

Document Type: Informed Consent Form

Official Title: Relationship Between Income, Obesity, and Food Purchasing Using an Experimental Grocery Store Study (Meals-for-Moms)

NCT Number: NCT03710525

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INFORMED CONSENT

TITLE: Meals-for-Moms Study

PROJECT DIRECTOR: Lisa Jahns, Ph.D., RD

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DEPARTMENT: USDA Grand Forks Human Nutrition Research Center

A person who is to join in the research must give his or her informed consent. This consent must be based on a grasp of the nature and risks of the research. This form provides details that are crucial for such knowledge. Research projects include only those who choose to take part. Please take your time in making your choice as to whether to join. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be in a study about how the price of foods affects food buying choices at the grocery store. We are interested in this topic because the price of foods can have a big impact on what people choose to buy and prices change over time. We are doing this study to see how changes in food prices affect what foods mothers choose for their families.

HOW MANY PEOPLE WILL PARTICIPATE?

About 80 people will take part in this study. Half of them will be using federal food assistance programs at the time of the study. The other half will not be using these programs.

HOW LONG WILL I BE IN THIS STUDY?

You will make a single visit to the Grand Forks Human Nutrition Research Center (GFHNR) for testing. It will take roughly 1.5 hours.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked not to consume foods or beverages (water is OK) for two hours before your visit. When you arrive for your visit, you will be given play money and asked to "buy" foods in our laboratory-based grocery store. Foods will be symbolized by pictures along with their price. Using your play money, you will be asked to "buy" enough food for your family for a one week period. During this study we will change the price of certain foods to see how that affects your choice to put them in your grocery cart.

You will be asked to fill out a questionnaire asking about your age, gender, race, ethnicity, income, and people in your household. You will also be asked to fill out questionnaires asking

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about how you would react to certain money situations, stress, hunger level, and your knowledge about food and health. Your height and weight will also be measured.

WHAT ARE THE RISKS OF THE STUDY?

Questionnaires - There may be some awkward feelings answering questions about demographic features and income. It may be possible for some people to be emotionally uncomfortable while answering the questionnaires, but only relevant questions required to determine eligibility and assess factors related to the research will be asked. Any questions or concerns will be addressed by the PI or his delegate.

Financial Risk - There are minimal financial risks. The only known expenses are transportation costs and income taxes.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit directly from being in this study. However, we hope that, in the future, other people might benefit from this study. Results of this research may give more knowledge about how food price changes affect diet patterns.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will be expected to provide your transportation to and from the GFHNRC. We do not withhold income, social security, unemployment taxes, or any other taxes because you are not an employee of the GFHNRC. You may have to pay income taxes on the money you receive. All tax questions relating to the taxability of the payment should be directed to your personal tax accountant or to your local Internal Revenue Service Office. Each calendar year we provide the amount paid to you, your name, address, and social security number (required before checks can be written) to the National Finance Center, New Orleans, LA. If you are not a United States citizen, check your documentation to make sure you can receive money from a non-University source without risking your status in the United States.

WILL I BE PAID FOR TAKING PART?

You will receive \$70 for being in this research study. You may choose to receive a 2-month individual membership or 2-month family membership to Choice Health & Fitness, instead.

WHO IS FUNDING THE STUDY?

The US Department of Agriculture is funding this research study. No one on the research team will receive a direct payment or an increase in salary for leading this study.

CONFIDENTIALITY:

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, we will describe the study results in a summarized manner so that you cannot be identified. Your study record may be reviewed by Government agencies, the

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University of North Dakota (UND) Research Development and Compliance office, the UND Institutional Review Board, and the GFHNRC.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

Confidentiality will be maintained by means of assigning study participants unique subject identification (ID) numbers that will not contain any personal identifiers. This subject ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to an individual subject. A master list linking the participants' names to the ID numbers will be kept in a separate locked file in the principal investigator's office, or in a computer file with a password protected access restricted to study staff.

Confidential information may be made available to the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records, to UND, and as required by law or court order. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov).

COMPENSATION FOR INJURY:

In the event that this research study results in an injury, treatment will be available including first aid and emergency treatment. 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.). If you are injured while taking part in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you.

IS THIS STUDY VOLUNTARY?

You may choose not to join or you may stop taking part at any time without penalty or loss of benefits to which you are otherwise allowed. Your decision will not affect your current or future relations with the GFHNRC or UND.

CONTACTS AND QUESTIONS:

The researcher leading this study is Lisa Jahns, PhD, RD. You may ask any questions you have now. If you have questions, concerns, or complaints about the research later, please contact Dr. Jahns at 701-795-8331.

If you have questions about your rights as a research subject, you may contact the UND Institutional Review Board at (701) 777-4279. You may also call this number about any problems, complaints, or concerns you have about this research study. Please call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the

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research team. General information about being a research subject can be found by clicking "Information for Research Participants" on the web site: <http://und.edu/research/resources/human-subjects/research-participants.cfm>.

REQUEST TO CONTACT FOR FUTURE STUDIES:

We would like to alert you about studies you may qualify for in the future. Please indicate below if you consent to be contacted.

(Please circle one) YES NO

Initials _____

CONSENT:

Your signature shows that this research study has been explained to you, your questions have been answered, and you agree to take part in this study. You will receive a copy of this form.

Your Name Printed

Your Signature

Date

I have discussed the above points with the subject.

Signature of Person Who Obtained Consent

Date

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