

Salt Sources Study

CONSENT FORM

Because you took part in the Minnesota Heart Survey, we would like you to join our study about food sources of salt. In this study we will ask you about your diet and salt use. The purpose of the study is to find out the amount of salt in food and drinks and added salt to foods reported by healthy adults. This study is being conducted by Dr. Lyn Steffen at the University of Minnesota's (UMN) Division of Epidemiology and Community Health, and is funded by the Centers for Disease Control and Prevention (CDC).

If you decide to take part in this study, we will ask you to complete one clinic visit and four telephone diet interviews, and keep track of your salt use. We may also ask you to collect four urine samples.

Clinic Visit. The clinic visit will last less than 1 hour. At this visit, we will confirm your contact data, measure your height and weight and ask you questions about your use of salt. We will ask you to choose four days over the next two weeks on which we will call you to ask you about your diet. During these two weeks, we also will ask you to collect salt that you add in cooking or at the table the day before each phone call.

Diet Interviews. A nutritionist at the UMN Nutrition Coordinating Center will call you on the four days on which we agreed to ask you questions about your diet and use of salt. Each phone call will take about 20-30 minutes. To thank you, for each complete call about your diet and salt collection combined, we will give you \$10, up to \$40 for all four phone calls.

Urine Collections: You may be asked to collect four 24-hour urine samples. We will measure these samples for nutrients (sodium, potassium, and creatinine). If you choose to collect urine samples, we will ask you to use our 'salt' to add in cooking or at the table for 11 days instead of your own household salt. Our 'salt' is a compound called 'lithium-tagged salt' which contains a very small amount of lithium and has been safely used in many other studies. Lithium is a metal found in trace amounts in all plants and animals. You may choose not to take part in this part of the study. If you do decide to take part, we would like to store the urine samples for future studies about diet. We will give you \$20 for for each 24-hour urine sample brought to the clinic, up to \$80 for four.

Risks and Benefits. There are no known health risks to measuring weight, asking questions about diet and salt use, or collecting urine samples. There are no known health risks to using the study 'salt'. Some of the questions asked may be somewhat sensitive to some people. You can choose not to answer any such questions and stay in this study. There are no direct benefits in taking part in this study. You will receive the results from your clinic visit and a report on your diet if you would like them.

Confidentiality

Any data we obtain will only be used for research purposes. In any report we publish or present, we will not include your name or anything that you say to us for this study that would identify you.

To protect your privacy, a code number will be assigned to your research records, your diet reports, and your urine samples (if you choose to collect your urine). Your name, address, or other personal data will be kept in locked files and password-protected computer files at all times. These personal data will not be released. Only the clinic and diet staff has access to personal data linked with your study code number. They have been trained to keep your personal data private.

Potential Risks

Medical Care Related to Being in this Study. In the event that taking part in this study results in an injury, treatment will be available. Treatment can include first aid, emergency treatment, and other care as needed. Care for such injuries will be billed to you or your insurance company as for your routine health care. The chance of such injury in this study about diet and salt use is rare.

Sharing of Data and Samples

Your coded urine samples (if this applies to you) and/or research records may be used by skilled persons for research purposes only. At the end of the study, your coded data will be sent to the CDC, the funding group. As mentioned earlier, your samples and data will be labeled only with a code number and will not include any personal data. The UMN takes extreme care to protect your identity and privacy.

Right to Refuse or Withdraw. Taking part in this research is your choice. You can agree to take part in this study about the food sources of salt and not agree to collect urine samples or to allow us to store your urine sample. Your choice whether or not to take part in this study will not affect your future dealings with UMN in any way, nor will it affect your health care. If you decide to join the study, you are free to quit the study at any time. You can withdraw your consent at any time as well.

Protected Health Information (PHI)

Any of your PHI (name, date of birth, social security number, address, and medical history) created or received for this study is protected under the "Privacy Rule." The "Privacy Rule" is a Federal rule under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. See separate HIPAA form.

If you have any questions or concerns about the study and would like to talk to someone other than the research staff, please call (612) 672-7692 or toll free at (866) 508-6961. This is the Fairview Research Helpline. You may also contact this office in writing or in person at UMN Medical Center, Fairview Riverside Campus, 2200 Riverside Avenue,

Minneapolis, MN 55454. If you have questions about the study or feel you have been injured or harmed by the study, you may contact Dr. Steffen at UMN, (612) 624-1818. You may also contact [clinic manager] at the clinic, (612) 62X-XXXX.

Your signature shows you have read the above statements and understand them, that you agree to take part in the study, and that any questions that occurred to you have been answered. You may ask other questions at any time. You also may have a copy of this consent form, if you want one.

Statement of Consent

I have read the above consent form. I have asked questions and have received answers.

I consent to join this study:

Agree Do not agree

I consent to join the sub-study, that is collect urine and use the study salt:

____ Agree Do not agree

I consent to having my urine stored for future studies about diet:

____ Agree Do not agree

Signature of Person taking part in the study

Date Signed

The above person has been given the chance to have his/her questions about the study methods answered.

Signature of Person getting Consent