Study ID #: HSM#16-00407/GCO# 16-1050 **Form Version Date: 1/20/2016**

HRP-502a-MSHS TEMPLATE CONSENT DOCUMENT-ADULT 1.20.16.doc

TITLE OF RESEARCH STUDY:

Title: **Multi-level supermarket discounts of fruits and vegetables' impact on intake and health.**

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Dr. Allan Geliebter

Physical Address: Mt Sinai St. Luke's Hospital 1111 Amsterdam Avenue, BSRU, S&R 11th Fl., New York, NY 10025

Mailing Address: Mt Sinai St. Luke's Hospital 1111 Amsterdam Avenue, BSRU, S&R 11th Fl., New York, NY 10025

Phone: 212-523-4574

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to estimate how the price of fruits, vegetables, and calorie-free beverages influences food purchases, eating patterns, body weight, and overall health.

You may qualify to take part in this research study if you are between the ages of 18 and 70, have a body mass index (BMI) of 24.5 – 50 kg/m^2, have been weight stable ± 5% in the past 3 months, do not have any serious medical conditions, are not pregnant or planning to become pregnant during the study period, have identified yourself as the primary shopper in your household, currently shop for at least 30% of your total groceries at a single Allegiance affiliated supermarket, and agree to do 100% of food shopping at a single designated Allegiance affiliated supermarket during the study. You also should not eat out/order take out more than 5 times per week or travel out of town for more than 6 weeks total or 4 consecutive weeks during the study. In addition, you should not be actively participating in a weight loss program or be enrolled in another research study.

Funds for conducting this research are provided by the National Institutes of Health (NIH).

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last 56 weeks (13 months). After an initial consultation/screening visit, there will be 5 additional visits, 2 months apart between the first two visits and 4 months apart for the rest of the visits. All visits will last 60 minutes.

The number of people expected to take part in this research study at Mount Sinai, St. Luke's Hospital is 300.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

We may recruit you for the study in the Allegiance affiliated supermarket where you shop or over the phone when you call us in response to an advertisement you have seen. We will ask you some questions to see if you may qualify to be in the study.

If you qualify after the initial in-store/phone screening, we will ask that you come to Mount Sinai St. Luke's Hospital to complete a secondary medical screening visit to determine if you qualify for the study. Prior to this visit, you will need to fast overnight for 12 hours. During this period, you will be asked not to eat food or drink any caloric beverages. All participants will be asked to provide a urine sample for drug testing.

At this visit you will be asked to provide a detailed medical history and have your body temperature, weight height and body composition taken, to determine if you qualify. We may then ask you to complete questionnaires related to your household size and health habits. We may also ask you questions related to drug, alcohol use, depression, and suicide. For example, we will ask you about how many glasses of beer, wine, or hard liquor you drink per day/week/month; in addition, we may ask you about whether you are experiencing feelings of depression or having thoughts about suicide. If you let us know that you have recently had thoughts about suicide we are obligated to refer you to appropriate services within the Mount Sinai network and follow-up with you to ensure you see a licensed provider in a timely manner. We will ask you these questions to determine if this study is a good fit for you. You do not have to answer any questions that make you feel uncomfortable.

If you are female and under 55 years of age, a urine sample pregnancy test will be done before you begin the study (at Screening Visit).

Next, we will measure your blood pressure, and complete a blood test, where we will collect two small tubes of blood. The total amount of blood drawn is less than 1 tablespoon (0.6 tablespoons). From these blood samples, we may obtain your blood sugar concentration, blood lipid values, hemoglobin A1c /protein bound glucose (reflects long-term blood sugar), C-reactive protein (CRP), electrolytes, and liver function. We will also collect a urine sample for drug testing. We will send your samples to Quest Diagnostics for analysis. You have the option of using your real name or a pseudonym.

Some blood samples will be sent for vitamin analysis to Jean Mayer USDA Human Nutrition Research Center. The samples can be labeled in one of two different ways: one way will send your specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will send your specimens anonymously (Tufts will not know who the information is from). It will not be sent both ways, so you must choose one of these two options. Please note that if you choose to have your specimens sent anonymously, you will not be able to change your mind.

(1) Do you give the researchers permission to **contact you** in the future to collect additional information about you, or to discuss possible participation in another research project? Please initial your choice:

Yes_____ No_____

(2) Do you give permission for your PCP to be contacted if any information in your lab results are concerning?

Yes_____ No_____ PCP Name:_____ Phone #:_____

If you qualify based on the screening visit, an account will be created for you through BagIQ, which will keep track of your purchases throughout the study. You will be asked to turn in your current Allegiance affiliated supermarket reward card at your first study visit in exchange for a new card.

This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: **3/8/2019** **DO NOT SIGN AFTER THIS DATE →** **10/20/2019**

At your first study visit, you will be asked to come in after fasting for 12 hours (avoiding food and caloric beverages) and repeat the body temperature measurement, blood pressure and blood work. In addition to your weight, we will also estimate your body composition with a Tanita scale. You will be asked to stand barefoot for one minute on the scale while an imperceptible current (you will not feel this) is transmitted through your legs to measure electrical resistance.

During the visit, we will ask you to complete five questionnaires that include information about income, smoking, diet, food likes, medications, and physical activity. You will also be instructed on how to complete a 24-hour dietary recall, and how to estimate the portion sizes of foods. We will also conduct a 7 day physical activity recall. You will also complete a Food Frequency Questionnaire on-site.

At the end of this visit, you will receive, in paper and e-mail format a summary of the foods and non-caloric beverages available for discount during the study, as well as a list of conditions that must be met to participate in the study. You will be asked to shop for all (100%) of your food at the designated Allegiance affiliated supermarket, using the new reward card. We will ask you to complete three unannounced 24-hour recalls over the phone once, or every 2 months, during the baseline period, and twice, or every 4 months during the intervention period. An International Physical Activity Questionnaire-Short Form (IPAQ-SF), will be administered on one of the three 24-hour recall phone sessions. Lastly, you will receive an individualized timetable for future study visits.

Once the account has been created and your new card has been issued, you can begin the study with the tracking of your shopping to start at a designated date. You will shop at one of the Allegiance affiliated supermarkets included in this study with your new reward card for the first 2 months. Just prior to month 2 (Visit 2) you will be randomized into 1 of 3 discount level groups (0%, 15%, or 30%) on selected fruits and vegetables and non-caloric beverages. The discount groups will receive their discounts during month 2 through 10. Should you by chance fall into the group with 0% discounts, you will have the opportunity to shop with a 30% discount for 4 months after the study is over from month 14 to month 18. If, during the discount period, you are shopping at your designated Allegiance affiliated supermarket and do not receive the discount you expected, you should save your receipt(s) from your shopping trip(s) to bring in at your next hospital visit. If you have any issues obtaining your assigned discount during this time, please present the issue to us for reimbursement. Store staff and/or managers should not be contacted regarding study issues.

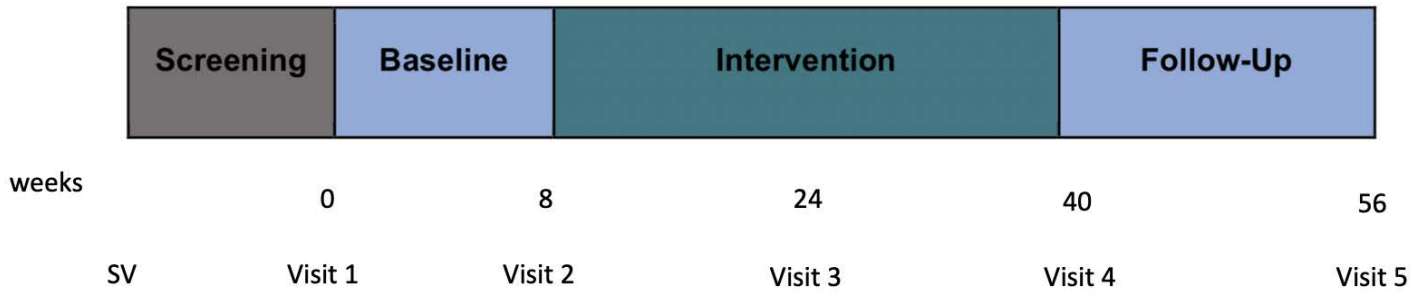
At weeks 8, 24, 40 and 56 (Study Visits 2-5, *see diagram below)*, you will be asked to fast overnight for 12 hours and to return to the hospital to complete body composition, blood pressure, body temperature measurement and bloodwork. In total, over the entire study period, approx. 3.6 tablespoons of blood will be collected for blood work.

Three days prior to those visits we will email you two questionnaires to be completed online in advance of the visit and you will have to complete two additional questionnaires in person during the visits.

At every visit you will again be asked to complete five questionnaires on-site and will receive, in paper and e-mail format, a summary of the foods and non-caloric beverages available for discount during the study, as well as a list of conditions that must be met to remain in the study. In addition, at each visit, you will be asked to show us the designated Allegiance affiliated supermarket tag provided to you for use in the study. You will also be reminded that you will receive three unannounced 24-hour recalls and one International Physical Activity Questionnaire, over the phone during subsequent weeks.

At Study Visit 2 (Week 8) and Study Visit 4 (Week 40), the blood samples collected will also be used to obtain your carotenoid and vitamin C levels, which reflect fruit and vegetable intake. If you are taking vitamin A or C supplements, you will not be tested for these variables. The total amount of blood drawn for these measures will be slightly more than the screening visit (but still less than one tablespoon). At Study Visit 5 (Week 56), you will be asked to complete an exit interview, receive information about the study (debriefing) and nutritional guidance.

Research Study Timeline



You will be responsible for attending all hospital visits. If you miss a study visit, you will be provided one opportunity to reschedule within 1 week of your original appointment. If the rescheduled visit is missed, you will be withdrawn from the study and the discount card will be deactivated.

The study discount condition you receive will be chosen by chance, like pulling names out of a hat. Neither you nor the study doctor will choose what condition you receive. You will have an equal chance of being in each of

the discount groups. You will be made aware of which study treatment you are receiving just after Visit 2 (Week 8) of the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: You will be asked to turn in your old Allegiance affiliated supermarket rewards scan card. You will then be given a new scan card, which will automatically provide you with discounts and record your shopping patterns. You will be asked to shop as you normally would, using this scan card every time you shop. If, during the discount period, you are shopping at your designated Allegiance affiliated supermarket and do not receive the discount you expected, you should save your receipt(s) from your shopping trip(s) to bring in at your next hospital visit. You may not lend anyone else your scan card for shopping or use your card to shop for anyone else outside your household. Violations will lead to withdrawal from the study. You may not take trips or vacations that will exceed 6 weeks total or 4 consecutive weeks or participate in another research study at the same time. You will be responsible for adhering to doing 100% of your food shopping at the selected Allegiance affiliated supermarket for the entire study. You will be responsible for attending all hospital visits. If you miss a study visit, you will be provided one opportunity to reschedule within 1 week of your original appointment. If the rescheduled visit is missed, you will be withdrawn from the study, and the discount card will be deactivated.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you **up to $575** for your time and effort. You will be compensated with a mailed check of $50 for the screening visit and $85 for each subsequent study visit and a $100 bonus for study completion, for a possible total of $575. You will also be mailed a check reimbursing you for metro travel expenses to and from the hospital (projected value: $5.50 round trip). If your travel by public transportation would exceed 30 min, you will receive check reimbursements for taxis. Proof of travel expenses, such as receipts, will be required. These incentives will repay you for your travel and time spent at the hospital.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. However, possible benefits may include improvement in eating habits and health status.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The risks involved in this study are minor and include:

- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Risk of feeling uncomfortable being asked questions about drug and alcohol use and depression. If you feel anxious while completing some of the study tasks, please let the research staff know. If necessary, you will be referred by the principal investigator and clinical psychologist, Dr. Geliebter, for further evaluation and treatment.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number (212) 523-4574.

If you experience an emergency during your participation in this research, call 911 or go to the emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the appropriate person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014, Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk with your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, data directly related to you (e.g., birth date), email, social security number, medical records, health plan numbers, biometric identifiers, biological specimens, and photographic images.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Obtaining blood pressure, body composition, and biomarker data (bloodsamples)
- Completing the procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. *If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside of Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: **Quest Diagnostics or hospital laboratory.**
- Your **PCP**. If your lab results are at all concerning, your PCP will be contacted and he/she will receive a copy of your lab results for further follow-up.
- Bag IQ, the company that is tracking your Allegiance affiliated supermarket purchases (name and date of birth)
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: **National Institute of Health (NIH)**
- The United States Department of Health and Human Services and the Office of Human Research Protection
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety

In all disclosures outside of Mount Sinai, BagIQ and Allegiance Corporate you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers.

Additionally, when applicable, the monitors, auditors, the IRB, *the Office for Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page.

Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside of Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai

has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE →	**10/20/2019**

Signature of subject	Date
Printed name of subject	Time

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: **3/8/2019** **DO NOT SIGN AFTER THIS DATE →** **10/20/2019**

Witness Section: For use when a witness is required to observe the consent process, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

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.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time

This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: **3/8/2019** **DO NOT SIGN AFTER THIS DATE →** **10/20/2019**