

Document Type: Informed Consent Form

Official Title: Assessment of Dopaminergic Neurotransmission in Response to Tasting Chocolate (The Chocolate Study 2.0)

NCT Number: NCT04037020

IRB Approval Date: 07/11/2019

CONSENT TO PARTICIPATE IN RESEARCH

Project Title: *The Chocolate Study 2.0*
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Department: *ARS-USDA Human Nutrition Research Center*

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this study?

We expect that your taking part in this research will last at least 1 week. This includes 4 testing days. Testing will only take place during the work week.

Why is this research being done?

The purpose of this study is to test how the brain responds when you eat enjoyable foods such as chocolate. We know that eating certain types of foods can make you want to keep eating even when you are full. The chemical in the brain that causes this is called dopamine. We can measure this response by looking at changes to how your eye responds to light.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will be fill answer questions about your usual diet and how you feel about eating chocolate. We will also measure your height and weight. You will then be scheduled for your testing visits. At each testing visit a different type of chocolate will be tested. The types of chocolates are supreme dark, which contains 90% cocoa, dark, which contains 70% cocoa, milk and white.

Testing will take place in the morning after an overnight fast or in the afternoon/evening 3 to 4 hours after you have eaten a meal. During the time between your meal and testing visit you will not be allowed to eat or drink anything except water and no exercising. When you arrive at the Center you will be greeted by a member of the research team and taken to the testing room. We

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(THE CHOCOLATE STUDY 2.0)

will show you how we will measure your eye's response to tasting food and you will have time to ask questions. You will rate your hunger and desire for food and answer questions on how you are feeling. Next, you will be given a small piece of chocolate to hold in your mouth and we will measure your eye's response to tasting the chocolate. After all testing, you will again answer questions about how you are feeling.

The eye testing is done with a hand-held instrument called an electroretinographic light stimulator, otherwise called an ERG. For the ERG measurement we will place a sensor on your cheek just below your eye that will be connected to the ERG by a small cable. A light will be shown in your eye that your retina (the back portion of your eye) responds to. The signal from your retina is carried by the sensor to the ERG. This will happen two times at each testing visit, before and while tasting chocolate.

Could being in this research hurt me?

There is no foreseeable risk involved with doing the test that was just explained.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research. We hope that, in the future, other people might benefit from this study because the knowledge we will gain from your participation will help us better understand the impact foods like chocolate have on eating behavior.

How many people will participate in this research?

Approximately 20 people will take part in this study at the Grand Forks Human Nutrition Research Center.

Will it cost me money to take part in this research?

You will not have any costs for being in this research study. You will be expected to provide your own transportation to and from the Center. In addition, we do not withhold taxes from any money you will receive. Any questions you have related to taxes will need to be directed to your personal accountant or the Internal Revenue Service.

Will I be paid for taking part in this research?

You will be paid for being in this research study. You will receive \$180 for completing all testing visits. If you are not able to complete all testing visits you will be paid \$35 for each chocolate testing visit you complete.

Who is funding this research?

The Grand Forks Human Nutrition Research Center and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

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What happens to information collected for this research?

Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- U.S. Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records
- UND Research Development and Compliance office
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.). No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

What if I agree to be in the research and then change my mind?

If you decide to leave the study early, we ask that you contact us as soon as possible to let us know about your d. Your decision will not affect your current or future relations with the Center or the University of North Dakota.

We will let you know about any new information that might cause you to change your mind about being in this study.

We reserve the right to stop your involvement in the study if we feel you are not complying with the study protocol or if we feel your safety and well-being, or that of other study participants, is being affected.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

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- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: <http://und.edu/research/resources/human-subjects/research-participants.html>

Your signature documents your consent to take part in this research. You will receive a copy of this form.

Subject's Name: _____

Signature of Subject

Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

Signature of Person Who Obtained Consent

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