***For use by investigators performing research to be reviewed by the Hamilton Integrated Research Ethics Board***

**SAMPLE INFORMATION SHEET/CONSENT FORM FOR MEDICAL RESEARCH**

A Consent Form should contain the elements identified on the following pages to ensure that research participants have sufficient information to make a fully informed and free decision about whether to participate in the research study.

**This form should be used as a guideline and may not be applicable to all types of studies.**

* Use of 12 point font is recommended. Larger type may be necessary for elderly or visually compromised participants.

Avoid italics or ornate type.

* Use of questions or headings to highlight the various elements is strongly recommended.
* Use of bullets, tables, and charts is also recommended.
* Use of ‘white space’ makes the document easier to read.
* Include a page header or footer, numbering on each page with the protocol reference, version number and/or date, and the version number and/or date of the consent form.
* If the investigator proposes to include his/her own patients in a study, the invitation to participate should be made and the informed consent should be obtained by persons on whom the participants have no dependency.

**If the clinical trial is not registered please include this statement in the information sheet/consent form:**

“This clinical trial will not be registered with a recognized, publicly-accessible clinical trial registry and therefore it is unlikely the study results will be published by established medical journals.”

**Use Appropriate Letterhead/Logo**

**PARTICIPANT INFORMATION SHEET**

**Title of Study:**

**Locally Responsible Investigator and Principal Investigator, Department/Hospital/Institution:**

**Co-Investigator(s), Department/Hospital/Institution: (Listing of Co-Investigator(s) is optional)**

**Sponsor:** *e.g. pharmaceutical company, granting agency, university or hospital.*

**You are being invited to participate in a research study conducted by** **Dr …** **because you have …** *[insert the participant’s condition or circumstance that makes him/her eligible for the study. If the study is recruiting healthy volunteers indicate:* **… because you are a healthy individual**]. *If this is a student project, indicate* **“This is a student research project conducted under the supervision of Dr….** *[insert name].* **The study will help the student learn more about the topic area and develop skills in research design, collection and analysis of data, and writing a research paper.**

**In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.**

**…….** *[insert name of Hospital or Institution]* **and the investigator Dr. …** *[insert Locally Responsible Investigator’s name]* **are under contract with the Sponsor of this study and are receiving compensation to cover the costs of conducting the study.**

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators and this study. A conflict of interest exists if there is potential benefit to the investigator(s) beyond the professional benefit from academic achievement or presentation of the results.

**WHY IS THIS RESEARCH BEING DONE?**

Explain in layman’s terms the background for the study.

**WHAT IS THE PURPOSE OF THIS STUDY?**

*Explain in layman’s terms the purpose of the study.*

**WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?**

**If you volunteer to participate in this study, we will ask you to do the following things:**

*Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. The more invasive the procedures, the more detail should be provided.*

*Identify all procedures that are experimental*.

*Explain to the participant:*

* *What will happen at each visit including the specifics of any procedures, tests, questionnaires, interviews;*
* *Include screening visits;*
* *What is being done as part of the research vs. what is being done as part of standard care;*
* *The frequency of procedures, tests, etc.;*
* *The location of procedures, tests, etc.;*
* *How the participant will be assigned to study groups, with a lay description of the randomization process, if applicable, and explanation of the chances of being assigned to any group*;

 *For example,* **The participants in the study will be assigned at** **random, that is, by a method of chance (like a flip of a coin), to one of two** **groups. You will have a** *[specify 1 in 2, 3 in 4, etc.]* **chance** **of being in the group that receives Drug A and** *[specify 1 in 2, 3 in 4, etc.]* **chance of being in the group that receives Drug B.** **Neither you nor your study doctor will know which** **group you are in. However, in the case of an** **emergency the code can be broken.**

* *The length of time for each visit;*
* *The total time commitment for participation, i.e. number of weeks/months;*
* *The drugs that will be administered and their therapeutic action in lay terms [e.g. “hydrochlorothiazide”, which is a “water pill” designed to help get rid of excess fluid in your body];*
* *The need for “washout” of any drugs the patient is currently taking and the potential risks/discomforts of this;*
* *Any follow-up contacts by phone, mail, or email and what is involved, how long each will take.*

*If the trial involves a placebo rather than an active comparator, describe what a placebo is and indicate what the chance is of receiving the placebo vs. the active drug(s). Indicate whether the patient’s condition may fail to improve or worsen on placebo.*

*For example,* **This is a placebo-controlled study. That means you will be assigned by chance (like a flip of a coin) to a group of people who receive either (Drug A) or a placebo. A placebo is an inactive substance, like a sugar pill. In this study you have a 50% chance of receiving the placebo and a 50% chance of receiving Drug A. If you receive placebo, it is possible that your …** *[specify condition]* **may not improve or may worsen. Your condition will be carefully monitored. If it does worsen, the study doctor will …** *[specify action to be taken].*

*Provide details about the collection of specimens or human tissues. Indicate:*

* *What the sample(s) are to be used for, for example, for the current study only, or for future unknown research (banking);*
* *Where and how the samples will be stored;*
* *Whether the participant will receive the results of the testing;*
* *Whether the sample(s) will be linked to the participant;*
* *How long they will be stored;*
* *How they will be disposed of; and*
* *Describe the possibility for commercialization of research findings and what the subject may expect in way of compensation*.

*For example,* **The sample(s) will be discarded or destroyed once they have been used for the purposes described above. The samples will be used for research and such use may result in inventions or discoveries that create new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researchers/sponsor. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.**

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

*Describe any reasonably foreseeable risks, harms, discomforts, inconveniences (including for example, physical, psychological, emotional, financial and social) to the participant (and, when applicable to an embryo, fetus, or nursing infant) and how these will be managed.*

* *If there are risks to participation, describe them for each procedure and drug;*
* *Group the risks into those that are frequent, occasional, or rare and give the frequencies for each of these groups (e.g. “rare”: less than 1 in 1000 patients);*
* *List all side effects, no matter how rare, that are life threatening or potentially life altering (for example, visual loss, anaphylaxis, paralysis, aplastic anemia);*
* *Explain the ramifications of some risks (for example, what is the importance to the participant if liver enzyme tests indicate an abnormality?);*
* *Studies that present real and potential risks of fetal or reproductive harm should have a description of this risk. If reproductive risk exists, participants should be advised not to become pregnant (or father a baby) while in this study.*

*For studies affiliated with St. Joseph’s insert either of the following pregnancy clauses:*

**Pregnancy and this study are not compatible. Due to the risk of potential risk to the fetus, females who are pregnant , or planning to become pregnant, are therefore excluded from this study. Females of childbearing potential are advised to discuss appropriate family planning with their doctor if they are interested in enrolling in this study. Unless you have had a hysterectomy, a tubal ligation, are post-menopausal, or not at risk of pregnancy, you are advised to practice an appropriate method of family planning.**

***Or***

**It is not known whether xxx (name of drug) may cause side effects to pregnant females, to an unborn child (an embryo or a fetus), or to children of breastfeeding females. Because of these unknown risks, if you are pregnant or trying to become pregnant you cannot enter the study. If you are breastfeeding a child, you cannot enter the study.**

**If you can have children, you are required to have a negative pregnancy test result before enrolling in the study. You are a female who can have children if:**

* + **you have not completed menopause;**
	+ **you have not had a hysterectomy;**
	+ **you have not had surgery to become sterile (i.e., a tubal ligation);**
	+ **your sexual partner has not had surgery to become sterile (i.e., a vasectomy).**

**If you are sexually active and can have children, you must not become pregnant during the time you are participating in the study, and for a period of xx months after the study.**

**If you miss a menstrual period or think you might be pregnant during the study, you must tell the study doctor immediately.**

**If you become pregnant during the study or within xx days from your last dose of the study drug, the study doctor will ask to follow the outcome of your pregnancy and the condition of your newborn.**

**Men who are participating in this study also need to understand the danger of taking the study drug whose effects on a fetus are unknown. Female partners of male participants cannot be pregnant during the time their male partner is participating in the study, and for xx days after the last dose of the study drug. Please speak to a doctor to discuss which family planning method is best suited for you.**

* *If the risk of fetal harm is not known, then indicate it is not known.*
* *If there are no risks associated with the research, then indicate no known risks.*
* *Wherever possible, present risks in a table format to enhance participant comprehension.*

**In addition to the risks listed above, you may experience a previously unknown risk or side effect** *[not necessary for no risk or minimal risk studies].*

Incidental Findings

* *Include this only if incidental findings are likely to occur, such as when using radiological testing.*

During this study information may be learned about your health status, medical condition, etc. that may require further diagnosis and/or treatment. Your study doctor will advise you if this is the case and what options may be possible.

**If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.**

**HOW MANY PEOPLE WILL BE IN THIS STUDY?**

Indicate the numbers locally and the total number for a multi-site study.

**WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?**

*Describe benefits to participants expected from the research. If the participant will not benefit personally from participation, clearly state this fact.*

*For example*, **We cannot promise any personal benefits to you from your participation in this study. However, possible benefits include …** *[specify benefits]***.** **Your participation may help other people with …***[specify, e.g. cancer]***in the future.** *If there is likely to be no medical benefit to participation, then state:* **There are no medical benefits to you from your taking part in this study**.

**IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

**It is important for you to know that you can choose not to take part in the study. There are other choices such as …** *[specify choices].* **Your study doctor will discuss these with you.**

***Or***

**An alternative to the procedures described above is not to participate in the study and continue on just as you do now. Your study doctor will discuss this alternative with you.**

*Describe how you would care for a participant who is not part of this research study or describe the options that you would normally offer a person who did not participate in the study. If applicable, include supportive care as an option.*

*If the study involves patients, the following statement must be added at the end of this section*: **Choosing not to participate in this study will in no way affect your care or treatment.**

**WHAT INFORMATION WILL BE KEPT PRIVATE?**

**Your identifiable data will not be shared with anyone except with your consent or as required by law. All personal information such as your name, address, phone number, OHIP number, family physician’s name will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed, will be securely stored in a locked office in** *the research laboratory, locked cabinet, locked office, etc.***.**

**For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of any institutional regulatory body, a Health Canada representative** *[include* ***Health Canada*** *if this is a clinical trial involving a drug, device or natural health product regulated by Health Canada]* **or …** *[list the designated institutions where relevant, such as the U.S. Food and Drug Administration]* **and representatives of …** *[name of the sponsoring company if relevant]* **may consult your research data and medical records. However, no records which identify you by name or initials will be allowed to leave the hospital. By signing this consent form, you or your authorized third party authorize such access.**

*If information will be released to any other party (such as foreign governments and regulatory agencies) for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure*.

*In order to permit access to a participant’s health records if they are admitted to another hospital during the study, or if they die during their participation, it is recommended that you include the following wording:*

 **If you are admitted to another hospital for any reason or die from natural or other causes while participating in this study, your medical records will be requested in order to collect information relevant to your study participation. By signing this consent form, you are allowing such access.**

**If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. However, it is important to note that this original signed consent form and the data which follows, may be included in your health record.**

*If activities are to be audio- or videotaped or digitally recorded, describe the participant’s right to review/edit the tapes, who will have access, if they will be used for educational purposes, and when they will be erased. For example,* **Video tapes will be viewed only by members of the research team and they will be destroyed after ….** *[specify # of]* **years.**

**CAN PARTICIPATION IN THE STUDY END EARLY?**

**If you volunteer to be in this study, you may withdraw at any time and this will in no way affect the quality of care you receive at this institution.** *Indicate whether the participant has the option of removing data and/or tissue already collected. For example***: You have the option of removing your data from the study *OR* information provided up to the point where you withdraw will be kept unless you request that it be removed. You may also refuse to answer any questions you don’t want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.**

**WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**

**If you agree to take part, we will reimburse you $\_\_\_\_\_\_ (indicate amount) for study related expenses.** **In the event that you cannot complete the requirements of the study, you will receive a pro-rated amount at the rate of $X/per hour/session.** *Indicate if the amount is pro-rated for study visit completion.*

**WILL THERE BE ANY COSTS?**

*Tell participants what charges they or their insurance will have to pay***. Your participation in this research project may involve additional costs to you for** *[indicate source of cost, e.g., drugs, device, diagnostic procedure, therapeutic procedure]***. Your health care insurance probably will not pay for all of these additional costs.** *Also, tell participants what they may expect to receive for free*. *For example,* **Your participation in this research project will not** **involve any additional costs to you or your health** **care insurer**.

**WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?**

 **If you suffer an injury from participation in this study, medical care will be made available to you by your study doctor, or you will be referred for appropriate medical care. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.**  *There should be no exculpatory language whereby the participant waives or appears to waive, any of his/her legal rights, including any release of the sponsor, institution or its agents from liability for negligence.*

**IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?**

**If you have any questions about the research now or later, or if you think you have a research-related injury, please contact*…*** *For greater than minimal risk, include night/emergency phone numbers.*

**CONSENT STATEMENT**

* *Not all of the following signature lines are required*
* *Please select the signature lines that are appropriate for your study*

**Participant:** (*required for participants capable of consent)*

**I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |

**Person obtaining consent**: (*required for all studies)*

**I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.**

|  |  |  |
| --- | --- | --- |
| **Name, Role in Study** | **Signature** | **Date** |

 **Authorized Third Party:** *(required if child is under age 16 or participant is incapable of consent)*

**I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I understand that I will receive a signed copy of this form.**

**I give my permission for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to participate in this study.**

|  |  |  |
| --- | --- | --- |
| **Name, Relationship to Participant** | **Signature** | **Date** |

**Witness:** *(required if participants are unable to read, or if translation is necessary)*

**I was present when the information in this form was explained and discussed with the participant. I believe the participant understands what is involved in this study.**

|  |  |  |
| --- | --- | --- |
| **Name**  | **Signature** | **Date** |

* ***HiREB Statement***
* *Include the following statement at the end of the signature page*
* *DO NOT ALTER this statement*

**This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.**

#  February 2018