## **Section 1.0 – Study Overview (\*mandatory for clinical trials)** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Clinical trial ([per NIH definition](https://grants.nih.gov/policy/clinical-trials/definition.htm)) that will be registered ([Article 11.3 TCPS 2 2014](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/#toc11-1b))\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Regulations are identified appropriately in application form:
 | Yes[ ]  | No[ ]  |  |
| 1. Multi-site research but not eligible for [CTO](http://www.ctontario.ca/)/[OCREB](https://ocreb.ca/about-ocreb/guidelines-templates-and-sops/) review:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Start and end dates are realistic:
 | Yes[ ]  | No[ ]  |  |
| 1. No issues have been noted in previous REB reviews:
 | Yes[ ]  | No[ ]  |  |

* Click here to enter text.

## **Section 2.0 – Study Details** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Supervisor added to ‘Project Info Tab’ for students & letter of support attached:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Ethics training certificates/exemption attached:
 | Yes[ ]  | No[ ]  |  |
| 1. Independent scientific review attached for all clinical trials > minimal risk:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Additional approvals have been identified:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. For Indigenous populations, a description of how the relevant community will be engaged or justification as to why the research is exempt from community engagement has been provided ([TCPS 2 2014 Chapter 9](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#toc09-1)):
 | Yes[ ]  | No[ ]  | N/A[ ]  |

* Click here to enter text.

## **Section 3.0 – Study Description** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The purpose/rationale for the research is acceptable and written in plain language\*:
 | Yes[ ]  | No[ ]  |  |
| 1. The study design/methodology is explained\*:
 | Yes[ ]  | No[ ]  |  |
| 1. The statistical/data analysis plan is explained\*:
 | Yes[ ]  | No[ ]  |  |
| 1. Protocol attached\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Primary and Secondary objectives are provided\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Justification for use of placebo is explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Provisions to break the code of a double-blinded are explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. If deception or partial disclosure, the debriefing materials and plan for debriefing participants is adequate ([TCPS 2 2014 Article 3.7B](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b)) or justification is provided:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Secondary use of data plans are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

Click here to enter text.

## **Section 4.0 – Health Canada Regulated Study Information\*** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Description of how the Drug/Health Product will be used in the study outside of the parameters of the conditions of use approved by Health Canada \*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Description of the medical devices covered under the Investigational Testing Application (ITA) with Health Canada provided\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. No Objection Letter (NOL) – Health Canada attached:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Investigator Brochures (IB), Product Monographs (PM), Device Manuals or equivalents attached:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

Click here to enter text.

## **Section 5.0 – Biological Specimen Collection** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The collection, use, retention, labeling, transfer, security, future use of biological samples is described:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. The plan for the return of genetic testing results is described:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Plan for disclosing/not disclosing incidental findings is described:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Withdrawal of sample procedures are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

## **Section 6.0 – Imaging** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Exposure to radiation/radiopharmaceuticals above standard of care is described:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. A plan for disclosing/not disclosing incidental findings is provided:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 7.0 – Other Health Related Interventions** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Justification provided video and/or audio recording:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Professional credentials for conducting, administering or supervising tests are appropriate:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Delegation of [Controlled Acts](https://www.cpso.on.ca/Policies-Publications/Policy/Delegation-of-Controlled-Acts) are appropriate pet the [RHPA:](https://www.ontario.ca/laws/statute/91r18)
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. The use of the proposed surveys, questionnaires, interviews or focus groups is explained and all supplemental documents have been attached:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 8.0 – Participants** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Sample size is justified\*:
 | Yes[ ]  | No[ ]  |  |
| 1. Considerations made for an increased risk of identification for studies with low participant numbers/ focus groups and/or conducted in remote/rural communities/communities with small populations:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. The selection of participants is equitable or justification provided:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Safeguards for [vulnerability](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#toc04-1) (TCPS 2 2014 Chapter 4) in research have been considered (*lack of decision-making capacity/emergency research/pediatric research*):
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Pediatric studies: research presents the prospect of direct benefit to the individual participants if research is > minimal risk ([21 CFR 50 Subpart D](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.4))\*\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. The eligibility (inclusion/exclusion) criteria are provided\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Procedures above standard of care described:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Withdrawal/denial from standard therapy/eligibility for future care is explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Care is planned in the event of an emergency/study related jury\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. The stopping rules are appropriate (i.e. when participants can be removed from the study by the PI/Sponsor)\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. A plan for disclosing/not disclosing incidental findings is acceptable:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 9.0 – Recruitment** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Procedures for identifying potential participants is explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Recruitment procedures are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Individual(s) that will be recruiting participants have been identified:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Strategies for minimizing coercion/power imbalance/undue influence are in place:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Recruitment materials (scripts, emails, posters, screen shots) are attached:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Considerations have been to eliminate unsolicited recruitment:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

## **Section 10.0 – Informed Consent** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Consent form reviewed against [HSREB LOI/ICF Checklist](https://www.queensu.ca/urs/ethics/queens-university-health-sciences-and-affiliated-teaching-hospitals-research-ethics-board) or CTO Checklist:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

Click here to enter text.

## **Section 11.0 – Incentives and Reimbursement for Participants** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Information about compensation, reimbursement, and expenses are explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Compensation is justified, appropriate in type, amount and is not significant enough that it could be perceived to be an enticement:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Compensation plan is equal for all participants and the lump sum/payment schedule is explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 12.0 – Risks and Benefits** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. All risks to participants/researchers have been identified\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Plans to mitigate risks to participants are explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Plans to mitigate risks to third parties are in place and applicable ICFs have been/will be developed (e.g., pregnant partner ICF)\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Benefits to society are explained\*:
 | Yes[ ]  | No[ ]  |  |

Click here to enter text.

## **Section 13.0 – Confidentiality** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Justification acceptable for collecting all Personal Health Information (PHI):
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Data collection forms provided and accurately reflect the collection of information:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Personal Health Information will be encrypted if stored on a portable device:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. The type of information that could be generated from linking data sets is described AND adequate measures to protect confidentiality if identifiable information can be generated through the data linkage have been explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Security measures if transmitting data to another site/Sponsor have been explained (secure file transfer, encryption):
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Measures for safeguarding information, for collection, use, dissemination, retention, long term plans (disposal/repository/store indefinitely) are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 14.0 – Publication/Dissemination** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The plan for communication of the study results are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

## **Section 15.0 – Investigational Agent** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Storage, drug labelling, shipping/ordering, temperature monitoring, and drug accountability procedures explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

Click here to enter text.

##  **Section 16.0 – Safety and Monitoring** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The safety/monitoring plan monitoring plan is explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Is the description of the DSMB/C or the justification for not having a DSMB/C is provided\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

Click here to enter text.

## **Overall**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Budget is provided for clinical trials\*:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. All questions have been completed:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Potential COIs are declared and adequately addressed:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. PI is qualified (CV) and attestation provided:
 | Yes[ ]  | No[ ]  | N/A[ ]  |