Guidance Document HREB General 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 Homepage.

- 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.

1.8: Telephone Number:

Please provide a telephone number for the person responsible for paying the invoice.

1.9: Protocol Number (if applicable):

1.10: Date of Protocol (if applicable):

Tab 2: Study Timeline

2.1: Anticipated completion date:

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

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

- o Yes
- o No
- o Not Applicable

Tab 3: Data Sources

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 primary data sources:

- o Patients
- o Health Providers
- o General Public
- o Not Applicable

3.2: Check secondary data sources:

- o Health records
- o Pre-existing dataset
- o Archived blood and/or other biological samples
- o Discarded blood and/or biological samples
- o Other
- o Not Applicable

3.3: Please specify:

Please provide details of the secondary data sources selected in response to question 3.2 and upload the “**Variable list**” (signed by the data custodian) under the “Attachments” tab of the application.

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

3.5: 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.

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

- o Yes (please complete question 3.9)
- o No

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

Tab 4: Objectives of Study

4.1: Provide a numbered list of the research objectives of the study in plain language starting with the primary objective.

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

Tab 5: Introduction

5.1: 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 6: Blood and other biological samples: collection and use

6.1: Does your study involve blood and/or other biological samples?

If you answer "Yes" to this question, please complete tab 7.

Please select "Yes" if:

- your study involves the collection of any blood and/or other biological samples for the purposes of this study.

OR

- archived blood/ biological samples are being accessed and used for this study.

Please select "No" if your study does not involve the access to or collection of any blood and/or other biological samples.

- Yes
- No (please skip questions 6.2 – 6.5)

6.2: List the blood and/or other biological samples, to be used in the study, the frequency of sampling and the amount of sample:

1. Please describe what blood and/or other biological samples will be taken, how often, and in what amounts, e.g. "xx ml of blood (xx teaspoons) will be taken over 'x' visits during the 'x' month study".

2. Describe testing such as "Routine safety bloodwork including chemistry, CBC, liver function tests (these are examples only). It is not necessary to list every test being performed.

3. Is testing performed in local lab or central lab?

4. Explain which blood and/or other biological samples are mandatory for the study and which blood and/or other biological samples are optional (if applicable).

6.3: Will any discarded blood and/or other biological samples or blood and/or other biological samples now archived by a health care institution be used in the study?

If 'Yes', then please upload a copy of 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.

Please attach the "**Variable List**" (signed by the data custodian) to the "Attachments" tab and select the Doc/Agreement as Variable List.

- o Yes
- o No

6.4: Will any blood and/or other biological samples be sent outside the province?

Please select 'Yes' if any of the blood and/or other biological samples are going to be sent/shipped outside of the province of Newfoundland and Labrador. If you selected 'Yes', please proceed to question 6.5.

If no blood and/or other biological samples will be sent/shipped outside of the province of Newfoundland and Labrador then you can select 'No'.

- o Yes (please complete question 6.5)
- o No

6.5: Please explain:

If you selected 'YES' in question 6.4, please explain:

- o Where the blood and/or other biological samples will be sent (address location)
- o Who has custody and control of the blood and/or other biological samples at the location noted in (a). (e.g. name of the lab)
- o Are the blood and/or other biological samples being anonymized or de-identified prior to being shipped from the Site?
- o Describe the purpose for which the blood and/or other biological samples are being sent (e.g. for analyses)

Tab 7: Blood and other biological samples: Retention and Storage

7.1: Will any blood and/or other biological samples be kept after completion of the study?

Please select "No" if none of the blood and/or other biological samples collected will be kept after study completion.

Please select "Yes" if any of the blood and/or other biological samples will be kept after study completion. If any of the blood and/or other biological samples collected will be kept after study completion, please complete question 7.2 – 7.8. It is important to note that questions 7.2 – 7.8 are in relation to blood and/or other biological samples retained after study completion only.

- o Yes (please complete questions 7.2 to 7.8)
- o No

7.2: Please indicate why the blood and/or other biological samples are being retained:

Please explain why the blood and/or other biological samples are being retained after completion of the study (e.g. specific research question, specific area of research, bio banking, unknown future research and/or use).

7.3: What specific research question will be addressed?

Please outline what specific research question will be addressed using these retained blood and/or other biological samples, if known.

7.4: How long will the blood and/or other biological samples be kept?

Please specify the time-period for which retained blood and/or other biological samples will be kept after completion of the study until destruction.

7.5: Where will the blood and/or other biological samples be stored?

Please provide the storage location (exact address) for any blood and/or other biological samples that are retained after completion of the study.

7.6: Please name the person or organization who will have custody and control of the blood and/or other biological samples that are retained after completion of the study:

7.7: Can blood and/or other biological samples be withdrawn?

- o Yes
- o No

7.8: Please describe the process for withdrawal or provide rationale for why blood and/or other biological samples cannot be withdrawn:

If you selected "Yes" to question 7.7, please describe how participants may request to have their blood and/or other biological samples withdrawn and the process in which the request to withdraw takes place (e.g. participant informs the local site verbally and local site contacts the data custodian of the retained blood and/or other biological samples). Also explain what will happen to the data collected from the blood and/or other biological samples once the blood and/or other biological samples are withdrawn.

If you selected "No" to question 7.7, please provide a rationale (e.g. blood and/or other biological samples have been de-identified and link has been destroyed).

Tab 8: Research Interventions and/or other modes of Data Collection

8.1: List any interventions which would not be part of a participant's daily life:

Please list all interventions that are included in this study. This should reflect the study procedures described in the consent form.

8.2: List questionnaires, information sheets, covering letters, telephone or face to face interview scripts/outlines or variable lists to be used:

Please use the full titles of questionnaires (no abbreviations) and include the version date. Please attach any documents to the Attachments tab. For questionnaires and telephone or face to face interview scripts/outlines, please select the Doc/Agreement as 'Research Instrument' and in the Description please indicate whether it is a questionnaire or telephone or face to face interview script/outline. For variable lists, please select the Doc/Agreement as 'Variable List'. For information sheets and covering letters, there are options in the Doc/Agreement list that have a similar name

Tab 9: Description of Study

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.

9.1: Give a brief description of the study, including interventions, methodology, outcomes of interest, and outcome measures in plain language. Describe briefly what the participant will be asked to do:

Please consider the following elements as applicable in describing the study:

- What is the study design? (such as observational, RCT, blind/non-blind)
- What is being compared (such as x compared to y over z weeks)
- What are the outcome measures
- Please do not include the interventions listed in Section 8.
-

Tab 10: Sample Size

10.1: Quantitative studies: Give the basis – power, alpha, difference to be detected, etc., for the choice of sample size. If this question is not applicable, please mark 'N/A' in the box below:

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 comparative interventions. It is understood that a calculated sample size is not appropriate for qualitative, pilot or feasibility studies.

10.2: Qualitative studies: Give the rationale for the number of participants to be included in the study. If this question is not applicable, please mark 'N/A' in the box below:

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

Tab 11: Participants

11.1: Please describe the participants to be contacted or whose health record information will be used:

Please make special note of populations or participants such as children under 18, pregnant people, persons incompetent to give consent, etc. If including Indigenous peoples or communities, a copy of the

research agreement or letter of support from the relevant community groups and boards is required (refer to Article 9.10 of the TCPS2).

11.2: Please make note of circumstances, if any, that may make participants vulnerable in the context of the research study. Please justify their inclusion in the research study:

11.3: Will a control group be used?

- Yes (please complete question 11.4)
- No

11.4: Please justify the choice of control group(s):

Please justify the choice of control group(s) to the REB by demonstrating that the choice is:

- relevant to the research question;
- appropriate for the population of interest;
- consistent with the criteria for clinical equipoise.

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

- Yes (please complete questions 11.6 and 11.7)
- No

11.6: What is the total number of participants at all sites?

11.7: Number of participants at this site:

11.8: Where is the main study site?

Tab 12: Recruitment and First Contact

12.1: Please describe in detail the means you will use to identify eligible participants:

It is important to describe the means of identifying eligible participants. For example, the first contact may be verbal or in writing and simply informs the potential participant that a study is underway. If they are interested, they may leave their contact information with the person approaching, the community agency, someone in the physician's office, et al. or be given a telephone number to contact the research team directly. In this way, only those names of patients interested in learning more about the study will be given to the research team.

In the case of patients, the HREB expects that the person making first contact will be in the patient's circle of care. Examples include, but are not limited to: The patient is contacted by the PI who is also providing clinical care; the clinician providing care asks the patient if they are interested in meeting with the PI/RC/RA as applicable; or a letter is mailed from the primary clinician informing the patient of the

study. For participants in the community, it may include contact by random digit dialing, community agency, support group, workplace manager, newspaper ads, posters, etc.).

12.2: Will contact be made with potential participants?

- o Yes (please complete question 12.3)
- o No

12.3: Who will make the first contact to provide information about the study?

For participants in the community, it may include a community agency, support group, workplace manager, newspaper ads, posters, contact by random digit dialing, etc.

In the case of patients, the HREB expects this person to be in the patient's circle of care. Examples include, but are not limited to: The patient is contacted by the PI who is also providing clinical care; the clinician providing care asks the patient if they are interested in meeting with the PI/RC/RA as applicable; or a letter is mailed from the primary clinician informing the patient of the study.

12.4: Please specify the means of contact (check all that apply):

Please upload copies of letters, telephone scripts, ads, posters, etc. to the Attachment tab and select the Doc/Agreement as "Recruitment Document" and include in the Description the type of document that it is, i.e. invitation to participate letter, telephone script, ad, poster, etc. An ad template is available on the 'Attachments' tab.

- o In person
- o Letter
- o Telephone
- o Advertisement
- o Poster
- o Other (e.g. email and social media) (Please complete 12.5)

12.5: Please specify:

Tab 13: Consent Process

The Principal Investigator is the person ultimately responsible for the consent process.

13.1: Who will obtain the consent?

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

13.2: 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 the consent form home, if applicable?
- How will consent for individuals with an altered or diminished capacity to consent be achieved?

13.3: Does this study involve deception?

Please refer to the TCPS2 for further information re: deception in research.

- Yes (please complete question 13.4)
- No

13.4: Please describe and justify the use of deception and outline the process you will use to debrief participants:

Please complete this section if you answered 'Yes' in 13.3.

13.5: 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 13.6)
- No

13.6: 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.

13.7: Describe the potential risks for the participant. If there is potential risk that a participant could be emotionally disturbed, please describe the procedure for immediately addressing the situation:

The HREB expects the applicant to reflect on the full spectrum of risks which may be involved – physical, emotional, social and economic. Please include the risk management strategies.

13.8: Describe the potential discomforts for the participant:

This section should include information that would be perceived as discomfort for participants. This may include things such as: Discomfort answering study specific questions, blood draws may cause pain, bleeding, bruising and/or development of a small scars.

13.9: Describe the potential inconveniences for the participant:

This could include information such as:

- attend multiple study visits
- complete x number of questionnaires
- be asked sensitive or private questions about things you normally do not discuss

- may not be able to take part in future studies
- Please include the expected amount of time associated with visits, questionnaires, etc.

Tab 14: Safeguards of Participant Confidentiality and Info

The protection of the privacy and confidentiality of all research participants and their data 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.

14.1: 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 Homepage.

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.

14.2: If you did not check all of the boxes in Question 14.1, please provide, in detail, the rationale for the exception to the recommended privacy protections:

14.3: 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.

NOTE: For researchers affiliated with MUN: Memorial University requires the retention of data for a minimum period of five years after the date of publication of research findings.

Tab 15: Retention of Data

15.1: How will data be collected?

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

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

15.4: 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.

15.5: 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.

15.6: 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 to the Sponsor/Lead 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.

15.7: How will the data be stored?

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

15.8: 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 e-mail 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.

15.9: 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.)

15.10: 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.)

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.

Tab 16: Dissemination of Research Results

16.1: 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 17: Reimbursements/ Payments/ Honoraria/Lottery Opportunity

17.1: Do you intend to reimburse participants for expenses incurred?

- o Yes (please complete question 17.2)
- o No

17.2: Please specify what expenses will be reimbursed:

Please list eligible expenses and describe how reimbursement will be made. Please include whether receipts are required from participants prior to reimbursement being issued.

17.3: Will there be any payment for referral of patient participants?

- o Yes (please complete question 17.4)
- o No

17.4: Please specify the amount per patient:

If you selected 'Yes' to section 17.3, please complete this section.

17.5: Do you intend to provide a gift, honorarium, or lottery opportunity to participants?

- o Yes (please complete questions 17.6 and 17.7)
- o No

17.6: Please describe. At what point in the study would this be offered?

The HREB requests details on any gift, honorarium or lottery opportunity.

Best practices dictate that participant compensation is provided at the time of consent as opposed to later in the process as the TCPS 2 requires that participants not be penalized for withdrawing from a study.

Tab 18: Budget

Please upload a copy of the budget under the 'Attachments' tab and include all sources of funding.

18.1: 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.

18.2: For MUN – affiliated PIs only: Will the budget be administered through the University Finance Office?

- o Yes
- o No

Tab 19: 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.

19.1: Does any investigator have direct or indirect financial interests in any device, drug, and/or intervention being using in this study?

- o Yes (please complete question 19.4)
- o No

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

- o Yes (please complete question 19.4)
- o No

19.3: Will any investigator receive an honorarium or other benefits from the funder(s) (apart from fees for service), indirect financial or other benefit?

- o Yes (please complete question 19.4)
- o No

19.4: 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 20: 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.

20.1: 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.

20.2: 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 20.3)

20.3: Please list

Tab 21: Checklist

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

21.1: 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.
- o A copy of the Principal Investigator's TCPS2 Tutorial Certificate of Completion, if a first time applicant.
- o A copy of a current curriculum vitae for the Principal Investigator, if a first time applicant.
- o A copy of the consent document, if applicable.
- o Any study questionnaires, surveys, recruitment advertisements, covering letters etc.
- o A copy of the budget.
- o The "Variable List" (signed by the data custodian) including all variables requested from the data custodian.
- o Optional consent sections (or separate consent) for DNA/tissue storage/use are included, if relevant.
- o If this study involves Indigenous peoples, a copy of the research agreement or letter of support from the relevant community groups and boards.
- o Signed Supervisor Attestation form, if applicable.

21.2: Does this project include a genetic component?

- o Yes
- o No

21.3: The consent form has been assessed at a reading level of... (must be grade 9 or less).

Tips for writing in plain language and more information on how to test the readability of a document can be found under 'Useful Links' on the Researcher Portal Home page.

Tab 22: 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.

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

- o Agree
- o Disagree

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

- o Agree
- o Disagree

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

- o Agree
- o Disagree

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

- o Agree
- o Disagree

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

- o Agree
- o Disagree

22.6: 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:

- o Agree
- o Disagree

22.7: 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

22.8: 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

22.9: 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

22.10: 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