**INSTRUCTIONS (READ BEFORE STARTING)**

Use the Microsoft Word desktop app rather than the SharePoint online version of Word. Access the Desktop App from the Editing button drop down on the main ribbon beside Help on the upper right side of your screen. Checkbox functionality does not work reliably on the web-based versions of Word.



Fill out this form when reviewing a new application sent to the REB for ethics review.

Article 2.1 of the TCPS-2 defines research requiring Research Ethics Board review as Research involving:

* living human participants;
* human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals.

Article 2.2 through 2.6 of the TCPS-2 reviews the types of research and research-like activities that do not require Research Ethics Board review including:

* Research that relies exclusively on public information
* Observation of people in public places when there is no expectation of privacy, no dissemination of personal information, and no interventions.
* Research that relies exclusively on secondary use of anonymous information or biological materials that does not have a reasonable risk of identifying an individual.
* Quality assurance, quality improvement studies, program evaluation activities, performance reviews, assessments done in class that are only used to generate grades for students.

If during review, you believe that the research project has the possibility of being exempt from REB review, inform the Research Ethics Board Chair to provide guidance on how to continue.

Contact the Research Ethics Board Office at reb@cnc.ca to receive support if you are having difficulty interpreting any of the review criteria presented in this form.

Read through this form entirely before starting to populate it. Each question is designed to capture specific information to demonstrate your ethics review is complete.

Information presented in research ethics review submission is confidential and not intended for distribution. Do not consult with anyone outside of the REB about the contents of a submission for ethics review unless you have received approval from the REB Chair to do so.

# **GENERAL INFORMATION**

|  |  |
| --- | --- |
| **Name of Reviewer:** |  |
| **Date Review Completed:**  |  |
| **Title of Research Project:** |  |
| **Name of Principal Investigator:** |  |

# **CHAPTER 1: CORE PRINCIPLES**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 1.1 Respect for Persons |[ ] [ ]   |
| Article 1.1 Concern for Welfare |[ ] [ ]   |
| Article 1.1 Justice |[ ] [ ]   |

# **CHAPTER 2B: APPROACH TO RESEARCH ETHICS BOARD REVIEW**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful or identifying potential ethical risk)** |
| --- | --- | --- | --- |
| Article 2.9 Research Project is Minimal Risk |[ ] [ ]   |
| Article 2.10 Evaluation Completed of Risks to the Participants That are Attributable to the Research Identified |[ ] [ ]   |
| Article 2.11 Research Considers Risk Based on Participants Membership to Specific Communities  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |

# **CHAPTER 3: CONSENT**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 3.1 Consent Given Voluntarily |[ ] [ ]   |
| Article 3.2 Consent is Informed |[ ] [ ]   |
| Article 3.3 Consent is Ongoing  |[ ] [ ]   |
| Article 3.4 Material Incident Findings Managed Appropriately |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.5 Consent Precedes Access to Data |[ ] [ ]   |
| Article 3.7A Alterations to Consent Requirements Meet Criteria |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.7B Debrief Process Planned When Altering Consent Requirements |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.9 Consent Requirements for Those Lacking Capacity are Met |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.10 Third Party Authorization for Those Lacking Capacity Meet Criteria |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.11 Research Directive for Participation During Future Incapacity or Death Meet Criteria |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 3.12 Consent is Documented |[ ] [ ]   |
| Article 3.13 Broad Consent for Future Unspecified Research Meets Criteria |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |

# **CHAPTER 4: FAIRNESS AND EQUITY**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 4.1 Appropriate Inclusion |[ ] [ ]   |
| Article 4.2 Those Identifying as Women are not Inappropriately Excluded Based on Gender or Sex |[ ] [ ]   |
| Article 4.3 Women not Excluded Because of Reproductive Capacity, Pregnancy, or Breastfeeding |[ ] [ ]   |
| Article 4.4 Children are not Inappropriately Excluded  |[ ] [ ]   |
| Article 4.5 Elderly People are not Inappropriately Excluded Based on Age |[ ] [ ]   |
| Article 4.6 Individuals Lacking Capacity are not Inappropriately Excluded |[ ] [ ]   |
| Article 4.7 Vulnerable Individuals are not Inappropriately Included or Automatically Excluded |[ ] [ ]   |
| Article 4.8 Researchers Will Disseminate Analysis of Data and Interpretation of Research Results |[ ] [ ]   |

# **CHAPTER 5: PRIVACY AND CONFIDENTIALITY**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 5.1 Promises of Confidentiality are Reasonable |[ ] [ ]   |
| Article 5.2 Disclosure Requirements Identified |[ ] [ ]   |
| Article 5.3 Information Safeguards Identified |[ ] [ ]   |
| Article 5.4 Institutional Support Identified  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 5.5A Consent for Secondary Use of Personal Information Made Appropriately |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 5.5B Researcher Identifies Only Secondary Use of Non-Identifiable Information |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 5.6 Contact Made with Subjects of Secondary Use of Personal Information Conducted Appropriately |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 5.7 Data linkage Appropriately Assesses Re-identification Risk and Mitigate it  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |

# **CHAPTER 7: CONFLICTS OF INTEREST**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 7.4 Researcher Indicates Risk of Real, Potential or Perceived Conflict of Interest |[ ] [ ]   |

# **CHAPTER 9: RESEARCH INVOLVING THE FIRST NATIONS, INUIT, AND MÉTIS PEOPLES OF CANADA**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 9.1 Researcher Indicates Appropriate Engagement with Indigenous Community |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.2 Researcher Conducts Appropriate Consultation with Indigenous Community before Researcher Begins. |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.3 Formal Permission to Engage with Indigenous Community Received  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.4 Ethical Review Completed by Indigenous Community Representatives |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.5 Complex Community Authority Structures Adequately Considered |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.6 Avoid Exclusion of Underrepresented Community Groups |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.7 Critical Enquiry Managed Appropriately |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.8 Recognize Community Customs and Codes of Practice |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.11 Research Agreement Established and Provided |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.12 Collaboration between Indigenous Community and Researcher is Appropriate |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.13 Research Mutually Benefits the Indigenous Community |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.14 Research Enhances Skills of Indigenous Community Through Reciprocal Learning.  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.15 Research Provides Appropriate Recognition of Knowledge Holders |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.16 Researchers Apply Community’s Interpretation of OCAP |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.17 Indigenous Community Participates in the Interpretation of Research Findings |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.18 Intellectual Property Rights Related to Research Appropriately Allocated |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.19 Research Agreement Addresses Appropriate Use of Biological Materials  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.20 Research Agreement Addresses Appropriate Secondary Use of Personal Information |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.21 Culturally Informed Advice is Sought for Publicly Available Information |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 9.22 Research Address Mosaic Risk Mitigation for Two or More Anonymous Data Sets |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |

# **CHAPTER 10: QUALITATIVE RESEARCH**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 10.1 Research Begins After Ethics Application Completed  |[ ] [ ]   |
| Article 10.2 Process to Seek and Confirm Consent is Clearly Documented |[ ] [ ]   |
| Article 10.3 Researcher Adequately Explains Exception to Requirement for Consent when Appropriate |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 10.4 Dissemination of Research Results Does Not Result in a Privacy Breach |[ ] [ ]   |
| Article 10.5 Researcher Provides Plan to Engage REB When Using Emergent Design in Data Collection |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |

# **CHAPTER 11: CLINICAL TRIALS**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Notes** |
| --- | --- | --- | --- |
| Article 11.2 Is the Research Project a Clinical Trial? |[ ] [ ]  Stop! If this has been answered yes, CNC does not have the expertise to review this application for research ethics. Determine if another institution is involved in the Research Project that can advise on ethical risks and mitigation strategies. Ask the REB Chair for support. |

# **CHAPTER 12: HUMAN BIOLOGICAL MATERIALS INCLUDING MATERIALS RELATED TO HUMAN REPRODUCTION**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Comments (must be completed if a No answer is given. May be completed optionally for a Yes response if helpful)** |
| --- | --- | --- | --- |
| Article 12.1 Consent for Collection and Use of Human Biological Materials Appropriate |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 12.2 Additional Consent Requirements for Collection and Use of Biological Materials Met |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 12.3A Secondary Use of Biological Materials Conducted Appropriately |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 12.3B Secondary Use of Biological Materials Maintains Complete Anonymity  |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 12.4 Contacting Individuals for Additional Biological Materials is Appropriate |[ ] [ ]  *[If not relevant select Yes and replace with N/A here. If No is selected, replace with concerns in this section.]* |
| Article 12.6 - 12.22 Research Involves Pregnant Individuals, Human Embryos, Fetuses, Stem-Cells, and Cell Lines |[ ] [ ]  Stop! If this has been answered yes, CNC does not have the expertise to review this application for research ethics. Determine if another institution is involved in the Research Project that can advise on ethical risks and mitigation strategies. Ask the REB Chair for support. |

# **CHAPTER 13: HUMAN GENETIC RESEARCH**

| **Consideration demonstrated in Ethics submission and associated section under TCPS-2 (2022)** | **Yes** | **No** | **Note** |
| --- | --- | --- | --- |
| Article 13.2 The Research Project has been identified as Genetic Research?  |[ ] [ ]  Stop! If this has been answered yes, CNC does not have the expertise to review this application for research ethics. Determine if another institution is involved in the Research Project that can advise on ethical risks and mitigation strategies. Ask the REB Chair for support. |