**REB Review Criteria**

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

**Resource Documents:**

1. **TCPS 2 (2022) — 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 (2022) (ethics.gc.ca)](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.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>

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| **Study Team** |  |

| **Study Team** | **Yes** | **No** | **N/A** | **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:** | | | | |

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| **Scientific Merit** |  |

| **Scientific Merit** | **Yes** | **No** | **N/A** | **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 sufficiently answered? | **Yes** | **No** |  |  |
| **Overall Feedback/Assessment:** | | | | |

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| **Methods** |  |

| **Methods** | **Yes** | **No** | **N/A** | **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. Has the research team considered perspectives (i.e., cultural, socio-economic, contextual etc.) of the study population in the design of the research study (i.e., methods, recruitment, and strategy etc.) | **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** | **N/A** |  |
| * 1. If yes, is the identified sampling strategy appropriate? | **Yes** | **No** | **N/A** |  |
| * 1. Are there plans to engage the community early, purposefully and/or often? | **Yes** | **No** | **N/A** |  |
| 1. Have the researchers provided a power calculation or otherwise justified their sample size? | **Yes** | **No** | **N/A** |  |
| 1. Are there opportunities for reciprocity in the design of the study, such that both the community and researcher benefit? | **Yes** | **No** |  |  |
| 1. Have the researchers stated how they will handle participant drop-outs (including data) in the analysis? | **Yes** | **No** | **N/A** |  |
| 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:** | | | | |

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| **Data Management & Analysis** |  |

| **Data Management & Analysis** | **Yes** | **No** | **N/A** | **Comments** | |
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| 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** |  |  | |
| 1. If the study uses human biological materials. Have proper steps been taken to keep the data deidentified? | **Yes** | **No** | **N/A** |  |
| **Overall Feedback/Assessment:** | | | | |

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| **Ethical Considerations** |  |

| **Ethical Considerations** | **Yes** | **No** | **N/A** | **Comments** |
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| 1. Has more than one REB performed an ethics review for the study? | **Yes** | **No** |  |  |
| * 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** |  |  |
| 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** | **N/A** |  |
| * 1. Are the inclusion criteria and recruitment strategy reflective of diversity, equity, and inclusion considerations (i.e., age, ethnicity and culture, gender, race, religion, sexuality, capabilities etc.) | **Yes** | **No** | **N/A** |  |
| * 1. Are the limitations described? | **Yes** | **No** | **N/A** |  |
| 1. Does the recruitment process minimize coercion and undue influence? | **Yes** | **No** | **N/A** |  |
| 1. Are there biases, privilege and/or power imbalances that could impact the study? If so how will they be mitigated? | **Yes** | **No** |  |  |
| 1. Is the first point of potential participant contact appropriate (*i.e., circle of care, respecting participant privacy*)? | **Yes** | **No** |  |  |
| 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. 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** |  |  |
| 1. Is the language used in all documents, especially consent forms and other participant/ community forms and documents, inclusive and respectful? | **Yes** | **No** |  |  |
| **Overall Feedback/Assessment:** | | | | |

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| **General Waiver of Consent Considerations** | **N/A** |
| ***Only assess if a waiver of consent has been requested for any component of the study*** |  |

| **General Waiver of Consent Considerations** | **Yes** | **No** | **N/A** | **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** |  |  |
| **Overall Feedback/Assessment:** | | | | |

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| **Consent Process & Consent Form Content** |  |

| **Consent Process & Consent Form Content** | **Yes** | **No** | **N/A** | **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, | **Yes** | **No** | **N/A** |  |
| * 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** | **N/A** |  |
| * 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 and participants freedom to do 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 certain circumstances make it impossible or impracticable for participants to withdraw their data and materials from the study, have the researchers described which data and at what point in the study this can no longer occur? | **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 yes, are participants’ study related costs being adequately covered by the study? | **Yes** | **No** | **N/A** |  |
| 1. Does the study involves secondary use of data (including samples)? | **Yes** | **No** | **N/A** |  |
| 1. Is there a mechanism outlined that will be used to ensure participants are providing informed and ongoing consent about storage and future use of data and materials? | **Yes** | **No** | **N/A** |  |
| 1. Has the mechanism for storing data and who will have access to it been described? | **Yes** | **No** | **N/A** |  |
| 1. 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** |  |  |
| * 1. Sponsor information | **Yes** | **No** |  |  |
| * 1. Purpose of the study | **Yes** | **No** |  |  |
| * 1. Study intervention | **Yes** | **No** |  |  |
| * 1. Risks | **Yes** | **No** |  |  |
| * 1. Risk management | **Yes** | **No** |  |  |
| * 1. Benefits | **Yes** | **No** |  |  |
| * 1. Study procedures | **Yes** | **No** |  |  |
| * 1. Time commitments | **Yes** | **No** |  |  |
| * 1. Timing of study procedures | **Yes** | **No** |  |  |
| * 1. Consequences of not participating or withdrawing | **Yes** | **No** |  |  |
| * 1. Participants rights | **Yes** | **No** |  |  |
| * 1. Who to contact (*i.e., research team and REB*) | **Yes** | **No** |  |  |
| * 1. Circumstances under which participation may cease | **Yes** | **No** |  |  |
| * 1. Disposition of data and biological samples | **Yes** | **No** |  |  |
| * 1. Local and total number of participants | **Yes** | **No** |  |  |
| * 1. Confidentiality | **Yes** | **No** |  |  |
| * 1. Access and purposes of access to data | **Yes** | **No** |  |  |
| * 1. Data protection | **Yes** | **No** |  |  |
| * 1. Conflict of interest disclosure | **Yes** | **No** |  |  |
| * 1. 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** |  |  |
| 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** | **N/A** |  |
| 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** |  |
| 1. If the study involves participants who are unable to provide their own consent, 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. Are consent processes reflective of how communities wish to be engaged (to the extent possible)? | **Yes** | **No** | **N/A** |  |
| **Overall Feedback/Assessment:** | | | | |

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| **Genetic Research Considerations** | **N/A** |
| ***Only assess if study includes genetic research*** |  |

| **Genetic Research Considerations** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Have all uses of genetic material been outlined? | **Yes** | **No** |  |  |
| 1. Have the 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, and explaining findings to participants that may be revealed through the genetic research? If yes, does the plan take into account the following factors? | **Yes** | **No** | **N/A** |  |
| 1. Clinical relevance of the information | **Yes** | **No** | **N/A** |  |
| 1. Risks and potential benefit for participants and others who may be affected by the information | **Yes** | **No** | **N/A** |  |
| 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. Do the researchers plan to share genetic findings with participants and/or others who may be affected by the findings? 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** | **N/A** |  |
| 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** | **N/A** |  |
| 1. Have the researchers confirmed that, and detailed when genetic counseling will be made available to participants/impacted individuals? | **Yes** | **No** | **N/A** |  |
| 1. Is the type(s) of stem cell research planned permitted under the Canadian legislation (TCPS2 Article 12.10)? | **Yes** | **No** | **N/A** |  |
| 1. Does the research involve human pluripotent and human totipotent stem cells that have been derived from an embryonic source; and/or will be transferred into humans or non-human animals? | **Yes** | **No** | **N/A** |  |
| * 1. If yes, has the researcher provided evidence of CIHR Stem Cell Oversight Committee (SCOC) approval (requirement)? | **Yes** | **No** | **N/A** |  |
| 1. In addition to information outlined in the consent section, have the researchers also provided participants with the following during the informed consent process? | **Yes** | **No** | **N/A** |  |
| 1. explanation that the cell line(s) will be anonymized or coded; | **Yes** | **No** | **N/A** |  |
| 1. assurance that prospective research participants are free to not participate and have the right to withdraw at any time until it becomes impossible or impracticable to do so; | **Yes** | **No** | **N/A** |  |
| 1. explanation that the research could result in the production of a stem cell line that could be maintained for many years, distributed to other parts of the world, and used for various research purposes; | **Yes** | **No** | **N/A** |  |
| 1. explanation that the research participants will not directly benefit financially from any future commercialization of cell lines; nor will there be any personal benefit in terms of dispositional authority over any embryonic cell lines created (i.e., there will be no directed donation of the cells or cell lines to particular individuals). | **Yes** | **No** | **N/A** |  |
| **Overall Feedback/Assessment:** | | | | |

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| **Clinical Trial Considerations** | **N/A** |
| **Only assess if the study is a clinical trial** |  |

| **Clinical Trial Considerations** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Is there a study steering committee? | **Yes** | **No** | **N/A** |  |
| 1. If yes, have the members of the study steering committee been identified? | **Yes** | **No** | **N/A** |  |
| 1. If yes, is the study steering committee’s role described (*i.e., with respect to oversight of the study*)? | **Yes** | **No** | **N/A** |  |
| 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** | **N/A** |  |
| 1. If yes, is the blinding mechanism adequate? | **Yes** | **No** | **N/A** |  |
| 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:** | | | | |