**Unity Health Toronto Research Ethics Board (REB)**

**Consent Form Template and Guideline**

**17 May 2022**

Template and Guideline Legend (each text type is differentiated by both a colour and a format style)

**Mandatory Text** – Must appear in the consent form (this text has no special formatting)

**Placeholder Text** – Replace or adapt the text with the indicated information as it applies to your study (this text is dashed underlined)

**Information/Guidance** – Advice on how to complete a section and some example wording (this text is in italics)

**Conditional Text** – Mandatory and placeholder text to be used if it applies to your study (this text is shaded)

Conditional Text Instructions – describes when to include the conditional text that follows (this text is in bold italics)

How to Use this Template and Guideline

1. Review the document and un-highlight any shaded conditional text that is applicable to your study, using the conditional text instructions as guidance to help determine what needs to be included.
2. Delete any remaining shaded conditional text and all conditional text instructions.
3. Replace the placeholder text with the indicated information as it relates to your study, using the information/guidance text as guidance.
4. Delete all information/guidance text.
5. Change all remaining text to black.

You can delete all conditional text instructions or information/guidance at the same time by using the ‘Styles’ section on the Home tab (it is towards the right side of the ribbon). To do this:

1. Right click on the relevant style (“ICF – Instruction Text” or “ICF – Conditional Instructions”)
2. Select the ‘Select All xx Instance(s)’ option.
3. Hit ‘Delete’ on your keyboard.

*NB If you copy example wording from the information/guidance text, you will need to update the style of the copied text to “ICF-Body”, or it will be deleted when you use this ‘Styles’ method to delete information text.*

Accessibility - Changing the Colour and Styles used in this Template and Guideline

To make this consent form template/guideline easier for you or your audience to read, the colour and style (underline, bold, italics, font, etc.) of the placeholder, information/guidance, conditional text instruction, and body text used in this template can be changed throughout the whole document at the same time.

For example, if you prefer that all of the conditional text instructions appear as Arial, size 14, double underlined, purple text, this can be done quickly using the ‘Styles’ section on the Home tab (it is towards the right side of the ribbon).

1. In the Styles section, right click on the style that you wish to modify.
* Placeholder text can be changed by changing the “ICF - Placeholder Text” style.
* Information/Guidance text can be changed by changing the “ICF – Instructions” style.
* Conditional text instructions can be changed by changing the “ICF – Conditional Instructions” style.
* Header, Sub-header, Sub-sub-header, and body text are all similarly labelled (e.g. “ICF -…”).
1. Select ‘Modify’ and update the style as you would like.
* Additional formatting options, such as underline options (dashed, doubled, etc.), can be found by clicking the ‘Format’ button in the bottom left of the Modify window (underline options can be found under ‘Font’).

Shading of the conditional text is the only text format used in this template that cannot be modified using this method.

General Consent Form Guidelines

* The consent form should be written in lay language and at a Grade 7 or lower reading level.
* The consent form should be written in the second person (i.e. using “you” and “your”), except for the signature page, which should be in first person (i.e. “I” and “me”).
* Ensure that spelling, grammar, and punctuation are correct.
* All text should be 11pt font or larger; maintain consistent formatting throughout the document.
* All acronyms and abbreviations should be defined on first use.

**[Unity Health Toronto Site Logo]**

**Letter of Information and Consent to Participate in a Research Study**

If this study has separate consent forms for different participant groups: **For** **Group Name**

|  |  |
| --- | --- |
| **Study Title:** | Complete study titleThis should exactly match the title on the protocol.  |
| If there is a short title:**Study Short Title:** | Short title for the studyThis could be a short or lay language version of the study title. |
| **Study Team** | **Principal Investigator:** | Local PI Name, CredentialsDepartment, HospitalTelephone number (hours of availability at that number) |
| If this is a regulated study, and the PI is not an MD:**Qualified Investigator:** | Local QI Name, CredentialsDepartmentTelephone number (hours of availability at that number)*The Qualified Investigator must be a licensed MD in good standing. If the PI is not an MD, a Co-I MD must be identified as the QI.* |
| **Co-Investigator(s):** | Local Co-I Name, CredentialsDepartment,Contact InformationInclude all local Co-Is who will be involved in medical oversight, will have contact with participants, or can be contacted to answer questions about the study. For interventional studies, at least one MD Co-I must be listed. |
| **Research Staff:** | Name, Position or Role, Department, Contact InformationList the main research assistants/coordinators/managers, all of whom must have appropriate TCPS2, GCP, and/or Division 5 training. |
| If this is a greater than minimal risk study:**24 Hour Contact Information:** | Name and Telephone NumberInclude the name and number of an after-hours contact for this study. This can be the name of a person or a group (e.g. cardiology residents, neurologist on-call). |
| **Study Sponsor:** | Name of the Study SponsorThe sponsor is the company or organization that is responsible for the overall conduct of the study, generally it is the group that has written the protocol. |
| **Study Funding:** | Funding Source and (if industry) their link to this study.List all sources of funding for this study, including grants, department funds, and in kind donations. If the funding source is the company that sells or owns the investigational product, this should be stated. |

Conflict of Interest Statement:

The consent form should identify all actual, potential, or perceived conflicts of interest for all members of the study team. If you have indicated a conflict of interest in your response to Question 8 on the TAHSN application, it should be listed here. If there is no conflict of interest to declare, this should also be stated.

If there is a conflict of interest to declare:

Provide the name of the study team member with the conflict of interest; declare their conflict of interest, including the type of incentive, inducement, or benefit and the source of such potential benefit.

Example:

Company A is the pharmaceutical company that makes Drug A. and is the sponsor of the study. The study sponsor initiates the study and provides the study investigators with funding (money) to run the study and provides the study drug. Dr. A and Dr. B are involved with Company A as medical advisors for developing new research studies and products, and they receive honoraria for their time spent on these activities. Staff A occasionally works as a paid consultant for Company A.

If there are no direct financial incentives to conduct this study, but you would like to declare that the study team is being compensated for the time and resources used to conduct the study:

Company is the sponsor of this study and is providing funding to Unity Health Toronto to cover the costs of conducting the study. The study investigators and research staff are not receiving any direct payments to do the study.

If the study team has no conflicts of interest to declare:

The principal investigator, co-investigators, and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

If this study is a student research project conducted as part of an academic program:

Student Project Declaration:

This study is a student project conducted by name of student, a type of affiliation with Unity Health (e.g. resident, graduate student) at Unity Health site name as part of their thesis/course requirements at academic institution. This study is supervised by name of supervisor, a title at Unity Health site name.

If this study will be obtaining Substitute Decision Maker consent:

Information for a Substitute Decision Maker

This consent form is intended for the person who is eligible to take part in this study. Please note that the use of the term “you” in this document refers to the person who is eligible to participate in this study. However, if the person does not have the capacity to provide consent, the consent of their authorized representative (substitute decision maker) will be sought. If the participant becomes capable of providing consent at any time during this study, their informed consent to continue participating in this study will be sought.

Introduction

You are being asked to consider participating in this research study because reason this person is being approached.

All research is voluntary – you do not have to participate and you can withdraw at any time.

Before agreeing to take part in this study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in this study. If you have any questions, ask a study team member.

If any of the study investigators may also be part of the participant’s clinical care team:

You should be aware that it is possible that the Unity Health site name(s) study investigator(s) will also be your treating doctor(s).

If you choose to participate in this study, you will need to sign this Letter of Information and Consent form. You should not sign this form until you are sure you understand the information. If the time frame for starting the research procedures allows the person time to discuss it with others: You may also wish to discuss the study with others, such as your family doctor, a family member, and/or a close friend.

1. Background and Purpose of the Study

Describe the health issue that this study is aiming to address.

Describe the usual process for treating or managing the health issue.

Explain why this study is being done; introduce the study intervention or research activity.

Example:

Individuals with [disease or condition] often experience [problem or concern]. Usually, we treat [disease or condition] by [treatment]. However, [treatment] can sometimes cause [problem with treatment] or be less than ideally effective. We are conducting a study to determine whether [intervention] can [hypothesized outcome].

Provide any other relevant background information; describe the context for this study.

This could include: the mechanism of action of the study drug; information on previous studies; how many patients have previously received the study drug/device and when and where that happened; an explanation on the importance of doing this study; and/or information on how the results of this study will be used.

If this study will use a drug or device that is not approved in Canada:

Drug/Device name is investigational in Canada, meaning that it has not been approved by Health Canada for use outside of a research study. Health Canada has reviewed and authorized its use in this study.

If this study will use a drug or device that is being used outside of its approved indication:

The use of name of drug/device in this study is considered investigational because it has not been approved by Health Canada for describe why it is investigational in this study.

Examples:

* treating condition a
* use in combination with therapy b
* the drug dosage being used in this study
1. Study Design and Duration

Study Design

Describe the design of this study.

Possible descriptors include observational, randomized, blinded, active-control, placebo-control, crossover, registry, phase 1, 2 or 3, etc.

Example:

This is a randomized, double-blind, placebo-controlled Phase 3 research study.

The following definitions are provided to help explain some of the words being used to describe this study:

Explain what the descriptors mean.

Examples:

Observational

Observational studies are a type of research where researchers gather information on your health outcomes based on ‘observations’ (such as lab tests, questionnaires, etc.), but do not make decisions about the care you receive.

Placebo-Controlled

A placebo-controlled study is one where placebos are used to find out if the active drug works better or is safer than receiving only the usual care for a specific medical condition. A placebo is an inactive substance made to look like an active drug. The placebo used in this study is [placebo substance].

Randomized

Randomized means you will be put into a group by chance, like flipping a coin. A computer program will place you in one of the study groups. Neither you nor the study team can choose your group. You will have a(n) [equal, 1 in 3] chance of being placed in 1 of x groups. The groups are [group 1], [group 2], etc.

Double-Blind

This is a double-blind study, which means that neither you nor the study team will know which group you are assigned to. However, if it is necessary for your safety or in the event of an emergency, the study team can find out which group you are in.

Phase 1

Phase 1 studies look at how safe a drug is and try to determine the best dose. Phase 1 studies are done on a small group of research participants to gain some experience with a new drug.

Phase 2

Phase 2 studies are done to determine whether the dose of the drug that was determined to be safe in a previous trial is effective. Phase 2 studies may also compare different doses or schedules of giving the drug. In Phase 2 studies, researchers study the drug in a relatively small group of people who have the condition the drug is intended to treat.

Phase 3

Phase 3 studies are done to confirm the safety and effectiveness of a new drug and to look at the side effects in a large group of participants.

Pilot Study

This is a pilot study to see if the study plan that we are using is feasible. The results of this study will help us plan a future study looking at whether [intervention] can [hypothesized outcome].

Participant Population and Study Enrollment

This study will include overall participant number participants.

Provide a breakdown of the numbers of participants at each Unity Health site and in the overall study, by health condition, population, and/or by recruitment location, as applicable.

Examples:

* There will be x participants with [condition a] and x participants with [condition b].
* x participants will be enrolled at [site name], the remaining participants will be recruited from other sites worldwide.
* x participants with [condition] will be recruited from [unit] at [site name] and x healthy volunteers will be recruited from the community.
* x participants will be physicians working in [area] and x participants will be hospital administrators.

Study Duration

Overall, this study will run for about expected duration of study. Your involvement in this study will last for about anticipated length of participant’s involvement.

1. Description of Research Activities

If this study involves an intervention:

Study **Drug/Device/Intervention and Changes to Standard Care**

Provide the details of how the study drug, device, or intervention will be administered or implemented.

Include information such as dosage, timing, duration, and method of administration. If applicable, describe the differences in the administration or implementation of the intervention between study groups.

If this study involves changes to standard care:

Describe which (if any) aspects of their standard care would be different or withheld because of participation in this study.

If there will not be any changes to standard care:

The care that you receive for your condition will not be changed if you decide to participate in this study. All research interventions and activities will be in addition to usual care.

If this study involves research tests or procedures:

Research Tests and Procedures

The following tests will be done as part of this study. If there will be overlap between research and clinical procedures: Some of the tests will be done as part of your clinical care and the results will also be included in the study data; some of the tests will be done as part of clinical care, but will be done more frequently because you are in this study; and some of the tests will be done only because you are in this study.

For each research test and procedure that will be done as part of this study, describe the test or procedure and state the duration and frequency of the test or procedure.

Clearly delineate any tests/procedures that are done solely for research from those that are being done as part of clinical care with the results used in this study. Do not include tests/procedures that are part of clinical care only (i.e. results will not be included in the research data).

Example:

Electrocardiogram (ECG)

An ECG is a test that measures the electrical activity of your heart. An ECG is non-invasive and painless. During the ECG, sensors (electrodes) with wires attached will be placed on your chest (and sometimes your arms and legs). No electricity is sent through your body. An ECG usually takes about 10 minutes. This test will be done once as part of your clinical care, and will be done two additional times for research.

If biologic samples will be collected for research purposes:

Biologic Samples for Research Use

Mandatory genetic testing should be outlined in its own sub-section (below).

For each sample type being collected, describe the type of sample, the amount (for blood samples, give the amount in both mLs and tablespoons), frequency, and method of collection.

Explain what the sample will be tested for and/or the purpose/intended use of the sample.

Specify where the testing will be done (i.e. at which institution(s))

If biologic samples will be tested for diseases that are subject to mandatory reporting:

It is important to note that it is mandatory that positive results of tests for reportable diseases being tested for be reported to local health authorities.

If the samples will be used for mandatory genetic testing:

Genetic testing of samples

Explain what genetic tests will be done.

Describe whether the testing will be targeted or exploratory, or if whole genome sequencing may be done.

Describe the plan for managing any health information revealed through genetic testing.

The plan to manage health information can reference or direct participants to the incidental findings section later in the consent form (section 17 in this template).

If this study involves questionnaires or surveys:

Research Questionnaires and Surveys

Describe each research questionnaire or survey that the participant will be asked to complete.

Give a brief description of the purpose of the questionnaire/survey and an estimate of how long it will take to complete.

Describe how the questionnaire(s) or survey(s) will be administered (e.g. by hand using a paper form, on a tablet in the clinic, logging onto a website at home, via email, etc.)

If participants can skip questions:

You can skip questions that you do not wish to answer. If you have any questions or concerns while answering these questions, please talk to a study team member. Indicate whether they may choose to skip an entire questionnaire.

If skipping questions will affect the ability to include the participant in this study, or to include the participant’s data in analysis:

To participate in this study, you will be asked to provide a response to all of the questions in the questionnaire(s)/survey(s). The questionnaire(s)/survey(s) will include questions about list the potentially sensitive subject areas that will be covered in the questionnaires. If you think that you will not want to provide responses to all questions, you should not participate in this study. If during the study you find that there are questions that you do not wish to answer, you are free to withdraw from participation.

If this study involves interviews or focus groups:

Research Interviews and Focus Groups

Describe any interviews or focus groups that the participant will be asked to take part in.

Give a brief description of the format of the interview or focus group and an estimate of how long it will take to complete.

You can skip any questions you do not wish to answer or pause or end the interview/leave the focus group at any time.

For focus groups, state how many other participants will be in the group.

Describe who will be conducting the interview or focus group, where it will take place, and whether it will be recorded.

If participant health information will be collected from a database or medical record:

Collecting Health Information From a Database or Medical Record for Research Use

If health information will be collected from the participant’s Unity Health Toronto medical record:

Collecting health information from your Unity Health Toronto medical record

If you agree to participate in this study, the study team will collect the following health information from your Unity Health Toronto medical record:

* List the categories or types of health information that will be collected from the medical record and the time frame of the data that will be collected.

Examples:

* pulmonary exacerbations from the past 5 years
* all neurologic exams done to date
* results of your most recent liver function test
* information related to an adverse event from onset to resolution

If health information will be collected from the participant’s medical record at another institution or healthcare provider:

Collecting health information from your medical records at another institution or provider

Describe the health information that will be collected from the external institution or provider, including the type of data that will be requested and the name of the party that the data will be collected from.

If health information will be collected from a non-clinical database at Unity Health:

Collecting health information from a non-clinical database

Provide the name of the database and any conditions on the use of the information from the database.

Describe the health information that will be collected from the database.

If this study involves ICES data linkage:

ICES data linkage:

We also require your permission to collect information on your clinical outcomes (e.g. list data points or data categories that will be collected). This will be done by linking your list the direct personal identifiers that will be sent to ICES to health care databases held at the Institute for Clinical Evaluative Sciences (ICES). The ICES databases contain information about physician, hospital, home care services and medications that are paid for by the Ontario government. The linkage of your data with ICES databases will be done in order to reason why the linkage with ICES is being done.

If data will be collected via email or text (e.g. intervention done via text or a survey by email):

Email and Text Messaging

Describe how emails and/or texts will be used, sent, and handled.

Describe the contents of the emails or texts that will be sent and describe what information will be expected in return.

If there are optional research activities or sub-studies that are part of this study, and occurring concurrently with the study and not in the future:

Optional **Research Activities/Sub-Studies**

In addition to the main study, we are asking you to consider taking part in an/number optional research activity(ies)/sub-study(ies). The optional activity(ies)/sub-study(ies) is/are:

* Name(s) of the optional activity(ies) or sub-stud(ies)

The(se) activity(ies)/sub-stud(ies), and consent to participate in it/them, are described in detail in an appendix at the end of this consent form/a separate consent form.

Consent for the optional concurrent research activities can be sought in an appendix to the main consent form or in a separate consent form.

Consent for optional sub-studies or research activities that are not occurring concurrently with the main study must be sought in a separate consent form.

If this study involves optional genetic testing:

Genetic testing

We are asking you to consider taking part in optional genetic testing. You will be given a separate document that will describe this optional research component and seek your consent to participate. You do not need to agree to the optional genetic testing in order to take part in this study.

Consent for optional genetic testing must be sought in a separate consent form.

If the study investigators or sponsor wish to use samples in the future:

Future use of samples

We would also like to ask that you consider allowing us to store your samples for use in the future. You will be given a separate document that will describe this optional storage and seek your consent to participate. You do not need to agree to the optional storage and future use of your samples in order to take part in this study.

Consent for future use of samples must be sought in a separate consent form.

1. Description of Study Visits

Summarize each type of visit, including the timing, length, location (if not at the Unity Health site(s) where this study is being conducted), and description of what will happen at the visit.

Any research activities listed in this section should have previously been described in the Research Activities sections above. If the study visits are happening at the same time as clinic visits, state this and describe how much extra time will be needed. Telephone visits should also be described.

If a number of study visits (e.g. the 3-, 6- and 9-month visits) are the same, the can be grouped together.

Example:

Visit 2 (Week 8)

This visit will take place at Week 8 from the date you started the study and will take approximately 1 hour. During this visit, you will have a physical exam, MRI, pregnancy test and you will be given a 4-week supply of the study drug. If you agree to take part in the optional pharmacokinetic sub-study, you will also have 2 blood draws.

If this study has several visits or many research activities, a table of study visits should be included:

Table of Study Visits and Research Activities

For your convenience, a table summarizing the study visits and outlining the research activities that will happen at each visit is included below/at the end of the consent form.

1. Participant Responsibilities

If you decide to take part in this study, it is important that you remember to:

* List the participant’s responsibilities while participating in this study.

Examples:

* provide accurate information about your health history, including any medications you are taking
* inform the study team about new drugs or medications you are taking
* report any changes in your health
* check with the study team before enrolling in another study
* bring unused study drug to every visit
1. Potential Risks

If this study involves an intervention:

Potential Risks of the Study Intervention

Describe the potential risks of the study intervention.

Provide information on the incidence/frequency and the severity as well as the reversibility of each of the risks listed.

For investigational drugs or devices, this should match the information that is listed in the product monograph, investigator’s brochure, or product manual. All listed risks should be included in the consent form.

The risks should be described in lay language, not in technical or medical terms.

There may be additional risks or harms that we do not yet know about.

If there may be restrictions to future treatment options as a result of participating in this study.

Describe how future treatment options may be impacted.

If the participant will not receive standard care while participating in this study:

Potential Risks of Not Receiving Standard Care

Describe the risks of not receiving standard care while they are in this study.

If there are potential drug-drug interactions or medications that should be avoided for safety reasons while in this study:

Potential Drug Interaction Risks

There may be additional risks if you combine the study drug with other drugs or supplements. If you take any of the following products, you must report them to a study team member:

* List contraindicated medications, including brand names for common products

For extensive contraindications lists, you can list only the common products or drug classes in this section and provide the participants with a wallet card or a separate list of all contraindicated medications.

Additionally, you must talk to a study team member before you take any new medications while participating in this study.

Potential Risks of Research Activities

Describe the potential risks, discomforts, and inconveniences of any research activities (e.g. tests, procedures, surveys, questionnaires, observations, interviews, etc.).

Only include the risks related to the research activities. Activities done for clinical purposes should not be included in this section. However, if you feel it is important to mention the risks of a standard care procedure, a short preamble to the information should be included. For example, “The risks of x would have been discussed with you already as part of your clinical care. As a reminder, some of the more common clinical risks are described below…”

If the nature of this study or particular research activities may cause or reveal participant distress:

If you choose to participate in this study, you may experience a negative reaction or feelings of distress when responding to some of the questions during the interview/in the questionnaire(s). If this happens, you can pause or stop your participation in the interview/questionnaire. You can also choose to withdraw from the study. The study team is available to discuss your concerns and/or to refer you to appropriate resources.

If this study involves genetic testing:

Potential Risks of Genetic Testing

Due to the rapid pace of technological advances, there may be potential future risks associated with the use of genetic information that are presently unknown. Your participation in this study is confidential; however, there is a small chance that your genetic data (results from genomic sequencing) could identify you or family members. This is because each person’s genomic make up is unique, similar to a fingerprint. Because your family’s genetic make-up is very similar to yours, your sequencing data could potentially identify them. We will take steps to ensure that your identity is protected; but because of the uniqueness of your genetic data, we cannot guarantee confidentiality for you or your family members.

If pregnancy or becoming pregnant are exclusion criteria in the protocol for this study or if there are risks related to reproduction or nursing an infant:

1. Reproductive Risks

If there are risks related to being or becoming pregnant or getting someone pregnant:

The effects that the study drug(s) may have on eggs (ova), sperm, or on an unborn baby (fetus) are unknown/detail the known risks. You should not become pregnant or get someone pregnant while taking the study drug(s).

Participants who are able to become pregnant or produce sperm must agree to both of the following while taking the study drug(s) and for length of time afterward: i) not to get pregnant or get someone pregnant and ii) to use an appropriate family planning method as discussed and decided upon in consultation with a study investigator.

If you become pregnant or get someone pregnant while taking the study drug(s) or for length of time afterward, you should immediately notify the study investigators, who will discuss next steps with you.

If there are risks related to being or becoming pregnant:

If you are able to become pregnant, a study investigator will order a blood/urine pregnancy test prior to the start of your participation in this study to confirm that you are not pregnant. To confirm that you have not become pregnant during the study, blood/urine pregnancy tests will be done throughout your participation in the study.

If the participant will be asked to consent to allow the study team to follow a pregnancy that occurs during this study:

If you become pregnant or get someone pregnant while you are taking the study drug, the study team may ask if you/the person who is pregnant would be willing to provide information about the pregnancy as part of this study. A separate consent document will be used to request permission to collect this information. You/The person who is pregnant may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This decision will not affect your participation in this study and will not affect the health care that any person receives at Unity Health Toronto.

If there are risks to a nursing infant:

You should not nurse (breastfeed or chestfeed) an infant while in this study because the study drug(s) may be present in your milk and could be harmful to a nursing infant.

If there are risks to future reproductive ability:

The drug(s) used in this study may affect your ability to reproduce (become pregnant or produce sperm) in the future. A study investigator will discuss this with you.

1. Potential Benefits

If the participant may benefit from participation in this study:

Describe the potential benefits that the participant may reasonably be expected to experience because of participation in this study and the likelihood of such benefit.

Potential benefits to society may be included as benefits, but should be in a separate paragraph from any direct personal benefits.

As these are potential benefits, not guarantees, the use of wording such as “you may” rather than “you will” is recommended.

Benefits should not be overstated, as this may create an inducement to participate.

Remuneration for time, meals or out of pocket expenses is not considered a benefit.

Access to medical care and medical oversight of a condition are not considered benefits.

If there is no benefit to the participant:

There is no anticipated benefit to you for participation in this study.

1. Alternatives to Participation

If this is a healthy volunteer consent or if this study is not evaluating treatment alternatives for the participant:

This study is not researching ways to provide you with medical treatment, so the alternative to taking part in this study is to not take part in the study. Whether you choose to take part in this study or not, you will receive the same standard and level of care at Unity Health Toronto.

If there are treatment or care alternatives to taking part in this study, including receiving standard care:

You do not need to participate in this study to receive treatment for your condition. There are other options available to you, such as receiving standard care treatment. In making your decision, you should keep in mind that being in a study is not a form of treatment and that participating in a study is not the same as being treated.

The other options that are available to you include:

* Identify any other treatment alternatives, including other research studies and the known risks and benefits of these alternatives

A study investigator will discuss the other treatments for your condition with you before you decide whether you want to participate in this study. You can also discuss treatment alternatives with your treating doctor or health care practitioner.

State whether the participant can receive the study drugs or study intervention without participating in research.

If there are no alternatives (i.e. no available therapy):

There are no treatment alternatives available.

Explain whether there are non-treatment alternatives that can be discussed with the study or treating doctors.

1. Privacy and Confidentiality of Your Personally Identifying Information and Study Data If collecting research samples: and Samples

This section describes how your personally identifying information and study data If collecting research samples: and samples will be accessed, disclosed, and stored during this study. All persons involved in this study are committed to respecting your privacy. Other than the individuals or groups described in this section, no persons will have access to your personally identifying information without your consent, unless required by law.

Personally identifying information is any information that could be used to identify you; this includes your name and address.

Study data is information that is generated by and/or collected for a study that has been stripped of personally identifying information.

If this is an anonymous study (no identifiers are being accessed or collected):

Anonymous Study

This is an anonymous study. This means that no information that could be used to identify you is being accessed or collected as part of this study and we will not be using or analyzing your data in a way that could identify you.

If collecting research samples:

Study samples are any biologic samples (e.g. blood, saliva, tissue) that are taken from you for use in a research study.

If you will be collecting personally identifying information:

Protecting Your Privacy

The study team will make every effort to keep your personally identifying information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario.

In addition to the study team, other authorized employees of Unity Health Toronto may have access to your personally identifying information so that they can carry out regulatory or institutionally required duties. Unity Health Toronto may also store personally identifying information that is collected or used for these duties for a period of time, in accordance with regulations and institutional policies.

No personally identifying information will be allowed off site in any form, unless required by law or as described in this consent form.

All data and samples collected for research purposes will be labelled with a unique study identification number instead of any of your personally identifying information. The principal investigator at Unity Health site name is in control of the key that links your study identification number to you personally and will keep it stored separately from the study data.

If you will be accessing medical records:

Medical Records

If you will be accessing Unity Health Toronto medical records:

Accessing and collecting information from your Unity Health Toronto medical record

By signing this form, you are authorizing access to your medical records by the study team. The study team will also collect information from your medical record. The information that will be collected is described in the Research Activities section. The study team will use this information to conduct this study.

You are also authorizing access to your medical records by representatives of the Unity Health Toronto Research Ethics Board, the study sponsor, and by applicable government regulatory authorities (e.g. Health Canada, the US Food and Drug Administration (FDA), and/or regulatory agencies from other countries). Such access will only be used to verify the authenticity and accuracy of the information collected for this study, without violating your confidentiality, to the extent permitted by applicable laws and regulations.

If you will be accessing medical records at other institutions:

Accessing and collecting information from your medical record at other institutions or providers

By signing this form, you are giving us permission to access your medical records held by other institutions or health care providers. These other institutions or providers may ask you to give separate consent to allow them to release your medical information to us. The information that will be collected from other institutions or providers is described in the Research Activities section. The study team will use this information to conduct this study.

Shared electronic health systems such as ConnectingOntario, PRO, RM&R, OLIS, HDIRS, eCHN, DPV, and IAR do not permit access for research purposes.

If you will be entering study data into the participant’s medical record:

Adding information into your Unity Health Toronto medical record

Your participation in this study will be recorded in your Unity Health site name medical record. If you participate in this study, the following study related information will be added to your hospital file and stored in the hospital’s electronic medical record system: describe the study related information will be put into the participant’s medical record, including documentation of consent discussion, consent form, study drug dosing, and results of tests done for study purposes.

Unity Health Toronto shares the patient information stored on its electronic medical records system with other hospitals and health care providers in Ontario so that they can access the information if it is needed for your clinical care. Any of these people may see that you were in this study and the study data listed above when they access your medical record for clinical purposes.

If personally identifying information (including whole genome sequences) will be leaving Unity Health Toronto:

Transfer of Personally Identifying Information Outside of Unity Health Toronto

Describe the personally identifying information that will be transferred outside of Unity Health and the reason(s) for this transfer.

State the organization or company that the information will be transferred to and where they are located.

Describe how the information will be securely transferred.

Describe the measures the external location will take to maintain the privacy of the information at a level that is at least equivalent to Unity Health, Ontario, and Canadian data protection laws and policies.

State how long the identifiable information will be retained at the external location.

For studies that will be transferring identifiable data outside of Unity Health Toronto, please consider consulting the Unity Health Privacy Office early in the application process.

If this study involves ICES data linkage:

Linking to ICES

Personally identifying information will be securely transferred from Unity Health site name by or on behalf of the study investigators to the Institute for Clinical Evaluative Sciences (ICES) so the required linkages can be made to gather the information for this study. The information that will be sent is described in the Research Activities section. The study investigators will be permitted to access de-identified information only (i.e., any information that can directly identify you will be removed or replaced with a code that is not known to the study investigators).

If this study will use a third party survey platform, website or web based app to collect data:

Online Surveys, Third Party Websites, and Web Based Apps

State the name of the third party and describe what aspect(s) of this study use(s) their website or web app.

Specify what (if any) identifiable information (such as email or IP address) would be collected when using the survey or website.

Provide the location of the company and/or their servers.

Example:

The online survey is hosted by (company), which stores survey data on servers located in (country). You will need to provide an email address to create an account. Your information may be processed in and transferred or disclosed to countries in which (company)’s affiliates are located and in which their service providers are located or have servers.

For more information on the use of survey platforms for research, please consult the Privacy & Security Guideline on Survey Tools in Research, which can be found in the Templates and Guidelines section of the REB website.

If this study will use a third party device or installed app to collect data:

Third Party Devices and Downloaded or Installed Apps

State the name of the third party and describe what aspect(s) of this study use(s) their app or device.

Specify what (if any) identifiable information (such as device identification number, email, IP address, etc.) will be collected when using the device, app, or to create a user account.

Describe how the privacy of the data collected using the app or device will be maintained and/or provide a link to the third party’s website/privacy policy.

Provide the location of the company and/or their servers.

Example:

Fitbit is an American company that is not owned or operated by Unity Health, but we would like you to use this device and app so that we can collect data from it for this study. You will need to provide personally identifying information to Fitbit to create an account. The Fitbit privacy policy and data flows apply to any information you put into the app (available at <https://www.fitbit.com/en-ca/legal/privacy>). The study team will ask you for your Fitbit account to collect the data from Fitbit for this study. At the end of this study, you may choose to continue to your participation in Fitbit or you may close your account, but it is your responsibility to do so.

If this study will use email and/or text messaging to communicate with participants:

Use of **Email/Texting** for Research

There are common risks of using email and/or texting to communicate:

* Information travels electronically and is not secure in the way a phone call or regular mail would be.
* If someone sees these emails and/or texts they may know that you are a participant in this study or see the health information included in the email and/or text.
* Emails and/or texts may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, “free internet” providers).
* Copies of an email and/or text may continue to exist, even after efforts to delete the email and/or text have been made.
* There is always a chance with any unencrypted email and/or text, however remote, that it could be intercepted or manipulated.

Do not use email and/or text messaging for medical emergencies. If you require immediate help, call your clinic or healthcare provider, or seek emergency services.

For more information on the use of email and text messaging for research, please consult the Privacy & Security Guidelines on Email and Texting in Research, which can be found in the Templates and Guidelines section of the REB website.

If this study involves a focus group:

Focus Groups

All participants in the focus group will be reminded to keep the discussion confidential; but the study investigators cannot guarantee that other participants will not share your information or responses.

1. Storage and Retention of Your Personally Identifying Information and Study Data If collecting research samples: and Samples

If this study involves audio recording:

Audio Recording Storage and Retention

All audio recordings will be transcribed word for word (except for any personally identifying information, which will not be transcribed).

Recordings will be destroyed once the transcribed information has been assessed for accuracy.

If the recording will be transcribed by an external service:

Transcription will be completed by an external transcription service.

If this study will be collecting samples for research purposes:

Study Biologic Sample Storage and Retention

Describe where (Province and Country) samples will be stored and for how long.

Describe who will control access to the samples.

Describe how the samples will be labelled and linked to the participant.

Describe what will be done with any sample remaining after analysis.

If mandatory whole genome sequencing will be done:

Describe storage of whole genome sequence data and the retention period for this information.

Personally Identifying Information Storage and Retention

If this study is not collecting personally identifying information:

No personally identifying information is being collected as part of this study.

If this study will be collecting personally identifying information:

All personally identifying data used in this study will be securely stored.

Describe how and where paper copies of data with personally identifying information will be stored.

Describe how and where electronic copies of personally identifying data will be stored.

If this study is subject to Health Canada regulations:

Personally identifying information collected for research purposes will be kept by the Principal Investigator and Unity Health Toronto for as long as required by Health Canada regulation and Unity Health Toronto policy (currently 15 years after a study ends), at which point any documents with personally identifying information will be destroyed.

If this study is collecting personally identifying information and is not Health Canada regulated:

Personally identifying information collected for research purposes will be kept by the Principal Investigator and Unity Health Toronto for as long as required by Unity Health Toronto policy (currently xx years after this study ends), at which point any documents with personally identifying information will be destroyed.

Refer to Unity Health’s Records and Retention Policy to determine the length of storage required for your study documents.

Study Data Storage and Retention

As a reminder, study data is information that is generated by or collected for a study that has been stripped of personally identifying information.

Study data will be securely stored at Unity Health Toronto. Study data may also be transferred outside of Unity Health Toronto and shared with others for purposes related to the conduct of this study.

Study data may be kept indefinitely and may be used for other research or analyses by the study investigators and the study sponsor.

Individual level study data may also be made available to scientific journals, their reviewers, other researchers inside or outside of Unity Health Toronto, or the public.

1. Study Results and Study Registration

Results

The results of this study may be presented at a scientific conference or published in a scientific journal. If you are interested in obtaining the results of this study, you can contact the study team. We estimate that the results of this study will be available in xx year(s).

You will never be personally identified in any publication, report, or presentation that may come from this study.

If direct quotes from an interview, focus group or questionnaire will be used:

Direct quotes from your responses to interview/focus group/questionnaire questions may be used in reports or publications, but the quotes will not be attributed to you or contain any information that could be used to identify you.

If direct quotes from an interview, focus group or questionnaire will not be used:

No direct quotes from your responses to interview/focus group/questionnaire questions will be published or used in reports.

If this study is being registered:

Registration

If this study is being registered on ClinicalTrials.gov (mandatory for studies subject to FDA regulations):

For trials that are subject to FDA regulations, the following paragraph must be exactly as written below.

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.

The registration number for this study is NCTXXXXXXXX.

If this study is being registered on another registration site:

This study will be registered on registration site. The site will include information about the study but will not include any personally identifying information. You can search the site for this study; the registration number is registration number.

If you would like to communicate with the participant’s family doctor:

1. Notifying Your Family Doctor About Your Participation

If communication with the family doctor is optional:

On the signature page of this consent form, you will be asked whether you consent to allow the study team to contact your family doctor to inform them of your participation in this study. This will help your family doctor to make informed decisions about your care.

If communication with the family doctor is mandatory:

By signing the consent form, you give permission to the study team to contact your family doctor (and your other health care providers) to inform them of your participation, allowing your family doctor to make informed decisions about your care. If you do not want your family doctor to be notified, you cannot participate in this study.

1. Potential Costs and Reimbursement

If there are no costs and the participant will not receive any honoraria or compensation for time:

There are no costs to you for participation in this study. You will not be paid for your participation in this study.

If there will be out of pocket costs for the participant (e.g. transportation, meals):

List any additional costs to the participant that may result from participation in this study, for example, transportation costs, meal expenses, etc.

Describe how and when the participant will be reimbursed for these out of pocket expenses.

Include whether there is a maximum reimbursement amount.

State whether receipts need to be provided.

The Unity Health Finance department may classify reimbursement without receipts as an honorarium rather than reimbursement; this may have income reporting and tax implications for the participant. Please contact Research Finance for more information.

If the participant will receive compensation for their time or an honorarium for participation:

State the purpose of the compensation or honoraria (e.g. “as a thank you”, “in recognition of your time”, etc.).

Provide the amount of the compensation or honoraria, and when and how it will be provided.

If you withdraw from this study before completing it, you will receive compensation for the parts of the study that you have completed.

If compensation or honoraria will be processed through the Unity Health Toronto Finance department:

In order to process your reimbursement/honoraria, the Finance department at Unity Health Toronto will be provided with list the information that will be provided to the Finance department. The department will use this information for the sole purpose of processing your compensation and will retain this information in accordance with the department requirements.

Any participant who might receive more that $500 in honoraria in a single calendar year for participation in Unity Health Toronto studies will be required to provide their Social Insurance number (SIN) to the Finance department and the honoraria may be reported to the Canada Revenue Agency as income. Please contact Research Finance for more information.

If a third party will be used to provide compensation or honoraria:

Name the third party and describe what information the third party will receive about the participant.

Describe the procedures for receiving compensation through the third party.

State whether there are alternatives to receiving compensation through the third party.

Provide a link to any website describing the third party’s data handling practices.

If a discovery is made or a commercial product or method is derived from this study, it will be the property of the study sponsor and you will not be entitled to any financial benefits resulting from it.

If this study involves an intervention:

1. Compensation for Injury

If you are injured due to your participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigator(s), study sponsor, or involved institution(s) from their legal and professional responsibilities.

1. Participation and Withdrawal

Participation in this Study

Your participation in this study is voluntary. If you choose not to participate, there will be no impact to the medical care received at, employment at, or other relationship with Unity Health Toronto now or in the future for you or your family.

Withdrawal from this study

If you choose to take part in this study, you can change your mind without giving a reason, and you may withdraw from this study at any time without any effect on the medical care, employment or other relationship you or your family have at or with Unity Health Toronto.

If this is not an anonymous study:

If at any time you choose to withdraw from this study, please contact a member of the study team.

If participation in this study may be stopped by the study team:

Your participation in this study may be stopped without your consent for the following reasons:

* If continuation in this study appears to be harmful to you
* If it is discovered that you do not meet the eligibility requirements
* List and describe any other protocol defined reasons why participation may be stopped (e.g. become pregnant, lost to follow up, etc.)

This study may be terminated by the study investigators or by the study sponsor at any time for any reason.

If this study involves an intervention:

If you are withdrawn from this study or if this study ends early, a study team member will discuss possible next steps with you.

If a participant who withdraws will be asked to come in for an end of study visit or to be followed for safety purposes:

Describe any end-of-study research activities that are mandatory for participant safety.

Outline any safety assessments that are recommended if the participant withdraws from this study early.

At the time of your withdrawal, you will be asked to participate in these recommended assessments.

If a participant can withdraw from the intervention and still participate in follow up activities:

During the study, you can decide to withdraw from the intervention portion of this study but continue to participate in follow-up data collection activities and/or study visits.

Describe the steps that will be required to withdraw from the intervention portion of the study.

List the study activities and procedures they could still take part in without continuing with the intervention.

If this study involves sub-studies or optional research activities:

Describe whether and how withdrawal from the main study will affect their participation in the sub-study (and vice-versa).

Continued collection and use of your data after withdrawal

If you withdraw or are withdrawn from this study, no more data about you will be collected If this study involves an intervention: unless it is necessary to follow up on an adverse event that is not resolved at the time of your withdrawal.

Describe any other conditions on the continued collection of data after withdrawal (e.g. vital status collection at the end of this study).

If this is an anonymous study:

Because this is an anonymous study, we will not be able to withdraw any data that you have already provided because we do not know which information belongs to you.

If this is not an anonymous study:

Any study data collected about you up to the time you withdraw will no longer be used/ still be used for analysis.

We may be required to retain the personally identifying information and study data that we have already collected until after the end of this study (described in the Privacy and Confidentiality section).

If study data will be added to the participant’s medical record:

Any data that has been added to your medical record cannot be deleted from the record.

If this study will be collecting biological samples for research purposes:

Continued use of your samples after withdrawal

If you withdraw or are withdrawn from this study, data from samples that have already been analyzed will be withdrawn/ still be used. No further analysis will be done on your samples and any remaining samples will be destroyed.

If this study involves an intervention:

After the study

Describe what will happen to the participant at the end of this study including whether they may continue to have access to the study drug/device/tool.

1. New Information About this Study

We may make changes to this study as it progresses. We may also learn new things about this study that you may need to know. Some of the new information or changes might affect your decision to continue taking part in this study. You will be notified about any new or changed information in a timely manner and we will ask you if you consent to remain in this study. You may be asked to sign a new consent form at that time.

If this study may uncover actionable medical findings:

1. New Information About Your Health (Incidental Findings)

The tests or procedures that we do during this study might reveal medical information about you that is not part of the objectives of this study but may be relevant to your health. This type of medical information is called an incidental finding. Some incidental findings could be related to treatable conditions or they could be related to factors that may affect your current or future health care. With your consent, we will communicate all medically actionable incidental findings to you.

1. Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Unity Health Toronto Research Ethics Board Office at 416-864-6060 ext. 42557 during business hours (9:00am to 5:00pm).

Unity Health Toronto is a health network that includes Providence Healthcare, St. Joseph’s Health Centre, and St. Michael’s Hospital.

1. Study Contacts

If at any time during this study you have questions about the study or the research activities, you should contact the Principal Investigator, Name, at (XXX) XXX-XXXX (hours of availability), If this is a regulated study, and the PI is not an MD: the Qualified Investigator , Name, at (XXX) XXX-XXXX (hours of availability), or one of the/the research coordinator(s), Name, at (XXX) XXX-XXXX (hours of availability).

If this is a greater than minimal risk study:

If you have a question or concern that requires urgent attention outside of these hours of availability, you can contact name of person or group that 24-hour number directs to (e.g. a study team member, the departmental person on-call) at 24-hour number.

In case of emergency, please go to the nearest emergency department or call 911 for assistance. Let them know that you are in a study, and the Principal Investigator’s name.

1. Signature Page**(s)**: Documentation of Informed Consent

Study Title: **Complete Study Title**

**Participant Statement of Consent**

By signing this consent form, I acknowledge that:

* This research study has been explained to me, and my questions have been answered to my satisfaction.
* I have been informed of the alternatives to participation in this study.
* I know that I have the right not to participate and the right to withdraw from this study without affecting the medical care received at, employment at, or other relationship with Unity Health now or in the future for me or my family.
* The potential risks and benefits (if any) of participating in this study have been explained to me.
* I have been told that I have not waived my legal rights nor released the study investigator, study sponsor, or involved institutions from their legal and professional responsibilities.
* I know that I may ask, now or in the future, any questions I have about this study.
* I have been told that information about me and my participation in this study will be kept confidential and that no personally identifying information will be disclosed without my permission unless required by law.
* I have been given sufficient time to read the information in this consent form.
* I will be given a signed and dated copy of this consent form.

If this study has mandatory physician notification:

* I am aware that my family doctor will be notified about my participation in this study.

If this study has optional physician notification:

Please initial one of the boxes below to indicate whether or not you want your family doctor to be told about your participation in this study.

|  |  |
| --- | --- |
|  | **YES**, I agree that the study team can tell my family doctor that I am participating in this study. |
|  | **NO**, I do not want the study team to tell my family doctor that I am participating in this study. |

If this study may reveal incidental findings:

Please initial one of the boxes below to indicate whether or not you want to be informed of all medically actionable incidental research findings.

|  |  |
| --- | --- |
|  | **YES**, I agree to be told about any medically actionable incidental findings. |
|  | **NO**, I do not want to be told about medically actionable incidental findings. |

I consent to participate in this study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Participant name (print) |  | Participant signature |  | Date |  | Time |

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
| Name of person obtaining consent (print) |  | Position/Title of person obtaining consent (print) |  | Signature of person obtaining consent |  | Date |  | Time |

If this study will use substitute decision maker consent, include the following 2 sections:

Study Title: **Complete Study Title**

**Statement of Consent for the Substitute Decision Maker**

**Participant Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By signing this consent form, I acknowledge that:

* This research study has been explained to me, and my questions have been answered to my satisfaction.
* I have been informed of the alternatives to participation in this study.
* I know that I have the right not to consent to their participation and the right to withdraw them from this study without affecting the medical care received at, employment at, or other relationship with Unity Health now or in the future for them, myself, members of their family, or members of my family.
* The potential risks and benefits (if any) of their participation in this study have been explained to me.
* I understand that I have not waived their legal rights nor released the study investigator, study sponsor, or involved institutions from their legal and professional duties.
* I know that both they and I may ask, now or in the future, any questions we have about this study.
* I have been told that information about them and their participation in this study will be kept confidential and that no personally identifying information will be disclosed without permission unless required by law.
* I have been given sufficient time to read and understand the information in this consent form.
* I will be given a signed and dated copy of this consent form.

If this study has mandatory physician notification:

* I am aware that their family doctor will be notified about their participation in this study.

If this study has optional physician notification:

Please initial one of the boxes below to indicate whether or not you want the participant’s family doctor to be told about their participation in this study.

|  |  |
| --- | --- |
|  | **YES,** I agree that the study team can tell their family doctor about their participation in this study. |
|  | **NO,** I do not want the study team to tell their family doctor about their participation in this study. |

I consent to their participation in this study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Name of substitute decision maker (print) |  | Signature of substitute decision maker |  | Date |  | Time |

Substitute decision maker relationship to participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Substitute decision maker contact information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have explained to the above-named Substitute Decision Maker the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
| Name of person obtaining consent (print) |  | Position/Title of person obtaining consent (print) |  | Signature of person obtaining consent |  | Date |  | Time |

Study Title: **Complete Study Title**

**Statement of Consent (Participant capacity regained)**

By signing this consent form, I acknowledge that:

* I understand that permission was given for me to participate in this study by my Substitute Decision Maker while I was unable to make my own decisions.
* This research study has now been explained to me, and my questions have been answered to my satisfaction.
* I have been informed of the alternatives to participation in this study.
* I know that I have the right not to continue participating in this study and the right to withdraw from this study without affecting the medical care received at, employment at, or other relationship with Unity Health now or in the future for me and my family.
* The potential risks and benefits (if any) of participating in this study have been explained to me.
* I have been told that I have not waived my legal rights nor released the study investigator, study sponsor, or involved institutions from their legal and professional responsibilities.
* I know that I may ask, now or in the future, any questions I have about this study.
* I have been told that information about me and my participation in this study will be kept confidential and that no personally identifying information will be disclosed without my permission unless required by law.
* I have been given sufficient time to read and understand the information in this consent form.
* I will be given a signed and dated copy of this consent form.

At this time, I am now able to make my own decisions and (initial as decided):

|  |  |
| --- | --- |
|  | **YES,** I agree to allow my collected study data to remain part of this study. |
|  | **NO,** I do not consent to allow my collected study data to remain part of this study |

If this study may reveal incidental findings:

Please initial one of the boxes below to indicate whether or not you want to be informed of all medically actionable incidental research findings.

|  |  |
| --- | --- |
|  | **YES**, I agree to be told about any medically actionable incidental findings. |
|  | **NO,** I do not want to be told about medically actionable incidental findings. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Participant name (print) |  | Participant signature |  | Date |  | Time |

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
| Name of person obtaining consent (print) |  | Position/Title of person obtaining consent (print) |  | Signature of person obtaining consent |  | Date |  | Time |

If this study may involve participants or substitute decision makers who may for any reason be unable to read independently or unable to sign the consent:

Study Title: **Complete Study Title**

**Declaration of Assistance – Witness to Consent Process**

Study Participant’s Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ASSISTANCE DECLARATION AND SIGNATURE:**

I have provided assistance during the consent discussion between the potential participant and the person obtaining consent by (please check one):

🞎 Acting as a witness to the consent discussion

🞎 Acting as a witness to consent to participate in the study (signature or verbal agreement)

🞎 Assisting in delivery of consent discussion (reading/oral), including communication of questions and responses

🞎 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I attest that the information was accurately explained to, and apparently understood by, the participant and the participant has freely given consent to participate in the research study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Name of person assisting consent (print) |  | Signature of person assisting consent |  | Date |  | Time |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Contact Information of Person Assisting Consent |  | Relationship To Study Participant |

If this study may involve participants or substitute decision makers who have limited proficiency in English (or other language in which the consent form is written):

Study Title: **Complete Study Title**

**Declaration of Assistance – Interpreter**

Study Participant’s Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**INTERPRETER DECLARATION AND SIGNATURE:**

I am competent in the English language and in the preferred language of the potential participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of language)

I am not involved in the research study or related to the participant. I agree to keep confidential all personally identifying information of the participant. I have faithfully interpreted the consent discussion, and provided a sight translation of the written informed consent form as directed by the study team member obtaining consent.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Name of interpreter (print) |  | Signature of interpreter |  | Date |  | Time |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Contact Information of Interpreter |  |

If there are optional research activities or sub-studies that are part of this study, and occurring concurrently with this study (if there are multiple optional activities, replicate this section as needed):

Appendix **#**: Optional **Sub-Study/Research Activity** – Name of **Sub-Study/Research Activity**

Introduction

In addition to taking part in the main portion of this study, you are being asked to consider participating in an optional sub-study/research activity. The details of the optional sub-study/research activity are described below. You do not have to take part in this optional sub-study/research activity in order to take part in the main study.

Purpose of the Optional **Sub-Study/Research Activity**

State what the optional sub-study/research activity is and provide an explanation of why it is being done.

Describe the research question that is being addressed by the optional sub-study/research activity.

Describe how the objective of the sub-study/research activity relates to the main study.

Explain which participants in the main study will be asked to participate in the sub-study/research activity.

List the number of participants at each Unity Health site and in the study overall that are expected to participate in the sub-study/research activity.

Description of the Optional **Sub-Study/Research Activity**

Provide the details of the optional activities that the participant will be asked to complete.

*(if applicable)* For each sample type being collected, describe the type of sample, the amount, frequency, and method of collection.

*(if applicable)* Explain what the sample will be tested for and/or the purpose/intended use of the sample.

Describe the length of time involved in taking part in the sub-study/research activity.

Describe the participant’s responsibilities while taking part in the sub-study/research activity.

Risks of the Optional **Sub-Study/Research Activities**

Describe any potential risks that are specific to the optional sub-study/ research activity.

Benefits of the Optional **Sub-Study/Research Activity**

Describe the potential benefits that are specific to the optional sub-study/research activity.

Privacy and Confidentiality of the Optional **Sub-Study/Research Activity** Data **and Samples**

Include any privacy considerations that are specific to the sub-study/research activity.

This could include data and sample storage locations that differ from the main study, use of a third party app or device, sample labelling, etc.

Costs and Reimbursements Related to the Optional **Sub-Study/Research Activity**

Describe whether the participant will be compensated for time and/or reimbursed for costs associated with the sub-study/research activity.

Participation and Withdrawal from the Optional **Sub-Study/Research Activity**

Describe the process for withdrawing from the sub-study/research activity.

If you agree to take part in the optional sub-study/research activity and later decide to withdraw from the optional sub-study/research activity, you can continue to take part in the main study.

State whether or not the participant can withdraw from the main study and remain in the sub-study.

If you withdraw from the optional sub-study/research activity, data collected about you up to that time will be withdrawn/ still be used. No more data about you will be collected for the optional sub-study/research activity.

(*if applicable*) Indicate what will happen to the samples (both analyzed and unanalyzed) if the participant withdraws or is withdrawn.

Consent to Participate - **Name of Sub-Study/Research Activity**

The optional sub-study/research activity has been explained to me, and my questions have been answered to my satisfaction.

I consent to participate in this optional sub-study/research activity.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Participant name (print) |  | Participant signature |  | Date |  | Time |

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks associated with participation in this optional research sub-study/research activity. All questions that have been raised about the research have been answered.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
| Name of person obtaining consent (print) |  | Position/Title of person obtaining consent (print) |  | Signature of person obtaining consent |  | Date |  | Time |

If there is a table of study visits and you do not wish to include it in the main body of the consent form:

Appendix **#**: Table of Study Visits and Research Activities

Insert Table of Study Visits.

This section should be limited to one page, be a legible font size and written in lay language. If a study visit will be timed to coincide with a clinic visit, this should be noted.

Page orientation can be changed to landscape, if appropriate.

Example:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Visit Number | 1 | 2 | 3 | 4 |
| Timing of Visit | Week 0 | Week 4 | Week 8 | Week 24 |
| Length of Visit | 1 hr | 2 hrs | 0.5 hrs | 1 hr |
| Informed Consent | X |  |  |  |
| Eligibility Check | X |  |  |  |
| Physical Exam | X | X | X | X |
| Pregnancy Test | X | X | X |  |
| Study Drug Dispensing |  | X | X |  |
| Questionnaires | X |  |  | X |

**If you would like to ask for the participant’s consent to be contacted for future research studies:**

Appendix **#**: Consent to be Contacted in the Future for Research Purposes

We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below.

Clearly define the limits of this contact.

This should include information related to:

* Who may contact them (e.g. the PI’s study team, other investigators in the PI’s department, etc.)
* When they may be contacted (e.g. for research done over the next 5 years, etc.)
* Why they may be contacted (e.g. follow-up studies to this study, studies that relate to the subject area or disease/condition of this study)
* How they may be contacted (e.g. telephone, email, mail)

Describe the information about the person that will be stored for future contact for research (e.g. name, contact information, disease/condition, etc.)

Describe where and how the person’s information will be stored and who will have access to it.

You are not obligated to participate in any research studies that you are contacted about.

If you no longer want to be contacted about future research studies, please contact contact name at phone number.

Statement of Consent To Be Contacted in the Future for Research Purposes

Please initial the boxes below to indicate which methods of communication can be used to contact you in the future for research purposes.

|  |  |
| --- | --- |
|  | I agree to be contacted by **email**.Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\*Please note that email is not secure. Emails can be intercepted, viewed, changed or saved by others.* |
|  | I agree to be contacted by **mail**.Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | I agree to be contacted by **telephone**.Telephone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | I agree that the person calling can **leave a voicemail or message** if I do not answer the telephone. |

I have read the above information, and I agree to be contacted for future research as indicated above.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Participant name (print) |  | Participant signature |  | Date |