**CONSENT FORM FOR RESEARCH PARTICIPATION**

***INSTRUCTIONS:***

* Use this template to prepare a document with the information from following sections.
* As you are writing the consent **remove all instructions in italics** so that they are not contained in the final version. Remove all gray highlights.
* Depending on the nature of your study, some sections may not be applicable to your research and may be removed.
* Ensure your consent form is at a grade six – eight reading level for adults, and if applicable, at a grade three reading level for children. Information about the Flesch Reading Ease test and Flesch-Kincaid Grade Level test can be found on Google or [here](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#ID0EBDD=Older_versions_of_Office).
* Ensure all acronyms are spelled out.
* Ensure the footer is updated. (Double-click on the footer section to edit it, and remove the content in the { }.)

Template adapted from: Clinical Trials Ontario. (2021, July 27). Clinical Trial Informed Consent Template – English. <https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/tools-and-resources/>

Note: Unlike a funding agency, the REB cannot begin an ethics review of a study until it receives the full and final plan of the study including the protocol, recruitment documents, data collection documents, and all other supporting documents.

Table instructions:

* Resident Projects should include the name/contact information of their supervisor in the “MGH Principal Investigator” section.
* The co-Investigators column should include all co-investigators and their contact information. Resident Projects should identify all resident co-investigators. Residents/students must use a tehn.ca email account unless the research involves recruiting physicians/residents/staff who already have access to the investigator’s personal or institutional email address.
* If the Principal Investigator is the study Sponsor, this row may be removed from the table.

|  |  |
| --- | --- |
| **Study Title:** | ***Insert the exact title of your protocol here*** |
| **MGH Principal Investigator:** | *Name*  *Contact number*  *TEHN Contact email (if applicable)* |
| **Co-Investigators:** | *Name*  *Contact number (work)*  *Contact email (if applicable)* |
| ***Sponsor:*** | *Name* |

**INTRODUCTION**

You are being invited to participate in a research study. You are invited to participate in this study because you have *explain the main features of the population to which the research applies.* This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

**IS THERE A CONFLICT OF INTEREST?**

*Instruction: Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker’s fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source. See examples below.*

The *identify individual, e.g.,* study doctor, *insert name*, is receiving personal financial payment from *Identify source of funds e.g., the study Sponsor* for *include reason for payment e.g.*, *providing advice on the design of the study*. You may request details about this payment.

*or*

There are no conflicts of interest to declare related to this study.

*or*

The *insert recipient of funding e.g., hospital* is receiving financial payment from the *identify source e.g., Sponsor/Funder* to cover the cost of conducting this study.

**WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?**

*Instruction: Describe the background information relevant to the study, including (as applicable) the standard of care for the population and the reason for conducting the study in lay language. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information.*

**WHY IS THIS STUDY BEING DONE?**

*Instruction: Explain the purpose of the study or what you plan to evaluate in lay terminology.*

**WHAT OTHER CHOICES ARE THERE?**

*Instruction: Explain the alternative options applicable to the study population, and their important potential benefits and risks. An example for therapeutic intervention studies is included below.*

*Example: You do not have to take part in this study in order to receive treatment or care. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:*

*List applicable treatments available to participants (examples below may be used as applicable). The standard of care does not need to be repeated in this list.*

* *list treatment options*
* *no therapy at this time*
* *other research studies may be available if you do not take part in this study*

*Please talk to your usual doctor or the study doctor about the known benefits and risks of these other options before you decide to take part in this study. Your usual doctor or the study doctor can also discuss with you what will happen if you decide not to take any treatment at this time.*

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

It is anticipated that about *insert total number of participants* people will take part in this study, from research sites located in *indicate participating provinces/countries*.

This study should take *total length of study in months or years* to complete and the results should be known in about *time to anticipated analysis in months or years*.

**WHAT WILL HAPPEN DURING THIS STUDY?**

*Instruction: If there is more than one study group, describe how participants are placed into study group(s). See randomization example below. If randomization is not applicable, provide a lay description appropriate to the specific protocol.*

*Example: If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have explain probability of randomization e.g., an equal/one in three chance of being placed in either/any group. Neither you, the study staff, nor the study doctors can choose what group you will be in.*

**WHAT IS THE STUDY INTERVENTION?**

*Instruction: Describe the intervention by study group, including a clear identification of experimental components of the study. See suggestion below. If this suggestion is not applicable, provide a detailed description appropriate to the specific protocol.*

*Example: If you agree to take part in this study, you will identify intervention, including description of method: e.g. be given [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure. Include length of procedure/intervention for all non-oral interventions e.g., The procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., This will happen every <X> weeks for <X> months.*

**WHAT ARE THE STUDY PROCEDURES?**

*Instruction: Describe the procedures that are used in the study, including clear identification of those procedures that are experimental. It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar.* *Include information of where treatment will take place, and if it will be at the same location every time.*

*Example: refer to Clinical Trials Ontario* [*Informed Consent Form Templates*](https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/tools-and-resources/) *for language re: experimental procedures, non-experimental procedures, focus groups, questionnaires, participant diaries.*

**HOW LONG WILL PARTICIPANTS BE IN THE STUDY?**

*Instruction: Include a statement about the time commitments of the research participant including the duration of intervention, follow-up schedule, and total length of research involvement. See suggestion below, or revise as applicable to the research.*

*Example: The study intervention will last for about insert duration. If intervention length varies by group assignment, ensure this is specified.*

**CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?**

*Instruction: It is important to state clearly that participation is voluntary and that the participant can choose whether or not to participate or continue in the study. This includes the right to withdraw without affecting the care they receive, or in the instance of staff participants, that withdrawal will not affect their employment/job-related evaluations. Tailor this section to ensure that it fits for the group for whom you are seeking consent.*

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason.

If you choose to withdraw from the study, please let study staff know as soon as possible.

You may be asked questions about your experience with the study intervention, and to have laboratory tests and physical examinations considered necessary to safely stop your study involvement.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the MGH Principal Investigator or study staff know. However, this would also mean that you withdraw from the study.

*For clinical trials with regulatory oversight, include the following:*

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

*OR If the participant can withdraw information collected prior to withdrawal:*

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the MGH Principal Investigator or study staff know if you choose this.

**WHAT ARE THE POSSIBLE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?**

*Instruction: Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of intervention, and should be tailored to the specific issue and situation. There may be no risks; it is okay to state this. Explain what supports are provided to participants.*

**WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?**

*Instruction: Inform participants of potential benefits to themselves and in general that may arise. If there is no known clinical benefit, ensure this is stated.*

**HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?**

*Note: If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.*

If you decide to participate in this study, the study team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

*Include only those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:*

* *Insert sponsor name, the Sponsor of this study*
* The Research Ethics Board who oversees the ethical conduct of this study in Ontario
* This institution and affiliated sites, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your *disclose identifiers e.g., participant code, initials, sex, and date of birth*.

*The following organizations may also receive study data:*

*Include organizations with permission to receive study data only (organizations with direct access must be included in the list above). Include a brief description of their role in the research.*

* *Identify any other organizations with permission to receive study data only.*

*If race/ethnicity information is collected as part of the study, identify this and provide a rationale. See suggested text, or modify as applicable.*

*Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary/required.*

*If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:*

*Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.*

*If health information is being collected for other research/database:*

*In addition to the data that will be collected for this clinical trial, the researchers will also be collecting the following personal health information:*

* *List all additional information being collected.*

*This additional data is being collected to insert purpose e.g. to help researchers better understand common trends between your condition and other health problems. This additional information is not required for the purpose of this study, but for other research interests at insert organization name.*

*If identifiable data will be sent outside the institution:*

*This study requires the transfer of identifiable information to insert name of institution/individual for the purposes of specify purpose. The following information will be transferred:*

* *Specify identifiable information to be transferred.*

*If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals.*

*Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.*

*If data or samples will be sent outside of Canada*

*Any information and/or samples sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.*

*For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality. For example:*

*Data collected using the insert app/tool/device name resides on the insert name e.g., Apple servers and no assurance can be made about its confidentiality or that it will only be used for research purposes.*

*Other future research*

*Instruction: If de-identified data or samples may be used or shared for future research, include the following:*

*Your coded study data and/or coded samples may be used or shared with other researchers (inside and outside of Canada) for future studies. “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the study data and/or samples.  This may include storing the coded study data and/or samples in controlled-access databases/biobanks, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database. The goal of sharing is to make more research possible. However, the code matching your study data and samples with your name and other directly identifying study data will not be shared.*

*You will not be asked for further permission to use your study data and/or samples in future research studies. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data and/or samples.*

**WHAT IS THE COST TO PARTICIPANTS?**

*Instruction: Inform the participant of any anticipated expenses associated with participation in the clinical trial.*

**WILL PARTICIPANTS RECEIVE PAYMENT OR REIMBURSEMENT?**

*Instruction: State clearly what you will provide the participants with as a result of their participation. Minimal tokens of appreciation are acceptable but should not incentivise participation. Reimbursements may include, for example, travel costs and reimbursement for time lost.*

**HOW WILL THE STUDY RESULTS BE SHARED?**

*Instruction: Identify your plan for sharing the findings with the participants. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.*

**QUESTIONS AND CONTACT INFORMATION**

*Instruction: In addition to the language below, provide the name and contact information of someone who is involved, informed and accessible to answer questions about the study, i.e., a local person who can actually be contacted. Include the language provided below. Do not include any statement indicating that the REB has “approved” the study, since this may appear to offer a guarantee of safety.*

This study has been reviewed by the Michael Garron Hospital (MGH) Research Ethics Board (REB). The REB is independent of the researchers. If you have any concerns or questions about your rights or your experiences as a research participant, you may contact Dr. Sherry Rezaie, Chair of the MGH REB at 416-469-6580 ext. 3853, during business hours.

**CONSENT AND SIGNATURES**

|  |  |
| --- | --- |
| **Study Title:** | ***Insert the exact title of your protocol here*** |

* This study has been fully explained to me and all of my questions have been answered to my satisfaction.
* I understand how I will be involved in this study.
* I understand that my participation is voluntary and that I may withdraw my participation at any time.
* I understand that I have the right to refuse to anything I find disturbing or uncomfortable.
* I have been informed of the risks and benefits, if any, of participating in this study.
* I have been informed of any alternatives to participating in this study.
* I do not give up any legal rights by signing this form.
* My signature below indicates my consent and agreement to take part in this study.
* I will receive a signed and dated copy of this consent form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Print Name of Participant |  | Signature of Participant |  | Date signed |

My signature below attests that I have personally explained the research to the participant and have answered all of their questions. I believe the participant understands what is involved in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Print Name of Person Obtaining Consent |  | Signature of Person Obtaining Consent |  | Date signed |