**Reminder information for the PI; please read the information below and ensure the protocol and informed consent form (ICF) address the issues. Delete this information from the ICF template.**

* Information given to a subject or a subject’s legally authorized representative (LAR) is to be in language understandable to the subject or the LAR.
* Informed consent may **not** include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
* Informed consent will be documented by the use of a written ICF approved by the IRB and signed by the subject of the subject’s LAR. A written copy will be given to the person signing the ICF.
* Before involving a human subject in research, an investigator is to obtain the legally effective informed consent of the subject or the subject’s LAR. An investigator is to seek consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the LAR is to be in **language understandable** to the subject or the LAR.
* A subject or the LAR must be provided with the information that **a reasonable person would want** to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
* Informed consent as a whole must present information in sufficient detail relating to the research, and **must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR’s understanding of the reasons why one might or might not want to participate.**

|  |  |  |  |
| --- | --- | --- | --- |
| http://staffnet/Staff/Reference/MarketingandBrandingResources/CHALogoForEveryday.png | **INFORMED CONSENT AND**  **AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**  **FOR RESEARCH** | | |
| We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study. | | | |
| **Study Title:** | | | |
| **Your name (Participant):**  **A study team member is to print the participant’s name or verify the participant has legibly written his/her name.** | | | **Today's Date:** |
| **Not including this study, are you taking part in any research now?**  **Yes**  **No** | | | |
| **Name of Principal Investigator:** | | | |
| **Name of Co-Investigator(s):** | | | |
| **Consent form version date or number:** | | | |
| **Name and telephone number of study contact to call with questions:** | | | |
| **CHA IRB Number:** CHA-IRB- | | **Study Sponsor(s):** | |

|  |
| --- |
| **Key Information**   * Informed consent **must begin with a concise and focused presentation of the key information** that is most likely to assist a prospective subject or LAR in understanding the reasons **why one might or might not want to participate in the research**. This part of the informed consent **must be organized and presented in a way that facilitates comprehension**. * **Key information includes:** * Consent is being sought for research; participation is voluntary. * Purposes, expected duration of participation, study procedures. * Reasonably foreseeable risks or discomforts to subjects. * Benefits to subjects, others that may reasonably be expected. * Alternatives, if any, that might be advantageous. |

**Introduction**

Note: Provide an opening paragraph to introduce the research study.

**Sample Language:**

You are invited to take part in a research study done by Dr.       and people who work with this doctor.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in the study, you may leave the study at any time for any reason. If you don’t want to take part, it does not change any part of the standard health care you may receive at Cambridge Health Alliance.

If you decide to take part in this study, you will be asked to sign this form. We will give you a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

We will tell you about new findings that may cause you to change your mind about being in this study.

**Purpose for the Study**

Note: The objectives and goals of the research should be clearly stated in lay terms. It should be clear that the study involves research and that there is not only an immediate purpose, but ultimately, a larger purpose for conducting the research. State approximately how many subject will be part of the study at CHA, and nationally/internationally, if applicable.

**Sample Language:**

The purpose of this research study is to learn if      .

Approximately       participants will be in this study at Cambridge Health Alliance.

**Reasons why you have been invited to be in this study**

Note: It is important to tell potential participants why they are being invited to participate. A participant should be told why s/he is being selected for the study (*e.g.,* because they have a particular condition, or they are a healthy volunteer).

**Sample Language:**

The reason why you have been invited to be part of this research study is      .

**Period of Participation (how long you will be in this study)**

Note: Include how long a subject’s participation will last and approximately how long each visit will last. A participant should be informed of the number of visits required by the study, as well as the total number of participants expected to be enrolled – both at CHA and nationally, if applicable. If there is a large number of visits required for the study, consider inserting a table or outline with study visit details.

**Sample Language:**

If you choose to participate in this research study, you will be in this study for       days/weeks. There are       study visits. Each study visit will last for       hours. We will follow you in this study for       weeks.

**Procedures (what will happen during this study)**

Note: This section should include a detailed explanation of the study and should clearly state all procedures involved. A clear distinction must be made between standard practice and research procedures. Avoid technical language. Define any technical terms or abbreviations.

State whether clinically relevant research results, including individual research results, will be disclosed to each subject, and if so, under what conditions.

The following are important to include:

* Explanation of study design (pilot study; survey, investigational drug or device study).
* Physical exams, blood collection, *etc*.
* Medical history
* Questionnaires, surveys, diaries of activities, rating scales, *etc*.
* Dietary restrictions
* Medication restrictions (including over-the-counter drugs, herbal/supplement restrictions)
* Ancillary tests, including explanations (*e.g.,* ECG, MRI, CT scan, urinalysis).
* Pregnancy testing/birth control requirements. The ICF is to state if there is a need to use birth control in the study. This applies to male and female participants. Depending on the age of minors to be enrolled, this information may also be added to an [Assent form](http://www.northshorelij.com/body.cfm?id=1147&oTopID=1147&PLinkID=1142#assent_minor_participate#assent_minor_participate).
* Focus groups; specify if any audio or video recording will be done.
* Follow-up visits, phone calls, *etc*.
* If it is an investigational drug trial, explain if it is [randomiz](http://www.northshorelij.com/body.cfm?id=1147&oTopID=1147&PLinkID=1142#random_cross_over#random_cross_over)ed, if there is a crossover, if it is [double-blinded](http://www.northshorelij.com/body.cfm?id=1147&oTopID=1147&PLinkID=1142#random_cross_over#random_cross_over), if a [placebo](http://www.northshorelij.com/body.cfm?id=1147&oTopID=1147&PLinkID=1142#random_cross_over#random_cross_over) is used, if it is [open label](http://www.northshorelij.com/body.cfm?id=1147&oTopID=1147&PLinkID=1142#random_cross_over#random_cross_over), any washout periods, *etc*.
  + If the drug/device is investigational state whether it will be available to participants after they complete the study.
  + Describe all drugs and/or devices administered as part of the study. Drug names should be written-out in full and include both the generic and trade name. Use either the drug or trade name consistently throughout the ICF. Dosage should **NOT** be abbreviated. It must be written out (*e.g.,* milligrams, not mg). The route of administration must be stated and the frequency of dosage.
  + Specify if the drug/device is approved/not approved by the FDA. If the drug/device is FDA approved, but is not FDA approved as used in the study this must be stated. (e.g., The drug/device’s use in this study is investigational because it is not approved by the FDA for the treatment of\_\_\_\_\_.  However, it is approved for treatment of \_\_\_\_\_).
  + Do not use “new drug,” “medicine,” “new therapy,” or “novel treatment,” if the drug/device is investigational; instead use “investigational” drug/device or “experimental” drug/device, *etc*.

**Sample Language:**

If you decide to take part in this research study, the following procedures will be done as part of the study:



If birth control is relevant to study participants include the necessary related information, for example (**sample language below is to be tailored to the study**):

**Birth Control**

Are you pregnant or think you are pregnant?  Yes  No  Not applicable

Are you able to get pregnant?  Yes  No  Not applicable

Are you planning or trying to get pregnant?  Yes  No  Not applicable

The risk of the study drug/device/intervention to an unborn baby is NOT known at this time. As a result, women should **NOT** be in this study if they are pregnant, breast-feeding, or trying to become pregnant.

If you are a woman who can get pregnant, use birth control for the entire time you are in this study and for       months afterwards. You should be on a birth control pill or use another accepted form of birth control, such as a diaphragm, an intrauterine device (IUD), or not have sex. You may have to use 2 methods of birth control. The study doctor will discuss this with you.

If you are a male with a partner who could become pregnant, then you should use condoms for the entire time you are in this study and for       months afterwards. You should also encourage your partner to use an acceptable form of birth control such as a birth control pill, a diaphragm, or an intrauterine device (IUD), or you should not have sex.

**Collection of identifiable private information or identifiable biospecimens**

NOTE: Any research that involves the collection of identifiable private information of identifiable biospecimens is to include:

* A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or his/her LAR, if this might be a possibility.
* A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether subjects will or will not share in this commercial profit;
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Possible Risks, Discomforts, Side Effects, and Inconveniences**

Note: List all risks/discomforts that are reasonably foreseeable. Not all risks will be to the individual. Some risks may be delayed or may impact only certain people. Each item mentioned in the procedure section should be addressed, *e.g.,* drug side effects, risks associated with blood collection. Even for things that may seem harmless (such as the uneasiness of certain questions in a survey, the potential contraindication of herbal therapies) pose risks. If there is a risk of symptoms worsening, especially during a washout or if randomized to receive placebo, this is to be detailed. Risks to pregnant/nursing women/fetus must be addressed. Again, please tailor or delete any of the following sections, as applicable to the study.

**Sample Language:**

The following are possible risks and side-effects associated with your participation in this study:



**For Social/Behavioral Studies**:

Some of the questions that you will be asked are of a personal nature. They may cause you to be embarrassed or stressed. You may ask to see the questions before deciding whether or not to participate in this study.

Your part in this research study consists of allowing the research team to use data from your medical record. The tests and treatments you will receive are part of the standard care for your condition. This study does not require you to have any additional procedures or treatments. Therefore, being in this study does not involve any risks that you would not face during your routine treatment and care.

**For Drug/Device Trials:**

Unknown Side Effects:

As with any       there may be side effects that are unknown at this time. Members of the study team will monitor you for any side effects. It is also important that you tell the study staff right away about any unusual events or changes in your health.

Known Side Effects:



**For Ancillary Tests:**

These scans are being performed for research purposes only. The results will not be used to make decisions related to your diagnosis or regular care. If a scan shows a condition that could affect your health, you will be referred for follow-up care.

Please tell the study staff if you have any metal in your body. If you have any metal in your body like a pacemaker or surgical pins or clips you may not be able to take part in the study. If you work with material or tools that could leave small pieces of metal in your eyes or skin you may not be able to take part in study.

If you feel anxious or scared when in a tight space, these feelings could happen while in the MRI machine. If you become uncomfortable in the machine tell the researchers and the procedure will be stopped.

**Blanket Statement:**

We will be happy to answer any question you have about these risks and/or side effects. Please talk with a study team member if you have any study-related questions or concerns.

**Alternatives to Participation**

Note: State appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects. Clearly state that a participant does not have to be in the study to receive any treatment/intervention that is already available. If, for example, the protocol involves a comparison between 2 drugs that are commercially available, an alternative would be to receive either without participating in the study.

If this is a drug or device study, list any drug/treatment/medical intervention options that a volunteer might choose as an alternative to participation, including other investigational interventions, alternative treatments, non-pharmaceutical treatments, *etc*. Both the generic and trade names of any alternative drugs should be given.

**Sample Language:**

An alternative is to not participate in this study.

**OR**

You may choose not to participate in this study and continue to receive standard care**.**

**Benefits (good that may come from being in this research)**

Note: List all benefits from participating in this research. Also, note that some of these benefits may not help each participant directly. Compensation/payment for participating in research is not a benefit.

**Sample Language:**

Potential benefits to you from being in this study are:



**OR**

This research is not designed to directly benefit you.

**OR**

This research may not help you directly. However, what we learn may help others in the future.

**Costs**

Note: Clearly state if a participant or a participant’s insurance will be financially responsible for any or part of the procedures, *etc*., or if the intervention/drug and/or study-related procedures will be paid by the sponsor. Using the term “at no cost” is preferable to “free,” which could be considered coercive.

**Sample Language Depending on Funding Source:**

You will not have any costs from being in this study. All study-related visits and procedures will be given to you at no cost. Costs related to your standard care will be billed as usual to you or your insurance.

**For Investigational Drug or Device Trials:**

The study drug/device, study-related visits, and study-related procedures will be given to you at no cost. All other costs will be billed to you and your insurance company in the usual way, as part of your standard care.

**Payment**

Note: Payment is not a benefit of participating in the study. Payment cannot be held until the end of the study; that is potentially coercive. The protocol and ICF must state the payment schedule (*e.g.,* given at the end of each visit, payment will be mailed to the participant’s home address on file) and method (*e.g.,* check, gift card, cash) in the ICF.

**Sample Language:**

You will be paid $      for each study visit. Each payment will be a $      gift certificate to      .

**OR**

You will be paid $      for each study visit. Each payment will be $      in cash.

You will only be paid for each visit that you complete. You will be given your payment at the end of each visit. If you complete every visit in this study you will be paid a total of $      for your time and travel expenses.

**Study-Related Injury**

**Sample Language:**

If you get hurt or get sick as a direct result of being in this study emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

**For Investigational Drug or Device Trials:**

Provided you followed the research guidelines, if you get hurt or sick in this study the sponsor has agreed to pay for treatment of any research-related injury.

**Voluntary Participation**

Note: It is very important to re-emphasize that participation is voluntary and refusing to participate will not affect the care that a subject will otherwise receive. State the potential consequences of a subject’s decision to withdrawn from the study and the procedures for doing so safely. State the circumstances under which a subject’s participation may be terminated by the PI without the subject’s/LAR’s agreement.

**Sample Language:**

Taking part in this study is voluntary. If you do not take part you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

Any information collected from you before the date you leave the study will be used in the research study.

The research team may decide that you can no longer be in the study. This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. You did not follow all the study rules.

**Privacy / Confidentiality**

Note: The language below meets HIPAA requirements; it must be present in all ICFs that will collect PHI:

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law.

We will protect all of your health information, including your Protected Health Information or “PHI.” Your PHI is your individually identifiable health information.

If you take part in this study, you agree to let the research team use your medical information. Do not take part in this study if you do not want the research team to access your health information.

We will follow these guides:

* The research team will view your health information only during the life of this study.
* We will not include any information that could identify you in any publication.
* At the end of the study, we will remove all of your identifiable information (name, address, telephone number, *etc*.) from the study database.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

* Other researchers conducting this study,
* The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study
* Accrediting agencies,
* Data and Safety Monitoring Board (this is an independent group of experts who monitor study participant data and safety while a study is taking place),
* Clinical staff not involved in the study, but involved in your regular treatment,
* Insurance companies.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

NOTE: Delete any of the bullet points/information above that do not apply to this study.

If this study will be posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) the following must appear in the ICF unaltered, per federal regulation:

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US 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.

**Period of Authorization**

Note: As required by HIPAA, you must include a date or event after which the PHI collected pursuant to the Authorization will no longer be used. For research purposes, you may state that the Authorization remains in effect until the "end of the study and any applicable record retention period," or, if the data are being collected to compile a research database or for a similar purpose (e.g., longitudinal research), then you may state that there is either no expiration date or data will be stored until the end of the study, which entails an extensive period of time. Other possible expiration dates/events are: Completion of the study; end of data collection; destruction of database; “\_\_\_” years after the end of the study; FDA approval of study drug/device; or a specific date. In choosing an end event, it is important to make sure the date/event allows for retention of PHI for any applicable record-retention periods.

Your authorization expires when this study is terminated. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

**Getting Help (Contacts)**

Note: The key contact names and telephone numbers must be included in the ICF.

**Sample Language:**

If you have questions about this study please ask a member of the study team. Some questions people have:

* What are the risks and benefits of being in this study?
* What other choices are available?
* What are my rights as a research participant?
* What should I do if I feel pressured to take part in this study?
* How is my health information used in this study?
* How will my health information be protected?

Call the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

**XXX (Principal Investigator)** xxx-xxx-xxxx

**XXX** xxx-xxx-xxxx

**XXX** xxx-xxx-xxxx

On weekends, holidays, or after regular business hours:

XXX (Principal Investigator) xxx-xxx-xxxx

If you have questions about your rights as a study participant please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair: 617-806-8702

Patient Relations Manager: 617-665-1398

**Confirmation from Person Obtaining and Documenting Consent**

Note: The Legally Authorized Representative lines below are to be included only if the protocol and application specifically requested enrollment of decisionally impaired persons and detailed the permission/assent process. The IRB must explicitly approve the enrollment of decisionally impaired persons (noted on the IRB approval letter); otherwise that population cannot be enrolled in the study. If the IRB approval letter does not specifically note that decisionally impaired persons can be enrolled, please delete the Legally Authorized Representative lines below.

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Participant’s Signature Date

I have informed the study participant,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_of:

Participant’s Printed Name

* The procedures, purpose, and risks related to participation in the above-described study;
* How his/her health information may be used, shared, and reported, and;
* His/her privacy rights.

The study participant has been provided with a signed copy of this form.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Researcher Obtaining Consent Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Printed Name of Researcher Obtaining Consent

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant’s Legally Date

Authorized Representative

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Printed name of Participant’s Legally Date

Authorized Representative

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Interpreter Role ❒ CHA employee

Printed Interpreter Printed Name(if used) ❒Other**\_\_\_\_\_\_\_\_\_\_\_\_\_**