Ontario Shores
Centre for Mental Health Sciences

INFORMED CONSENT FORM TEMPLATE

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Note: **The consent form template given below is a general example for clinical trials and can be modified for most research studies. There may be other aspects of study that need additional information or removal of some elements from the consent form. For example, studies that link to external databases or use audio/video recordings need specific wording to address privacy/confidentiality concerns inherent with such methods. For Non- Clinical studies, simplify the template given below omitting information that are not needed.**

Guidance: If this consent form is for a particular sub-group within the study (e.g. healthy controls; care givers; Substitute Decision Makers etc.) add the group name here.

Title	{Enter the full title of study, exactly as it appears on the Protocol. Add protocol number if applicable.}
Investigator	{Enter the name with title and telephone number of the Principal Investigator.}
Co-Investigators	{Enter the name(s) with title(s) of Co-Investigators if applicable.}
24 Hour Phone Number	{Enter telephone number where participants can reach study staff 24 hours a day if there if necessary [e.g. blinded study].}
Sponsor	{Enter name of all sponsor(s), including funding sources and drug suppliers.}

Introduction

This section should contain the following wording.

You are being invited to ***voluntarily take part*** in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish such as your family, friends or family doctor etc..

Background and Purpose

Guidance: Provide background information on what prompted the need for this study. Refer to standard of care, knowledge to date etc. Describe the primary reason for the study and draft a paragraph that provides basic information about it. Define any concepts that may not be well understood outside of the research setting (e.g. efficacy, randomization, blinded study etc.). Samples of the type of detail that should be included in the purpose can be found in the bulleted sentences below.

[Sample Language for a Clinical Trial]

- You have been asked to take part in this research study because you {e.g. have Type 2 Diabetes}. [Be as specific as possible. Do not list inclusion/exclusion criteria].
- Usually this condition is treated with/by {Insert usual standard of care}.
- The problem with/limits of this regular treatment is/are {Explain limitations}.
- This study will look at {Insert name of study intervention} as a {new/safer/cheaper} option to {e.g. treat your diabetes}.
- The {study drug/device} used in this study has not been approved for use by Health Canada but is approved for use in this research study. This is why {study drug /device} is considered an experimental {study drug/device}.
- About {“x” total number} subjects from {“y” number} sites will be in the study. About { “z” number} subjects will come from Ontario Shores Centre for Mental Health Sciences (Ontario Shores).

[Sample Language for a Natural History and Qualitative Research Study]

- You have been asked to take part in this research study because {clearly state the hypothesis of this study} and you have been involved in/are affected by {define that which makes this person a good candidate for the study}.
- While we know {summary of the body of knowledge so far}, it is not clear if {be specific about the gaps in knowledge that the research intends to fill}.
- About {“x” total number} subjects from {“y” number} sites will be in the study. About {“z” number} subjects will come from Ontario Shores.

Study Design

Guidance: Describe the approach to conducting this research study including if it is randomized, blinded, multi-centre, if a wash-out is required, and other details as appropriate. If subjects are to be randomized to 2 or more conditions, the chance of being in any one condition needs to be clearly specified by ratio and/or percentage (e.g., 50:50 or 1 in 2; 33% [1 in 3], etc.) It might also be specified if the chance of receiving study drug is different from the chance of being in a condition – for instance, if there are 5 conditions, the chance of being in any one condition is 1 in 5 but if 4 of the conditions involve study drugs then the chance of receiving study drug is 4 in 5. If a placebo condition is used, participants should clearly understand that they may not receive any study drug or that they may not receive any medication. See the sample explanations below and use them in your consent form if applicable. As reminder, be sure to describe details in plain language. Include all that apply and add any additional information as necessary.

- This study compares the study drug with a placebo. A placebo looks just like {the study drug} but contains no active medication.

- Whether you get the study drug or the placebo will be decided randomly (by chance) like flipping a coin or rolling a dice. The number of research subjects getting study drug will be {"x" number} and the number of research subjects getting placebo will be {"y" number}.

- This study will be blinded. This means that you will not be told whether you are on {the study drug/intervention} or on {the placebo/ study drug/intervention} until the study is finished.

- This study will be double-blinded. This means that neither you or the study team will not know whether you are on {the study drug/ intervention} or on {the placebo/ study drug/intervention} until the study is finished. This information can be found out at any time in case of an emergency.

- You will be in this study for {duration of participation}.

- There will be {"x" number} of visits during the study. Most visits will last for {"y" minutes/hours}, though some may be as long as {indicate time length as it applies to the study – eg. for Infusion studies}.

Study Visits and Procedures

Guidance: Name each procedure that the participant will be involved in and explain each one in lay terms.Verify that the consent form and protocol are consistent. It is helpful to include the purpose of the visit and separate the phases of the study under specific headings (e.g. Screening, Baseline, Randomization, Follow-up, etc.). Include how long each visit and procedure will take. If similar tests are done on multiple visits, try to minimize redundancy by grouping visits together, e.g. "on Visits 1, 2, 4, 6, and 10 the following tests will be done".

The following items should also be considered in this section:

- *Describe all tests, measures, questionnaires, procedures, interventions, or treatments, that are outlined in the research protocol. Repeated explanations/definitions is usually not necessary so only define/explain at first instance.*
- *Make the distinction between research-related procedures and standard-of-care procedures clear. The consent should focus on research-related procedures and discuss standard-of-care where necessary.*
- *Describe the type of information that will be asked in the questionnaires. If responses to the questions are of a sensitive nature, e.g. HIV, illicit drug screen, depression testing, pregnancy, the subject should be forewarned and a sample of the type of question should be provided. If the response necessitates further action, describe what will happen (e.g. Report to public health, refer for counseling, etc). Subjects should also be told they can refuse to answer any questions.*

[Sample Language for Study Visits]

Screening: The first study visit will be a screening visit. The following will take place at this visit:…
The results of the tests/questions at the screening visit help the researchers to decide whether you can continue in this study. Some of these tests are part of standard of care while some are being done solely for the study.

Baseline: The study team needs to find out about your {eg. Type 2 Diabetes} before you begin taking {study drug/intervention} so they can see how well {the study drug/intervention} works. This is called the Baseline visit. The results of the tests/questions at the baseline visit help the researchers to decide whether you can continue in this study.

[Choose one of the following]

- In this study this will happen at the same time as the Screening visit.
- In this study this will happen at the visit when {the study drug/intervention} begins.\In this study this is a separate visit before you begin {the study drug/intervention}.

The following will take place at this visit:…

Randomization: [Describe visit. Refer to guidelines and examples shown above].

Study Visit "x": [Describe visit. Refer to guidelines and examples shown above].

[Sample Language for Study Procedures]

Eg. ECG: Electrocardiogram. In this test patches attached by wires to a machine will be put on your chest, so that the machine can record the pattern of your heart beats. In some cases we may need to trim or shave your body hair.

Eg. Focus Group: A group of 10 people will meet together in a room to talk about {general discussion topic}. This meeting will take about an hour.

Eg Blood draw: [State volume and purpose of blood tests]. You will have {"x number of} tubes of blood drawn {about "y" number of tablespoons/mls} to check blood counts and liver function.

Calendar of Visits

Guidance: Using a calendar of visits and procedures can help illustrate what is involved in the study. In chart form, list what will happen at each visit. Ensure the entire chart fits onto one page and is not separated on to two pages. Consider creating the table in excel and inserting the chart into your document.

Eg. 1

Boxes marked with an X show what will happen at each visit:

Visit	Blood test	Questionnaire	Focus Group	ECG	Time
Screening	X	X	X	X	2 hours
Baseline	X	X		X	1 hour
Visit 1 (Week "X")	X			X	20 min
Visit 2 (Week "X")	X			X	20 min

Eg. 2

Boxes marked with an X show what will happen at each visit:

Visit	Screening	Baseline	Visit 1 (Week "X")	Visit 2 (Week "X")
Time	2 hours	1 hour	20 min	20 min
Blood test	X	X	X	X
Focus Group	X			
ECG	X	X	X	X
Questionnaire	X	X		

Reminders

Guidance: List important things to remember during the study.

It is important to remember the following things during this study:

- You should not eat for 12 hours before visits.
- Do not take medications before visits.
- Do not eat or drink grapefruit during this study.
- Ask your study team about anything that worries you.
- Tell study staff anything about your health that has changed.
- Return study medication/diaries.
- Tell your study team if you change your mind about being in this study.

Risks Related to Being in the Study

Guidance:

- *Include a list of all study related side effects. Separate side effects by study drug or study intervention as appropriate. Use lay language to describe or explain.*
- *Address the frequency and severity of side effects. Sometimes risks need to include side effects that have not been clearly linked to the study drug, e.g. increases and decreases in blood pressure have been noted in some patients receiving the study drug but it is not clear whether these effects are truly related to the study drug.*
- *Address reversibility of side effects, long term side-effects as applicable and any treatments, interventions or precautions that may be taken to address these risks.*
- *Address psychological risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues (e.g. mental health, sexuality).*

This study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in study subjects to date. Some can be managed. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study. The risks we know of are:

[Language for Quantitative Research ONLY]

Guidance: List frequencies/percentages in order of importance.(In some instances the drug will have only been tried on limited numbers of study subjects [e.g. less than 50] and percentages may not be appropriate due to small sample sizes.)

Study intervention 1: {“x” number of} people have taken this {drug/had this procedure}. The numbers in brackets shows how often the side-effect happened.

Serious: [These could be common or rare. Include percentage frequency with side-effect including an upper limit.]

Very likely/ Common: (≥ 21%) [Include percentage frequency with side-effect.]

Less likely/Occasional: (5-20%) [Include percentage frequency with side-effect.]

Rarely: (1-4%) [Include percentage frequency with side-effect.]

Very Rarely (less than 1 in 100 people): (less than 1%) [Include percentage frequency with side-effect.]

Rare but serious: allergic reaction, heart rhythm problems

Study intervention 2
[Continue for Each Study intervention]

[Sample language for Quantitative and Qualitative Research]

Guidance: List all potential employment, social, psychological, emotional, financial, and legal risks that may occur. Explain in plain language any mitigating study interventions, or precautions that may be taken to minimize these risks.

There are no medical risks if you take part in this study, but being in this study may make you feel uncomfortable. You may refuse to answer questions or stop the interview at any time if there is any discomfort.

Risks Related to Pregnancy

It is not known if the drugs used in this study affect an unborn baby or sperm. You should not become pregnant or father a child while in this study. Men and women who agree to take part in the study must use an effective method of birth control. The study doctor will tell you which birth control methods are acceptable.

If you do get pregnant, you should tell the study doctor. [If applicable] The sponsor would like your permission to follow your pregnancy until term to gather information regarding the pregnancy and the health of the infant. Should pregnancy occur, and you agree to be followed, you will be asked to sign a separate consent form.

Benefits to Being in the Study

Guidance: Avoid overstating the benefits. When there is no intended medical benefit or personal benefit to the subject, the subject should be made aware of this. Do not include monetary reimbursement in the benefits section. If applicable, this should be included in a separate section called "Reimbursement".

This following standard wording should be considered.

You {may or may not/will not} receive {any} direct benefit from being in this study. Information learned from this study may help other people {with your condition} in the future.

Voluntary Participation

This section should contain the following standard wording.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your {care/employment status/academic standing}. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying "pass".

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Alternatives to Being in the Study

Guidance: For non-clinical studies this section may not be necessary. Include a disclosure of appropriate procedures or courses of treatment that may be an alternative or standard of care alternative. If the subject can receive the same medications or study intervention without participating in research this must be stated. Address palliative care or non-treatment as alternatives, where applicable.

You do not have to join this study to receive treatment for your condition.

- The following are approved medications/interventions for your condition:
  - medication2
  - medication3
- There are also other research studies looking at other treatments for your condition.
- You may choose not to have any treatment for your condition.

Your doctor will discuss any of these options with you.

Confidentiality (For Clinical Trials only)

Guidance: The wording below is for an industry sponsored/Health Canada registered study. An example of wordings for non-industry sponsored/non-Health Canada registered study (Non-Clinical Trials) is given below at the end of the document.

<u>Personal Health Information</u>

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study.

Personal health information is any information that could be used to identify you and includes your:

- Name,
- Address,
- Date of birth,
- New or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 25 years. Research data in electronic form containing identifying information will be stored on computers, laptops and USB keys that are encrypted and password protected.Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper procedures, laws and guidelines:

- The study sponsor or its representatives/partner companies.
- Representatives of the Ontario Shores' Research Ethics Board.
- Representatives of Health Canada, or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.

<u>Study Information that Does Not Identify You</u>
Some study information will be sent outside of the hospital to the Sponsor or third party. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

The Sponsor may use the study information and share it with its partner companies or with national and international regulatory agencies to help answer the study question, to get approval to sell {insert study drug name/intervention}, to develop future studies on this product or for research related to this study.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law.
You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used (or not used). No new information will be collected without your permission.

In Case You Are Harmed in the Study (Participant's rights)

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study (Reimbursement)

Guidance: Include whether participants will incur any expenses as a result of their participation in the study. Include any remuneration, gifts in-kind, vouchers, etc to subjects and how reimbursement will be pro-rated if subjects withdraw early from study.

You will not have to pay for any of the procedures {or study drug/intervention} involved with this study. You {will be reimbursed/will not be reimbursed "$X"} for {transportation, meals, time, inconvenience, etc}.

Conflict of Interest

Guidance: Include information about any conflicts of interest. Note that the most common form of conflict of interest is the professional benefit gained by the Investigators. Include all of the following information that applies.

{Name of company}, the sponsor of this study, will pay the hospital/institution and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study. Indicate the possibility of commertialization of research findings and the presence of apparent, actual or potential conflict of interest of researchers, hospital/institution or sponsor.

Questions About the Study

This section should only contain the following standard wording.

If you have any questions, concerns or would like to speak to the study team for any reason, please call: {Principal Investigator} at {Phone} or {Study Coordinator} at {Phone}. [The 24 hour contact number can be repeated here if determined to be needed for the study (e.g. blinded study)]

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Ontario Shores' Research Ethics Board (REB) or the Research Ethics Board office number at ***905-668-5881 x 6996.*** The REB is a group of people who oversee the ethical conduct of research studies.These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This section should contain the following standard wording.

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study. You will be given a signed copy of this consent form

Study Participant's Name	Signature	Date (YYYY/Mmm/dd)

My signature means that I have explained the study to the participant named above. I have answered all questions..

Name of Person Obtaining Consent	Signature	Date (YYYY/Mmm/dd)

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Name of Translator	Signature	Date (YYYY/Mmm/dd)

Relationship to Participant	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, and has had any questions answered.

Name of Witness	Signature	Date (YYYY/Mmm/dd)

Relationship to Participant

CONFIDENTIALITY – Non- Industry Sponsored/Non-Health Canada Registered Multi-site or Ontario Shores only Study (Non-Clinical Trials).

If you agree to join this study, the study doctor/PI and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your

- Name,
- Address,
- Date of birth,
- New or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor/PI for XX years. Research data in electronic form containing identifying information will be stored on computers, laptops and USB keys that are encrypted and password protected. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper procedures, laws and guidelines:

- Representatives of the study organizing committee.
- Members of Ontario Shores Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used (or not used). No new information will be collected without your permission.