**MINIMAL RISK INFORMED CONSENT FORM**

**USE OF THIS FORM**

TCPS2 defines “minimal risk research” as research where possible harms expected by participation is no greater than those encountered by participants in their everyday-life. Some examples of minimal risk research would be interviews, surveys, and focus groups. These examples may also fall into the higher than minimal risk category depending on the study design or study population (e.g., research with a vulnerable population).

The minimal risk Informed Consent Form (ICF) template is designed to meet current regulatory and ethical standards. The Study ICF should follow the structure as set out in this template, but should be specifically adapted for your study.

**This template is NOT for use in a clinical trial.**

**How to use this template:**

* Instructions are indicated in *italics/grey background*
* Text with yellow highlighting reflects text that will require editing for your specific study
* Suggested text/examples in blue font may be omitted if they are not relevant to the specific protocol
* Suggested text/examples in orange font may be omitted for studies without substitute decision makers
* Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
* All text included in the ICF must be applicable/appropriate for that specific study
* After all edits have been made, all text should be black
* **Delete this instructional page**

**Tips for writing the consent form:**

* Define all acronyms and abbreviations when they first appear
* Use the term “study doctor” when referring to physicians involved in the study to ensure there is no confusion with the participant’s treating or primary care doctors. For non-MD investigators, please use the term ‘researcher’
* Ensure that the final form is properly formatted and free of spelling or grammar errors
* If assistance is provided during the consent process, or if consent is obtained from a substitute decision maker, more information(including the role or relationship of the impartial witness/interpreter/substitute decision maker) should be documented in the clinical and/or research chart
* Use plain (lay) language that is easy for a non-medical person to understand:
* Use short sentences and sections and simple words; avoid scientific or technical explanations
* Eliminate repetition of information
* Aim for between a grade 6-8 reading level. Readability levels can be tested here: <https://readabilityformulas.com/readability-scoring-system.php>

**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.

**Simple Language Examples**

**Background Suggestions:**

**PET**

Using an imaging technique called positron emission tomography (PET), we can see the connections between brain cells (called ‘neurons’). PET uses radioactive substances called ‘tracers’ that are injected into the body. These tracers allow us to measure your neuron connections and number of neurons (called ‘density’).

**MRI**

Using an imaging technique called Magnetic Resonance Imaging (MRI), we can see how the brain is working (called ‘brain activity’) and the shape of your brain. This machine can measure how your brain works while you learn or remember things.

**Informed Consent Form for Participation in a Research Study**

|  |  |
| --- | --- |
| **Study Title:** | *Insert study title as written on the protocol* |
| **Principal Investigator:** | *Insert name**Insert department*Email: *Insert* *e-mail*  |
| **Funder:** | *Insert the full name of the funder*  |
| **ROHCG REB Number:** | *Insert the REB number as assigned* |

**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. If the participant gains the capacity to consent, your consent for them will end. Throughout this form, “you” means the person you are representing.

You are invited to participate in this research 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 if you want 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 can decide not to take part or to leave the study later with no penalty to you or your health care or employment.

We thank you for taking the time to read this consent form and considering participating in this study.

**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. See examples below.*

The *identify individual* is receiving personal financial payment from *identify source of funds* 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 Full name of Sponsor/Funder to cover the cost of conducting this study.

**WHY IS THIS STUDY BEING DONE?**

*Provide a very brief background. Explain the purpose of the study in simple terms and define any required scientific terms and/or procedures that will be used during the study*

**WHAT WILL HAPPEN DURING THIS STUDY?**

*Describe the research procedures and give a clear outline of the study visits, including what will be done and how long it will take. Ensure that the information accurately describes the procedures being used in this specific study and the experiences the participant may have (i.e., any unusual sounds or sensations from the procedure). Some suggestions are provided below:*

If you choose to participate in this study, you will attend x visits at location.

**Visit x: Visit Title (time estimate)**

In this visit online/at location, you will [insert items as required below].

***Survey:***

You will be asked to complete a/an [online / paper] **survey(s**). The purpose of the survey is *include description of purpose (e.*g., *to understand how you feel about your experiences with your illness)*. This questionnaire will take about *x minutes* to complete.

We will ask some personal details, including your age, sexual preferences, ethnicity, etc. You may choose not to answer any question you wish. The information you provide is for research purposes only.

*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.

***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*. For this scans, you will *describe procedure in terms of their experience (e.g. You will be asked to lie down on a bed, etc.)*.

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 a**focus group***.* A focus group is a small group of people who are asked to speak about their opinions as part of the research.Each focus group discussion will be about *specify length in minutes or hours* in length. 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.* During this interview, you will speak/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. You will be asked to provide information about *explain topics of discussion e.g., your experiences with condition/intervention*.

***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.*

We will be collecting and testing the samples (described below) to *insert* s*tudy-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.

Once these tests have been completed, any leftover samples will be returned to the facility where they were obtained if needed, or destroyed 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 (DNA testing to look at if *specify condition* runs in families) will not be done on these samples.

*Or*

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

*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.

**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.*

A **urine sample** 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 *describe any information shared.*

While safeguards are used to protect your information, 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.

***Database studies:***

We will collect information about you from *specify source of information e.g., your medical chart* to *include description of purpose for this information (e.g., confirm your eligibility)*. The researchers will enter this information into an electronic database that can only be accessed by members of the research team. Please talk to the research team if there is information that you do not feel comfortable sharing.

**Table 1**: Study Visits Sample Only applicable for studies that have more than 1 visit

|  |  |  |  |
| --- | --- | --- | --- |
| Visits | Activities | Time / Duration | Location |
| Visit 1 | List study items | Time per item | Location |
| Visit 2 |  |  |  |
| Visit 3 |  |  |  |

Optional Research

You can participate in extra research to help researchers understand more about x. If you are interested, you will be given another consent form to read and sign. You may decide not to participate in the extra research and still participate in this main study.

**WHAT ARE YOUR RESPONSIBILITIES AS A PARTICIPANT?**

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

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

* *Specify any responsibilities (e.g. complete the survey; attend all of the study visits, etc.)*
* 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.

**CAN YOU CHOOSE TO LEAVE THE STUDY?**

You can choose to end your participation in this study at any time. You do not have to provide a reason.

*For General Studies*

If you choose to leave (called ‘withdraw’) from the study, please contact the research team.

*For Online Survey*

If you choose to leave (called ‘withdraw’) from the study, close your browser any time before completing the survey. Any information completed before you closed the browser will/will not be used for the study.

*Describe what will be done with their data and if they can ask for it to be removed*

*If all data will be used:*

Information about you that was recorded before you left the study will be used for the purposes of the study but no new information will be collected after you withdraw.

*If data can also be removed:*

If you choose to leave the study, you may also withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, if the information or samples has/have already been analyzed, it will not be possible to withdraw those results. D*escribe what will happen to samples if participant withdraws consent, (e.g., returned to the hospital where they were obtained; or data will be destroyed).*

*If samples will be anonymized at a certain point:*

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

**CAN YOUR PARTICIPATION IN THIS STUDY END EARLY?**

*Identify reasons why participants may be taken off the study. Examples are outlined below. Include or modify bullets below as applicable. This section may not be applicable for all studies.*

Your participation on the study may be stopped early, and without your consent, for reasons that will be explained to you. These could include:

* 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 withdraws permission for this study to continue

**WHAT ARE THE RISKS OR HARMS TO YOU FROM PARTICIPATING?**

*Inform participants of all reasonably foreseeable risks, harms, discomforts or inconveniences as well as the safety response by the team to respond to these risks.*

*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 triggered or uncomfortable. You may refuse to answer questions or leave the study at any time if you experience any discomfort. *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.*

***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 TO YOU FROM PARTICIPATING?**

*Inform participants of potential benefits to themselves and in general that may arise.*

*If there is no likely benefit to participation, include the following*

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.

*If the benefit is known, include:*

The expected benefit from taking part in this study is *specify*.

**WHAT IS THE COST FOR YOU TO PARTICIPATE?**

*If participation could result in additional costs, include an explanation of these potential costs.*

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*

There are no additional costs to you or your private health care insurance.

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*.

 **HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?**

***Note:*** *If there will be disclosure of personal identifiers, 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.*

The research team will only collect the information they need for this study (called ‘study data’). Your name, address, or other information that may directly identify you will not be used for the study. Records identifying you at this site will be kept confidential and, to the extent permitted by the applicable laws, will not be shared or made publicly available, except as written in this consent document.

*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 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 removed.

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

*If de-identified data will be sent out of the institution.*

This study requires the transfer of study data to *insert name of institution/individual* for the purposes of *specify purpose*.

*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 data or samples will be sent outside of Canada*

Any information and/or samples, sent outside of Canadian borders may increase the risk to privacy 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:*

We collect data using *insert app/tool/device name*. The information you provide will be stored on their *insert name e.g., Apple* servers. We cannot guarantee its confidentiality or that it will only be used for research purposes.

Authorized representatives of the following organizations may look at your original (identifiable) medical records and study data, 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 Royal Ottawa Health Care Group Research Ethics Board (ROHCG REB) who oversees the ethical conduct of this study in Ontario;
* The Royal’s Institute of Mental Health Research, to oversee the safety and quality of research at this location

**WILL YOU BE PAID TO PARTICIPATE IN THIS STUDY?**

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

*If there is no payment for participation.*

You will not be paid or reimbursed 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 paymen*t *including indication of payment interval if applicable e.g., every three months* as a token of appreciation.

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

*If there is re-imbursement 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-imbursement, 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 samplesand/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.

*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 YOU?**

Incidental findings are unexpected discoveries about your health that are found when completing tests or scans for the study you are participating in. The significance of these findings can range from minor *(insert example specific to your study*) to severe *(insert example specific to your study).* As health care providers concerned with your health and well-being, our preference is to always inform you and your designated health care provider of any incidental findings. However, you have the right to decline to be informed about any incidental findings.

Please indicate your preference regarding incidental findings below:

[ ]  Yes, I agree to be contacted about any incidental findings.

[ ]  Yes, I agree that results may be communicated to my designated health care provider for medical

 follow up and further tests as appropriate.

Name of Primary Healthcare Provider:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address and telephone number of Primary Healthcare Provider:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you do not have a primary healthcare provider, a study physician will provide you with a referral and follow-up upon an incidental finding.

[ ]  No, I do not wish to be contacted about any incidental findings.

**WHOM DO YOU 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**

This study has been reviewed and approved by the Royal Ottawa Health Care Group Research Ethics Board (REB) as study #\*\*\*\*\*. If you have any ethical concerns about the study, or the way it is conducted, please contact the REB office: Alexis.Dorland@theroyal.ca

**HOW CAN YOU FIND RESULTS ABOUT THIS STUDY?**

Results of the study are expected to be published in x years. If you would like, the study staff can also send you a copy of the results afterwards.

|  |  |  |
| --- | --- | --- |
| **I would like a copy of the results to be sent to me** | [ ] YES | [ ]  NO |
| **Initials:** |  |
| **Email Address or Mailing Address:** |  |

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN A RESEARCH STUDY?**

As a participant, you have the following rights:

1. You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.
2. You have the right to be informed of the results of this study once the entire study is complete.
3. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.
4. By signing this form, you do not give up any of your legal rights to legal recourse 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.
5. You will be given a copy of this signed and dated consent form prior to participating in this study. *If online, use instead:* Please save a copy of this consent form in your records.

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

**SIGNATURES**

* All of my questions have been answered and I can ask further questions during my time in the study,
* I understand the information within this informed consent form,
* I allow access to my medical records and specimens and related personal health information as explained in this consent form,
* I do not give up any of my legal rights to legal recourse by signing this consent form,
* I understand that any incidental findings will be communicated based upon my preference chosen in this consent form,
* I agree, or agree to allow the person I am responsible for, to take part in this study.

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

Signature of Participant PRINTED NAME Date

/Substitute Decision-Maker

If consent is provided by Substitute Decision Maker:

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

PRINTED NAME OF Participant

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

Signature of Person Conducting PRINTED NAME & ROLE Date

the Consent Discussion

*Please remove this section if not applicable*

**Participant Assistance**

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

**Complete the following section only if the participant/substitute decision maker is unable to read or requires an oral translation:**

[ ]  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/substitute decision maker, and any questions have been answered.

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

Signature of Impartial PRINTED NAME Date

Witness

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

Relationship to Participant

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

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

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

Signature of Interpreter Printed Name Date

*Please note: More information regarding 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.*