## **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 11.10 TCPS 2](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter11-chapitre11.html#10) )\*:
 | 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[ ]  |  |

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## **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 to application or TRAQ user profile:
 | Yes[ ]  | No[ ]  |  |
| 1. Independent scientific review attached for all clinical trials > minimal risk:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Additional approvals have been identified (e.g., TRAQ DSS, In-person research)::
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. For Indigenous and/or community based research 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 Chapter 9](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter9-chapitre9.html)). Documented support provided as required:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

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## **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. Implementation strategy and platforms specified for all methods and supporting documents attached:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 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 study are explained\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. If deception or partial disclosure, the debriefing materials and plan for debriefing participants is adequate ([TCPS 2 Article 3.7B](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html#7b)) or justification is provided:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Secondary uses of data are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

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## **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[ ]  |

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## **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[ ]   |

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## **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[ ]   |

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Justification provided for 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/Physicians/Policies-Guidance/Policies/Delegation-of-Controlled-Acts) are appropriate per the [RHPA:](https://www.ontario.ca/laws/statute/91r18)
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Methodologies identified and implementation is explained, documents attached:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

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## **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](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter4-chapitre4.html) in the context of research (TCPS 2 Chapter 4) 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[ ]   |

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## **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 made to eliminate unsolicited recruitment:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

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## **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[ ]  |
| 1. Justification has been provided for any waivers or alterations to the consent process as per TCPS [Article 3.7A](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html#b):
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Justification has been provided for not obtaining consent for use of identifiable secondary biologicals/information as per TCPS [Article 12.3A](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter12-chapitre12.html#c)/[Article 5.5A](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html#d):
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Informed consent process has been explained including strategies for minimizing coercion/power imbalance/undue influence and all applicable documents attached:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Assent process explained for those not providing/unable to provide consent:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Process for documenting the consent/assent process has been explained:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

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## **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[ ]   |

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## **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 and benefits to participants (or none) are explained\*:
 | Yes[ ]  | No[ ]  |  |

Click here to enter text.

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Justification acceptable for collecting all Personal Information (PI) and / or sensitive information and / or Personal Health Information (PHI) and / or Demographic information:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Types of information be collected identified appropriately (e.g., anonymous, anonymized/de-identified, secondary):
 | Yes[ ]  | No[ ]  |  |
| 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[ ]   |

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

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

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The safety/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 provided\*:
 | Yes[ ]  | No[ ]  | N/A[ ]  |

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## **Overall**

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

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