**IWK REB Review**

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| **Romeo File No.** |  |

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| **Study summary (provided by researcher):** |

**Reviewer A - Ethics Application Form (EAF), Protocol and other study documentation**

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| **EAF Section** | **Immediate Action Items** |
| **Section 3: Administrative**  Is this a student project, are there appropriate supervisors listed? Is funding needed and in place? Appropriate departmental review? For multi-site studies are other REB reviews and approvals provided. Is the signature sheet signed? |  |
| **Section 4: Research Summary**  Adequate descriptions for the main study and any sub-studies? Background, rationale, hypothesis, methodology (incl. method of randomization, degree of blinding, sample size justification, use and storage of biological material, genetic testing), data analysis, harms/benefits, and outcome measures clearly laid out? |  |
| **Section 5: Participants/Protocol**  **Participants:** Adequate description of where and how many participants are to be recruited. Inclusion and exclusion criteria clear. Recruitment plan adequately addresses the principles of justice & inclusiveness? If vulnerable populations involved are appropriate plans in place?  **Standard of care:** IWK standard of care clearly described? Description of how the research deviates from, or modifies the standard of care described?  **Placebo:** Justification of use of placebo.  **Safety monitoring and follow-up care:** Appropriate detail provided regarding methods of monitoring, reporting of adverse events, additional safeguards. Detailed plan for participant withdrawal, follow-up, emergency care, ongoing care for participants adversely affected by participation in the study, notification of the participant’s principal/primary caregiver. |  |
| **Section 6: Compensation/Conflict of Interest**  Details & justification for payments, honoraria, or other incentives. Real or perceived financial or other conflict of interest described? Details of how the potential conflict will be managed. Budget details provided? |  |
| **Section 7: Participant Identification and Informed Consent**  **Participants:** Adequate description of how participants are to be identified for recruitment. Who & how will initial screening/identification occur. If PHI is to be accessed for recruitment; will it be done with or without prior consent, and by whom (inside the *Circle of Care?*), or will participants self-select,volunteer, or respond to advertisements, for example.  **Consent:** A full description of the consent process should be provided or an SOP attached. Who provides information on study participation? Who obtains consent? Is there a pre-existing relationship that may influence the consent process? |  |
| **Section 8: Privacy and Confidentiality**  **Collection of PI/PHI:** Complete details of PI/PHI, including what will be collected, why it is necessary, the sources for PHI, how it will be used, stored or linked. Is the PHI de-identified? Has justification been provided if data matching is to be done?  **Access to PHI:** Personnel accessing/using PHI must be identified and justified.  **Safeguards and Security**: a plan should be provided which includes the potential risking of using PHI and a description of where and how PHI is stored and protected. Clear details are needed if PHI is to be transferred, it should be de-identified or express consent is required. |  |
| **Section 9: Other Ethical Issues**  Are there any other ethical issues to consider and are they appropriate? |  |
| **Section 10: Application for Access to PHI**  This section is for those that need access to patient records. Are all persons requiring access listed? Is the data collection form attached? |  |
| **Section 11: Request for Waiver of Consent**  Is waiver necessary and justified? Is it: limited to only what is necessary to accomplish the research, in the most de-identified form possible, used in a manner that ensures its confidentiality? Is it *impracticable* to obtain consent? |  |
| **Section 12: Research Registry**  Is the request appropriate? (e.g. accessing the appropriate age group, clinic, etc.) |  |
| **Additional Comments:**  Are there issues with either the EAF or protocol that have not been addressed above? |  |
| **Comments From Reviewer B** on EAF and/or Protocol |  |

**Reviewer B - Consent Form(s)**

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| **Consent Sections** | **Immediate Action Items** |
| Language level an appropriate level? Version date and page numbers in the footer? |  |
| **Opening:**  The full title and simplified title (if appropriate) included? All team members listed along with their professional designation, institutional affiliations, and role in study? Funding agency or name of sponsor listed. |  |
| **Introduction:**  Must state or describe that the project involves research, the initial consent process, the ongoing consent process and if applicable, describe what a clinical trial is. |  |
| **Why are the researchers doing the study?**  Must provide an explanation of the topic being explored, the hypothesis that is being tested, and/or the question the research is seeking to answer and an explanation of why and how the study might be important. |  |
| **How will the researchers do the study?**  Must state or describe the research design (e.g. randomized, double-blind controlled trial or observational study), single site or is part of a multi-center project and the # of subjects to be enrolled at this site and in total. If a double-blind method has been used, details of when and how a code may be broken must be included. In lay language, all research specific design techniques such as randomization, blinding, or placebo control. If a placebo is used, a definition of what a placebo is and an explanation of the likelihood of receiving the placebo must be included. |  |
| **What will I be asked to do?**  Must provide a detailed description of what participation entails for the research subject including all tests and interventions, the time requirement for participation, what is being done as standard care and what is being done for the purposes of research and a description of access to health and any other personal records. |  |
| **Burdens, harms and potential harms:**  All foreseeable harms and potential harms (including physical, reproductive, emotional psychological, social, legal, financial risks and/or inconvenience) should be stated. |  |
| **Possible benefits:**  Must state or describe that the study intervention may provide no direct benefits to the subject.  Must NOT include: reimbursement or compensation as a benefit and the provision of more extensive diagnostic testing, or monitoring and attention of medical staff as this implies that the subject who refuses participation may receive lesser care from IWK and their medical team. |  |
| **Alternatives to participation:**  Must state or describe that not participating in the study is one option, and choosing not to participate will not affect the care the potential subject or family receives at the IWK Health Centre. |  |
| **Withdrawal from the study:**  Must state or describe that subjects can withdraw from the study at any time, instances when it is not possible for a subject to withdraw from the research (e.g. part way through a surgical procedure, or for safety concerns), withdrawing from the study at any time will not affect the care the potential subject or his/her family will receive from the IWK Health Centre |  |
| **Study costs:**  Must describe any costs that will be incurred by the subject. Whether, and how much, the subjects will be reimbursed for expenses (e.g., travel, childcare) and/or inconvenience of participation, |  |
| **Conflicts of interest/possible profit from commercialization:**  Includes any actual, perceived or potential conflicts of interest on the part of the researchers and/ or the institutions, including financial, or that of academic achievement or if none, state there are no conflicts. Potential profit from commercialization of the results of the research should be stated, and what, if any, plans have been made to share these profits with the research subjects: |  |
| **Study results:**  Participants should be offered the results of the research. The subject should not have to contact the researcher to obtain results. |  |
| **Is the service/drug/intervention available after study is complete:**  States whether the service/drug/intervention/ device/program will be available to the subject once the research is complete and, if so, under what conditions. |  |
| **Privacy:**  Describes where and for how long records including data forms, identifying information, samples, video recordings, photographs etc. will be maintained in storage. Describes the extent to which privacy can be protected.  Describe limits on the protection of confidentiality relating to ongoing monitoring of research activities (includes identity and nature/purposes of access to the information.  Describes where and what information about participation will be recorded apart from research files (e.g. in health records).  States that if the results of the trial are published, the subject’s identify will remain confidential.  The assurance of anonymity can only be given when the researcher will have no way of connecting data to individuals. Names and other easily identifiable elements have not been noted directly on documents or data that are sent out of the Health Centre.  Indicates whether or not the subject’s primary care physician will be notified of their participation in the study. |  |
| **Team contact information:**  Provides the name and contact phone number and e-mail of the researcher who can answer questions about the study. Also provides information as to when this person is available to research subjects. Provides advice on seeking medical care if necessary. |  |
| **Research rights:**  *A statement regarding possible compensation if the subject is injured as a result of the research is mandatory. This section must include the following wording*:  “Nothing written here about treatment or compensation in any way alters your right to claim damages”.  “Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. If you become ill or injured as a direct result of participating in the study, necessary medical treatment will be available at no additional cost to you. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.”  “If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-7879, Monday to Friday between 8:00 a.m. and 4:00 p.m.”. |  |
| **Future contact/future research/future use:**  Explicit consent is needed for the following:  If the researcher would like to be able to contact the subjects again in the future to seek their involvement in subsequent research projects. If the researcher would like to keep the information/samples gathered during this study for other research. If the researcher would like to use the information/samples gathered at some time in the future for purposes other than research (e.g., teaching). |  |
| **Signature Page:**  Includes study title and consent statement.  Has signature line for participant and person obtaining consent.  Includes space for contact information for study results.  Include applicable check boxes and statements (e.g. future contact, use of data) |  |
| **Comments from Reviewer A on consent and supporting documents** |  |

**Assent Form:**

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| **Assent** | **Immediate Action Items** |
| Language level should be at an appropriate level.  Version date and page numbers should be in the footer. |  |
| **Opening:**  Has the full title and simplified title (if appropriate) been included. All team members should be listed along with their professional designation, institutional affiliations, and role in study. Funding agency or name of sponsor. |  |
| **Why and how are researchers conducting the study:**  This there an adequate description of the study? |  |
| **What will I be asked to do:**  This there an adequate description of what is being asked of the subject? |  |
| Burdens/Harms and Benefits:  This there adequate description provided |  |
| **Withdrawal:**  Are subjects told they can withdraw or not take part at all? |  |
| **Privacy:**  A description of how privacy will be protected is needed. |  |
| **Comments from Reviewer A on consent and supporting documents** |  |

**Supporting Documents**

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| **Document Name** | **Immediate Action Items** |
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