Preparing a Consent Form
Tissue Banking and Genetic Research

Several study protocols have optional tissue banking and biomarker sub-study components associated with the core study protocol. These sub-studies are sometimes presented in a separate information and consent form. In other cases, the sub-studies are described and boxes are included in the signature page for participants to select or refuse. This is appropriate for most studies looking at changes in blood or tissue drug, protein or RNA content, within the context and duration of the study.

If the tissue samples are to be kept for future research (undefined) and/or there is a possibility that genetic research may or will be conducted with the samples collected, the REB recommends that the information be presented as a separate (supplementary) consent appended to the study. This is to assure particular regard for the privacy and confidentiality issues that tissue banking / genetic research may warrant. Nesting all of the information relevant to genetic testing within a larger protocol tends to reduce the subjects’ particular attention to these matters.

Consent Form for tissue banking / genetic research
The consent form is one aspect of a process to inform a potential research subject so that he/she can make a decision about participation in a study. Generally, consent begins when a potential subject is first informed of the existence of a study and ends some time after its conclusion. In the case of tissue banking, permission to store tissue samples for future research is often for an indefinite period of time.

The consent form has the following objectives:
(a) It is an information tool. In theory, it is read carefully by a potential research subject before agreeing to participate. It is not a substitute for good communication between the researcher and a potential participant.
(b) It is a reference document for the research subject.
(c) It reminds the research subject of relevant legal rights.
(d) It is a source of information for the researchers in outlining all of the information that must be communicated to a potential research subject and how to communicate that information.

There are four essential elements in a consent form:
(a) The voluntary nature of participation and the right to withdraw from a study at any time are the cornerstones of the consent process and must be stated unequivocally.
(b) There must be a clear and understandable description of the purpose of the study and of all the procedures so that a potential research subject is informed of the extent of his/her involvement.
(c) There must be a comprehensive description of the benefits and risks associated with the study.
(d) There must be an indication of how the researcher intends to safeguard the anonymity of the participant and the confidentiality of the information collected.
Tissue banking

When blood, body fluids and tissue samples are collected, the consent form must include all of the requirements of The Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS) Article 10.2.a.

(a) The purpose of the research
(b) The type and amount of tissue to be taken, as well as the location where the tissue is to be taken
(c) The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation
(d) The potential uses for the tissue including any commercial uses
(e) The safeguards to protect the individual’s privacy and confidentiality
(f) The identifying information that will be attached to specific tissue, and its potential traceability
(g) How the use of the tissue could affect privacy

Genetic studies

The TCPS defines genetic research as the study of genetic factors responsible for human traits and the interaction of those factors with each other and, in some instances, with the environment.a. Such research includes identification of genes and different forms of genes that make up the human genome, the functions of the genes and characterization of normal and disease conditions in individuals, biological relatives, families and groups.

There are unique ethical issues presented by genetic research involving human subjects that must be addressed in the application for REB review and approval and in the consent form. The TCPS Section 8 has seven articles that must be considered by the researchers and the Research Ethics Board.

| Article 8.1 | The genetics researcher shall seek free and informed consent from the individual and reports results to that individual if the individual so desires. |
| Article 8.2 | The researcher and the REB shall ensure that the results of genetic testing and genetic counselling are protected from access by third parties, unless free and informed consent is given by the subject. Family information in databanks shall be coded so as to remove the possibility of identification of subjects within the bank itself. |
| Article 8.3 | Researchers and genetic counsellors involving families and groups in genetic research studies shall reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project. |
| Article 8.4 | Genetic researchers and the REB shall ensure that the research protocol makes provision for access to genetic counselling for the subjects, where appropriate. |
| Article 8.5 | Gene alteration (including “gene therapy”) that involves human germline cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval. |
| Article 8.6 | Though the banking of genetic material is expected to yield benefits, it may also pose harms to individuals, their families and the group to which they may belong. Accordingly, researchers who propose research involving the banking of genetic material have a duty to satisfy the REB and prospective research subjects that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the subject, and future contact of subjects, families and groups. |
At the outset of a research project, the researcher shall discuss with the REB and the research subject the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.


http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm

The following document provides a step by step description of each element of a consent form for tissue banking and genetic studies, taking into account the unique requirements described in sections 10 and 8 of the TCPS. **It is intended as a guide only. Not all elements are necessary or required for each study. The consent form must be appropriate in length and content to the characteristics of each study.** The consent form must address the potential research subject directly (“You are invited …”) with language appropriate to the age and reading level of the intended subject. The style must be simple, avoiding or explaining in lay terms scientific or medical words or expressions. Legalistic phrases or expressions are also to be avoided so the consent form does not read like a contract.

**Suggested wording for each section is provided in text boxes.** Researchers are free to cut and paste keeping in mind the text should be adapted to the specificity of the study.
The heading “Subject Information and Consent Form” should specify, if necessary, to whom it is directed (index case, unaffected family members or control individuals)

**Title of Study**
- Should convey that the proposed intervention is for research rather than for educational, diagnostic, treatment, or other purposes.

**Principal Investigator**
- Name,
- Institution and affiliation to Institution
- Contact Telephone Number(s)

**Sub-Investigator(s)**
- Name, Institution and affiliation to Institution.
- If the researcher is a student, this must be explicitly stated and the supervisor clearly identified.

This is not required in all studies, particularly if sub-investigators have little or no contact with study participants (e.g. for referrals, or doing laboratory tests).

**Sponsor**
- Name(s) of industry sponsor or granting agency (as applicable)

**INTRODUCTION**
The introduction is the invitation to participate. The reason to invite these particular individuals should be stated by describing characteristics of the individual or sample population that are important for the study.

The introduction also stresses the voluntary nature of participation and the right to withdraw at any time.

**Suggested Wording**
You are invited to take part in this research study because {…. your diagnosis justify to consider xx …}.

Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you will not affect your {care, employment or academic standing, as applicable}.

Please take time to read the following information carefully. You can ask the study doctor or staff to explain any information that you do not clearly understand. You may ask as many questions as you need. Please feel free to discuss this with your family, friends or family physician before you decide.
WHO IS CONDUCTING THE STUDY?
This section is used to list all agencies contributing funds and other resources to the study. It is also used to declare any other actual or potential conflicts of interest for conducting or being involved with any part of the study. For instance, the possibility of commercialization of research findings that may benefit the local institution and / or researchers should be mentioned, when applicable.

Suggested wording
Scenario #1
The study is being conducted/sponsored by the {name of research group, e.g., Industry sponsor/Granting agency}. The {study doctor, and institutions, as applicable} are being paid to conduct this research study.

Scenario #2
The sponsor of this study {name} will reimburse {study doctor and the institution} for the costs of undertaking this study. However, neither the institution nor any of the investigators or staff will receive any direct financial benefit from conducting this study.

Scenario #3
The researchers have no financial interests in the outcome of this study. They are not being paid in addition to their regular salary to conduct this study.

WHY IS THIS STUDY BEING DONE?
This section provides a brief explanation why the tissue banking / genetic research is / are being done.
Key points to include in this section, when applicable:
- explain why a blood or tissue sample is requested from the research participant.
- for genetic studies, provide a general introduction to the nature of genetic research
- define the specific genetic or other information that will be obtained from the samples the participant is being asked to provide [i.e., specific markers or specific objectives for testing]

Suggested wording
This study is being done because … {add brief explanation of the research objectives}.

The fact that DNA (deoxyribonucleic acid) is the basis of heredity is common knowledge today. A gene is the unit of heredity, which is passed from parents to children. A gene is a stretch of DNA consisting of coded information that is unique for each individual. Differences in the expression or composition of our genes accounts for the differences (e.g. eye colour, height, hair colour) between people. There are now ways for researchers to study the genetic reasons for differences between individuals that may explain why some people may be more or less susceptible to develop a disease or react differently when they get the same medicine. If a gene is related to the development or progress of a disease, potential ways to diagnose and treat that disease may be developed, based on our understanding of the gene functions.

In this study we hope to learn …..

WHAT DOES THE STUDY INVOLVE?
This section is used to describe the scope of the research project, the sample requirements (type, amount and location of tissue to be taken) and what will be done with the samples as part of the study and with any remaining samples upon completion of the study. If blood collection is involved, the amount of blood to be taken may be indicated in mL, followed by lay terms (e.g.
“teaspoons (≈5mL) or tablespoons (≈15mL)”). It should be indicated what (if any) identifying information will be attached to the samples and the potential traceability. Finally, the research subject should be informed of personal health information needed with the samples and how this information will be obtained (from clinic visit, medical chart review, questionnaire, etc).

**Suggested wording**
This study is being conducted at { ...define where the samples are being collected and analyzed}. It is expected to involve about {insert number, worldwide and locally} participants. In this study, we will be examining { ...tissue, gene, as applicable} that may be responsible for { ...the disease that affects you or members of your family, as applicable}.

You are asked to … {test previously collected samples} to donate … {a blood sample, a bone marrow sample, a skin or tissue biopsy, as applicable}. The procedure {describe} should take about { ?} hour(s) of your time.

Describe what will be done with the samples collected:

1. Will the tissue/DNA extraction and storage and testing occur at the local site or will the samples be sent to other researchers or facilities?
2. How will the samples be identified (or de-identified)?
3. What personal health information will be collected along with the samples?
4. Will the data collected contain any personal identifiers or hospital/pathology record number that could be used to identify the research participant?
5. Are the samples to be destroyed at the end of a defined testing period (e.g. duration of the study) or stored for future research, with permission?

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**
This section is required for all studies. It is used to identify benefits to participant, if any. In research projects where there may be anticipated benefits to society or to a specific group, these potential benefits may be explained in a separate sentence / paragraph so as not to confuse potential benefits to others with potential benefits to the research subject.

**Suggested wording**
There will {will not be} a direct benefit to you or your family by participating in this study. This study may improve our understanding of {gene x} in {disease specific information, as applicable}. Information learned about {gene x} may increase general knowledge and provide scientists with a better understanding of this disease which could eventually lead to improved treatments. The study may lead to the development of commercial products but there are no plans to share with you any financial profits resulting from the use of your samples or data.

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**
This section is required for all studies that pose more than minimal risk to a research subject. With the exception of gene therapy, the physical risks in genetic research are generally similar to those seen in other forms of research. There is a great deal of uncertainties as to the personal implications of much of the genetic information generated today. While most of the risks remain speculative, the possibilities of social and psychological harms (non-physical risks) must be addressed with the research subject.
**Suggested wording**

**Physical Risks**
Describe risks associated with biopsies, blood draw or bone marrow collection, as applicable.

**Non-Physical Risks**

**Scenario 1**
The main risk with this study is inadvertent release of your personal health and genetic information. The [Sponsor] has taken measures to protect the privacy of your information and the risk is considered very small.

**Scenario 2**
Genetic research, which involves testing for tendencies toward certain diseases or the actual genetic marker indicating the presence of a disease, raises certain questions about informing you of any such results. Possible risks of knowing such results include: anxiety or other psychological stress and the possibility of insurance and job discrimination. A possible risk of not knowing the results includes being unaware of a need for treatment. These risks can change, depending on the results of the research and whether there is a treatment or cure for a particular disease. Gaining knowledge of this genetic information may also have implications for other family members. In cases where parents and children are tested, tests may reveal the possibility that the father is not the biological parent.

**WILL I BE INFORMED OF THE RESULTS OF THE STUDY?**
Genetic research by its nature generates data that is on a continuum ranging from unknown clinical value to being causative / predictive of a medical condition. The consent process should clearly indicate if results of genetic research will be released to the research subject and should acknowledge the participant’s right not to know certain results. If applicable, genetic counseling should be offered prior to the participant deciding whether he/she would like the results disclosed as well as after the results have been disclosed. Genetic counseling needs to be available to the research participant if there is potential for non paternity issues or issues pertaining to morbidity of participants or their biological relatives.

**Suggested wording**

**Scenario #1**
You will not be informed of the results of your tests. Your results are not for clinical diagnosis or treatment. The information gathered is for scientific purposes. The study doctor and the sponsor will not release your individual results to anyone (e.g. family members, family physicians, insurers or employers) under any circumstances, unless required by law.

**Scenario #2**
You will have a choice whether you want the researchers to notify you of the results of the study. You will be given the opportunity to discuss the research and the results of the study with {...study doctor, genetic counselor, .... as applicable}.

**WHAT HAPPENS IF I DECIDE TO WITHDRAW?**
The right to withdraw consent at any time, for any reason and without repercussions is a central element in research ethics. However, there are instances that impose practical limitations to the right to withdraw. For instances, some bio-banks have a sample double-coding procedure where the linkage between the research subject and the samples is destroyed after some time. Likewise, data from genetic research is often rapidly and widely disseminated. Thus, in many instances it may be impossible to retrieve and destroy samples and /or data in response to a withdrawal
request. These limitations on the right to withdraw (if present) must be clearly explained to a potential research subject as part of the initial consent process.

_Suggested wording_

**Scenario #1**
Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your care [for employment or academic status, as applicable] will not be affected. If you wish to withdraw from this study, please inform your study doctor to have your sample(s) destroyed. However, information collected up to the point of withdrawal will be kept for analysis.

**Scenario #2**
Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your care [for employment or academic status, as applicable] will not be affected. You may request that your sample(s) and all data relating to it be destroyed at any time by contacting the study doctor. However, this may only be possible …… (explain limitations).

**WHAT HAPPENS IF SOMETHING GOES WRONG?**
This section is required for all studies in which there is potential harm to the research subject from participation.
There are three essential statements in this section:

- That in the event of an adverse event, the research subject seeks immediate medical attention.
- That medical attention will be provided at no costs to the research subject.
- That the research subject is not waiving any legal rights to seek compensation for damages by signing the consent form.

This section is not necessary if testing is on samples left-over from diagnostic procedures or tissue collection simply requires a blood draw or mouth swab.

_Suggested wording_

In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study doctor. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

**WHAT WILL THE STUDY COST ME?**
This section should stipulate whether or not the subject will incur any personal expenses (e.g., parking, meal, etc.) as a result of participation and whether or not these will be reimbursed. If an honorarium is to be paid (instead of reimbursement for specific expenses), the total dollar amount should be specified, as long as it is not large enough to constitute an “inducement”. The honorarium should be presented in the sense that subjects are being reimbursed for their time, travel expenses, and the inconvenience of being a research subject.
WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?
This section is used to remind a research subject of his/her privacy rights and to disclose where, how and for how long the information collected will be kept. There are two main concerns: anonymity (how will the investigator prevent identification of participants in a study) and confidentiality (what steps are taken by the researchers to safeguard access to the information collected). For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and subject as there is between physician and patient or counselor and client. Thus, a guarantee of complete confidentiality, or "strictest confidentiality," should not be given or implied.

Suggested wording
In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected.

Your name will not be used in the study records. Your samples and the study records will be identified by [indicate de-identification protocol]. They will be kept for [XX years] in a secure area [at research center]. Tissue samples and results of the study without your name or other information that could identify you will be sent to [sponsor and ...] and combined with information from other participants for analysis. Your participation, the results and the consent form, which will be kept separate from the results, will be kept in a secure file apart from your medical records. If the results of this study are presented in a meeting, or published, your identity will not be disclosed.

No information that discloses your identity will be released or published without your specific consent. Some authorities have a duty to check your study records to make sure all the information is correct. Your study records may be inspected in the presence of the investigator or his/her qualified designate by representatives of (insert here, if relevant to the study- the study sponsor, Health Canada, the U.S. Food and Drug Administration and the [institutional] Research Ethics Board).

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?
This section is used to provide contact information for the Principal Investigator for questions about the study and to the Research Ethics Board for questions concerning the subject’s rights and experiences as a research subject.
SUBJECT CONSENT TO PARTICIPATE
This section is the “signature page” of the consent form and should start on a new page. The participant is signing the form to indicate that he/she has either read (or otherwise been informed), and understands the information concerning the study. The first person pronoun (“I”) is used for this section. Contractual-sounding language should be avoided and it should be clear that the participant does not give up any legal rights by signing it.

In cases of minors or individuals with cognitive handicaps unable to provide consent, the TCPS places certain conditions on when these individuals can be invited to participate in research (see articles 2.5, 2.6, 2.7 and 5.3). If these conditions are met, it should be determined whether a parent, guardian, or other representative has the legal authority to give consent to the proposed research, and if so, that individual’s consent must be obtained. An assent form in appropriate language for minors or adults without capacity should also be used, when applicable. If not, the form should indicate that assent from the subject has been obtained even if the parent/proxy has consented. A means of recording that assent was obtained (signature line with yes/no checkboxes) should be included in the consent form, if an assent is not used. Individuals, who verbally or behaviourally indicate that they do not wish to participate, must be allowed to withdraw even when proxy consent has been given. If a subject becomes able to consent on his or her own behalf during the course of the study, this consent must be obtained in order for the subject’s participation to continue.

There is no clear basis in Saskatchewan law for a “legally authorized representative” to make decisions for a non-competent individual for research purposes. It is the researcher’s responsibility to ensure that the person providing consent has the authority to do so. It is suggested that the “authorized representative” be defined, for example:

“An authorized representative in this study is the person who has the authority to make a decision about participation in the study on behalf of a subject who does not have the capacity to decide, as the subject’s parent or guardian or as someone who was entrusted by the subject to make such decision when the subject was competent. The authorized representative should decisions according to the subject’s wishes and best interests.”

If the consent form is being translated verbally for the research participant, then the translator must also sign the consent form indicating that the translation was to the best of his/her ability.

The signature of a witness is optional. It is not required by law but is recommended by the International Conference on Harmonization (ICH) / WHO Good Clinical Practice standards (ICH-GCP).

A copy of the signed and dated consent form must be given to the subject.
Suggested wording

CONSENT TO PARTICIPATE

- I have read (or someone has read to me) the information in this consent form.
- I understand the purpose and procedures and the possible risks and benefits of the study.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.
- I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my continued health care or my relationship with the study doctor.
- I understand that all the information that I provide will be kept confidential and that any research communication will not use my name or any other personal identifiers.
- I have been told that there are no plans to share with me any financial profits resulting from the use of my samples.
- I give permission for the use of my tissue samples and the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- I understand that by signing this document I do not waive any of my legal rights.
- I will be given a signed and dated copy of this consent form.

I consent for my samples to be used only for \{genetic\} research on \{specific gene, disease or condition\}.

□ Yes □ No

I consent for my samples to be used for \{genetic\} research on \{other diseases or conditions\}.

□ Yes □ No

Please indicate whether you authorize the study doctor to contact you in the future. You are not obligated to participate in any future research.

I authorize the study doctor to contact me in the future for research purposes.

□ Yes □ No

Name of Participant: ______________ Signature: ______________ Date: ______________

I have discussed this consent form with the research participant.

Name of Person Obtaining Consent: ______________ Signature: ______________ Date: ______________