sponsor Information

1.1: Is this project industry sponsored and subject to a review fee?

All industry sponsored research projects submitted to the HREB are subject to a review fee. For further information on review fees, please refer to the HREA website. A link to this can be found under 'Useful Links' on the Researcher Portal Home page.

- o Yes (Please complete and attach the **'HREA Invoice for Industry Sponsored Research'**.)
- o No (Please skip questions 1.2 - 1.10)

1.2: Name of Sponsor:

1.3: Forward Invoice to:

- o PI
- o Sponsor

1.4: Company to be Invoiced:

Please provide the name of the Sponsor/CRO responsible for paying the invoice.

1.5: Complete Mailing Address:

Please provide the complete mailing address for the person responsible for paying the invoice.

1.6: Email Address:

Please provide the e-mail address for the person responsible for paying the invoice.

1.7: Contact Name:

Please provide the contact name of the person responsible for paying the invoice.

Tab 2: Study Timeline

2.1: Anticipated completion date:

2.2: Is this research project required by your program of study?

Examples include course requirement, major research project, thesis, dissertation, Resident research project

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Tab 3: Data Sources

Keep in mind that if any data will be collected prospectively this project will need to be submitted on the 'HREB General Application Form' not the 'HREB Secondary-Use Application Form'.

If using data previously collected for another purpose (i.e. secondary use of data), please include under the Attachments tab the "'**Variable list**"' (signed by the data custodian) which describes the information sought.

Please note: the term "data" referenced within this application includes blood and/or other biological samples.

3.1: Check data sources:

To access data held by a data custodian, please provide the "**Variable List**" (signed by the data custodian) for HREB review. The "**Variable List**" template is available for download under the "Attachments" tab of the application.

- o Health records
- o Pre-existing dataset/s
- o Archived blood and/or other biological samples
- o Discarded blood and/or other biological samples
- o Other

3.2: Please specify:

Please provide details of the secondary data sources selected in response to question 3.1 and upload the "**Variable list**" (signed by the data custodian) under the Attachments tab of the application.

3.3: Please give name(s) and location(s) of the data custodian(s) for all secondary data sources:

3.4: Time period (month, year) of records/secondary sources/blood and/or other biological samples to be accessed:

Please indicate the time frame for the records/secondary sources/blood and/or other biological samples that you are accessing. For example, records from Jan 2017-Dec 2018.

3.5: How will relevant records/secondary sources/blood and/or other biological samples be identified?

e.g. Request to medical records department for all records/charts meeting inclusion criteria over a three month period; request for access to ER logs to characterize patients over a one month period; request to pathology for all requisitions meeting inclusion criteria; request to cancer registry for all patients diagnosed with bile duct cancer from 2001-2006.

3.6: Proposed number of charts/records/blood and/or other biological samples to be accessed.

3.7: What type of information is being requested from the data source(s) identified in question 3.1

Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

Coded information - direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).

Anonymized information - the information is 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 or very low.

Anonymous information - the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

- o Directly Identifiable
- o Indirectly Identifiable
- o Coded (de-identified)
- o Anonymized
- o Anonymous

3.8: Will any data be contributed to a larger study?

- o Yes
- o No

3.9: Will any data with identifiers be sent outside the province?

- o Yes (please complete question 3.10)
- o No

3.10: How will the data be transferred?

Please describe how data will be transferred from the local site and what safeguards are in place to protect the data in transit.

3.11: Is this a part of a national/international study?

- o Yes (please complete question 3.12)
- o No

3.12: Where is the main study site?

3.13: Does this study involve a Material Transfer Agreement (MTA) or a Data Transfer Agreement (DTA)?

- o Yes (please complete question 3.14)
- o No

3.14: Please indicate the parties of the MTA or the DTA:

Tab 4: Previous Review

4.1: Was any of the source data originally collected for research purposes (as opposed to for clinical care)?

- o Yes
- o No (please skip questions 4.2 – 4.6)

4.2: Please indicate the title and HREB reference # for the original study, if applicable. Indicate N/A if not applicable:

4.3: If you answered 'N/A' to question 4.2, please explain:

For example, the study may have been reviewed by another REB.

4.4: Was the data identifiable when it was originally collected?

- o Yes
- o No

4.5: Was the data collected with consent from participants?

- o Yes (please complete question 4.6)
- o No

4.6: Please describe the elements of consent re: data sharing and future use that participants agreed to.

This information can commonly be found by consulting the data custodian, the consent form for the previous study and/or the website associated with the database, if applicable.

Tab 5: Objectives

5.1: Provide a numbered list of the research objectives of the study in plain language:

Please include **all** study objectives, using plain language when possible.

Tab 6: Introductions

6.1: Introduction to the study including the rationale for the study and a brief summary of previous work in this area:

- In language that can be understood by non-experts and community members, please explain why this study is important.
- Give a brief summary of previous work which provides the background to the study. All references should be included in the attached research protocol, so shouldn't be added to application.
- Please provide the full wording for all acronyms and abbreviations, the first time they are used in the application.

Tab 7: Description of Study and Consent

The description of the study should include a brief overview of the study describing the key elements in plain language to inform all members of the HREB.

7.1: Give a brief description of the study, including interventions, methodology, outcomes of interest, and outcome measures in plain language:

Please describe the processes involved in the completion of this study: Interventions (e.g. chart review) Methodology (e.g. thematic analysis) Outcomes of Interest (e.g improvements to health outcomes) Outcome Measure (e.g. quality of life measurement).

7.1: Give a brief description of the study, including interventions, methodology, outcomes of interest, and outcome measures in plain language:

Please describe the processes involved in the completion of this study: Interventions (e.g. chart review) Methodology (e.g. thematic analysis) Outcomes of Interest (e.g. improvements to health outcomes) Outcome Measure (e.g. quality of life measurement).

7.2: Does this study involve a waiver of consent?

Please refer to the TCPS2 for further information re: waiving requirements of consent.

- Yes (please complete question 7.3)
- No (please complete questions 7.4 and 7.5)

7.3: Please describe and justify the requirement of a waiver of consent:

Please refer to TCPS2, Chapter 3.7A and confirm that the five requirements for waiver of consent are met.

7.4: Who will obtain the consent?

(Examples include: Principal Investigator, Research Assistant, Research Coordinator)

7.5: Explain, in detail – setting, timing, person approaching and persons to be approached - the procedure you will use to obtain consent:

Special consideration is required if the study involves individuals with an altered or diminished capacity to consent (e.g. children, incompetent persons, etc.). If applicable, describe in detail how proxy, community and/or parental consent and child assent will be obtained.

For further information on obtaining consent, please refer to the 'HREB Guidelines for Consent' available under the Attachments tab.

This section should explicitly outline the details of the consent process.

- Where and when will consent take place?
- Who will be approaching the participant and conducting the consent process?
- What is the timeline for consenting to participate?
- Will participants be permitted to take consent form home?
- How will consent for individuals with an altered or diminished capacity to consent be achieved?

Tab 8: Level of Analysis

8.1: Please describe the level of intended identification in the analysis, eg. three digit postal code, community, census subdivision.

Please include a list of both direct and indirect identifiers in this section.

8.2: If identifiable data is to be collected, please justify the inclusion of each data element.

8.3: If data are to be shared with persons or agencies not named in this application and/or record linkage is anticipated, please describe how confidentiality of the data will be protected.

For example, will identifiable data be transferred to another organization? Please list the data elements that will be provided. Once the data linkage is completed, will the final file be de-identified?

Tab 9: Sample Size

9.1: A description of the calculation used to obtain sample size should be included for any study which will measure statistically the difference or equivalence of comparison groups and the basis for the choice of sample size – power, alpha, difference to be detected:

In the case of a qualitative analysis, convenience sample, etc. please provide a brief rationale for why the number of records being accessed is appropriate for reaching the study objectives, without unnecessarily over collecting data.

Tab 10: Privacy and Confidentiality

The protection of the privacy and confidentiality of all research participants and their information is the responsibility of all members of the research team. This pertains to any personal information and personal health information collected from identified participants or their records. The following privacy protections are recommended by the HREB. Please check those currently in place for this study. If you plan exceptions for these requirements please provide, in detail, the rationale for this decision.

10.1: The following privacy protections are recommended. Please check those currently in place for this study. Organizational safeguards are the responsibility of the Principal Investigator:

A link to the template 'Oath of Confidentiality' can be found under 'Useful Links' on the Researcher Portal Home page.

- All members of the research team will be briefed on their responsibility for privacy protection.
- All members of the research team will sign an oath of confidentiality.
- Any data-sharing agreements between the researcher and other researchers and/or institutions will be signed prior to providing or obtaining access to data.
- Consequences for breach of confidentiality will be clearly stipulated to the research team.
- All computer files pertaining to the study will be password protected.
- All paper abstract forms and printouts of electronic files will be kept in secure storage – limited number of storage areas, limited access rooms, locked filing cabinets

10.2: If you did not check all of the boxes in Question 10.1, please provide, in detail, the rationale for the exception to the recommended privacy protections:

10.3: List the names of ALL members of the research team who will have access to identifiable data. Please describe why their access is necessary, their role in relation to the project, and how and where they will be accessing the data throughout the project.

All members listed here must also be listed under the Project Team Info tab. TCPS2 certificates must be provided for all people on this list. In order to protect participant privacy, please limit the number of people requiring access, as much as possible.

Tab 11: Retention of Data

11.1: How will data be collected?

11.2: Will any data be shared outside of your institution? If so, how (e.g. secure file transfer, encrypted USB, etc.)?

11.3: Will you be linking the data to other data sources? How will the linkage occur?

11.4: How long will the data be stored?

Memorial University researchers, please keep in mind that your institution requires that all study data be retained for a minimum of 5 years.

11.5: If you are keeping your data for longer than 5 years, please justify the longer retention period:

Please keep in mind that if you wish to store data indefinitely this poses risks that must be managed.

11.6: Where will the data be stored? Give the exact street address, including room/office number:

1. Please provide the exact location where local data will be stored while the study is active.

2. If applicable, please describe how data will be transferred from the local site and what safeguards are in place to protect the data in transit.

3. Please provide the exact location where local data will be stored when the study closes.

4. Please provide the exact location where all study data will be stored when the study closes.

11.7: How will the data be stored?

Please indicate whether your files are electronic or paper files and explain the process for ensuring proper storage.

11.8: Who will have custody and control of the study data? Include their name and contact information:

Please provide the full name or role and contact information (including telephone and/or email contact) of the person who will have custody and control of the study data, including who is responsible for the data while the study is active and who is responsible for the stored data after the study closes.

Please note, data custodians (e.g. Eastern Health) require that supervisors be responsible for the data generated by student's projects.

11.9: List any participant identifiers – name, postal code, study code, to be retained and give the rationale for retention:

If you will be retaining any participant identifiers please list them individually and provide an explicit rationale for the retention (e.g. name and MCP numbers will be kept to identify participants and link to health record in the event of a regulatory inspection.)

11.10: Describe how the data will be disposed of after the retention period:

(e.g. Paper records will be shredded by local NAID certified shredding facility. Electronic data will be disposed of by ensuring the drives on the device are appropriately sanitized (securely deleted or destroyed) prior to the disposal or repurposing of the system or any storage components.)

Tab 12: End of Study Responsibilities

There is an expectation that research results will be disseminated to the academic community and, where appropriate, to participating individuals in a timely manner. For research involving an Indigenous community, community leaders or partners should vet final reports, manuscripts and other dissemination materials for cultural and factual accuracy. However, there should be no restrictions placed on publishing: instead, researchers should allow for dissenting views to be expressed in publications.

12.1: Explain the plan for sharing research results with participants, relevant agencies or communities and the research community. Details of any restrictions on publication or dissemination should be included.

Tab 13: Budget

If your study **IS** funded, please upload a copy of the budget to the Attachments tab and include all sources of any funding.

13.1: Please list all sources of funding for this research:

Please ensure that if funding is routed through MUN, it must be linked in the Researcher Portal. For more information on this process please contact Research Grant and Contract Services.

13.2: For MUN-affiliated investigators - will the budget be administered through the University Finance Office?

- o Yes
- o No

Tab 14: Potential Conflict of Interest

The HREB requires disclosure of any real, potential or perceived individual conflicts of interests, as well as any institutional conflicts of interests of which you are aware that may have an impact on your research and explain how you intend to manage this conflict, particularly situations where any of the investigators will be paid to be involved in the study, own shares in the sponsor company, receive honoraria for lectures, workshops, or stand to gain personally.

14.1: Does any investigator have direct or indirect financial interests in this study?

- o Yes (please complete question 14.4)
- o No

14.2: Does any investigator function as an advisor, employee, officer, director or consultant for any funder(s)?

- o Yes (please complete question 14.4)
- o No

14.3: Will any investigator receive an honorarium or other benefits from any funder (apart from fees for service)?

- o Yes (please complete question 14.4)
- o No

14.4: Please describe and explain how that conflict is being managed to ensure participant rights and welfare are not affected.

Please disclose to the HREB any real, potential or perceived individual conflicts of interests, as well as any institutional conflicts of interests of which you are aware that may have an impact on your research and explain how you intend to manage this conflict.

Tab 15: Additional Requirements

Researchers should be aware that institutions, organizations, or other groups under study may have requirements for allowing access to their sites and to participants, and that some of these may have established mechanisms or guidelines e.g., school boards, Indigenous communities, correctional services, Regional Health Authorities, and community groups. Therefore, once your study has received ethics approval from the HREB, organizational approval may also be required. Organizational approval is not another ethics review; it is a separate and distinct process. It is possible that studies may be approved by the HREB but be unacceptable to an authority, agency or institution because of overuse of a particular group of patients, unavailability of space, personnel, equipment at the time of the proposed trial or incompatibility with the values of the community in which the trial will be conducted. It is your responsibility to seek the necessary organizational approval from the Regional Health Authority or other organization as appropriate prior to commencing your study.

15.1: I have read and acknowledge the above statement:

Further information on obtaining organizational approvals can be found on the HREA website: www.hrea.ca.

- o Yes, I have read and acknowledge the above statement.

15.2: Please select the institutions, organizations and/or communities involved or in support of this research:

Please ensure all data custodians, supporting institutions and communities/organizations associated with this research are identified here.

- o Eastern Health Regional Health Authority
- o Central Health Regional Health Authority
- o Western Health Regional Health Authority
- o Labrador Grenfell Health Regional Health Authority
- o Newfoundland and Labrador Centre for Health Information
- o Memorial University of Newfoundland and Labrador
- o Other (please complete question 15.3)

15.3: Please list:

Tab 16: Checklist

Please review the items below to ensure your application is complete and that necessary supporting documents have been attached.

16.1: Please review the list below of supporting documents to be uploaded under the "Attachments" tab (check all those that apply):

- o The full research proposal/protocol.

- A copy of the Principal Investigator's TCPS2 Tutorial Certificate of Completion, if a first time applicant.
- A copy of a current curriculum vitae for the Principal Investigator, if a first time applicant.
- A copy of the consent document, if applicable.
- Any study questionnaires, surveys, recruitment advertisements, covering letters etc.
- A copy of the budget.
- The "Variable List" (signed by the data custodian) including all variables requested from the data custodian
- If this study involves Indigenous peoples, a copy of the research agreement or letter of support from the relevant community groups and boards.
- Signed Supervisor Attestation form, if applicable.

Tab 17: Declaration

Note: this tab must be completed by the site Principal Investigator. By submitting this application, I assume full responsibility for this research study and verify that the information provided in this application is accurate and complete. I request the Health Research Ethics Board (HREB) to act as the research ethics board of record for this study.

17.1: I verify that the information provided in this application is accurate and complete:

- Agree
- Disagree

17.2: I will conduct the study according to applicable laws, regulations and guidelines:

- Agree
- Disagree

17.3: I will conduct the study consistent with applicable ethical norms:

- Agree
- Disagree

17.4: I will conduct the study according to the approved protocol and consent form(s):

- Agree
- Disagree

17.5: I will accept the authority of, and abide by, the decisions of the HREB as the board of record:

- Agree
- Disagree

17.6: I will comply with the HREB requirements, including timely filing of documents as required by the HREB and provide access to study documents for any random or for cause monitoring by the HREA:

- Agree
- Disagree

17.7: I will ensure there will be no changes to the research without prior HREB review and approval, except where necessary to eliminate an immediate hazard to participants.

- o Agree
- o Disagree

17.8: I will report immediately to the HREB any unanticipated problems in the research, significant deviations from the study protocol, or changes increasing the risk to participants or affecting significantly the conduct of this study.

- o Agree
- o Disagree

17.9: I will report promptly to the HREB all adverse reactions that are both serious and unexpected and new information that may affect the participant's willingness to participate in the research.

- o Agree
- o Disagree

17.10: I will request an annual ethics renewal for each year this study is active and submit a final report once this study is complete.

- o Agree
- o Disagree