Official Title: Sodium Regulation in Individuals on Known Dietary Sodium Intake

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University of California, San Diego
Consent to Act as a Research Subject

Sodium Regulation in Individuals on Known Dietary Sodium Intake
(MEASURE Study)
Screening Phase

Introduction

Dr. Cheryl Anderson and associates are conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends or your physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

This study is about the effect of eating high-salt and low-salt diets on the storage of sodium (salt) in the skin, muscle, and bones of adults. The purpose of this screening phase of the study is to collect information to identify individuals who might be eligible to participate in the main MEASURE study. There is no direct benefit to you for taking part in this screening phase, but the information you provide will be used to help determine whether you qualify to participate in the main study.

If you decide to participate in this screening phase, we will ask you questions about your health history and eating preferences, measure your height, weight, blood pressure and heart rate, collect blood and urine samples, and assess your ability to eat the study foods. Your participation in these screening procedures will last about 1 hour.

The most commonly expected risks of this screening phase of the study are possible pain, bruising, and/or fainting from drawing blood.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how were you selected, and what is the approximate number of participants in the study?
You have been asked to participate in the screening phase of this research study because you are an adult with high blood pressure living in San Diego. Approximately 50 total participants will take part in the MEASURE research study.

What will happen to you in this study, and which procedures are standard of care and which are experimental?
In addition to the information at the beginning of this form, here are some additional details about what will happen to you if you agree to be in this study. All questionnaires, measurements, and samples collected during screening procedures are being done for research purposes.

If you agree to take part, during the screening visit we will do the following to see if you are eligible to take part in the main study:

1. Ask you questions about your health history and food preferences (online, via Zoom);
2. Measure your height, weight, blood pressure, and heart rate (at our UCSD study clinic);
3. Collect approximately 1 tablespoon of blood (at our UCSD study clinic);
4. Ask you to collect a small sample of urine during your visit (at our UCSD study clinic); and
5. Provide a meal for you to eat during the screening visit (either in-person or online, via Zoom).

If you are a female and capable of childbearing, we will do a pregnancy test using a small amount of your urine sample, in order to be as sure as possible that you are not pregnant. It is important to be as sure as possible that you are not pregnant, because procedures in the main study may cause harm to an unborn child.

Based on the information you provide during the screening visit, you may be asked to complete some additional activities at home to help investigators determine your final eligibility for the study. These activities include:

6. Eat two sample meals prepared by the study dietician;
7. Collect a 24-hour urine sample; and
8. Collect a stool sample.

All sample meals and supplies for collecting urine and stool samples will be provided to you by the study.

Based on the information you provide during the screening phase of the study, you may or may not be eligible for the main MEASURE study. If you are not eligible for the main study, you will be notified, and no additional information or activities will be requested of you. If the study team determines you are eligible for the main MEASURE study, you may be contacted in the future and invited to participate in another study visit. At that visit, you will be asked to review and sign a separate consent form that describes the procedures, benefits, and risks of participation in the main study. You will have the opportunity to review the consent form and ask questions about the study. You are not obligated to participate in the main MEASURE study; you can choose to participate or not in the study.

How much time will each study procedure take and how long will the study last?
Your individual participation in the screening phase will last up to approximately 2.5 hours total, divided into an online visit (via Zoom) and an in-person visit at our UCSD study clinic, plus up to an additional 1 hour at home if asked to complete the additional screening activities.

What risks are associated with this study?
Participation in this screening may involve some added risks or discomforts. In addition to the risks described at the beginning of this form, the following are possible minor risks or discomforts from the screening activities.

1. **Blood draw**: There may be some discomfort, bruising, or bleeding where the blood is drawn. Rarely, fainting occurs because of drawing blood. Precautions will be taken to minimize these risks by using sterile techniques and applying pressure to the site after the needle is withdrawn.

2. **Urine and stool collection and health questionnaire:** There are no physical risks associated with these procedures, but you might experience momentary embarrassment or discomfort. During the questionnaire, you can skip any question that makes you uncomfortable and you can stop the questionnaire at any time.

3. **Loss of confidentiality**: Loss of confidentiality is a risk related to the research. Although this risk is a possibility, safeguards are in place as listed in the confidentiality section.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Are there risks to the reproductive system or a developing fetus?
Some procedures in the main study may involve risks to the embryo or fetus that are currently unforeseeable. For this reason, participants in this investigational study should not become pregnant. All female participants of childbearing potential will be tested for pregnancy during the screening phase using a small amount of urine collected at our study facilities. If you have a positive pregnancy test, you will not be eligible to participate in the main study. If, you become pregnant or suspect you have become pregnant, please contact Dr. Anderson or research personnel immediately so that your continued participation in the study can be reevaluated.

What are the alternatives to participating in this study?
Participation in this research study is voluntary and the only alternative is to not participate.

What benefits can be reasonably expected?
There may not be any direct benefit to you for participating in this screening phase. The information you provide will be used to help determine if you qualify to participate in the MEASURE study, but does not guarantee you will be accepted into the study. The main MEASURE study may benefit society by providing data on new and novel procedures for measuring sodium distribution in body tissues, which can potentially benefit many research topics and lead to new diagnostic and therapeutic tools.

What happens if you change your mind about participating?
If you decide that you no longer wish to continue in this study, simply inform a research team member in person or by phone at 858-633-7251 or contact Dr. Cheryl Anderson at (858) 534-4456. You will be requested to return to the study office for a final measurement visit.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from screening phase of the study for the following reasons:

1. If the researchers believe it is in your best medical interest to withdraw.
2. If you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
You will not receive any compensation for participating in this screening phase of the MEASURE Study.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. If you are not already a UCSD patient, a medical record including your name, date of birth, and phone number will be entered in UC San Diego Health's electronic medical record system (EPIC) in order for you to be seen for study appointments at our research clinic. You will also be assigned a unique study identification number that will be used on your research records instead of your name. The list that matches your name with the code number will be separate from any other identifying information and will be kept in a locked file in the study office or on a secure server. All study documents will only be available to study staff and will be kept in a file cabinet in a locked room for at least 3 years after the end of the study. All study staff are trained and will adhere to the Health Insurance Portability and Accountability Act (HIPAA) regulations regarding your medical records. Research records may be reviewed by people and organizations responsible for conducting the research and for performing oversight of the research. This includes members of the research team and other authorized staff at the University of California, San Diego; the UCSD Institutional Review Board; the Federal Office of Human Research Protections; and the National Institutes of Health who is sponsoring this research.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 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 *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or 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 federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding the project or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also 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 research to release it.

This research does not include whole genome sequencing.

Personal identifiers will be removed from the information or biospecimens (blood, urine, and stool) collected and stored for future use as part of the research; only your unique study code will be included on stored information and specimens. The stored information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. The principal study investigator will keep information that links your personal health identifiers with the unique study code that is on the stored sample. This information will be kept in a secure location and would only be shared with research associates in or outside of UCSD with Institutional Review Board approval. If you would like to withdraw consent for future use of your samples or data, please contact Dr. Cheryl Anderson at (858) 534-4456 and she will destroy any of your remaining biospecimens and research data that has been stored. However, samples or related information that have already been used by researchers cannot be withdrawn or destroyed.

Biospecimens (such as blood or urine) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

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.

We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities.

Will you receive any results from participating in this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

Future contact
Dr. Anderson and her associates may conduct future studies related to nutrition and/or hypertension and may wish to contact you about your interest in future research studies. Please indicate whether you agree or disagree to be re-contacted for future research by checking and initialing the corresponding option below.

☐ Yes, I may be contacted for future research opportunities as described. _____ (initial)

☐ No, I do not wish to be contacted for future research opportunities as described. _____ (initial)

Who can you call if you have questions?
This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Cheryl Anderson at (858) 534-4456.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Subject's signature Date

_____ _____
Signature of the person conducting the informed consent discussion Date

For participants who cannot read: An impartial, literate witness must be present during consent procedures and must read and sign the statement below:

I, the witness, attest that the information contained in this written consent form has been read and explained to the participant. The participant appears to understand the purpose, procedures, risks and benefits of the study and has voluntarily agreed to participate in this study.

_____ _____
Signature of witness Date