For use by investigators performing research to be reviewed by the Research Ethics Boards (REBs) of:
Hamilton Health Sciences/McMaster University, Faculty of Health Sciences;
St. Joseph’s Healthcare, Hamilton; and other affiliated institutions.

SAMPLE INFORMATION SHEET/CONSENT FORM FOR GENERAL RESEARCH
Revised March 2008

A Consent Form should contain all, or some of the elements (modify if needed depending on the type of study) 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. (Note that some statements only are applicable to certain types of trials) Please use common sense and attention to detail when creating your consent form and contact Alison van Nie, Research Ethics Officer (905-525-9140 x22057) with any questions.

This form should be used as a guideline – some of the elements may not be applicable to all types of studies. Please note the references to ‘if applicable’ used throughout this sample form.

• 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 footer, including numbering (i.e., page 1 of 4), on each page, and the version number/ date of the form. Please note that a current date on the consent is required for tracking and approval purposes – each time the consent is modified, revised or re-approved, the date on the consent must be updated.
• You also may include the protocol reference # (if applicable), and include a space for subject initials on each page of the consent if this is a clinical research trial.
• Please Note: If the investigator proposes to include her/his own patients/ students/ staff members, etc., in the study, the invitation to participate should be made and the informed consent should be obtained by persons on whom the participants have no dependency.

Use Appropriate Letterhead/Logo
NOTE: Use the SJHH logo for studies conducted at SJHH, the HHS logo for studies conducted at HHS, and the McMaster University FHS logo for studies conducted under the auspices of the FHS. The use of more than one letterhead is permissible but do not use logos/letterheads that are not relevant.

PARTICIPANT INFORMATION SHEET

Title of Study:

Local Principal Investigator and Principal Investigator, Department/School/Programme/Hospital/Institution:

Co-Investigator(s), Department/School/Programme/Hospital/Institution:

Sponsor: e.g. pharmaceutical company, granting agency, university, or hospital. Sponsor in this case is identified as the funding sponsor (including in-kind support for the research).

You are being invited to participate in a research study conducted by ... 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: e.g., because you are a healthy individual; ....a student …; a faculty member; .a nurse…].

Consent Form Date: _____________ Page 1 of 6 Protocol # and version date ______________
Subject Initials: ______________
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, and/or your family physician [if appropriate include this reference to family physician]

[If there is a funding body for the study ... [insert name of Hospital or Institution] and the investigator Dr. ... [insert Local Principal 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 lay terms/simply the background for the study.

WHAT IS THE PURPOSE OF THIS STUDY?

Explain in lay terms/simply 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/risky the procedures, the more detail should be provided.

Explain to the participant:
- What will happen at each visit/contact point with the researcher including telephone/letter, etc., and, including the specifics of any procedures, tests, questionnaires, interviews; focus group, etc.
- The frequency of procedures, tests, interviews, focus groups, etc;
- The location of procedures, tests, interviews, focus groups, etc;
- Any follow-up contact by phone or mail and what is involved, how long each will take.
- The length of time for each visit;
- The total time commitment for participation;

Clinical Trials:

- If applicable... 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.
- If applicable... 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];
- If applicable... The need for “washout” of any drugs the patient is currently taking and the potential risks/discomforts of this;
- Identify any procedures that are experimental
- If applicable... What is being done as part of the research vs. what is being done as part of standard care;

If applicable... 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].

If applicable... 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.

If applicable... If samples for genetic testing are being taken you must have a separate consent form. (see genetic consent sample at http://www.fhs.mcmaster.ca/csd/ethics/reb/forms.htm)

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, foetus, or nursing infant) and how these will be managed.

- If there are risks to participation, describe them for each procedure, and (if applicable) drug;
- Any psychological, emotional, social and/or financial, etc., risk should be well described including loss of privacy or confidentiality, feelings of loss or sorrow, potential loss of income and/or status, etc.
- If there are no risks associated with the research, then indicate no known risks.

Clinical Studies:
- 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 – do not use < or >- less than or greater than must be written out in full);
- List all side effects, no matter how rare, that are life threatening or potentially life altering (for example, visual loss, anaphylaxis, paralysis, aplastic anaemia);
- 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 foetal 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.
- If the risk of foetal harm is not known, then indicate it is not known.
- Wherever possible, present risks in a table format to enhance participant comprehension.
- If there are no risks associated with the research, then indicate no known risks.

If applicable (not necessary for no risk or for minimal risk studies)... In addition to the risks listed above, you may experience a previously unknown risk or side effect.

...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.
For clinical studies (if applicable) affiliated with St. Joseph’s Healthcare Hamilton insert either of the following pregnancy clauses:

You must not become pregnant while you are in this study. You will need to decide on the best way to avoid pregnancy by talking to your physician about different methods of birth control.

Or

You must not become pregnant while you are in this study. You will need to use an acceptable method to avoid pregnancy, such as birth control. Clinically acceptable methods include not having any sexual intercourse, using birth control pills, and using barrier methods such as condoms, vaginal diaphragm with spermicidal jelly, or sponge.

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 ... [specify, e.g., depression, heart disease cancer] in the future. If there is likely to be no-benefit to participation, then state: There is no anticipated benefit to you from your participation 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. [If applicable]...There are other choices such as ... [specify choices]. [If applicable]... Your study doctor will discuss these with you.

Or

An alternative to the procedures described above is not to participate in the study. [If applicable]... 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: e.g., Choosing not to participate in this study will in no way affect your care or treatment.

If the study involves students/staff members, etc, the following statement may be added at the end of this section: e.g., Choosing not to participate in this study will in no way affect your standing in this class/your standing as an employee, etc.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your 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, [if applicable include OHIP number and 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 office/on a secure server/on an encrypted hard drive, etc. The data for this research study will be retained for _______ years. [see retention policy: Health Canada Drug, Device or Natural Health Products studies require 25 year study-related record retention. Otherwise, there are no defined regulations or standards for other research trials. However, institutional or sponsor standards for record retention may apply. The REB recommended minimum standard is ten (10) years.]
For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the … [specify either the St. Joseph’s Healthcare Hamilton or Hamilton Health Sciences/FHS McMaster University] Research Ethics Board, a Health Canada representative [include Health Canada only 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 if applicable]. However, no records which identify you by name or initials will be allowed to leave the institution/university/hospital. By signing this consent form, you [if applicable…or your legally acceptable representative] authorize such access.

If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure.

If the study is international, indicate that representatives from foreign governments and regulatory agencies may also review your research record, including personal health information, medical reports and other personal information.

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. [For clinical trials add…]

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, 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. [If applicable….this will in no way affect the quality of care you receive at this institution/your work at…. /your role as a student in…..] 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. 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. [If applicable…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 if any, they will have to pay. Your participation in this research project may involve additional costs to you for [indicate source of cost, e.g., parking, visits for interviews, etc., drugs, device, diagnostic procedure, therapeutic procedure]. 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. You will receive the medication free of charge….. etc.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

[If applicable – primarily for clinical trials] If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.

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, [if applicable - or if you think you have a research-related injury], please contact… For greater than minimal risk, include night/emergency phone numbers.

If you have any questions regarding your rights as a research participant, you may contact… For studies affiliated with St. Joseph’s, insert the following contact: …the Office of the Chair of the Research Ethics Board, St. Joseph's Healthcare Hamilton, 905-522-1155 Ext. 33537. For studies affiliated with Hamilton Health Sciences/McMaster University, insert the following contact: the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100, ext. 42013.
CONSENT STATEMENT

SIGNATURE OF RESEARCH PARTICIPANT/LEGALLY-AUTHORIZED REPRESENTATIVE*

*NOTE: The use of a legally authorized representative is only needed for studies that will recruit participants who are not able to provide their own consent, (e.g., children, emergency situations, persons designated as incompetent to provide consent, etc.) – only use this designation/option in this case – see application form for further information) "If participants in the study are competent to provide consent, remove all references to a Legally Authorized Representative from the Information sheet and Consent statement"

I have read the preceding information thoroughly. I have had the 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.

If the participant is an older minor, the participant should sign to give assent to the research in addition to the guardian/legal representative’s consent. Assent is recommended for persons aged 7 – 15 years – please see sample assent form at http://www.fhs.mcmaster.ca/csd/ethics/reb/forms.htm

Name of Participant

Name of Legally Authorized Representative

Signature of Participant (or Legally Authorized Representative) date

Consent form administered and explained in person by:

Name and title

Signature date

[If applicable]…Signature of Witness to Consent Interview

A witness signature is not required by law, but may be required by the study Sponsor. The signature should be prefaced by a statement indicating what is being witnessed. Two examples are provided below:

My signature as witness, certifies that I witnessed the “Consent Interview” for the research study named above in this document. I attest that the information in this Information Sheet and Consent Form was explained to, and apparently understood by, the participant (or the participant’s legally authorized representative).

Signature date

Signature of Witness to Participant’s Signature:

My signature as witness, certifies that I witnessed the participant (or the participant’s legally authorized representative) voluntarily sign this consent form in my presence.

Signature date
In my judgement, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

____________________________________   ______________
Signature of Investigator     Date

NOTE: The signature must be an M.D. if the study involves a medical act (do not include this statement in the final consent form).

HHS/FHS & SJHH REB
Sample Consent
Revised March 2008 [do not include this filename in the final consent form].