**REVIEWER COMMENTS AND RECOMMENDATIONS**

**Faculty Investigator:**

**Student Investigator:**

**Study Title:**

**REB Number:**

**Describe your concerns or collegial comments below:**

|  |  |
| --- | --- |
| Major Concerns: |  |
| Minor Concerns: |  |
| Collegial Comments/Suggestions: |  |

**Reviewer’s Recommendation:**

Ethics Clearance (without hesitation)

Ethics Clearance (subject to clarification of minor concerns)

Defer Ethics Clearance (subject to clarification of major concerns)

Recommend Not Cleared

**Reviewer:**

**Date of Review:**

**Reviewer Checklist**

**Please complete this checklist as you review the protocol. Please indicate whether the researcher has given adequate consideration and safeguards to the following areas of concern.**

\*NOTE: C/R = Clarification Required; N/A = Not Applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **RESEARCH SUMMARY** | **Yes** | **No** | **C/R** | **N/A** |
| **Purpose and Background:** | | | | |
| Is the research question clearly stated? |  |  |  |  |
| **Comments:** | | | | |
| **Social and Scientific Value:** | | | | |
| Will the research generate knowledge that could reasonably benefit society? or well-being? |  |  |  |  |
| **Comments:** | | | | |
| **Participants:** | | | | |
| Are criteria for inclusion/exclusion equitable (i.e. no exclusions on basis of race, age, gender, etc)? |  |  |  |  |
| Does the nature of the research create vulnerability for any of the groups listed below?Check all that apply:  People with relevant health issues Children  People in medical emergencies  Elderly people  Aboriginal people  People in poverty  People in long-term care  People in prison  People with mental-health issues  People who are unable to consent  Other |  |  |  |  |
| Have the TCPS2 guidelines been followed in the recruitment of these individuals? |  |  |  |  |
| **Comments:** | | | | |
| **Participant Recruitment:** | | | | |
| Do you have any concerns about inappropriate inducement? |  |  |  |  |
| Does the recruitment process violate the participant’s privacy in any way? |  |  |  |  |
| Has someone within the participant’s circle of care or within the organization made the initial contact on behalf of the investigator? |  |  |  |  |
| Are recruitment procedures in any way coercive or unduly influential? |  |  |  |  |
| **Comments:** | | | | |

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| **RESEARCH SUMMARY** | **Yes** | **No** | **C/R** | **N/A** |
| **Methodology/Procedures:** | | | | |
| Is the methodology/design described in sufficient detail? |  |  |  |  |
| Is the methodology/design adequate to answer the research question? |  |  |  |  |
| Is the sample size sufficient to answer the research question? |  |  |  |  |
| Is the data analysis adequately described? |  |  |  |  |
| Is the data analysis appropriate? |  |  |  |  |
| **Comments:** | | | | |
| **Risk/Benefit Assessment:** | | | | |
| Are there any of the following possible risks (circle any that apply):  Physical Psychological Social Economic Academic |  |  |  |  |
| Are risks to participants minimized by a sound research design? |  |  |  |  |
| Are risks to participants reasonable in relation to anticipated benefits to participants? |  |  |  |  |
| Are any possible risks to participate greater than those the participants might encounter in their everyday life? |  |  |  |  |
| Is the information about risks in the research summary consistent with the Information Sheet? |  |  |  |  |
| **Comments:** | | | | |
| **Data Collection, Storage, Protection and Transmission:** | | | | |
| Will data be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)? |  |  |  |  |
| Are adequate provisions made to protect the privacy of participants and to maintain the confidentiality of the data? |  |  |  |  |
| Plan to ensure confidentiality of data is adequate? |  |  |  |  |
| Plan to ensure security and encryption of data is adequate? |  |  |  |  |
| Plan to ensure transmission/movement of data is adequate? |  |  |  |  |
| **Comments:** | | | | |

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| **INFORMATION SHEET AND CONSENT FORM** | | | | |
|  | **Yes** | **No** | **C/R** | **N/A** |
| Are information/consent documents appropriately headed and printed in large enough type? |  |  |  |  |
| Are information/consent documents free of unexplained technical terms, acronyms & jargon? |  |  |  |  |
| Are information/consent documents free of language that waives the participant’s legal rights, or that releases the investigator, institution, or sponsor from liability? |  |  |  |  |
| Is the Information sheet written consistently in the second person (“You”/”your”)? |  |  |  |  |
| **Comments:** | | | | |
| **PURPOSE OF THE STUDY:** | | | | |
| Is there an introduction in the Information sheet explaining:   * That this is research? * That this is an INVITATION to participate? * That participation is voluntary? |  |  |  |  |
| Is the purpose of the study clearly described? |  |  |  |  |
| Is the expected duration of participation in the trial described? |  |  |  |  |
| Is the number of participants to be involved in the study described? |  |  |  |  |
| **Comments:** | | | | |
| **STUDY PROCEDURES:** | | | | |
| Are any screening procedures included in the information sheet? |  |  |  |  |
| Are participant responsibilities described (e.g. order of procedures, amount of time required)? |  |  |  |  |
| **Comments:** | | | | |
| **RISKS & BENEFITS** | | | | |
| Are the foreseeable risks clearly described and the probabilityof their occurrence given? (e.g., psychological – risk of embarrassment, stress, etc.) |  |  |  |  |
| Are the potential benefits described? If there is no intended benefit to the participant, is this clearly stated? |  |  |  |  |
| **Comments:** | | | | |
| **COMPENSATION OR REIMBURSEMENT** | | | | |
| If participants are to be compensated or reimbursed for their participation, are the conditions and the amount of the compensation described including what happens should the participant withdraw from the study? |  |  |  |  |
| **Comments:** | | | | |

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| **INFORMATION SHEET & CONSENT FORM** | **Yes** | **No** | **C/R** | **N/A** |
| **CONFLICT OF INTEREST AND COMMERCIALIZATION** | | | | |
| Conflict of interest issues are clearly described? |  |  |  |  |
| Commercialization potential is clearly outlined and complete? |  |  |  |  |
| **Comments:** | | | | |
| **PRIVACY & CONFIDENTIALITY** | | | | |
| Does the Information sheet describe:   * Procedures to ensure confidentiality of data and anonymity of participants’ data? * Length of data retention? * Measures to ensure physical security of data? |  |  |  |  |
| If information will be released to any other party for any reason, does the Information sheet:   * State the persons/agencies with whom the information will be shared? * What may be disclosed? * The purpose of the disclosure? |  |  |  |  |
| **Comments:** | | | | |
| **WITHDRAWAL** | | | | |
| Does the Information sheet explain:   * Whether the participant has the choice not to answer any of the questions, and if not, why? * That the participant can withdraw from the study at any time? * Whether data can be removed from the study after it has been submitted, and if not, why the data cannot be removed? |  |  |  |  |
| **Comments:** | | | | |
| **CONTACTS** | | | | |
| Is the participant told whom to contact regarding the study? |  |  |  |  |
| Is the participant told whom to contact about their rights as a research participant, MCREB REB Coordinator, [rebcoordinator@mohawkcollege.ca](mailto:rebcoordinator@mohawkcollege.ca) |  |  |  |  |
| **Comments:** | | | | |
| **CONSENT/SIGNATURE PAGE** | | | | |
| Is the Consent form written in the first person singular(“I”, “me”, “my”)? |  |  |  |  |
| Does the Consent form indicate that the participant understands and agrees to participate in the research? |  |  |  |  |
| Are the appropriate signatures provided (i.e. printed name and signature of the participant or their legally authorized representative, the person obtaining consent and the date of each signature)? |  |  |  |  |
| Will minors give assent to the research, in addition to the guardian’s consent? Is an Assent form included? |  |  |  |  |
| Does the consent include a statement that “I will receive a SIGNED copy of this form”? |  |  |  |  |
| **Comments:** | | | | |