## **Section 1.0 – Study Overview** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 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[ ]  |  |

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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 (only mandatory for higher risk studies):
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. Additional approvals have been identified (e.g., TRAQ DSS/hospital, 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. 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 – 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. A plan for disclosing/not disclosing incidental findings is acceptable:
 | 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[ ]   |

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## **Section 5.0 – 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 6.0 – 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 7.0 – 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 8.0 – Risks and Benefits** [ ] **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. All risks to participants/researchers have been identified and safety protocols have been explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Plans to mitigate risks to participants/researchers and third parties
2. are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Benefits to society are explained and benefits to participants (or none) are explained:
 | Yes[ ]  | No[ ]  |  |

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## **Section 9.0 – 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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## **Overall**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. The plan for communication of the study results are explained:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Funding disclosed/Budget is provided (mandatory for clinical trials only):
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. Potential COIs are declared and adequately addressed:
 | Yes[ ]  | No[ ]  | N/A[ ]   |
| 1. PI(s) qualified, CV attached (mandatory for clinical trials only) and PI attested:
 | Yes[ ]  | No[ ]  | N/A[ ]  |
| 1. All questions have been completed:
 | Yes[ ]  | No[ ]  | N/A[ ]   |

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