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 GENETICS STUDY

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.

- 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/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 invited to be in a research study (or SUB STUDY) conducted by Dr **…** *[insert name]* involving (e.g., the analyses of how genes, blood components or DNA relate to the development and treatment of disease.)

……. *[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.

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.

Why am I being invited to donate this sample? *Explain in lay terms/simply the purpose of the study.*

You are being invited to e.g.*, donate a vial of blood (approximately 2 teaspoons) for the analysis of your genes, or DNA, and other components of your blood.* Your information will be used for ……Your agreement to donate this *'blood sample'* is optional and entirely up to you. You will receive the same treatment and care whether or not you decide to donate this *blood sample.*

What adverse (bad) effects (unwanted effect or health problem) can happen to me by donating this sample?

*Example……*A vial of blood (about 2 teaspoons) will be collected for genetic analyses (analyses of your genes, blood components, or DNA). A needle will be used to collect the blood from a vein in your arm. Most donors experience slight pain at the site of the needle insertion, and some may develop a bruise.

Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you. However, there is always a remote possibility that information from your participation in this study would adversely affect you or your family in some way, such as obtaining a job or health insurance. If, in any way, the genetic information from this study becomes available, it might reveal an increased risk for specific diseases that could affect your employability or insurability. The Investigator, site and investigator have taken special precautions to keep your genetic information confidential. However, as discussed below, absolute confidentiality cannot be guaranteed.

What benefit can I expect from the donation of this sample?

Examples: There is no direct benefit to you in donating the sample or having these analyses performed. However, there may be a future benefit to people with diseases related to Vitamin D insufficiency or deficiency and, possibly to people with other diseases, from donating your sample. The samples collected in this study, any genetic analyses, and any gene information are the sole property of the Investigator. Any cell lines, patents, diagnostic tests, drugs, and biological products developed directly or indirectly from those samples are also the sole property of the Investigator (and its successors, licensees, and assignees) and may be used for commercial purposes. You have no right to this property or to any share of profits that may be earned directly or indirectly as a result of these genetic analyses.

Will I be paid to participate in this study?
Indicate no or…sample wording…..
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 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]. 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.

What happens if I have a research related injury?

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 Investigator(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 Investigator, institution or its agents from liability for negligence.*

How will my personal information be protected?

If you agree to donate a sample, at the time of your blood draw, your donated sample will only be labelled with a unique sample number or 'code' number. The sample will not be labelled with your name. The unique code number is the only identifier people outside the study will see.

At the beginning of the study, the Investigator will use a computer file, also known as the "key", to connect the main study data to the code number assigned to your sample. At the end of the study, the Investigator will delete the key so that genetic analyses from your sample are no longer connected to any personal identifiers. Although there will always be a remote possibility that the key could be recovered, the Investigator agrees not to attempt to connect your sample back to you by any means after the key is deleted.

The types of study data that the Investigator normally collects include age, sex, ethnic group, health conditions, and laboratory measurements from blood samples. These data are associated with the sample by way of the unique code number. This is done so that the Investigator is able to study how genes and other blood components relate to disease and patients' response to drug therapy. These types of study data are connected to the sample even after the key is deleted. Personal identifiers such as your name, address, phone number, or your study doctor's name are not associated with your sample.

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 Investigating Company/Sponsor 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 legally acceptable representative authorize such access.

***If information will be released to any other party 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.*

***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. However, it is important to note that this original signed consent form and the data which follows may be included in your health record.

Will I be provided with the results of these analyses?

No, these analyses are done as part of basic research and will not be provided to you. Basic research analyses are performed under conditions that are different from commercial clinical testing labs. Therefore, it would be inappropriate for your doctor to use these preliminary results as part of your care. The Investigator also will not provide the genetic analyses to your family, any doctor involved in your care, your insurance company or your employer. Also, your name will not appear in any publication.

What will happen to my sample?

Your sample will be securely stored in the premises of……, located at……., labelled only with a unique sample number, for up to 25 years. The Investigator reserves the right to destroy your sample, for any reason, during or after the study.

Can I take my sample out of storage?

Yes, if you want the Investigator to take your sample out of storage and destroy it, please write a letter stating your request to the doctor who asked you to participate in the main study. You must make your request in writing for your sample to be removed from storage and destroyed. However, analyses already performed prior to your request will continue to be used as part of the overall research. Once the main study is concluded, your sample cannot be removed, since the computer file or "key" connecting the main study data to the code number for your sample will be deleted.

Whom do I call if I have questions?

For questions about the study or if you have a study-related injury, call the study doctor Dr…….

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. I consent to …… under the conditions described in this consent form.
In signing this form and donating samples for genetic research, I do not give up any of my legal rights.

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 (if applicable)

_____ _____
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 Sponsorr. 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

SIGNATURE OF INVESTIGATOR:

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 Genetic Consent
March 2008 (do not include this filename in the final consent form)