

CTO Observational Research Informed Consent Form Template

(Adapted with permission for local use by NYGH REB)

Instructions:

This Observational Research Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards.

How to use this template:

- Suggested text/examples in **blue font** may be omitted if they are not relevant to the specific protocol
- All text included in the study-wide ICF must be applicable/appropriate for that specific study
- Instructions are indicated in *italics/grey background*
- **Turquoise highlighting** provides a prompt to adapt text to the research study (e.g., to select from the available options highlighted)
- When developing the ICF, you should follow the instructions and insert the applicable study-specific content. The instructions and highlighting should be deleted from the study-specific consent form submitted to the NYGH REB

When writing the consent form, please remember to:

- Delete this instructional page
- Use plain (lay) language that is easy for a non-medical person to understand, and is consistent with the study population
- Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
- Define all acronyms and abbreviations when they first appear
- Use the term 'study doctor' when referring to physicians involved in the research, to ensure there is no confusion with the treating or primary care doctors. Non-physician investigators should be referred to as 'researchers'
- Ensure that the final form is properly formatted and free of spelling or grammatical errors
- After all edits have been made, all text should be black

REMINDER:

The informed consent form is only a component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants. Consent is an ongoing process throughout the conduct of the study to ensure consent for participation is maintained.

Informed Consent Form for Participation in a Research Study

Study Title: *insert study title as written on the protocol*

Sponsor's Study ID: *Insert sponsor's study ID if applicable*

Principal Investigator: *insert name, department and telephone or pager number*

Sponsor/Funder(s): *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

INTRODUCTION

For studies where consent is sought through a substitute decision maker, include the following paragraph:

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

You are being invited to participate in a research study. You are invited to participate in this study because *explain the main features of the population to which the research applies*. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study. *Specify any other potential areas where participants might be concerned about a potential penalty or discrimination, such as* *The decision will not affect your employment.*

IS THERE A CONFLICT OF INTEREST?

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. 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. See examples below.

The *identify individual, e.g., study doctor/researcher, insert name*, is receiving personal financial payment from *Identify source of funds e.g., the study Sponsor* for *include reason for payment e.g., providing advice on the design of the study*. You may request details about this payment.

or

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

or

The *insert recipient of funding e.g., hospital* is receiving financial payment from the *Sponsor/ Funder* to cover the cost of conducting this study.

WHY IS THIS STUDY BEING DONE?

Explain the purpose of the study in lay terminology

The purpose of this study is to *explain the purpose of the study*.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about *insert total number of participants* people will take part in this study, from research sites located in *indicate participating provinces/countries as applicable to the research*.

This study should take *total length of study in months or years* to complete and the results should be known in about *time to anticipated analysis in months or years*.

WHAT WILL HAPPEN DURING THIS STUDY?

Provide a description of the research procedures and the nature of participation. Some suggestions are provided below. Ensure that the information provided accurately describes the procedures being used in this specific study. If multiple techniques are included in the research, please include subheadings.

Database studies:

The researchers will collect information about you from *specify source of information e.g., your medical chart* and enter this information into an electronic database. The data will be securely stored, and will be maintained by *specify responsible individual/group*. The database can only be accessed by people who are involved in research.

Please talk to the research team if there is information that you do not feel comfortable sharing.

If the database information will be entered into secondary databases(s), this must be specified (including the reason and who the data will be shared with). For example:

Information about you kept in this database may be shared with national and international research partners and may be entered into other national and international databases. The sharing of this information is meant to *specify purpose e.g., allow researchers to work together and increase worldwide research efforts*. The information provided to them will not include information that can directly identify you, such as your name, address or phone number.

Imaging Studies:

You will be asked to have *insert name of standard clinical imaging procedure*. This scan is already used in medical care, but would not normally be done *explain deviation from normal care/life of the study population*. The scans would involve *briefly describe procedure*.

The scans are being done for research purposes only, and will not be used to guide your medical care.

Focus Groups:

You will be asked to participate in *specify how many* focus group(s) *if more than one focus group, provide information about timing e.g., before you begin the study and then every X weeks/months*. A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about *specify length in minutes or hours* in length and will take place *specify location*. You will be asked to speak about *explain topics of discussion e.g., your experiences with condition/intervention*.

Interviews:

You will be asked to participate in *specify how many* interviews *if more than one, provide information about timing e.g., before you begin the study and then every X weeks/months*. During this interview, you will *speak with/meet* with *a member/members* of the research team and *specify others if applicable*. Each interview will be about *specify length in minutes or hours* in length and will take place *specify location*. You will be asked to provide information about *explain topics of discussion e.g., your experiences with condition/intervention*.

Questionnaires:

You will be provided with *a* questionnaire(s) *provide information about the number and timing of questionnaires e.g., before you begin the study and then every two weeks for a year*. The purpose of the questionnaire(s) *is/are* *include description of purpose e.g., to understand how the study intervention and illness affects your quality of life*. Each questionnaire will take about *indicate estimated time to complete in minutes* to complete.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

If the questions are of a sensitive nature, explain that they might experience emotional distress, explain what should they do and what type of help will be provided if this happens.

If questionnaires include medically relevant information, but won't be reviewed, include the following:

Even though you may have provided medical information on a questionnaire, these responses will not be reviewed by your physician/health care team - if you wish them to know this information please bring it to their attention.

If audio/video records used:

You will be *audio/video* recorded during the *specify e.g., interview(s)/focus group*.

Participant Diaries:

You will be asked to keep a diary of *identify information to be recorded*. You will be asked to return the diary to this centre.

Specimen Collection:

Ensure that you describe the mandatory sample collection, including the sample type and amount and manner/safety of acquisition, purpose of the research (including any commercial use), measures employed to protect privacy and minimize risk, and length, method, and location of storage. See suggestions below, or revise as applicable to the research.

The researchers doing this study will be doing tests on samples (described below) to *insert study-specific LAY explanation of the research purposes for all samples collected*.

The collection of these samples is a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold.

Specify what will happen to samples once the mandatory research has been completed. For example:

Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed *include the following if applicable* unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign.

Include one of the following options

Hereditary genetic testing (to look at whether *specify condition* runs in families) will not be done on these samples.

Or

Hereditary genetic testing (to look at whether *specify condition* runs in families) *will/may* be done on these samples

If there is a possibility that a medically relevant sample will be exhausted:

If you participate in this study it is possible that there will not be enough of your tissue sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.

Even with protections in place, there is a risk that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your blood relatives. These results might contain information (e.g., an inherited genetic disease) that could result in problems for you or your relatives. There is no way to predict what effects such an information loss would have. You will be *given the choice/not given the choice* to find out about genetics testing results.

Describe who will be informed of the results of the mandatory research. For example:

Reports about any research tests done with your samples will not be given to you, the study doctor(s) or study staff, your doctor, or other health care provider(s). These reports will not be put in your medical records.

Or

Reports about research tests done with your samples will be given to *specify recipient e.g., the study doctor(s)*. If you would like to learn the results of this research, please let them know.

If the study includes genetic testing (mandatory or optional), include the following:

If you are a First Nations or an indigenous person who has contact with spiritual Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

Tissue Collection

Describe the method of tissue sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research

A small sample of your tissue that has already been removed by a previous surgery or biopsy will be obtained by the researchers doing this study. No further surgeries or biopsies are required of you for this purpose. *If applicable, explain whether they may still participate if a sample is not available or whether a fresh tissue sample will then be required – see below.*

If archived specimens are required from another institution, include the following:

If your biopsy or surgery were completed at another institution, signing this consent form means that you are consenting to the collection of your tissue sample, together with any related personal health information, from that institution.

If a fresh tissue sample is required

As part of this study, you will have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove *state how much tissue is to be taken e.g. a pea size piece of your insert tissue type e.g., liver.* *Explain in lay language whether this will be done using a local or*

general anesthetic and whether overnight hospital stay may be required. This procedure has risks such as *specify risks, e.g., blood loss, pain and rarely an infection at the biopsy site.*

Identify location where specimens will be retained. For example:

These tissue samples will be sent to a laboratory at *insert location* where they will be examined.

Blood/Urine Collection

Describe the method of blood/urine/other sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research

Urine will be collected *Specify number of samples to be collected and timing (e.g., specify if 24 hour collection) if multiple samples are required.* These urine samples will be sent to a laboratory at the *insert location* where they will be examined.

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your study related tests whenever possible, *describe sample timing e.g. at entry to the study and <X> weeks after you stop the study intervention.* *Specify amount of blood to be collected and timing if additional samples are required and the tests to be done on these samples.* These blood samples will be sent to a laboratory at the *insert location* where they will be examined.

How will samples be identified?

To protect your identity, the information that will be on your samples will be limited to *specify which identifiers will be on the sample(s).* *If additional personal information is also being provided to the laboratory (e.g., on additional forms provided with the review materials), include a description of the information provided, e.g., The laboratory will also receive information containing your...*

Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.

Can I withdraw these samples?

Describe the process for withdrawal of samples, and any limitations to the withdrawal. See the suggested text below, or revise as applicable

If you no longer want your samples to be used in this research, you should tell *specify appropriate contact role*, who will ensure the samples are *describe what will happen to samples if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed.*

Describe any limits of the withdrawal, if applicable. For example:

If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If samples will be anonymized at a certain point

You can request withdrawal of your specimens until *insert expected anonymization point*, when the samples will be made anonymous. It won't be possible to return samples after this because the researchers will not know which sample is yours.

State whether or not the participant may continue to participate in this main part of the study, if they withdraw these required samples.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

Identify participant responsibilities. Include, add to, or modify bullets below as applicable

If you choose to participate in this study, you will be expected to:

- *Specify any responsibilities*
- Not discuss with others any information you learn in the focus group. This includes information about other group members and any opinions or comments that are shared.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Specify the duration of research involvement. See suggestions below, or revise as applicable to the research

Your participation on this study will last for about *insert duration*.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

If the participant can withdraw information collected prior to withdrawal

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the research team know if you choose this.

Or Inform participants about any limits on withdrawal of information

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation on the study may be stopped early, and without your consent, for reasons such as:

Identify reasons why participants may be taken off the study. Examples are outlined below. Include or modify bullets below as applicable

- New information shows that the research is no longer in your best interest
- The research team decides to stop the study
- The research ethics board withdraw permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

Inform participants of all reasonably foreseeable risks, harms, discomforts or inconveniences. Include both physical, social/legal, and psychological/emotional risks as applicable to the research.

Suggestions (ensure these are correct and applicable to the research study):

There are no medical risks to you from participating in this study, but taking part in this study may make you feel uncomfortable.

Focus groups/interviews:

You may become uncomfortable while discussing your experiences. You may refuse to answer questions or leave the **group/interview** at any time if you experience any discomfort.

Focus groups:

While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Inform participants of potential benefits to themselves and in general that may arise. If there is no known benefit, ensure this is stated.

If there is no likely benefit to participation, include the following
There are no benefits to you for taking part in this study.

If the benefit is known, include
The expected benefit from taking part in this study is *specify*.

If applicable, include
You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with *specify* in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

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.*

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) **medical** records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

Include only those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:

- *Insert sponsor name, the Sponsor of this study*
- The NYGH research ethics board who oversees the ethical conduct of this study
- NYGH and affiliated sites, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your *disclose identifiers e.g., participant code, initials, sex, and date of birth*.

The following organizations may also receive study data:

*Include organizations with permission to **receive** study data only (organizations with direct access must be included in the list above). Include a brief description of their role in the research.*

- *Identify any other organizations with permission to receive study data only*

If race/ethnicity information is collected as part of the study, identify this and provide a rationale. See suggested text, or modify as applicable

This research study is collecting information on race and ethnicity as well as other characteristics of individuals because *specify reason e.g., these characteristics may influence how people respond*. Providing information on your race or ethnic origin is **voluntary/required**.

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.

If focus group/interview:

During the discussions, participants will be encouraged to refrain from using names. If names or other identifying information is shared during the discussion, it will not be included in the written records.

If video/audio recording, describe confidentiality measures including, for example, who will have access, how long they will be kept, and whether they will be sent outside the institution. For example:

The video/audio recordings will be stored in a secure location and viewed only by members of the research team. The recordings will be kept until they have been transcribed (turned into written records), and then they will be destroyed.

If health information is being collected for other research/database:

In addition to the data that will be collected for this study, the researchers will also be collecting the following personal health information:

- *List all additional information being collected*

This additional data is being collected to *insert purpose e.g. to help researchers better understand common trends between your condition and other health problems*. This additional information is not required for the purpose of this study, but for other research interests at *insert organization name*.

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*

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be *include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals*.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

If data or samples will be sent outside of Canada

Any information *and/or samples*, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those 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 be coded (this means it will not contain your personal identifying information 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 consenting to the disclosure of your coded information to organizations located outside of Canada.

For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality. For example:

Data collected using the *insert app/tool/device name* resides on the *insert name e.g., Apple* servers and no assurance can be made about its confidentiality or that it will only be used for research purposes.

WHAT IS THE COST TO PARTICIPANTS?

If participation could result in additional costs, include an explanation of these potential costs. Ensure that examples of extra costs are consistent with the research project

Taking part in this study may result in added costs to you. For example:

- You may miss work as a result of participation in this study.

OR If participation will not result in any costs, include the following

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

Describe compensation provided to participants, or state if no compensation is provided. Suggestions are provided below.

You must ensure that the information below matches the compensation/reimbursement provided at that site.

If there is no payment for participation

You will not be paid for taking part in this study.

OR If participants are paid (revise as applicable to the study)

If you decide to participate in this study, you will receive \$*specify amount of payment including indication of payment interval if applicable e.g., every three months.*

If you decide to leave the study, you will receive a prorated payment for participating in the study.

If there is re-imbusement of costs for participation

If you decide to participate in this study, you will be reimbursed \$ *enter actual or maximum dollar amount* for some study related expenses such as *list reimbursable expenses as applicable.*

If receipts or other documentation is required for re-imbusement, this must be described. For example:

You will need to provide your receipts for *insert expense types e.g., parking* to the research staff in order to be reimbursed.

If applicable (alter as needed to fit the research):

It is possible that the research conducted using your *samples and/or* study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. There are no plans to provide payment to you if this happens.

In the case of research-related side effects or injury, medical care will be provided by *specify response e.g., your doctor or you will be referred for appropriate medical care.*

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete.

Explain how the participant can obtain the results, for example: If you would like to be informed of the results of this study, please contact the research team *or* If you would like to be informed of the results of this study, please let the study doctor know.

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

By signing this form you do not give up any of your legal rights against the *researcher/study doctor, sponsor* or involved institutions for compensation, nor does this form relieve the *researcher/study doctor, sponsor* or their agents of their legal and professional responsibilities.

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

If incidental findings are anticipated as a result of the study, include the following section and address what information will be provided to participants.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, 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.*

Describe anticipated management plan. For example:

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

Name

Telephone

If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may contact the Chair of the NYGH Research Ethics Board, Rita Reynolds, by phone at 416-756-6448 or by email: Rita.Reynolds@nygh.on.ca, or reb@nygh.on.ca.

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to **medical records and transfer of specimens** and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I understand that my family doctor/health care provider **will/may** be informed of study participation
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Signature of Participant/
Substitute Decision-Maker

PRINTED NAME

Date

If consent is provided
by Substitute Decision Maker:

PRINTED NAME of Participant

Signature of Person Conducting
the Consent Discussion

PRINTED NAME & ROLE

Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

- The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

PRINT NAME
of Interpreter

Signature

Date

Language

- The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

PRINT NAME
of witness

Signature

Date

Relationship to Participant

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.