**REB Review Criteria**

**(REB Reviewer Checklist)**

| **Study Title:** |  |
| --- | --- |
| **Type of Study:** |  |
| **Principal Investigator:** |  |
| **Date of Review:** |  |
| **Name of Reviewer:** |  |

**Resource Documents:**

1. **TCPS 2 (2018) — the latest edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans:** [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)
2. **International Conference on Harmonisation Good Clinical Practice Guidelines:** <https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>
3. **Part C, Division 5 of the Regulations: Drugs for Clinical Trials Involving Human Subjects:** <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html>

| **Study Team** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Is a Local Investigator Required? | **Yes** | **No** |  |  |
| * 1. If yes, has the local investigator been identified? | **Yes** | **No** |  |  |
| * 1. If yes, has the role of the local investigator been clearly articulated? | **Yes** | **No** |  |  |
| 1. If yes, have the qualifications of the local investigator been verified (i.e. is there sufficient documentation/information to verify the local investigator is qualified to carry out their respective activates in the study)? | **Yes** | **No** |  |  |
| 1. Have the other members of the study team been identified (*i.e. those engaged in study conduct at the site*)? | **Yes** | **No** | **N/A** |  |
| * 1. If yes, has their specific role in the study been articulated? | **Yes** | **No** | **N/A** |  |
| * 1. If yes, have the qualifications of the other members of the study team been verified (*i.e. is there sufficient documentation/information to verify that each study team member is qualified to carry out their respective activities in this study*)? | **Yes** | **No** | **N/A** |  |
| 1. Have any potential, perceived or actual conflicts of interest of the study team members been disclosed? | **Yes** | **No** | **N/A** |  |
| * 1. If so, have measures been taken to manage any potential, perceived or actual conflicts of interest identified for study team members? | **Yes** | **No** | **N/A** |  |

**Overall Feedback/Assessment:**

| **Scientific Merit** |  | | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| 1. Has an independent scientific review been completed? | | **Yes** | **No** |  |  |
| * 1. If yes, have the results of this review been submitted? | | **Yes** | **No** |  |  |
| 1. Have the researchers provided an abstract suitable for a lay audience? | | **Yes** | **No** |  |  |
| 1. Are the rationale and the hypothesis clearly articulated? | | **Yes** | **No** |  |  |
| 1. Is the research question clearly articulated? | | **Yes** | **No** |  |  |
| 1. Have the researchers identified any societal benefits to the study? | | **Yes** | **No** |  |  |
| 1. Does the literature support the research question? | | **Yes** | **No** |  |  |
| 1. Are there other published (or unpublished) studies that have attempted to answer this question? | | **Yes** | **No** |  |  |
| * 1. If yes, do these studies support the methods being used? | | **Yes** | **No** |  |  |
| 1. Has the question already been answered? | | **Yes** | **No** |  |  |

**Overall Feedback/Assessment:**

| **Methods** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Is the study design/methodology clearly described? | **Yes** | **No** |  |  |
| 1. Is the study design/methodology appropriate for answering the research question? | **Yes** | **No** |  |  |
| 1. Have the researchers clearly defined the study population and how they will be selected (*i.e. recruitment strategy*)? | **Yes** | **No** |  |  |
| * 1. Are the inclusion and exclusion criteria clearly described? | **Yes** | **No** |  |  |
| * 1. Is the population appropriate for the question being asked? | **Yes** | **No** |  |  |
| * 1. Have the researchers identified potentially vulnerable participants within the study population? | **Yes** | **No** |  |  |
| * + 1. If yes, have additional safeguards been put in place to protect the rights and welfare of potentially vulnerable participants? | **Yes** | **No** |  |  |
| 1. Has the sampling strategy been described? | **Yes** | **No** |  |  |
| * 1. If yes, is the identified sampling strategy appropriate? | **Yes** | **No** |  |  |
| 1. Have the researchers provided a power calculation or otherwise justified their sample size? | **Yes** | **No** | **N/A** |  |
| 1. Have the researchers stated how they will handle participant drop-outs in the analysis? | **Yes** | **No** |  |  |
| 1. Are the study interventions/procedures clearly outlined? | **Yes** | **No** |  |  |
| 1. Is there a control group? | **Yes** | **No** |  |  |
| * 1. If yes, has the defined control group been justified (*i.e. active control or placebo*)? | **Yes** | **No** |  |  |
| 1. Have the researchers identified any potential study limitations? | **Yes** | **No** |  |  |
| 1. Are the outcome measures clear? | **Yes** | **No** |  |  |
| 1. Are the data collection tools/instruments valid? | **Yes** | **No** |  |  |
| 1. Have the researchers provided adequate justification for the choice of data collection tools/instruments? | **Yes** | **No** |  |  |

**Overall Feedback/Assessment:**

| **Data Management** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Do the researchers clearly identify what data (*i.e. variables*) will be collected? | **Yes** | **No** |  |  |
| 1. Do the researchers clearly articulate the methods for collecting data? | **Yes** | **No** |  |  |
| 1. Is the data analysis plan clearly articulated? | **Yes** | **No** |  |  |
| 1. Is the data analysis plan appropriate? | **Yes** | **No** |  |  |
| 1. Have the researchers adequately detailed how they will control for confounders in their *data analysis*? | **Yes** | **No** | **N/A** |  |
| 1. Have the researchers taken appropriate precautions to protect privacy of participant data (*i.e. security and safeguarding of personal information, personal health information and research data; justified access to data, access to data limited; de-identification whenever possible*)? | **Yes** | **No** |  |  |
| 1. Have the researchers accurately described their data retention and destruction plan? | **Yes** | **No** |  |  |
| * 1. If yes, is it consistent with THP policies? | **Yes** | **No** |  |  |
| 1. Will the data be used for secondary purposes? | **Yes** | **No** |  |  |
| * 1. If yes, have these secondary purposes been described? | **Yes** | **No** |  |  |
| * 1. If yes, are the secondary purposes acceptable? | **Yes** | **No** |  |  |

**Overall Feedback/Assessment:**

| **Ethical Considerations** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. If the study has been rejected by another REB, have the details of this rejection been provided? | **Yes** | **No** | **N/A** |  |
| 1. If the study includes assignment to different intervention arms, is there clinical equipoise between intervention arms? | **Yes** | **No** | **N/A** |  |
| 1. Has the current local standard of care/standard practice in this area been described? | **Yes** | **No** | **N/A** |  |
| 1. Have the study specific interventions/procedures and changes to local standard of care/standard practice been described? | **Yes** | **No** | **N/A** |  |
| 1. Have the researchers identified potential risks associated with the study? | **Yes** | **No** | **N/A** |  |
| 1. If yes, is there a satisfactory plan to minimize risks that have been associated with the study? | **Yes** | **No** |  |  |
| 1. Have adequate measures been taken to reduce risks/harm to participants? | **Yes** | **No** |  |  |
| 1. Have adequate measures been taken to protect vulnerable persons? | **Yes** | **No** | **N/A** |  |
| 1. If certain populations are being excluded, is there adequate rationale for exclusion? | **Yes** | **No** | **N/A** |  |
| 1. Is the recruitment process fair and justified? | **Yes** | **No** |  |  |
| 1. Does the recruitment process minimize coercion and undue influence? | **Yes** | **No** |  |  |
| 1. Is the first point of potential participant contact appropriate (*i.e. circle of care, respecting participant privacy*)? | **Yes** | **No** |  |  |
| 1. If the study involves participants who are unable to provide their own consent been has the inclusion of these participants been justified? | **Yes** | **No** | **N/A** |  |
| 1. Is the process of obtaining informed consent clearly described? | **Yes** | **No** | **N/A** |  |
| 1. Is consent being documented appropriately? | **Yes** | **No** | **N/A** |  |
| 1. Is professional translation/interpretation available for non-English speaking participants? | **Yes** | **No** | **N/A** |  |
| 1. If participant remuneration is being provided, is the amount of remuneration proportionate to the time and risks associated with participation? | **Yes** | **No** | **N/A** |  |
| 1. Are there any study specific costs to participants? | **Yes** | **No** |  |  |
| * 1. If yes, are participants’ study related costs being adequately covered by the study? | **Yes** | **No** |  |  |
| 1. Has an appropriate plan for the identification and disclosure of incidental findings been developed and clearly articulated (*i.e. considerations for study design and population*)? | **Yes** | **No** | **N/A** |  |
| 1. Do the benefits of conducting the study outweigh the risks? | **Yes** | **No** |  |  |

**Overall Feedback/Assessment:**

| **Waiver of Consent Considerations (*only assess if a waiver of consent has been requested for any component of the study)*** |  |  |
| --- | --- | --- |

| **General Waiver of Consent Considerations** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Have the researchers demonstrated that the study involves no more than minimal risk to participants (*mandatory; TCPS2 criteria*)? | **Yes** | **No** |  |  |
| 1. Have the researchers demonstrated that lack of the participant’s consent is unlikely to adversely affect the welfare of the participant (*mandatory; TCPS2 criteria*)? | **Yes** | **No** |  |  |
| 1. Have the researchers demonstrated that it is impossible or impracticable to carry out the research and to answer the research question properly, given the design, if the prior consent of the participant is required (*mandatory; TCPS2 criteria*)? | **Yes** | **No** |  |  |
| 1. Have the researchers confirmed (wherever possible and appropriate) that after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in the accordance with Articles 3.2 and 3.4 of the TCPS2, at which point they will have the opportunity to refuse consent in accordance with Article 3.1 of the TCPS2 (*mandatory; TCPS2 criteria*)?? | **Yes** | **No** |  |  |
| 1. Have the researchers verified that the research does not involve a therapeutic intervention, or other clinical or diagnostic intervention (*mandatory; TCPS2 criteria*)? | **Yes** | **No** |  |  |

**Personal Health Information Considerations** (*only assess if the waiver of consent involves a waiver of consent for the collection, use and/or disclosure of personal health information)*

**Overall Feedback/Assessment:**

| **Consent Process & Consent Form Content** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Does the consent process and associated documents follow THP requirements and templates (*i.e. voluntariness, minimize/avoid coercion*)? | **Yes** | **No** |  |  |
| 1. If the participant is not capable of giving informed consent, |  |  |  |  |
| * 1. Is the process for obtaining consent from an authorized substitute decision maker described? | **Yes** | **No** | **N/A** |  |
| * 1. If yes, is the process appropriate? | **Yes** | **No** |  |  |
| 1. Is a mechanism in place for obtaining assent for participants not capable of providing consent? | **Yes** | **No** | **N/A** |  |
| 1. If it is possible for consent to be withdrawn, has the process for doing so been clearly articulated (*i.e. have the researchers described what will happen with data collected up to the time of withdrawal*)? | **Yes** | **No** | **N/A** |  |
| 1. If an alternate to written consent is proposed, has adequate justification been provided? | **Yes** | **No** | **N/A** |  |
| 1. If there are study specific costs to participants, have these costs, and reimbursement amounts, been described in the consent documentation? | **Yes** | **No** | **N/A** |  |
| 1. If the study involves secondary use of data (including samples) is there a process described for opting out of this component? | **Yes** | **No** | **N/A** |  |
| 1. Are the implications of participating in the study explained to participants in language likely to be understood?   *This includes:* | **Yes** | **No** |  |  |
| * Sponsor information | **Yes** | **No** |  |  |
| * Purpose of the study | **Yes** | **No** |  |  |
| * Study intervention | **Yes** | **No** |  |  |
| * Risks | **Yes** | **No** |  |  |
| * Risk management | **Yes** | **No** |  |  |
| * Benefits | **Yes** | **No** |  |  |
| * Study procedures | **Yes** | **No** |  |  |
| * Time commitments | **Yes** | **No** |  |  |
| * Timing of study procedures | **Yes** | **No** |  |  |
| * Consequences of not participating or withdrawing | **Yes** | **No** |  |  |
| * Participants rights | **Yes** | **No** |  |  |
| * Who to contact (*i.e. research team and REB*) | **Yes** | **No** |  |  |
| * Circumstances under which participation may cease | **Yes** | **No** |  |  |
| * Disposition of data and biological samples | **Yes** | **No** |  |  |
| * Local and total number of participants | **Yes** | **No** |  |  |
| * Confidentiality | **Yes** | **No** |  |  |
| * Access and purposes of access to data | **Yes** | **No** |  |  |
| * Data protection | **Yes** | **No** |  |  |
| * Conflict of interest disclosure | **Yes** | **No** | **N/A** |  |
| * Mandatory vs optional components of participation | **Yes** | **No** |  |  |
| 1. Is it clear in the consent form how participation in the study differs from usual care, processes, etc.? | **Yes** | **No** | **N/A** |  |
| 1. Is the form free of any exculpatory language? | **Yes** | **No** |  |  |
| 1. Is there a statement indicating that the participant does not waive any of their legal rights through participation? | **Yes** | **No** | **N/A** |  |
| 1. Has the content of the consent document(s) been tailored to fit the local context (*i.e., medical coverage and applicable regulations; local logistical considerations*)? | **Yes** | **No** |  |  |
| 1. If written consent is required, is there a statement that the participant will receive a copy of the consent form? | **Yes** | **No** |  |  |
| 1. If there is an alternate consent process proposed, have the details been clearly articulated and justified? | **Yes** | **No** | **N/A** |  |

**Overall Feedback/Assessment:**

| **Genetic Research Considerations (*only assess if study includes genetic research*)** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Have all uses of genetic material been outlined? | **Yes** | **No** |  |  |
| 1. Have the privacy and confidentiality risks associated with genetic research been articulated (*i.e. in the protocol, and the consent documents*)? | **Yes** | **No** |  |  |
| 1. Have the researchers developed and articulated a plan for managing information that may be revealed through the genetic research? | **Yes** | **No** |  |  |
| 1. If yes, does the plan take into account the following factors? |  |  |  |  |
| * 1. Clinical relevance of the information | **Yes** | **No** |  |  |
| * 1. Risks and potential benefit for participants and others who may be affected by the information | **Yes** | **No** |  |  |
| 1. Have the researchers demonstrated that they will advise prospective participants of the plan for managing information revealed through the genetic research? | **Yes** | **No** |  |  |
| 1. Have the researchers described, and articulated a means to explain to participants, the types of findings that may be revealed through the genetic research? | **Yes** | **No** |  |  |
| 1. Do the researchers plan to share genetic findings with participants and/or others who may be affected by the findings?    1. If yes: Do the researchers provide participants/impacted individuals with an opportunity to: | **Yes** | **No** | **N/A** |  |
| * + 1. Make an informed choice about whether to receive the information? | **Yes** | **No** |  |  |
| * + 1. Express preference about whether information will be shared with their biological relatives or others with whom they have a relationship (family, community, groups)? | **Yes** | **No** |  |  |
| * 1. Have the researchers confirmed that, and detailed when genetic counseling will be made available to participants/impacted individuals? | **Yes** | **No** |  |  |

**Overall Feedback/Assessment:**

| **Clinical Trial Considerations (*only assess if the study is a clinical trial*)** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Is there a study steering committee? | **Yes** | **No** |  |  |
| * 1. If yes, have the members of the study steering committee been identified? | **Yes** | **No** |  |  |
| * 1. If yes, is the study steering committee’s role described (*i.e. with respect to oversight of the study*)? | **Yes** | **No** |  |  |
| 1. Have the researchers provided supporting evidence to justify the intervention in their protocol (*i.e. is there equipoise among the proposed interventions*)? | **Yes** | **No** |  |  |
| 1. Are the methods for administering, monitoring and evaluating the intervention appropriate (i.e. timeframe, intensity, modality etc.)? | **Yes** | **No** |  |  |
| 1. If the study involves a placebo group has justification for a placebo group been provided? | **Yes** | **No** | **N/A** |  |
| 1. Is blinding required? | **Yes** | **No** |  |  |
| * 1. If yes, is the blinding mechanism described? | **Yes** | **No** |  |  |
| * 1. If yes, is the blinding mechanism adequate? | **Yes** | **No** |  |  |
| 1. Have the researchers identified and described all known adverse events/effects? | **Yes** | **No** |  |  |
| 1. Have the adverse event/effect monitoring and reporting procedures been described? | **Yes** | **No** |  |  |
| 1. Is there a process in place for monitoring data to ensure the safety of participants? | **Yes** | **No** |  |  |
| 1. Does the language used in the consent form avoid therapeutic misconception (*i.e. with investigational interventions the term “study intervention” is used as opposed to treatment*) | **Yes** | **No** |  |  |
| 1. Is the likelihood of being assigned to each intervention group/arm provided within the consent form (i.e. is the process described in lay terms)? | **Yes** | **No** |  |  |
| 1. Is it clear in the consent form what aspects of the study are not part of usual practice/care? | **Yes** | **No** |  |  |
| 1. Have reproductive risks of participation been identified for males and females (*within protocol and consent documents*)? | **Yes** | **No** | **N/A** |  |
| 1. Have the risks of participation to embryo and/or a fetus been described (*within protocol and consent documents*)? | **Yes** | **No** | **N/A** |  |

**Overall Feedback/Assessment:**