UCSF University of California San Francisco
IRB NUMBER: 17-21905
IRB APPROVAL DATE: 01/18/2022
IRB EXPIRATION DATE: 01/17/2023

TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Jean Mayer Human Nutrition Research Center on Aging

INFORMED CONSENT TO PARTICIPATE IN RESEARCH PART 2

The Effect of SLC19A3 Inhibition on the Pharmacokinetics of Thiamine

Principal Investigator: Dr. Andrew Greenberg
Metabolic Research Unit (MRU): (617) 556-3042
Study Coordinator: Kim Vo Trinh: (617) 556-3320
Ryan Piccirillo: (617) 556-3077
Study Physician, Dr. Lisa Ceglia: (617) 556-3085, days

For emergencies at any time, including days, evenings, weekends and holidays, please call (617) 230-7545 to reach Dr. Ceglia, the study physician.

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.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are a healthy individual between the ages of 18 and 65.

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?
This research study is being conducted to determine whether commonly used medicine effect the body's ability to absorb and eliminate thiamine, which is also known as vitamin B1. Investigators hope to use the information from this study to learn more about how some drugs lead to adverse reactions. Understanding the mechanisms involved in how drugs change vitamin levels may help to develop more individualized, safe drug therapies and medications that will best care for an individual's needs and reduce side effects.

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How long will the research last and what will I need to do?
We expect that you will be in this research study for 11-20 days in addition to enrollment.

You will be administered two interventions (thiamine alone and thiamine plus trimethoprim together) in a specific order depending on your group assignment. There will be two (3 day) test cycles in this study, separated by at least 5 days. You will come to the Metabolic Research Unit on 3 days (Day 0; Day 1; Day 2) during each cycle. There will be seven center visits in total including screening. On the second visit (Day 1) of each cycle you will receive vitamin or a combination of drug and vitamin orally and will be evaluated through multiple blood samples and urine collection.

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?
Risk to you should be minimal. Potential discomforts include mild side effects related to administered drugs and/or vitamins including but not limited to abdominal or stomach discomfort, decreased appetite, nausea, and diarrhea. Everyone taking part in this study will be watched carefully for any side effects that may happen. Most, if not all, side effects should disappear shortly after the drug administration is ceased. All drugs and vitamins used in this trial have been administered to healthy volunteers at the same, if not higher, doses with mild to no side effects.

There could be discomfort associated with blood draws or IV insertion, but the nurses will do everything possible to ensure the IV access point remains comfortable. There is a slight risk of bruising at the draw site.

Any other inconveniences may include traveling to the research site for study visits, eating a strict controlled diet or fasting before visits. If any of these effect your psychological, social, or physical well-being, you may ask to withdraw your consent from the study and stop participation.

Loss of confidentiality and privacy is a risk of study participation. To protect you from loss of confidentiality and privacy, only the research staff will have access to the samples and records obtained. Information from this study used for scientific publication will not contain any identifying information.

To prevent any risk to babies, embryos and/or fetuses, pregnant or nursing females will not be enrolled in the study. To ensure non-pregnant status, we will ask all females to provide a urine sample on the first day (Day 0) of each cycle. Men should also avoid fathering a child while in the study. We ask both females and males to actively use birth control including, but not limited to, condoms, IUDs, and/or oral contraceptives.

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

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Will being in this study help me in any way?
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, participating in this study will add to our knowledge about how commonly prescribed drugs such as trimethoprim affect the absorption and disposition of thiamine. While these types of studies are unlikely to offer direct benefit to you at the time of your involvement, the information gained may be used to develop new therapies and/or revise dosing guidelines to improve survival or quality of life for you or other people like you in the future.

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. 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

You are being invited to take part in this study at the Human Nutrition Research Center on Aging at Tufts University (HNRCA) evaluating the effect of drugs on vitamin B1 (thiamine) levels because you are a healthy individual between the ages of 18 and 65. Thiamine is an essential vitamin meaning you must consume thiamine in from your diet in order stay healthy. Low thiamine levels can lead to adverse events. Thiamine is absorbed in the intestine by a transporter protein. This is made by the SLC19A3 gene. The SLC19A3 gene provides instructions for making the thiamine transporter protein, which moves thiamine into cells. Certain drugs, like trimethoprim, have been shown to interrupt the function of the SLC19A3 gene.

You will be administered a single dose of thiamine during one test cycle and a single dose of thiamine plus trimethoprim during the other test cycle of this study to determine whether taking a drug with a vitamin affects your body's ability to absorb, distribute, and eliminate thiamine. The levels of thiamine in your blood and urine will be measured before and after taking thiamine or thiamine in combination with trimethoprim.

You can receive the research drugs used in this study over-the-counter (thiamine) or with a prescription (trimethoprim) at your local pharmacy. Trimethoprim is an FDA-approved anti-bacterial drug that is often prescribed to treat infections such as urinary tract infections. Thiamine is a commercially available B-vitamin that is also found in many foods including beans, nuts, and meats. Thiamine will be administered to subjects orally. Drugs and thiamine will not be available to subjects upon conclusion of this study.

We expect to screen up to 60 participants with the aim of enrolling 14 study participants in this study at Tufts Medical Center/Tufts University in order to have 12 participants complete the study.

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PROCEDURES TO BE FOLLOWED

You will be administered two interventions thiamine only and a thiamine-trimethoprim combination in a specific order depending on your group assignment. There will be two cycles in this study, each separated by at least 5 days. You will come into the clinic three times during each cycle in which you will receive vitamin or a combination of drug and vitamin orally and will be evaluated through multiple blood samples and urine collection.

If you participate in this study, you will be randomized into one of two groups and will be administered a different sequence dependent on your group assignment:

Group 1: 5mg thiamine only (Cycle 1), 5mg thiamine and 300mg trimethoprim (Cycle 2)
Group 2: 5mg thiamine and 300mg trimethoprim (Cycle 1), 5mg thiamine only (Cycle 2)

Each cycle will include 3 visits to the HNRCA for a total of 6 study visits. On the start of each of the two cycles, you will be asked to come to the HNRCA to pick-up three thiamine deficient meals. You will take these meals home and will be asked to consume these meals/snacks throughout the day prior to your Day 1 visit. You will not be permitted to eat any food or beverages other than the food provided by the Metabolic Research Unit Dietary Department. Female subjects will be asked to provide urine to ensure non-pregnant status. The day after eating the study-provided food, you will arrive to the HNRCA following an overnight fast and will receive thiamine or a combination of thiamine and trimethoprim. Blood and urine collection samples will take place throughout the day. You will be permitted to leave after your last sample collection. You will be asked to continue to collect urine at home and fast overnight. The next day, you will arrive at the Metabolic Research Unit, submit your urine collection kit, and provide one more blood sample.

Total duration of the study including time to complete 6 study visits will be approximately 11-20 days depending on when you schedule the cycle visits. You will be expected to spend approximately 1-2 hours on the first day, 12 hours on the second day, and 1 hour on the third day at the Nutrition Center for each of the two cycles.

Fourteen blood samples will be drawn per cycle. Each sample will be approximately 2 teaspoons (10mL). The total volume of blood provided over the entire study (including screening) will be approximately 315mL (about 21 tablespoons). This is well within the Red Cross guidelines of 500mL over a 56 day period.

This study will take approximately 1-2 months to complete both cycles in addition to enrollment.

Cycle Schedule (Repeat for a total of two cycles – 6 total visits)

Visit	Activities	Expected Duration
Day 0	-Consent (cycle 1 only) -Randomization (cycle 1 only) -Weight, vitals -Health/med/AE review	1-2 hrs

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	-Meet with RD -Breakfast on site (optional) -Pick-up study meals to be consumed the rest of the day (or following day) -Fast overnight for eight hours into Day 1 -Urine pregnancy test for females	
Day 1	-Vitals measured -Health/med/AE review -Baseline urine sample -Drug/vitamin administration -Blood collections, drawn from IV (0h, 0.25h, 0.5h, 1h, 1.5h, 2h, 2.5h, 3h, 3.5h, 4h, 6h, 8h, 10h) -Urine collections (0-4 h, 4-8 h, 8-10 h) -Consume study diets -Instructions for urine and fasting overnight	12 hrs
Day 1, Overnight	-Urine Collection at Home (10-24 h)	
Day 2, *24-hours post-dose*	-Arrive fasting -Weight, vitals (Cycle 3 only) -Submit urine kit -Blood collection (24-hr post-dose) -Urine collection (if necessary) -Eat a standard breakfast	1 hr
Washout (5-14 Days) between Cycle 1 and 2	-No visit required -Resume usual diet -Complete two days of food diaries	

Blood Collection

You will have a total of 28 blood samples collected for this research study. All 13 blood samples on Day 1 will be collected by carefully putting a sterile IV line into a vein in your arm by one of the licensed study nurses. Nursing staff will then draw samples off of the same IV at the time intervals listed above. On Day 2, your blood will be collected by carefully putting a small sterile needle into your vein by one of our licensed study nurses. The amount of blood collected will at most be 147.5mL (about 10 tablespoons) per cycle. Loss of 550mL is not harmful and is typically replenished by the body within two to three weeks. The total volume of blood provided over the entire study, including screening, will be approximately 315 mL (about 21 tablespoons).

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This is well within the Red Cross guidelines of 500mL over a 56 day period. These samples will then be used to measure thiamine and trimethoprim.

Urine Collection
Female volunteers will be asked to provide a urine sample on Day 0 before meal pickup to confirm non-pregnant status. You will be asked to provide a urine sample when you arrive for your Day 1 visit. You will then be asked to collect your urine output throughout the day in two- to four-hour increments. The nursing staff will provide verbal instructions on how to perform this. You will then take a clean urine collection container home with you and collect any overnight urine output. You will be asked to return the urine collection kit when you come in for your Day 2 visit. These samples will then be used to measure thiamine and trimethoprim.

Questionnaires
You will be asked to complete food diaries for this study. We will provide you two food diaries to be filled out during your washout period. You are being asked to log your food intake for two different days when you return to your usual diet between cycles. You will then be asked to return these diary entries when you come in for the next cycle's meal pickup.

Study participants will receive both study treatments (vitamin only and vitamin + drug) in a different order. The order in which participants receive the treatments will be determined by chance. Neither you nor the study doctor will choose the order in which you receive the vitamin and vitamin + drug.

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.

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 when using identifiable information/samples to tell you, or to pay you, or to give any compensation to you or your family.

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 not contact you to let you know what they have found.

OPTIONAL GENETIC TESTING

In this study, the investigators may want to look at genes involved in processing thiamine and trimethoprim and any other gene that may influence how these molecules are taken up and removed from the body. Investigators may test other related genes using your blood samples/DNA. However, no additional blood samples will be drawn for this testing. Your blood sample will be frozen and stored for future DNA analysis including but not limited to genome wide association studies. Samples will be stored at UCSF DNA Bank which is located at Rock Hall 1550 4th St. RH 515 Mission Bay Campus SF, CA 94158. In some cases, your blood cells

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may be used to establish a specific cell line that may be shared in the future with other researchers. All DNA testing will be performed using blood samples or cells coded with a unique identification number, to minimize the risk of loss of confidentiality. It is important to understand that a loss of confidentiality, if details about yourself and your DNA are inadvertently disclosed, could negatively affect your access to insurance or employment, or could have an impact upon family or social relationships. For these reason, security of your data is taken very seriously and only the research staff will have access to the samples and records, and the key to the code. Information from this study that is used for scientific publications will not contain any information that could identify you.

From these banked samples, it is possible that a cell line could be created and can therefore be grown for prolonged periods. In addition, there is the potential for future genome-wide analysis. This could potentially identify genetic conditions. If this happens, you will not be contacted with this information and no genetic counseling will be made available to you. You will not be contacted by the tissue bank or any secondary recipient of your samples to report any test results at any future point.

After the initial period of data collection, your DNA will be stored at least 10 years. We may give your specimens and certain medical information about you (for example, blood pressure, age if less than 85) to other scientists or companies not at UCSF but we will not give them your name, address, phone number, or any other information that could identify you. Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for genetic research, we will not put the results in your medical record. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances, these may have potential commercial value. You will not receive any money if this happens. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.

You can withdraw your consent to have your DNA and/or cell lines stored at any time point during or after the study by writing a letter to Dr. Kathy Giacomini (School of Pharmacy, Department of Bioengineering and Therapeutic Sciences, 1550 4th Street, Box 0446, UCSF, San Francisco, CA 94143), or by calling her directly at (415) 514-4363. If you withdraw consent to have your samples stored, any identifiable samples still in possession of the research staff will be destroyed.

You may choose not to allow your samples to be banked for future research use. Tissue banking is not a requirement for this study. This decision does not affect any future care or treatment at Tufts Medical Center or Tufts University. You will not receive any direct benefit from participation in the specimen banking component of the study. Because your tissue samples will be de identified, we will not be able to communicate the research results to you from future research studies. You will be asked to either provide your permission or decline to participate on the final page of this consent form.

WITHDRAWAL

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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 he thinks it is in your best medical interest.

You may be discontinued from any part of the study at any time if you, the investigator, or the Sponsor feels that it is not in the subject's best interest to continue. The following is a list of possible reasons for study intervention discontinuation:

- Subject withdrawal of consent
- Subject is not compliant with study procedures
- Adverse event that in the opinion of the investigator would be in the best interest of the subject to discontinue study intervention
- Sponsor request for early termination of the study
- Positive pregnancy test or self-report of new pregnancy (females)

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.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you decide to leave the research, contact the investigator, Dr. Andrew Greenberg.

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

RISKS

Risk to you should be minimal. Potential discomforts include mild side effects related to administered drugs and/or vitamins including but not limited to abdominal or stomach discomfort, decreased appetite, nausea, and diarrhea. Everyone taking part in this study will be watched carefully for any side effects that may happen. Most, if not all, side effects should disappear shortly after the drug administration is ceased. All drugs and vitamins used in this trial have been administered to healthy volunteers at the same, if not higher, doses with mild to no side effects.

There could be discomfort associated with blood draws or IV insertion, but the nurses will do everything possible to ensure the IV access point remains comfortable. There is a slight risk of bruising at the draw site.

Any other inconveniences may include traveling to the research site for study visits, eating a strict controlled diet or fasting before visits. If any of these effect your psychological, social, or physical well-being, you may ask to withdraw your consent from the study and stop participation.

Loss of confidentiality and privacy is a risk of study participation. To protect you from loss of confidentiality and privacy, only the research staff will have access to the samples and records

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obtained. Information from this study used for scientific publication will not contain any identifying information.

To prevent any risk to babies, embryos and/or fetuses, pregnant or nursing females will not be enrolled in the study. To ensure non-pregnant status, we will ask all females to provide a urine sample at the meal pickup for each cycle. Men should also avoid fathering a child while in the study. We ask both females and males to actively use birth control including, but not limited to, condoms, IUDs, and/or oral contraceptives.

RESEARCH RELATED INJURY

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

There are no costs associated with participation.

PAYMENT

You will receive a total payment of $715 for completing the full study. You will receive $300 for completing first cycle (Days 0, 1, 2) of study days; an additional $415 for completing the second cycle (Days 0, 1, 2) of study days. If you withdraw from the study before completing all study visits, you will be paid for the portion of the study you have completed at that point, outlined in the chart below:

Cycle	Day 0	Day 1	Day 2	Total
1	$50	$50	$200	$300
2	$80	$80	$255	$415
Total Payment Over All Cycles and Days				$715

The payments will be mailed to you as a check, after each study phase. You should expect to receive the check within 2-3 weeks after mailing. However, in the event of government shutdown or other emergency situations, payments will be delayed until the shutdown/emergency ends and all systems are restored at the HNRCA.

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 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. Money for study-related parking, food and other expenses are not included in this IRS disclosure.

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PRIVACY AND CONFIDENTIALITY

The records identifying your name will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. The results of the study will only be published or presented as group data. No individual participants will be identified. Data forms will be identified with a unique study number and kept locked in the study office.

The blood and urine samples you provide will be labeled with unique identifiers and transferred to the Nutritional Evaluation Laboratory at the HNRCA, as well as laboratories at University of California, San Francisco, University of California Davis, and other collaborators deemed fit by the principal investigator. Samples will be coded and de-identified and only the Principal Investigator would be authorized and able to perform re-identification.

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 (Office for Human Research Protections, Department of Health and Human Services, Food and Drug Administration, National Institute of Health) and the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences, 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.

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.

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 National Institutes of Health which is funding this project or for

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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.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document
If the results of the study are published, your identity will remain confidential.

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.

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 University Health Sciences as well as other individuals at Tufts University Health Sciences 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 University Health Sciences
- Other researchers and institutions that are conducting or participating in this study,
- The study sponsor, The National Institutes of Health, 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.

The health information that we may use or disclose (release) for this research study includes all information in your medical record including the record of your care, as well as any information collected or created during the course of this study.

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Tufts University Health Sciences is required by law to protect your health information. By signing this document, you authorize 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.

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.

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: HIPAA Privacy Officer for Research, 800 Washington Street, Box 5100, 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

Should you have any problems or questions about this research study and our screening procedures, you may contact Dr. Andrew Greenberg, the study Principal Investigator, at:

Dr. Andrew Greenberg
HNRCA
711 Washington Street
Boston, MA 02111

You could also call Dr. Greenberg at his office (617) 556-3144 during daytime (9am to 5pm) or email him at andrew.greenberg@tufts.edu

For emergencies at any time, including days, evenings, weekends and holidays, please call (617) 230-7545 to reach Dr. Ceglia, the study physician.

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.

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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

Do we have your permission to include your tissue samples in a tissue bank for future research use, after this study is complete?

☐Yes ☐No

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
