Hebrew SeniorLife
Research Consent Form **Study Participant ID: _____**

Study title: The effect of sodium reduction on blood pressure and physical function in older adults

Principal Investigator: Shivani Sahni, PhD
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Co-Investigators: Stephen P. Juraschek, MD, PhD, Lewis A. Lipsitz, MD, Kenneth J. Mukamal, MD, MPH, MA, Roger B. Davis, DSc and Ginny McNally, RD

Version Date: 9.27.19

Concise Summary of Key Information

This study is being conducted to determine the impact of sodium reduction on blood pressure (BP) and physical function in residents of Jack Satter House. Study participation will include a prescreening phone call and 6 study visits. If you are interested in participating after speaking with our coordinator at the prescreening call, you will be scheduled for a screening visit, which will determine your eligibility. At the next visit you will be assigned to one of two meal plans. Each day for a two-week period, you will receive three meals and two snacks. The meals can be delivered to your residence, or picked up. You will be expected to eat all the meals provided by this study and avoid eating outside meals or your own foods for a period of two weeks. If you feel the size of your meal is too large or too small we will adjust the size. During the study visits, we will review your medication history, measure your blood pressure (seated, laying down and standing), height and weight, and test your ability to stand and walk a short distance. We will collect demographic information and will ask questions related to physical activity, dietary intake, taste of meals provided by the study, and health symptoms such as headache, light-headedness, dizziness, and fatigue. We will also collect a urine sample to measure the sodium, potassium, and creatinine level of your urine at the beginning and end of the study. Results from this study will be shared with you at the end of the study. Your identity will be kept confidential. Participants will receive a $40 gift card at the end of their participation in this study.

About this Consent Form

Please read this form carefully. This form provides important information about participating in a research study. As a research participant, you have the right to take your time in making decisions about participating in this research and you are encouraged to discuss your decision with your family and your doctor. If you have any questions about the research or any part of this form, please ask us. If you decide to take part in this research, you will be asked to sign this form, and a copy will be provided for you.

What you should know about a Research Study

Participation in research is voluntary, which means that it is something for which you volunteer. It is your choice to participate in the study, or to decline participation. If you

choose to participate now, you may change your mind and stop participating at a later date. Refusal to participate or withdrawal of participation will not result in any penalty or loss of benefits to which you are otherwise entitled.

Study Funding and Disclosure of any Special Interests

This study is being conducted by Dr. Shivani Sahni. The study is funded or sponsored by Interventional Studies in Aging Center (ISAC) at the Marcus Institute, Hebrew SeniorLife.

Purpose of the Research

You are being asked to participate in a research study that is being conducted to see if eating meals reduced in sodium, a major component of table salt, can lower blood pressure. Research studies suggest that reducing sodium in diet can lower blood pressure – a risk factor for heart disease and falls.

Approximately 45 residents of Jack Satter House will participate in this study. You are being asked to participate in this study because you are 60 years or older, and you live at Jack Satter House.

During this study, participants will receive one of two meal plans, containing either (1) lower sodium meals or (2) usual sodium meals provided by Jack Satter House. As a study participant, you will get three meals and two snacks delivered to your home for 2 weeks. In addition to the meals, your participation in the study will include five in-person visits, and two telephone interviews.

We will *not* ask you to change any of the medications you are currently taking that have been prescribed by your regular doctor.

Results of the study will be shared with the participants at the end of the study.

Research Procedures

In this research study, you will be asked to participate in the following procedures:

Prescreening: (approximately 15 minutes)

During the prescreening telephone call a member of the study team will explain the study and ask you about your interest in participating. If you are interested, the staff member will ask you questions about your medical history to determine if this study is right for you.

Visit #1: Screening/ baseline questionnaires (approximately 45 minutes)

During the screening visit we will determine if you are eligible to participate in the study by conducting the following procedures at the study clinic at Jack Satter House:

- We will perform a test of your memory, thinking and understanding.
- Review your medication history.
- Measure your blood pressure in three positions (sitting, lying, and standing).

If you are eligible and interested in the study, we will obtain information via questionnaires at this visit:

- Demographic information
- Physical activity
- Medication list

During this visit we will collect your height and weight.

Visit #2: Baseline assessments and randomization to the intervention (approximately 45 minutes)

During this visit we will conduct the following procedures:

- Assess your ability to stand, walk and balance.
- Obtain information on any symptoms such as headache, light-headedness, dizziness, fatigue.
- Collect a urine sample to measure your sodium, potassium, and creatinine levels.
- You will receive instructions about your meals (including about what will need to be refrigerated).
- How to report what you have eaten on the study forms, and
- We will schedule a time for you to have your first blood pressure reading (see visit 3, below).

Visits 3 and 5: Seated Blood Pressure (approximately 10 minutes, each visit)

- Your blood pressure will be taken at the study clinic at Jack Satter House by Ms. Abby Foley or Dr. Courtney Millar. Reminders for your study appointment will be sent through voice friend set-up at Jack Satter House along with the location of the study visit.

Visit #4: Telephone Call (Week 1, approximately 20 minutes)

We will call you on the phone during the first week of the study. During this call we will:

- Carefully review instructions with you.
- Review your eating and other habits.
- Collect information on any symptoms and adverse effects.

Visit #6, Follow-Up (Week 2, approximately 45 minutes)

During the visit, we will:

- Review your medication history.
- Measure your blood pressure in three positions (sitting, lying, and standing).
- Measure your height, weight, ability to stand, walk and balance.
- Collect urine samples to measure your sodium, potassium, and creatinine levels.
- Collect information on any symptoms and adverse effects.

Visit	Purpose	Procedures	Study Personnel	Duration	Location
Prescreening	Explain study and collect medical history	Read study explanation to resident. If they agree, collect medical history information.	Research assistant or postdoctoral fellow	15 minutes	By Phone
Visit 1	Screening/Baseline questionnaires/Height and Weight	Collect baseline information, Lying/seated/standing BP	Research Assistant	60 minutes	Study clinic at Jack Satter House
Visit 2,	Randomization and Baseline assessments	Collect baseline information, assess walking and balance, urine test	Research Assistant	45 minutes	Study clinic at Jack Satter House
Visit 3 (1-2 days before study starts)	BP visit	Seated BP	Research Assistant	10 minutes	Study clinic at Jack Satter House
Study meals start, Day 0	Meal delivery starts	Participant will be delivered one of the two meals either at their residence or they will pick up at the cafeteria	Chef Robert Crevatis and Ms. Karen Hagen	5 minutes	In home delivery at the participant's residence or in-person pick up at cafeteria at Jack Satter House
Visit 4, Day 7	Telephone visit	Instructions, review eating habits, symptoms and adverse events	Study dietician	20 minutes	By Phone
Visit 5 (Day 10 or 13)	BP visit	Seated BP	Research Assistant	10 minutes	Study clinic at Jack Satter House
Visit 6, Day 14	End of Study Visit	Collect follow-up information, lying/seated/standing BP, urine sample, symptoms and adverse effects, assess walking and balance	Research Assistant	45 minutes	Study clinic at Jack Satter House

Return of Research Results

During this research we may learn information which could be important for your health or your treatment. If we learn such information, it will be made available to you and your health care provider. The information may include your blood pressure, the results of the physical function test (the walking and balance test), and your urine test.

Risks and Discomforts of Participating in the Research

- We will monitor your blood pressure during your clinic visits. If it should rise to an unacceptable level, we will suggest that you discontinue participation and return to your physician for treatment.
- This is a low risk dietary intervention of a low sodium diet compared to a usual diet. It is possible that you are assigned low sodium diet, which may not be as palatable compared to your usual diet.
- There are several questionnaires we will ask you to complete. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.
- There is the risk that information about you may become known to people outside this study.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

In Case of Injury while Participating in the Research

We are not able to provide any care needed to treat any injury that directly results from taking part in this research study. However, we will arrange for the care to be provided to you at a nearby institution. This institution may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. You may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury beyond what is described above, should an injury occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of the study as soon as possible. The researcher's name and phone number are listed at the end of this consent form.

Benefits to Participating in the Research

You may not directly benefit from this study, but others may benefit from the knowledge gained in connection with your participation.

Confidentiality of Information Collected as Part of the Research

All personal information obtained in the study will be kept confidential, and this information will only be available to the research staff. The records identifying your name will be kept confidential in a locked study cabinet at the study clinic at Jack Satter House and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Identifiers will be removed before entering the data electronically in a database. The results of the study will only be published or presented as group data. No individual participants will be identified. Forms to collect data will be identified with a unique study number and kept locked in the study office.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Study Sponsor, the HSL Institutional Review Board, or others in order to meet regulatory requirements. Your protected health information may be reviewed by the clinical laboratories performing urine testing for this study.

Future Use of Biological Specimens or Data
Identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable private information may be used for future research of blood pressure management and falls. If the research investigator distributes your information to other researchers or institutions, your identity will be concealed with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your samples or information. No biological specimens will be stored as part of this study.

Compensation for Participating in the Research
All participants will receive $40.00 at the completion of all of their visits in this study.

Costs to Participating in the Research
There are no costs to you for participating in this study.

Withdrawal from the Research
Your participation in this research is completely voluntary. If you chose not to participate or withdraw from the study, you will incur no penalty or loss of usual benefits. You may withdraw your consent and discontinue participation at any time without affecting your employment, job evaluations, health care or other services you may be receiving. If you choose to take part in the study, you have the right to stop at any time.

Your participation in this research project may be terminated:
- If you are unwilling or unable to comply with the meals provided in this study.
- If the study procedures are determined to be inappropriate or potentially harmful for you.
- You need treatment that is not permitted in the study.
- You fail to follow instructions.

If you are taken out of the study early, we may use or give out your health information that has already collected if the information is needed for this study or any follow-up activities.

Authorization for Use and Disclosure of Your Protected Health Information
As part of this study, we will be collecting and sharing information about you with others. Please review this section carefully as it contains information about the federal privacy rules and the use of your information.

Protected Health Information (PHI)
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists such as: such as demographic information,

laboratory results, etc. as well as any new information generated as part of this study through health related questionnaires, physical measurements, dietary questionnaires that we may ask you to undergo. This is your Protected Health Information, or PHI.

People/Groups at HSL Who Will Use Your Protected Health Information

Your Protected Health Information, PHI, may be shared with the investigators listed on this consent form as well as the supporting research team (i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants). Your PHI may also be shared with the Institutional Review Board of Hebrew SeniorLife as it is responsible for reviewing studies for the protection of the research subjects.

People/Groups Outside of HSL with Whom Your Protected Health Information Will Be Shared

We will take care to maintain confidentiality and privacy about you and your Protected Health Information, PHI. We may share your PHI with the following groups so that they may carry out their duties related to this study:

- Other researchers and centers that are part of this study, Drs. Shivani Sahni, Courtney Millar and Lewis A. Lipsitz from Marcus Institute, Hebrew SeniorLife and Drs. Stephen Juraschek, Kenneth J. Mukamal and Roger Davis from Beth Israel Deaconess Medical Center (BIDMC). Laboratories not affiliated with HSL, Quest Diagnostics. Statisticians and other data monitors not affiliated with HSL, Dr. Roger Davis from BIDMC.
- People or groups that are hired to provide services related to this research Ms. Abby Foley from the Marcus Institute, Hebrew SeniorLife.
- Your health insurance company, for portions of the research and related care that are considered billable.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities

Those who receive your PHI may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

Why We Are Using and Sharing Your Protected Health Information

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document.

No Expiration Date - Right to Withdraw Authorization

Your authorization for the use and disclosure of your Protected Health Information, PHI, in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your PHI at any time by notifying the Principal Investigator in writing. If you would like to withdraw your authorization, please send a letter notifying the Principal Investigator to: Shivani Sahni at 1200 Centre Street, Boston, MA 02131. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your PHI that has already been used or disclosed before the Principal Investigator receives your letter.

Right to Access and Copy Your PHI
If you wish to review or copy your Protected Health Information, PHI, as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator. You may not be allowed to inspect or copy your PHI until this study is completed or terminated.

Notice of Privacy Practices
In addition to signing this document, you may also be asked to sign an HSL Acknowledgement Received Notice of Privacy Practices form to acknowledge that you have received the HSL Notice of Privacy Practices.

ClinicalTrials.Gov
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.

Important Contact Information
For questions about the research, or your participation in the research, please use the below information.

You may call…	Contact Information	For questions about…
Principal Investigator: Dr. Shivani Sahni	617-971-5382	• General questions about the research • Research related injuries or emergencies • Any research related concerns or complaints
Research Contact Ms. Abby Foley	508-935-3403	• General questions about the study • Research-related injuries or emergencies • Any research-related concerns or complaints
Institutional Review Board Main Office Dr. Madhuri Reddy, Chair	 617-971-5415 617-678-7592	• Rights of a research participant • Use of protected health information • Compensation in event of research-related injury • Any research-related concerns or complaints

Documentation of Informed Consent and Authorization:

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

Research Participant

_____ _____

Date (MM/DD/YEAR) Signature of Research Participant

Investigator or Associate's Statement & Signature:

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant /guardian and a copy of the hospital's privacy notification (if requested).

_____ _____

Date (MM/DD/YEAR) Signature of Investigator or Associate