**\*Please revise or remove language in RED**

* **Informed consent forms should be written in simple language that is understandable at an 8th grade reading level.**
* **Do not use terms such as “new”, “novel”, “medicine”, “medication” or “treatment” when referring to an investigational intervention as this may contribute to therapeutic misconception.**

**TUFTS MEDICAL CENTER
TUFTS UNIVERSITY**

**Department name**

**INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

**Title of study**

Principal Investigator:

Co-Investigators:

Study team telephone number:

## Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

[Add this paragraph when the research involves decisionally impaired persons.] A person who takes part in a research study is called a research subject. In this consent form “you” always refers to the research subject. If you are the legally authorized representative giving permission for the subject to take part in this study, please remember that “you” refers to the research subject.

[Add this paragraph when the research involves minors.] A person who takes part in a research study is called a research subject. This consent form is used to document the permission of a parent(s) or guardian(s) to allow a minor to take part in a research study. In this consent form “you” refers to the minor who will take part in the research study.

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research.]

## What should I know about a research study?

* Someone will explain this research study to you.
* Please also read all of the following information carefully.
* Whether or not you take part is up to you.
* You can choose not to take part.
* You can decide to take part and later change your mind.
* Your decision will not be held against you.
* You can ask all the questions you want before you decide. Do not sign unless you understand the information in it and have had your questions answered to your satisfaction.
* If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers, that you may wish to refer to.

## Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

## How long will the research last and what will I need to do?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

You will be asked to \_\_\_\_\_\_\_\_\_ [include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]

More detailed information about the study procedures can be found under the **“Procedures to be Followed”** section.

## Is there any way being in this study could be bad for me?

[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study]

More detailed information about the risks of this study can be found under the **“Risks”** section.

## Will being in this study help me any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]

## [Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

**PURPOSE OF STUDY**

Describe why the research study is being conducted. Explain what is investigational in the study.

State where the study will be conducted.

State the name of the sponsor (if applicable).

We expect up to [total number of subjects that can be consented] will be enrolled in this study at Tufts Medical Center/Tufts University in order to have [number of subjects needed to complete the study] complete the study. [This number should coincide with the information provided to the IRB on the Form I and protocol, as applicable.]

If a drug/device/biologic used in the study is experimental, state that it has not been approved by the U.S. Food and Drug Administration (FDA) for use in humans. If a drug/device/biologic used in a study is approved by the FDA, but is experimental as used in a study, make this point clear.

Include a statement about whether the drug/device/biologic/etc., will be available to participants after they complete participation in the study.

# PROCEDURES TO BE FOLLOWED

[Describe all the procedures to be carried out, using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* Give an estimate of the amount of time required for each study visit.
* State the expected duration of each subject’s participation and state the expected duration of the entire study (hours, days, weeks, months, years). If subjects will be followed until death, so state.
* The drugs or biologics that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient visits and telephone or written follow-up
* The length and duration of visits and procedures
* If blood will be drawn, indicate the amount [in teaspoons or tablespoons] and frequency
* If pregnancy testing will be performed, please state (specifying blood or urine pregnancy test).
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* What is being performed as part of the research study
* What is being performed as part of standard care
* What procedures are part of regular medical care that will be done even if the subject does not take part in the research
* 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.
* When applicable indicate that the subject will be contacted for future research.

[Include for a clinical trial that involves randomization. Otherwise delete.] The [drug/device/biologic/etc.] you get will be chosen by chance. Neither you nor the study doctor will choose what [drug/device/biologic/etc.] you get. You will have an [equal/one in three/etc.] chance of being given each [drug/device/biologic/etc.]. [For double-blinded research add] Neither you nor the study doctor will know which [drug/device/biologic/etc.] you are getting. [For single blinded research add] You will not be told which [drug/device/biologic/etc.] you are getting, however your study doctor will know.

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will/will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

If your study includes optional tissue banking, please provide either a separate informed consent form (ICF) OR describe the optional tissue banking in the main study ICF. Please refer to the [Worksheet – Tissue Banking](http://viceprovost.tufts.edu/HSCIRB/informed-consent/) for a list of the information that needs to be included in the optional tissue banking ICF. Please also refer to the [Tufts Health Sciences IRB Tissue Banking Policy](http://viceprovost.tufts.edu/HSCIRB/irb-regulations/guidelines-for-irb-review-of-tissue-banking-proposals/) for more information about tissue banking.

**GENETIC TESTING**

If genetic testing is being performed as part of the research, please detail:

* The clinical significance of the results, if any (based on technology, etc., now vs. at a future point in time when new test may be available, etc.)
* What will ultimately happen to the samples (discarded at the conclusion of the study, banked, etc. If banked – information about where samples will be banked, who is responsible, etc.).
* The potential risks associated with the testing, including risks to employability, insurability, learning upsetting information, etc.
* Any potential benefits (e.g., early diagnosis, no benefit, unknown benefit at this time).
* Whether or not the results will be shared with the subject and/or their personal physician.
* If applicable, information that the samples might be linked back to the subject if they are used in future research and are coded.

## WITHDRAWAL

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if [she/he] thinks it is in your best medical interest. [Also state other reasons why a subject may be withdrawn from the study.] You can also leave the research at any time it will not be held against you. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the subject, if any.]

[Include or revise as applicable to your study. This statement can be placed anywhere in the consent form:]

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. [Note: The consent document cannot give the subject the option of having data removed.] If you agree, this data will be handled the same as research data. [Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

**RISKS**

[Describe each of the following risks that may reasonably expected, if appropriate. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks]

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Omit the previous sentence if there are no known risks.] The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. [Omit the previous two sentences for research whose risk profile in pregnancy is well known.] You should not be or become pregnant [include as applicable “or father a baby”] while on this research study. If there is risk to a nursing baby, please include a statement. If birth control is required, please include a list of acceptable types of birth control. For men, clarify if they should avoid fathering a child while in the study.

If your study involves any research-related radiation exposure, please include and complete the following statement as approved by the Tufts Medical Center Radiation Safety Officer:

This study involves exposure to radiation for research purposes.  Radiation from any source, including radiation from our natural environment that we call “background radiation”, may increase our risk of cancer.  The radiation exposure from [specify procedure(s)] for research purposes in this study is approximately \_\_\_\_ [mrem / msv], which is the same amount of radiation as we receive every \_\_\_\_\_ [day(s) / months(s)] from natural background radiation.”

# RESEARCH RELATED INJURY

Based on the study, include this section as required.

Use this language when the study sponsor will pay for such injuries:

It is important that you contact a member of the study team immediately if you feel you have been injured or gotten sick because of taking part in this study. You can tell a member of the study team in person, call [PI Name] at [PI Telephone Number], or call [him or her] at the number provided on **page 1** of this document. If you are injured or become ill as a direct result of your participation in this study, you may choose to receive medical care at Tufts Medical Center or another hospital of your choice. Any required medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

If you have any injury or illness as a direct result of the proper administration of the study [drug/device/procedure, etc.] or study procedures, the study sponsor, [Name of Sponsor] will pay all reasonable and necessary medical expenses not otherwise covered by your insurance, healthcare provider, or other third party coverage, such as government programs, to treat your injury or illness provided that:

* You immediately tell [PI Name] or one of [his/her] study staff when you feel you have been injured or become sick
* You follow all of the study instructions that were given to you to the best of your understanding and ability.

Neither [Name of Sponsor] nor [Tufts Medical Center or Tufts University Health Sciences] will make arrangements to provide you any other money for injury or illness, including any payment for lost wages, disability, or discomfort that you experience in this study. [Name of Sponsor] will not pay the cost of medical care for treatment for your underlying condition, the natural progression of your disease or underlying condition, or any new illness which may develop during the study and is not directly caused by the study drug.

You have not given up any of your legal rights by signing this form.

Use this language when the sponsor will **NOT** pay for such injuries:

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

**COSTS**

Instructions for writing the Costs section:

* + - 1. If appropriate, state which study drugs/devices/biologics, tests, or procedures are provided at no cost to the subject.
			2. We recommend that investigators utilize an insurance coverage analysis of the study to ensure that billable and non-billable costs are appropriately identified. In most cases, all non-billable research costs should be covered by the study and provided at no cost to all participants.
			3. Outline any other pertinent financial impact or support.
			4. Make sure that you have committed funding for all costs identified as covered by the study.
			5. Make sure that all procedures listed as covered by the study align exactly with what is described in the protocol.
			6. You may state that there are no costs associated with participation, if true.

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your condition. This includes:

* The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
* The costs of getting the [insert name of drug/device/biologic] ready and giving it to you. [Include only if applicable to the study]
* Your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance will pay for and what it will not pay for if you decide to take part in this research study. Also, find out if you need approval from your plan before you can take part in the study.

Ask your study doctor for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

Include the following paragraph if the study includes exams, tests, and procedures done for research purposes only and paid for by the study. Change and add to the example bullets to include the exams, tests, and procedures that are covered by the study such as extra EKGs, blood tests, etc. Include the time point(s) at which each item is covered.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

* [State the exams, tests, and procedures that are covered by the study.]

You or your insurance provider will not have to pay for the [insert name of drug/device/biologic] while you take part in this study. [Include and adapt if one or more study drug/device/biologic is provided at no cost to subjects. Clearly state if study drug/device/biologic is covered for one group of subjects but not others.]

Use the following paragraph if the study might require more frequent clinic visits than the usual approach.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

* Have more travel costs.
* Need to take more time off work.
* Have other additional personal costs.

**PAYMENT**

If subjects are to be paid for their participation, state the schedule of payment, as well as the total amount to be paid, when, how, and in what format (i.e. ClinCard, check, cash, etc.) the payments will be made. If subjects will not be paid, please state that.

If the Greenphire ClinCard system will be used to pay subjects, please include the following information:

Payment will be made using a pre-paid debit card.  It works like a bank debit card.  We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts credit cards or you can use a bank machine to remove cash.  However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity.  You will receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company.  The company, Greenphire, will be given your name and social security number.  They will use this information only as part of the payment system.  Your information will not be used for any other purposes and will not be given or sold to any other company.  Greenphire will not receive any information about your health status or the study in which you are participating.

[Include the below as applicable]

Due to federal tax law, you are required to provide us your social security number in order to process your payments.  If you receive over $600 from [Tufts Medical Center or Tufts University Health Sciences] in a single calendar year (either in a single study or multiple studies), you will be issued an IRS 1099 form.  This may affect your taxes.  Only payments for being in research studies will be used to decide if you should receive the IRS form. [Only include the following sentence if such money is actually available from the study:] Money for study-related parking, food and other expenses are not included in this IRS disclosure.

# PRIVACY AND CONFIDENTIALITY

Include details about how subject privacy will be ensured.

Provide information about how confidentiality of data will be managed (e.g., coded, restricted access).

Sample language about data access:

If you decide to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities.

We will make every effort to keep your information private, but it cannot be completely guaranteed. Certain government agencies [PI to specifically identify: Office for Human Research Protections, Department of Health and Human Services, Food and Drug Administration, National Cancer Institute, the sponsor, etc. as applicable] and the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences, [specify the study sponsor or the sponsor’s designated representative, if applicable] may check records that identify you. This might include your medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include and edit if study gathers information that requires mandatory reporting (this applies to studies where the information is intentionally collected and to studies conducted by mandated reporters in a setting where abuse or neglect is directly observable, such as a home, school, day care, or nursing home); otherwise, delete this section] You should know that we are required to report information about [list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.]

[Include the below if the study is NIH funded]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose  information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

[If data will be shared (made publically available) according to NIH’s [Intramural Research Program Human Data Sharing (HDS) Policy](https://policymanual.nih.gov/3016)), include the following language:]

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the information combined from many studies to learn even more about health and disease.

If you decide to take part in this study, some of your genetic and health information will be placed into one or more scientific databases after it has been stripped of identifiers such as name, address or account number, so that it may be used for future research on any topic and shared broadly for research purposes. A researcher who wants to study the information must apply to the database and be approved. Researchers with an approved study may be able to see and use your information, along with that from many other people. We do not expect any direct benefits for you from research resulting in this sharing of your data and information.

[Include if genomic data will be shared]

When genomic data is shared, even when access is limited to approved users, confidentiality cannot be guaranteed because it may be possible to re-identify the data. De-identified data could be used to discriminate against or stigmatize you, your family or other groups to which you belong. However, state and federal laws provide some protections against genetic discrimination. If you have any questions, please ask the Principal Investigator.

You may stop participating in this study and withdraw permission for your individual data, specimens and health information to be used for additional or future research at any time. If you choose, you may request to have your [data/biological materials/interview transcript] destroyed. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

[Per NIH, consent documents must include the name and contact information of an NIH staff person to address participant questions.]

For any questions about this, please contact [Include the name and contact information of an NIH staff person to address participant questions.]

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

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.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Include the below section if HIPAA applies for your study

**AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION**

If you sign this document, you give permission to the Principal Investigator named above and research staff at [Tufts Medical Center or Tufts University Health Sciences] as well as other individuals at [Tufts Medical Center or Tufts University Health Sciences] who may need to access your information to do their jobs (such as for treatment, payment (billing) or health care operations) to use or disclose (release) your health information that identifies you for the research study described above.

The parties listed in the preceding paragraph may disclose the health information described below to the following persons and organizations for their use in connection with the research study:

* Individuals or organizations working under the direction of the Principal Investigator(s) for the study,
* Outside individuals or entities that have a need to access this information to perform activities relating to the conduct of this research, such as analysis by outside laboratories on behalf of [Tufts Medical Center or Tufts University Health Sciences]
* Other researchers and institutions that are conducting or participating in this study,
* The study sponsor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and any companies that they use to oversee, manage, or conduct the research,
* The Office for Human Research Protections in the U.S. Department of Health and Human Services, the United States Food and Drug Administration (FDA) and other federal and state agencies that have the right to use the information as required by law, and
* The members and staff of any Institutional Review Board (IRB) and Data and Safety Monitoring Board that oversee this study. Include reference to a Data and Safety Monitoring Board only if your study has a Data and Safety Monitoring Board.

The health information that we may use or disclose (release) for this research study includes all information in your medical record related to the diagnosis and management of your [condition or diagnosis subject to the research such as “cancer”], including the record of your care, as well as any information collected or created during the course of this study.

[Tufts Medical Center or Tufts University Health Sciences] is required by law to protect your health information. By signing this document, you authorize [Tufts Medical Center or Tufts University Health Sciences] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You may not be allowed to see or copy the information described on this form as long as the research is in progress, but you have a right to see and copy the information upon completion of the research in accordance with hospital policies.

Include one of the 2 following bracketed sections, as applicable:

[For research that involves **clinical care (such as an interventional drug study)** and is conducted by the covered entity or when the covered entity provides health care solely for the purpose of creating protected health information to disclose to a researcher **(such as a pharmacokinetic study in a healthy volunteer)** the following must be included]: You can decide to sign or not to sign this form. However, if you choose not to sign this form, you will not be able to take part in the research study and you may not receive any research-related clinical care.

**OR**

[For research that **does** **not involve research-related clinical care (such as an observational study)** by the covered entity or when the covered entity is not providing health care solely for the purpose of creating protected health information to disclose to a researcher]: [Tufts Medical Center or Tufts University Health Sciences] may not withhold or refuse to provide you with clinical care based on whether or not you sign this form.

This authorization does not have an expiration date. You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, this site’s clinical, administrative and research staff may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must write to: [(for Tufts Medical Center) HIPAA Privacy Officer for Research, 800 Washington Street, Box 5100, Boston, MA 02111 (for Tufts Dental School) HIPAA Privacy Officer for Research at One Kneeland Street, Room 334, Boston, MA 02111]. If you revoke this authorization, you may no longer be allowed to participate in the research described in this form.

**WHOM TO CONTACT**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert the name and phone number of the Principal Investigator in case a subject should have any problems or questions. Include both daytime and after-hours numbers. Include the name(s) and phone number(s) of other members of the research team (e.g., co-investigators). Please consider including the contact information of any Co-Investigators who interact with subjects. Include both daytime and after-hours contact information.]

If you have question about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress. This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

**Documentation of Consent**

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

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

Participant’s Signature Date Time (required for

 all [clinical trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) at

 Tufts Medical Center)

I have fully explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

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

Date Principal Investigator or Representative’s Signature

[If [Non-English Speakers](http://viceprovost.tufts.edu/HSCIRB/policies-regulations/short-form-policy/) or [subjects who cannot read, write, or have some impairment that hampers the consent process or documentation might be enrolled in this study](http://viceprovost.tufts.edu/HSCIRB/files/HRP-015_SOP-Subjects-with-impairments.pdf), please include the following Witness Signature line.]

Witness Signature:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

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

Witness’ Signature Date Time (required for

 all [clinical trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) at

 Tufts Medical Center)

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

Witness Printed Name

**---------------------------------------------------------------------------------------------------------------------**

**[Include this signature block only for parent guardian permission form for enrolling minors]**

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.

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

Parent/Legal Guardian’s Signature Date Time (required for

 all [clinical trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) at

 Tufts Medical Center)

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

Parent/Legal Guardian’s Signature Date Time (required for

 all [clinical trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) at

 Tufts Medical Center)

|  |
| --- |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. **[Delete if the IRB did not make this determination]**
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

[Add the following section if you will document assent of the subject.]

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

Child’s Assent (7 years and older)

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

I have fully explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

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

Date Principal Investigator or Representative’s Signature

**---------------------------------------------------------------------------------------------------------------------**

**[Include this signature block only when enrolling persons with impaired decision-making capacity.]**

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

Legally Authorized Representative’s Signature Date Time (required for

 all [clinical trials](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) at

 Tufts Medical Center)

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

Legally Authorized Representative’s Printed Name

[Add the following section if you will document assent of the subject.]

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

Assent

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

Check the relationship of the legally authorized representative to the subject (list is in order of recognized hierarchy):

[ ]  1. The health care agent, upon proper invocation of the health care proxy

[ ]  2. Legally appointed guardian or conservator

[ ]  3. Spouse

[ ]  4. Adult children – (majority consensus encouraged)

[ ]  5. The subject’s parent – (consensus encouraged)

[ ]  6. Adult siblings – (majority consensus encouraged)

I have fully explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the nature and purpose of the

 Legally Authorized Representative

above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

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

Printed Name of Principal Investigator or Position

Person Conducting the Informed Consent Discussion

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

Date Signature of Principal Investigator or Person Conducting Informed

 Consent Discussion