EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
Medical Research Studies

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1) To be told what the study is trying to determine.

2) To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.

4) To be told if you can expect any benefit from participating and, if so, what the benefit might be.

5) To be told the other choices you have and how they may be better or worse than being in the study.

6) To be allowed to ask any questions concerning the study, before agreeing to be involved as well as during the course of the study.

7) To be told what sort of medical treatment is available if any complications arise.

8) To refuse to participate or to change your mind about participating after the study has started. This decision will not affect your right to receive the care you would receive if you were not in the study.

9) To receive a copy of the signed and dated consent form.

10) To be free of pressure when considering whether you wish to agree to be in the study.

If you have other questions, please ask the research manager and/or study coordinator (freemanstudies@iit.edu or 312-567-5300). In addition, you may contact the Institutional Review Board (IRB), which is concerned with protecting participants in research projects. You may reach the IRB office by calling the Executive Officer, IIT IRB Phone number: 312-567-7141, e-mail: irb@iit.edu

_____ _____

Signature of Subject or Legal Representative Date

Version 5
21 Oct 2022

Subject's Initials_____

Illinois Institute of Technology, Chicago
CONSENT DOCUMENT FOR RESEARCH STUDY

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STUDY TITLE: Understanding dose related effects of strawberry intake on chronic inflammation, oxidative stress, and their relationship with endothelial function and insulin sensitivity.

INTRODUCTION

This is a research study. Your participation is voluntary. Research studies only include participants who choose to participate. As a study participant, you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is to make you better informed so that you may give or withhold your consent to participate in this research study. Please take your time to make your decision and discuss it with your family.

Low levels of inflammation in the body all the time is associated with diabetes and heart disease. Compounds in certain plant foods can help reduce inflammation and therefore reduce risk for disease. Strawberries are a food with specialized compounds with anti-inflammatory effects, but it is not clear how much strawberry people need to eat to get these benefits. Because inflammation is linked to how well our body manages glucose (blood sugar), we will also study the effects of eating strawberries on glucose control.

Therefore, this research study will test changes in blood markers of inflammation and glucose control in our body after eating 1 cup daily or 3 cups daily for 4 weeks. To clearly understand the effects of regular strawberries consumption we will have one group receive no strawberries (we call the control group). The best research always includes a control group.

The study will last approximately 4 weeks and will 4 in person clinic visits. Visits at the beginning (Week 0) and the end (Week 4) of the study period will last ~3 hours. Occasional check-in meetings will take place over the phone during the weeks you will not be coming to the CNR.

Strawberries are provided by the California Strawberry Commission and are conventionally grown strawberries comprised of varieties grown in California.

WHY IS THIS STUDY BEING DONE?

To determine if eating strawberries daily will influence your health, specifically by testing effects on inflammation and glucose control; and to determine if the amount of strawberries (1 cup or 3 cups) eaten per day makes a difference. Another words, is more better? Or, is less better?

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Sixty-six non-smoking, men and women will take part in this study. This study will use competitive enrollment. This means that when the full number of subjects begins the study, further enrollments will be closed. Therefore, it is possible that you could complete the screening phase, but not continue in the study if the target number of subjects has already been enrolled.

WHO ARE QUALIFIED FOR THIS STUDY?

To be qualified in this study, there are certain eligibility criteria you must meet. Although you may meet all eligibility criteria, there are some exclusionary criteria that will automatically disqualify you from participating in this specific study. The inclusionary and exclusionary criteria include the following:

Inclusionary (Must meet all to participate)	Exclusionary (not qualified if meet *any)*
✓ Men or women, 20-60 years of age ✓ High sensitivity C-Reactive Protein (hs-CRP), a global marker of inflammation, >1.0 and ⩽ 10 ng/L ✓ BMI ≥ 25 kg/m^2 ✓ Nonsmokers (Past smokers can be allowed if they have abstinence for minimum of 1 years). Occasional smoker may be allowed at investigator discretion ✓ Judged to be in good health on the basis of the medical history ie., no clinical evidence of cardiovascular, metabolic, respiratory, renal, gastrointestinal or hepatic disease ✓ Not taking any medications that would interfere with outcomes of the study, i.e. lipid lowering medications, anti-inflammatory drugs, dietary supplements, etc. ✓ Able to provide informed consent ✓ Able to comply and perform the procedures requested by the protocol (including dietary restrictions, consumption of study treatments, records of food diary and study visit schedule)	✓ Men and women who smoke regularly ✓ Men and women with known or suspected intolerance, allergies or hypersensitivity to study foods or treatments ✓ Men and women who have blood pressure >160 mmHg (systolic)/100 mmHg (diastolic) at screening visit ✓ Men and women who have fasting blood glucose concentration >125 mg/dL at screening visit ✓ Men and women with documented vascular disease, e.g., heart failure, myocardial infarction, stroke, angina, related surgeries, etc. that, in the opinion of the investigator, could interfere with the interpretation of the study results ✓ Men and women with cancer other than non-melanoma skin cancer in previous 5 years ✓ Men and women diagnosed with chronic constipation, diarrhea or other chronic gastrointestinal complaint (e.g. irritable bowel syndrome) ✓ Women who are known to be pregnant or who are intending to become pregnant over the course of the study ✓ Women who are lactating

✓ Able to maintain usual physical activity pattern ✓ Able to abstain from alcohol consumption and avoid vigorous physical activity for 24 hours prior to and during study visit	✓ Taking medication or dietary supplements that may interfere with the outcomes of the study; e.g., antioxidant supplement, anti-inflammation, lipid lowering medication, blood pressure lowering medication, etc... Subjects may choose to go off dietary supplements (requires 30-day washout); e.g., fish oil, probiotics, etc... ✓ Men and women who has participated in prebiotics or laxative trial within 3 months prior to enrollment or any other clinical trial within 1 month ✓ Major trauma or a surgical event within 2 months or longer depending on trauma or event and after consultation with PI. ✓ Vegan or other extreme dietary regimens (e.g., Atkins diet, etc.) as judged by the investigator. ✓ Has a known intolerance or sensitivity to any ingredients in the study products ✓ Has used antibiotics within the previous 2 months ✓ History of an eating disorder (e.g., anorexia nervosa, bulimia nervosa, or binge eating) diagnosed by a health professional ✓ Substance (alcohol or drug) abuse within the last 2 years ✓ Excessive coffee and tea consumers (> 4 cups/d) ✓ Donated blood within last 3 months ✓ Men and women who do excessive exercise regularly or are an athlete ✓ Unstable weight: gained or lost weight +/- 5 kg (11 lbs) in previous 2 months ✓ Women who are taking unstable dose and brand of hormonal contraceptives and/or stable dose and brand less than 6 months ✓ Unusual working hours i.e., working overnight (e.g. 3rd shift)

BEFORE YOU BEGIN THE STUDY

If you decide to volunteer, you will be assessed to find out if you meet the criteria for participating. You will be asked to come to our clinic (the CNR) on the IIT Campus, Chicago, IL, where the study will take place. This Screening visit will take ~ 1-1.5 hours.

Determining if you are eligible to participate. You will be asked to arrive at the CNR fasting for 10-12 hours, which means no food or drink other than plain water for 10-12 hours. We will measure your height, weight, waist circumference and body composition, and take your ear temperature, blood pressure and heart rate.

We will calculate a number from your height and weight called Body Mass Index (BMI). BMI is an estimate of body fat based on height and weight that applies to both adult men and women. For women under the age of 60 years, you will be asked to complete a pregnancy test.

We will check your blood sugar by a finger prick blood drop. We will collect 3 milliliters (mL) blood on your arm by butterfly needle to determine hs-CRP (high sensitivity C-Reactive Protein) which is a marker in your blood that tells about inflammation in your body.

We will measure your blood pressure and heart rate. You will be seated in a comfortable chair with legs uncrossed and relax for 5 minutes before we measure your blood pressure and heart rate. Your arm veins will also be assessed using a vein access scale test.

You will be asked to complete a questionnaire related to your health, dietary habits, and physical activity history online at home. Personal information, such as your name, date of birth, race, etc. will be asked. Additionally, questions about your medical history, and medications you take will also be asked.

All these procedures will be reviewed for meeting eligibility criteria. Eligible adults will be invited to participate in the study. Even if you do not meet eligibility criteria for this study you will be notified, and may be eligible for another study in our clinic.

You will have the opportunity to meet with one of the Investigators who will answer any questions you may have about the study and your participation.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?
If you decide to participate in this study, you will be asked to do the items described below

Diet and Medication restrictions: There may be a few foods we ask you to limit, such as NOT eating all other berries. We will want you to eat only the berries we give you so we can understand how they work in the human body. Our main request is that you do not alter your normal dietary patterns. However, there are a few items we ask that you do NOT consume while on the study because they could interfere with results of understanding what the strawberries do for you. We are happy to help you determine the sorts of foods or supplements you might want to take or not take to ensure they are OK for the study.

In general, please do not start anything new while in the study. If you must, please let us know right away. Certain medications can be taken, but we ask you do NOT take them within 48 hours of your study visit. If you are uncertain, please email or call us to be sure whatever you are thinking about taking is OK for the study.

You will be asked NOT to eat all types of berry products, such as strawberries, cranberries, blueberries, blackberries, boysenberries, raspberries, cloudberries, marion berries, jellies, jams, berry juices, red wines and other products made from berries during the study. We will also give you a list of foods to avoid for 3 days prior to each Study Day. You will be coached on what foods in your diet are rich in the components typically found in berries, red wine, tea, coffee, and dark chocolates (milk and white chocolate are OK) and will be provided with alternate options to avoid these component-containing foods.

We will ask you to avoid drinking any type of alcohol or caffeinated beverages and avoid vigorous physical activity for 24 hours prior to the study visit. Alternative beverages will be suggested except in the case of alcohol or caffeinated drinks, in which we need you to NOT drink alcohol or caffeine within 24 h of a visit (coffee or cola the day before up until noon time ok).

The reason for this is because all of them can alter metabolism of sugars and fats in your body, which we are also studying. Vigorous exercise can cause a short term increase in inflammation markers, which we are also studying. So these activities could interfere with our test results.

Food Intake: You will be trained to record food intake on a food diary.

STUDY DAY VISITS AND TREATMENT PERIOD

Before each study day visit

The day before each Study Day, you will read the instructions for "How to prepare for your study day".

This will include instructions for eating a repeatable dinner meal, recording a 24-h food recall, fasting overnight (at least 10 h overnight fasting – which is what most people do anyway), avoid vigorous physical activity and alcoholic beverages for the 24 h preceding a study day, aim for at least 7 hours of sleep and maintain normal diet except for the guidance provided for "Foods and beverages to AVOID or limit". If you did not get your usual amount of sleep during the two nights preceding a study day, please let us know and it will be best for us to reschedule your visit.

Continuous Glucose Monitor (CGM): Two days before Visit 1 (Day -2 ± 1, WK 0) and at Visit 2 (Day 21 ± 2, WK 3), you will have a continuous glucose monitor (CGM) inserted just under the skin by a licensed health care professional or trained CNR staff member. The CGM device is FDA approved. The CGM will be worn for 7-10 days following the time of insertion. The CGM will be removed by a licensed health care professional or CNR staff member at the Week 1 and Week 4 visits.

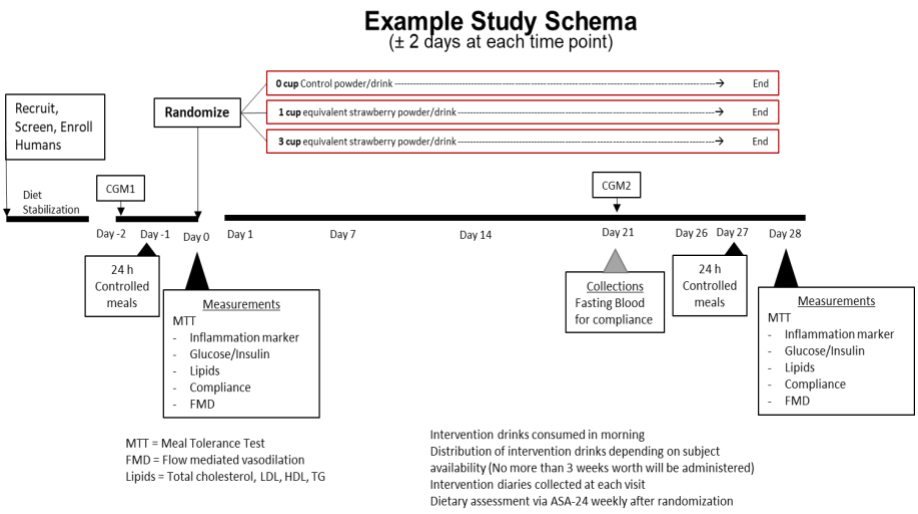
Dinner: You will have two dinner options: pick-up a Subway or Jimmy John's sandwich (reimbursed) or prepare your own dinner. We ask that whichever option you chose, you keep it consistent throughout the study. If you chose to have a Subway or Jimmy John's sandwich the day before your study visit, we will ask that you bring in your receipt for reimbursement.

24 h Food Recall: You will record what and how much you eat and drink all day from when you wake up until you go to sleep each week over the course of the study.

Fasting overnight: At least 10 hours before each study day visit, you will start fasting overnight, which means no food or drink other than plain water for at least 10 hours. Please drink plenty of water the day before and on your way to the clinic.

The procedures of each study day visit

The following procedures will be conducted during this study (Table 1). Every effort will be made to ensure your safety while participating in this study.



Confirmation you are ready to go for a study day visit: We will confirm that you have fasted overnight (like you would do for any doctor visit), consumed your dinner meal, avoided the food items requested by the study staff, had enough sleep and that dietary and exercise patterns are consistent with the study procedures as described above (we will have forms for you to complete, which we will go over together). This will include interview/discussion with study staff and a simple finger prick for measuring fasting blood glucose. After confirming your study day compliance to the study instructions, we will proceed to an exam room to collect your anthropometric measurements as well as check your vital signs (blood pressure, heart rate and ear temperature).

Anthropometrics: We will measure your height as well as weight and waist circumference at each study day visit. You will be asked to wear light comfortable clothing when coming to the screening and study related visits. We will have a light robe to change into for these measurements if preferred.

Vital signs: We will check your blood pressure, heart rate and your body temperature at each study day visit.

Blood collection and Meal Tolerance Test (MTT) [Fig. 2]: After a fasting blood draw is collected, you will participate in a meal tolerance test (MTT). You will be asked to consume a liquid meal containing a mixture of macronutrients (carbohydrates, protein and fat). A Licensed Health Care Professional (LHCP) will insert a catheter into your arm to obtain blood samples. As shown in Figure 2, blood will be collected at t = -10, -5, 15, 30, 60, 90, 120, 180, 240 ± 1 min (9 blood draws). To keep the catheter flowing, normal saline solution will be used to flush the catheter after each blood draw. Should the catheter fail (that is blood won't flow out), blood samples will be drawn by butterfly needles.

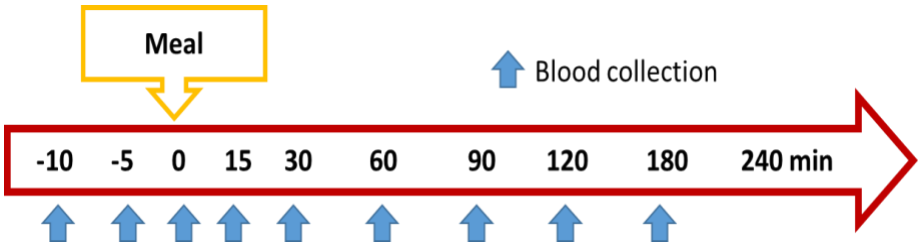


Figure 2. Meal Tolerance Test Schedule

The MTT will be conducted 2 times at about the same time of day (± 30 min) at Visit 1 (WK 0) and Visit 3 (WK 4). The total amount of blood collected in this study will be ~ 130 mL and will be less than the

amount of blood you would give during a single blood donation (~550mL). Blood will be processed to analyze blood sugar and insulin levels, inflammation and metabolic markers of disease risk.

Flow Mediated Dilation (FMD): This procedure is a non-invasive (no needles or poking) technique to measure the size of your blood arteries and blood flow using ultrasound technology. The procedure involves placing a blood pressure cuff on your arm and inflating it and deflating it similar to the way you would have your blood pressure checked. It will be done on the arm not used to draw blood. We will then use an ultrasound machine to measure how your arm artery reacts to the pressure. This procedure takes less than half an hour to perform and you will be asked to remain still while the procedure is underway.

At the end of the study day: After you are done with all blood collections, you will be evaluated for safety and/or discomfort/symptoms before leaving the study site. You will be asked to complete a 24h food recall online at home after the study visit. You will be given a take-home snack, your compensation and be discharged.

Test Strawberry Treatment: At the end of Visit 1 (WK 0), you will be provided with one of the study test beverages to incorporate into your daily meals. The beverages that you receive will depend on the intervention that you are randomly assigned. Randomization means that you are selected into one of three groups by chance. You will be given beverages at your first visit. Additional beverage pick-ups will be based on your availability, but you will be given no more than 3 weeks' worth. You will be asked to consume the beverages every day (7 days a week). We understand that you may miss a day now and then so there is some flexibility, but we ask that you try to consume the study foods 7 days a week. You will receive counseling on foods and drinks that you should avoid during the study.

Table 1 below provides a summary of all procedures conducted at each visit.

Activity	SCR Visit	1-week wash-in		Treatment Period			
			CGM1	Visit 1	CGM1 Removal	Visit 2 + CGM2	Visit 3
			(Day -2)	Week 0	Week 1	Week 3	Week 4
Written informed consent	x						
Demographics, Medical History	x						
Inclusion / Exclusion criteria	x						
Vital signs, anthropometrics	x			x		x	x
Training for study day	x						
Insertion of Continuous Glucose Monitor (CGM)			x			x	
Removal of CGM					x		x
Daily food diary				x		x	x
Randomization				x			
Purchased dinner meal night before Visits[#]				x		x	x
Meal Tolerance Test (MTT) ~4 hr				x			x
Blood Collection	x			x		x	x
Flow Mediated Dilation (FMD)				x		x	x
Study Treatment Pick-up				x	x	x	x
Adverse Events Assessment				x		x	x
Take-Home Snack	x			x		x	x
Subject Compensation	$10*		$20*	$90*	N/A	$90*	$130*
Public Transportation	x		x	x	x	x	x

*Compensation will be issued after completion of each Study Day Visit and compliance with protocol.
[#]Upon submitting a receipt of purchasing the dinner meal at the same sandwich shop, you will receive an additional $10 for each dinner meal for each Study Visit in the form of a Visa Debit Card after completion of all procedures at each visit.

RISKS

Being a subject in this study may have some added risk or discomfort. The concerns are as follows:

- We will ask you to adhere to your usual diet and exercise patterns throughout the study and may find this challenging and frustrating at times.
- You may be asked to consume test beverages for which you do not have a taste preference. In order to minimize the discomfort, we may provide a picture of the representative sample of the beverage and general information of ingredients. All study treatments are commercially available in local markets.
- You may experience discomfort due to fasting overnight and refraining from alcohol for 24 hours prior the study visit. All efforts will be made to accommodate your visit day preference to allow for the optimal time for an overnight and caffeine free fasting.
- There is a chance that you may feel light-headed, woozy, or the slight risk of fainting during or after blood collection. We will ask you about history and/or problems with blood, needles, or fainting or passing out for any reason. This information is also asked and collected during the initial pre-screening visit. Also, water intake during the course of the study should continue as advised. You will also advise to aim for at least 7 hours of sleep the night before the Study Day Visits. If you did not get enough sleep, the test visit will be rescheduled.
- There are some possible side effects and adverse effects after a blood draw. These include bruising, nerve damage, thrombophlebitis, syncope, vasovagal effects and infections. Infections from placing needles into veins for blood samples rarely occur, however, it is a risk. Proper sterile collection techniques will be used to minimize these risks.
- Female participants below 60 years of age will be tested for pregnancy at the first visit to make sure that participant is not pregnant at the beginning of the study. However, if you are pregnant or think that you could be pregnant, please inform the investigator. Pregnant participants should not participate in this study. Women who are breastfeeding will also not be allowed to participate in this study. This study does not pose risk to pregnant or breastfeeding woman, but multiple physiological systems such as metabolism are altered in these conditions and may change our results and their interpretation relative to our study outcomes. Please avoid getting pregnant during the course of this study. Non-hormonal methods for birth control are encouraged. If you become pregnant during the course of the study, please notify study staff immediately. Pregnancy will require dismissal from the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not personally benefit from participating in this study. This study is beneficial to understand the effects of regular consumption of strawberries on inflammation, glucose control and blood vessel flexibility. The information will help the scientific community and doctors to make recommendations in the future about fruit intake. The information will also be used by the sponsor (the California Strawberry Commission) to inform farmers and consumers about what strawberries do in the human body when consumed. This may or may not help them sell more strawberries. Regardless of the study results (positive or negative for strawberries), the data are intended to be published in a public scientific journal. You will NOT be identified. We will inform you of the results, if you are interested when they become available.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?
Your alternative is not to take part in this study. If you choose not to take part in this study, your relationship as a student or employee or any other affiliations with IIT will not be affected.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?
We will do our best to make sure that the personal information in your medical record will be kept private. However, a representative of sponsor may observe the study procedures at one or more study visits to ensure the procedures of the study are followed as planned. Your personal information may be given out if required by law. Your information will be limited to those directly involved with the research and a monitor designated by the Sponsor. If information from the study is published or presented at scientific meetings, your name and other personal information will not be used. All your personal information will be kept in a secure place and only relevant information will be transferred to computers for analysis. The latter will be coded.

WHAT HAPPENS IF I AM INJURED AS A DIRECT RESULT OF MY PARTICIPATION IN THIS STUDY?
If you are injured as the direct result of IIT's negligence in the performance of these research procedures, you will receive reasonably necessary medical treatment at no cost. Illinois Institute of Technology does not provide any other form of compensation for injury.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor.

WILL I BE COMPENSATED FOR BEING IN THIS STUDY?
For your participation in the study, you will be paid a total of $340 in the form of a cash gift card: $10 for the screening visit, $20 for CGM1, $90 for Visit 1, $90 for Visit 2 and CGM2, and $130 for Visit 3 (not including transportation). After completion of each study visit and food records, we will complete paper work indicating your participation and we will process the cash gift card. You will be provided with an IIT parking pass or an additional $10 cash gift card to cover your transportation costs during all visits to the CNRC. This gift card is a NON-REPLACABLE cash gift card. You will be responsible for the loss of the gift card in the situation of damage, stolen, lost, etc. If you drop out of the study early or are dismissed for any reason from the study early, you will only be eligible for compensation based on the time you have participated in the study. The amount you will be compensated for each Study Day visit is listed in Table 1.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time without penalty or loss of benefits otherwise entitled. No matter what decision you make, there will be no penalty to you. We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study. The researchers reserve the right to dismiss subjects who are not compliant with the protocol, who become pregnant during the study, who may develop health risks

during the study (as assessed and explained by their physician or by study investigators), or who are disruptive to other study participants or research staff at any time without further explanation.
The investigator may withdraw you from this research if circumstances arise which warrant doing so: you are unable to comply with study procedures or a change in your health status would significantly impact the outcomes of the study

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?
The investigator and research staff have no financial interest related to the outcomes of this study. Researchers do receive gift funds from various organizations to do research.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have questions, please ask us. You can talk to the Investigator about any questions or concerns you have about this study at:

Indika Edirisinghe Ph.D. at phone number 708-308-0178 (24 h number), iedirisi@iit.edu or 312-567-5300, freemanstudies@iit.edu.

As a participant in this study, you may contact study personnel, the IRB or Investigator for any concerns or questions at any time. If you are experiencing symptoms or a reaction you feel is a medical emergency, seek medical attention as you see appropriate. You are not required to call the Principal Investigator before seeking medical attention. You should handle any medical emergency while in the study in the same way that you would if you were not on study. Use your own judgment to seek medical attention and do not wait for any form of approval. If the medical emergency is determined to be due to IIT's negligence, you will be reimbursed for reasonably necessary medical treatment.
For questions about your rights while taking part in this study call the IRB Administration at (312) 567-7141 or E-mail to irb@iit.edu or write to the Executive Officer, Illinois Institute of Technology 10 W. 35th St., 7D7-1, Chicago, IL 60616. The IRB Executive Officer will inform the Institutional Review Board which is a group of people who review the research to protect your rights.
Affirmation of Participant
I understand the Illinois Institute of Technology is not responsible for any injuries or medical conditions I may suffer during the time I am a research subject unless those injuries or medical conditions are due to IIT's negligence. I have received a copy of this consent form.

_____	_____	_____
Signature of Subject or Legal Representative	Date	Time

_____	_____	_____
Signature of Investigator	Date	Time

Version 5
21 Oct 2022

Subject's Initials_____