# **Instructions for Informed Consent Form Development**

## The informed consent form (ICF) is one component of the informed consent process. Further guidance may be found in the HREB Guidelines for Consent for Research found under the Attachments tab in the Researcher Portal.

Brief instructions to consent authors are highlighted in this colour and/or [enclosed in square brackets]. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.

Edit the text examples as necessary to make the language specific to the study question since many statements throughout the template are generic.

Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.

Participant Study Calendars: Consider providing an easy-to-read-and- understandable participant study calendar. A participant study calendar may be included as an appendix or included in the main consent document.

Eliminate repetitive information.

Define all acronyms when they first appear and limit their use.

Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors.

Please delete this instruction page from the consent forms prior to REB submission.

## **(Insert your letterhead)**

## **Consent to Take Part in Genetic/Genomic Research**

**TITLE:**

**INVESTIGATOR(S)/STUDY DOCTOR(S)**: **Phone Number:**

**SPONSOR**: **[if applicable]**

You have been invited to take part in a research study. Taking part in this study is voluntary. You may choose to take part or you may choose not to take part in this study. You also may change your mind at any time. If you decide to stop participating in the study, your study doctor will discuss other options with you. Whatever you choose it will not affect your usual health care and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. It may use words that you do not understand. Please ask the [researcher/study staff] to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family. The [researcher/study staff] will tell you about the study timelines for making your decision.

**Introduction/Background:**

This section should provide a brief explanation about why the research is being done so that the participant can understand why a particular health problem/intervention needs to be studied.

This study will involve genetic research. Genetic research is a way for us to learn about the role of genes in human health and disease. Every person has their own unique set of genes, or “genome”. Genes, which you inherit from your parents, are responsible for determining some of our individual traits, such as eye colour, height and skin tone. Genes may also determine why people get certain diseases and how medicines may affect them. Genes can affect how well you respond to certain types of treatment.

Genes are made up of DNA which are tiny packets of information that contain the instructions for how our bodies develop. The sequence of your DNA forms the blueprint of you. The DNA sequence of a gene can vary slightly between people. These differences in DNA sequence are called variants. These variants may or may not be harmful. We are continuing to learn new information about genes.

Genetic research is being done in this study [explain reason for genetic research].

**1. What is the purpose of this study?**

Briefly describe the objectives, goals or purposes of the study. If there are optional components associated with this study, please briefly describe here.

Also include a statement regarding hereditary genetic testing, if applicable such as, We will be looking at changes found in your DNA (genes) and in the DNA of people related to you that may be **inherited** (passed on in families). This is called hereditary genetic testing. This type of research on DNA and blood cells may help to explain why some cancers run in families or why some people have side effects from treatment while others do not.

**2. How many people will take part in this study?**

Briefly describe where the study is being conducted, e.g. Newfoundland, Canada, North America, world-wide and how many people are expected to take part in total and how many at the local site.

For example:

This study will take place in North America. The study will enrol a total of 5000 people. We expect to enrol about 10 participants at this site/clinic/hospital.

**3.**  **What will happen if I take part in this study?**

Summarize what will happen to a person who takes part in the study in terms of procedures, tests, sample acquisition and storage, including:

* The type and amount of sample to be taken
* The manner in which samples will be taken, and the safety and invasiveness of acquisition;
* The type of genetic test (e.g. whole genome sequencing/whole exome sequencing/ a single gene panel test. Explain the genetic test and what the test will produce.)
* The results/outcome the test will provide.
* The location of storage of samples during and after the study, length of storage, rationale for retention and/or circumstances for samples to be destroyed
* The potential uses for the samples including any commercial uses (including when these may occur), and whether or not the participant will receive any monetary gain from said commercial ventures;
* How samples will be identified and the entity/person who has custodianship of the stored sample while in storage
* Explain who will/will not receive reports about any research tests done on these samples, whether the reports will or will not be put in their health records and/or reported to participant’s physician.
* Explain whether medical record will be accessed, what information will be collected, where it will be stored and the security of the database
* Describe the return of individual results as well as incidental findings as appropriate, including option not to receive information, and any results that will be withheld from participant, if applicable.
* Describe whether a genetic counsellor will be available and how counselling/other services will be provided.
* Describe family involvement, if applicable
* Study visits, interviews, questionnaires etc.
1. **If I decide to take part in this study, can I stop later?**

**Note:** requiring a written notification is not acceptable. It is the study team’s responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.

Edit as necessary:

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you (or your family, if applicable) will receive. If you decide to leave the study, you can contact the researcher/study doctor or a member of the study team to let them know. The researcher/study doctor will discuss other options with you.

Please describe the process for withdrawal and any limitations to the withdrawal.

Please describe the process for withdrawal and any limitations to the withdrawal. **You may select an option from the sample language below or edit to suit the study:**

* You may partially withdraw from the study. This means we will no longer contact you for any reason. You will still allow us to continue to access your medical records and use your medical data, questionnaire data and genetic information for the research purposes described in this consent form. We will also stop returning research findings if you had decided to receive them.
* You may fully withdraw from this study. This means we will no longer access your medical records or use your data for research and all data collected about you will be destroyed. Any remaining biologic samples will also be destroyed. We will no longer contact you for any reason. Any data that has already been merged with other data and analyzed cannot be destroyed or removed from the study. This is because we have to preserve the study’s scientific integrity. However, your data will not be used in future research.
* You may withdraw from this study. The study team will have a discussion with you about what will happen to the information about you [and/or your samples] already collected. Your study doctor will notify the sponsor who will ensure that the information/samples are [returned to the hospital from which they were obtained if needed, or destroyed]. You can request withdrawal of your specimens until [insert expected time point], at which point the code that links you to your sample will be removed. It won’t be possible to return samples after this because the researchers will not know which sample is yours.
* You have the right to request the destruction of your information [and/or samples] collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.
1. **Are there risks to taking part in this study?**

**Examples of risks are provided below. Please edit as necessary.**

When you give your biological sample (blood or saliva) for genetic testing you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA.

Genetic information can never be fully de-identified. 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 a risk that information gained from genetic research could eventually be linked to you. Due to the rapid pace of technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you. While this is very unlikely at this time, rapid scientific advances mean that re-identification may be more likely in the future. The potential re- identification or unintentional release of your information could lead to loss of privacy and to possible future discrimination against you or your biological relatives. The potential future use of genetic information is unknown and therefore not all potential future risks are known.

There is a risk of unintentional release of information if there is a security breach in the system that stores the data.

The potential psychological and social risks of participating and receiving genomic information are not fully known at this time. It may be upsetting to learn about genetic causes and medically actionable findings. Because parent(s) and children can share genetic variants, the discovery of harmful variants in your genome may lead to identifying the same variants in your family members’ genome. It may be upsetting to learn that other members of your family share harmful genetic variants with you.

[If family members are also participants in the study]: While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of your family will respect your privacy.

Also consider risks related to:

* Results that could cause stigmatization, discrimination or psychosocial risks to the participant’s family, ethnic community or to isolated populations
* Security breach of the information due to a vulnerability to the system
* Emotional distress and anxiety or social risks through receiving information that is unexpected or unwanted, including paternity information
* Emotional distress and anxiety from answering sensitive questions on questionnaires
* Disclosure of results that lack clinical utility or accuracy (false-positives or false negatives
* Physical risks associated with collection of blood sample (bleeding, bruising…for blood collection)
* Carrier status and whether prenatal counselling is available

**6. Are genetic counselling services available to me?**

**If genetic counselling services are available: Genetic counselling services will be available to you in this study. This means that someone with training or experience in genetics, such as a genetics counsellor, will provide you with the results of your genetics tests and answer your questions about how the results may affect you and your family.**

If genetic counselling is unavailable: **Genetic counselling services are not available to you in this study. P**lease provide rationale. You may refer to TCPS2 Chapter 13 for guidance.

1. **What if researchers discover something about me?**

During the study, the researchers may learn something new about your health. You will be given the opportunity to decide whether you wish to be made aware of that information. Your study doctor will explain the process, which may include genetic counselling, to help you understand what this result could mean for you or your blood relatives, such as your siblings and/or children.

**Examples:**

**Primary Findings:**

We will tell you if the genetic analysis identifies a genetic variant believed to be a cause of your condition. The study team will make appropriate referrals to discuss these findings. These findings will have to be verified in a clinical lab before the information is used for your health care and other important decisions.

**Secondary Findings:**

In genetic research, the researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings e.g. find out that you have another medical condition]. This is called a secondary finding. **Secondary findings are information that was discovered unintentionally.**

Some secondary findings may be **medically actionable.** Medically actionable secondary findings mean there is a high chance of a health problem AND treatment and/or screening is available for this health problem.

If we discover medically actionable findings or if any new clinically important information about your health is obtained as a result of your participation in this study, we will let you know. We will only talk to you about those medically actionable findings that we think are likely to have a major effect on health. Seeing a medical specialist could be helpful as there might be specific health recommendations for you and/or family member(s). We will work with you, your family and your doctor(s) during this process. Because many of these variants are passed from parent to child, identification of one of these variants in you could have implications for biological (blood) family members’ (such as parent(s) and siblings) health as well. **Any medically actionable secondary findings identified through this research study need to be confirmed in a clinical laboratory**. This will be discussed with the doctor involved in your care.

**American College of Medical Genetics and Genomics (ACMG) list of variants: (if applicable – not required)**

The ACMG maintains a list of disease-causing variants associated with serious but preventable/treatable illnesses that should be reported back to the patient if found. We will actively search for these variants. If you want to know more about these variants talk to your doctor or the research team.

**Medically non-actionable findings: (If applicable)**

There are also medically non-actionable findings. These findings may indicate there is a high chance for a disease but there is currently no treatment and or screening available (e.g., Alzheimer’s or Huntington’s Disease). We will not return these findings to you; we do not return information on incidental findings that are not medically actionable. We will not place this information into your medical records.

**Carrier status information:** **(If applicable)**

Sometimes, secondary findings may reveal information about carrier status. Some people are “carriers” of a genetic disorder; this means they have the gene that causes a disorder but they are not affected by the disorder. Children of carriers may be at an increased risk to have that specific genetic disorder.

Since knowledge of carrier status can be important for future family planning, if we discover a secondary finding about your carrier status of a serious disorder, we can talk with you about that finding. You can choose if you want to receive carrier status information.

**If applicable:** We will ask you again about your choices if we have test results to tell you.

1. **Will I benefit from being in this study?**

This information should include relevant information about the nature of any direct potential benefits to the participant and the likelihood of these benefits occurring. This should include any anticipated benefits to society or to a specific group, and these potential benefits must be explained in a separate paragraph so as not to confuse them with any potential benefits to the research participant.

**Example:**

It is not known whether this study will benefit you or your family.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

1. **Will it cost me anything to participate in this study?**

Please describe any compensation or reimbursement provided to participants and whether they will have to provide receipts to be reimbursed for costs.

**Example:**

Participation in this study is voluntary. You will not be paid to take part. You will not be reimbursed for transportation to the study site, parking or other expenses.

1. **What are my rights?**

**Edit as required**

You have the right to receive all information that could help you make a decision about participating in this study, in a timely manner. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

You have the right to be informed of the results of this study once the entire study is complete. Describe how the study results will be provided (as described in the application).

You will be given a copy of this signed and dated consent form prior to participating in this study.

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

**10. What about my privacy and confidentiality?**

**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.**

Protecting your privacy is an important part of this study. If you decide to participate in this study, the study doctors and study staff will collect and use information from your medical records. They will only collect and use the information they need for this study, including:

Edit as necessary.

* gender
* date of birth (Describe format. Preferably only year of birth collected)
* new or existing medical tests or procedures and medical conditions
* sensitive information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems
* medications
* information from study interviews and questionnaires

The personal health information or personal information collected about you will have your directly identifiable information removed (i.e., name, MCP) and replaced with a code or with a “study number”. There will be a master list linking the code numbers to names. The study doctor is responsible for keeping it separate from the samples and personal health information. This link will not be available to the [Sponsor/Funding agency/Coordinating centre].

Study information collected during the study will kept at this site and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will kept as long as required by law, which could be 25 years or more. This information will be stored [name the appropriate location].  [Name the appropriate person/role] is the person responsible for keeping it secure.

Study information sent to the sponsor, and companies working for the sponsor, will be stored in a secure central database. When the results of this study are published or presented at scientific meetings, your name and other personal information will not be used in the publication.

All information that identifies you will be kept confidential, and to the extent permitted by applicable laws, will not be disclosed or made publicly available, except as described in this consent document. Every effort to protect your privacy will be made. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. If there is a breach of your privacy resulting from your participation in this study you will be notified.

If data or samples will be sent outside of Canada:

Your study information and/or samples, will be sent outside of Canada so there is a possible increase in the risk of identifying you from the study data because the laws in other 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 have your directly identifying personal information removed (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 agreeing to the disclosure of your coded information to organizations located outside of Canada.

If participation will be noted in participant’s clinic chart or health record:

Your participation in this study will be noted in your hospital or clinic chart.

For studies using smartphones, apps or applicable technology, please provide details on the security/privacy/limits to the confidentiality.

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.

1. **Who will see my medical information?**

Representatives from the following organizations may come to the hospital/clinic to look at your personal health information under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

**Edit as needed**

* Sponsor Name, the company that makes the (drug/device/intervention) and its representatives and partner companies;
* Representatives of the Health Research Ethics Board
* Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

We may continue to review your health records that you have consented for the study to access for a period of time after your last study visit in order to check that the information we collected is correct.

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
* Indicate how this identifiable information will be protected, used, and disclosed.

**Your access to records**

* You have the right to see the information that has been collected about you for this study. If you wish to do so, please contact your study doctor.
* If applicable, include the following information: This is a ‘blinded’ study, which means that the research team cannot tell you which drug you are taking until the study ends. This is to prevent either you or your doctor from knowing which study treatment you received until the results are reported.

**17. Commercialization**

**Edit as necessary**

It is possible a new medical test or product may be developed as a result of this study. You will have no right to any products that may be created as a result of this study or any future research studies using this research study data. You will not receive royalties from any products that may be created as a result of this study or any future research studies.

1. **Declaration of financial interest, if applicable**

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. NOTE: 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.

A conflict of interest can occur when a person or group has more than one interest. In research, the people who run or work on studies must tell you if they have a conflict of interest.

If there are no conflicts, state:

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

If a conflict exists, see below example language

Dr. X, declares that he/she [may/will] gain financially by being involved in this study because he/she will be paid by [insert name of sponsor/agency] for his/her time and effort during the study. This may create a competing interest or conflict of interest.

**OR**

As a result of his/her participation in this study, Dr. X [has received/may receive] one or more of the following benefits from [insert name of sponsor/agency]: [speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.]. This may create a competing interest or conflict of interest.

**OR**

The spouse of Dr. X owns shares in the company [insert name of company/sponsor] that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest.

1. **What about questions or problems:**

If you have any questions about taking part in this study or if you suffer a research-related injury you can talk to your study doctor. You can also meet with the study doctor/principal investigator who is in charge of the study. That person is:

####  **Principal Investigator’s Name and Phone Number**

##### You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

######  Ethics Office at 709-777-6974

 Email: info@hrea.ca

**Signature Page**

My signature on this consent form means:

* I have had enough time to think about the information provided and ask for advice if needed.
* All of my questions have been answered and I understand the information within this consent form.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that I receive.
* I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
* I am aware of the risks of participating in this study.
* I do not give up any of my legal rights by signing this consent form.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
* I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form.
* I understand that my family doctor will/may be informed of my study participation
* I agree, or agree to allow the person I am responsible for, to take part in this study.
* [Insert any other research specific clauses that may be important to reiterate.]

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Signature of person authorized Printed name Day Month Year

as substitute decision maker **[If applicable]**

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Signature of person conducting Name printed Day Month Year

the consent discussion

**To be signed by the investigator:**

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

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Signature of investigator Name Printed Day Month Year

**Signature Page for Parent/Guardian**

My signature on this consent form means:

* I have had enough time to think about the information provided and ask for advice if needed.
* All of my questions have been answered and I understand the information within this consent form.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
* I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
* I am aware of the risks of my child/ward participating in this study
* I do not give up any of my my child/ward’s legal rights by signing this consent form,
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
* I allow access to my child/ward’s medical records and transfer of specimens and related personal health information as explained in this consent form.
* I understand that my child/ward’s family doctor will/may be informed of my study participation
* [Insert any other research specific clauses that may be important to reiterate.]

I consent for my child/ward to take part in this study.

 \_\_\_\_\_\_\_\_

Signature of parent/guardian Name printed Day Month Year

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Signature of person conducting Name printed Day Month Year the consent discussion

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**To be signed by the investigator:**

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the parent/guardian fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen for the child/ward to be in the study.

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Signature of Investigator Printed Name Day Month Year

**To be signed by the minor participant [if appropriate]**

**Assent of minor participant:**

**I understand the purpose of this research**

**I understand that it is my decision to take part in this study. I can stop taking part if I chose.**

**I understand that taking part in this research may not help me.**

**I understand that there may be risks to participating in this study.**

I agree that I will take part in this study

Signature of minor participant Day Month Year

Name printed Age

**Participant Assistance**

**Complete the following declaration only if the participant is unable to read:**

* The informed consent form was accurately explained to, and apparently understood by, the participant, and
* Informed consent was freely given by the participant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Impartial Witness |  | Printed Name |  | Date |

**Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows**:

* The informed consent discussion was interpreted by an interpreter, and
* A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

**Interpreter Declaration and Signature:**

By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Interpreter |  | Printed Name |  | Date |