

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

*Guidance: If this consent form is for a particular sub-group within the study (e.g. healthy controls) 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 only contain the following standard MSH wording.*

You are being asked to 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. Participation in this study is voluntary.

##### 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). 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 an {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} people from {“y” number} places will be in the study. About {z1 – z2} will come from Mount Sinai Hospital.

 [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} people from {“y” number} places will be in the study. About {z1 – z2} will come from Mount Sinai Hospital.

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 1 condition needs to be clearly specified by ratio and/or percentage (e.g., 50:50, 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 1 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 dice. The number of people getting study drug will be {“x” number} and the number of people 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 {“x” 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 “X” number of tablespoons/mls} to check blood counts and liver function.

[For studies involving sample collection, describe who will be informed of the results of the testing. 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, if results will be made available:]

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

[For studies involving genetic testing:]

This study involves genetic testing. Researchers will be looking at your genes (DNA).

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

[Include if applicable (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen):]

The study {will/may} involve whole genome sequencing. Whole genome sequencing is the analysis of the complete set of genetic instructions in a cell.

Every person has their own unique set of genes or ‘genome’. Sometimes there are differences between individuals, but these differences are very small. The reason this is important is because these results might contain information (for example, an inherited genetic disease) that could impact you or your biological (blood) relatives. When you donate your genetic information or materials you are sharing information about yourself, and it can be used to identify these relatives.

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 relatives. There is no way to predict what effects such an information loss would have. For example, if an insurer, a current or future employer, or law enforcement were to learn about your genetic code it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.

You will {be given the choice/not given the choice} to find out about genetics testing results.

If you are a First Nations or an indigenous person who has contact with 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.

**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 | Bloodtest | 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 Common: (50-100%) [Include percentage frequency with side-effect.]

Common: (20-49%) [Include percentage frequency with side-effect.]

Less Common: (1-19%) [Include percentage frequency with side-effect.]

Rare (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 two forms of effective method of birth control including one barrier method, e.g. condom. 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 MSH 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.

### Incidental Findings

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

{Samples collected/Images done/Tests conducted} for the study are not for the purpose of diagnosis, and results will not be reviewed by a doctor, or recorded in your medical history. However, a potential risk of participating in research is that investigators may discover an abnormality of uncertain significance that may impact on your health. You will be given the opportunity to decide if you wish to be made aware of this information. If warranted, a physician will meet with you to discuss the findings, and provide you with a letter to take to your family physician describing the circumstances of the findings, and a recommended course of action. Your family physician may, in turn, recommend further diagnostic tests, which may then have an impact on your health and insurance.

### Voluntary Participation

*Guidence: This section should always include the first 2 paragraphs below; the additional information which follows should be modified as appropriate for the nature of the study.*

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.

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

*Guidance: 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
* The study intervention does not work for you
* You are unable to tolerate the study intervention
* You are unable to complete all required study procedures
* The study doctor no longer feels this is the best option for you
* The Sponsor decides to stop the study
* The Regulatory Authority/ies (for example, Health Canada) withdraws permission for this study to continue
* Your group assignment becomes known to you *if applicable* or others (like the study doctor or study staff)
* If you plan to or become pregnant

{If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.}

If you are removed from this study, the study doctor will discuss the reasons with you {and plans will be made for your continued care outside of 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**

*Guidance: The wording below is for an industry sponsored/Health Canada registered study. Other wordings for different types of studies (e.g non-industry/non-sponsored studies) are available on the MSH REB webpage under the* [*Confidentiality template link*](http://www.mountsinai.on.ca/about_us/corporate-information/ethicsboard/confidentiality-wording-consent-form-template/)*.*

Personal Health Information

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 15 years. 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 laws and guidelines:

* The study sponsor or its representatives/partner companies.
* Representatives of the Mount Sinai Hospital 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.

Study Information that Does Not Identify You

Some study information will be sent outside of the hospital to the Sponsor. 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. No new information will be collected without your permission.

*Guidance: If the study involves tissue samples, describe the process for withdrawal of samples, and any limitations to the withdrawal. See the suggested text below, or revise as appropriate.*

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.]

*Guidance: If the study involves the use of email, the following language should be added.*

Email is not a secure form of communication and should not be used for conveying sensitive information, or in the event of an emergency.

*Guidance: If video/audio recording will be used, 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.

*Guidance: If the study includes the transfer of information outside of Canada, the following language should be added.*

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.

*Guidance: Include the following language for US FDA-regulated studies (as per 21 CFR 312-68 and 21 CFR 812.145).*

Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. If possible, the study doctor will inform you and confirm your consent at that time. By signing this consent form you are agreeing to this release of information. You should be aware that privacy protections may differ in other countries.

*Guidance: For studies using smartphones, apps or applicable technology, describe any limits to confirdentiality. 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.

*Guidance: If de-identified data or samples may be used or shared for future research, include the following language.*

Your coded {study data and/or coded samples} may be used or shared with other researchers (inside and outside of Canada) for future studies. “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the {study data and/or samples}. This may include storing the {coded study data and/or samples} in controlled-access {databases/biobanks}, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database.  The goal of sharing is to make more research possible. However, the code matching your {study data and samples} with your name and other directly identifying study data will not be shared.

You will not be asked if you agree to take part in future research studies using your {study data and/or samples}. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your {study data and/or samples}.

*Guidance: OR, for studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) where researchers will NOT be using specimens or information for future research (even if identifiers are removed), include the following paragraph. This paragraph is not required for non-US federally funded studies.*

Your study data {and/or samples} will not be used or shared with other researchers for future studies, even if the researchers remove any information that could directly identify you.

##### Clinical Trial Registration

*Guidance: This statement is required for all studies subject to the FDA’s jurisdiction. Do not modify text.*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Research Results**

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 study doctor/let the study doctor know}.

[or, if the results will be publically available in the Clinical Trial Registry]

The results of this study will be available on the clinical trial registry (see the “Clinical Trial Registration” section for more details).

##### In Case You Are Harmed in the Study

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**

*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}.

**Commercialization**

*Guidance: Include this information if applicable and modify as appropriate for the particular study.*

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. If this happens, {there are no plans to provide payment to you/you will receive [describe participant’s share in commercial profit]}.

##### 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 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.

**Communication with Your Famiy Doctor**

*Guidance: This section should be included when applicable.*

Your family doctor may be informed that you are taking part in this study so that your study doctor and family doctor can help you make informed decisions about your medical care.

# **Questions About the Study**

*This section should only contain the following standard MSH 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 the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics Office number at 416-586-4875. 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 only contain the following standard MSH wording. If the study includes the use of personal health information, the statement in parentheses should be included.*

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 {and to the use of my personal health information as described above}.

Print Study Participant’s Name Signature Date

(You will be given a signed copy of this consent form)

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

Print Name of Person Obtaining Consent Signature Date

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.

Print Name of Translator Signature Date

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.

Print Name of Witness Signature Date

Relationship to Participant