STUDY TITLE: Modifiable predictors of neural vulnerabilities for obesity

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University of Nebraska Lincoln

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Study Title: ***Preschool Problem Solving Study, MRI Follow-Up***

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You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

Key Information:
If you agree to participate in this study, the project will involve participants who are at least 19 years of age. Procedures will include magnetic resonance imaging (MRI), questionnaires, and measurements of height and weight. Only one lab visit will be required to participate. The visit will take approximately 2 hours and 30 minutes. There are only minimal risks associated with this study. You will be paid $125 in cash for your participation. You will be provided a copy of this consent form. Your participation is voluntary and you may decide not to participate at any time.

Why are you being asked to be in this research study?
You are being invited to participate because you have previously participated in the Preschool Problem Solving Study (P^2S^2) in the UNL Developmental Cognitive Neuroscience (DCN) Lab.

What is the reason for doing this research study?
We are interested in learning about how young adults process food-related images and tastes, and how factors from childhood and adolescence relate to patterns of brain activity and health.

What will be done during this research study?
You will be asked to visit the Center for Brain, Biology, and Behavior (CB3) at the University of Nebraska-Lincoln for a single session. We expect this session to last approximately 2 hours and 30 minutes. During the session, a trained Magnetic Resonance Imaging (MRI) technologist will invite you to participate in the brain scan part of the session. After the safety screening, you will be introduced to the MRI scanning machine. MRI uses magnetic fields and radio waves to make a picture of the brain. This study uses functional MRI (fMRI). fMRI relies on the properties of oxygenated (increased flow) and deoxygenated (decreased flow) blood to see images of changing blood flow in the brain associated with activity. The activity in different parts of the brain causes increased and decreased blood flow to 'light up' on the scan. fMRI is typically used for neurological and cognitive psychology research. This study will also utilize Diffusion Tensor Imaging (DTI) to examine how water travels along tracts in the brain while in the MRI scanner. In addition to MRI and DTI, this study will also utilize a non-invasive eye tracking system. The

eye tracking system will monitor your eye gaze. The equipment is located outside of the MRI machine and reads your eye gaze using a mirror attached to the head piece.

The MRI scanning session will take approximately 1 hour and 45 minutes once you are in the scanner.

The information from the MRI machine is only useful if you are able to complete the whole imaging session, and be still during the sequences. Therefore you will be encouraged to hold as still as possible, and communicate any discomfort to the investigators any time before or during a scan. You will have a squeeze bulb that will help to communicate with us while you are in the machine. You will also wear earplugs to minimize the loud noises made by the machine.

While in the machine, you will be asked to do several different things. In one task, you will look at pictures of different foods. In some trials, you will be asked to control your response to the image using some strategies that we will teach you. In another task, you will be delivered sips of flavored beverage or a tasteless solution. At other times, you will also be asked to lie with your eyes open in the absence of any specific task.

In addition to the MRI scanning session, you will complete a variety of data collection procedures outside of the scanner. Specifically, a research assistant will measure your height and weight, and ask you to complete questionnaires collecting background information and self-reported information about your health and mental health. All data collected as a part of this study will be linked with data collected from you and your family in earlier phases of the Preschool Problem Solving Project to allow for analysis of your data.

The Center for Brain, Biology and Behavior MRI Facility is a research facility. It is not a clinical MRI facility in a hospital. The MRI scan in which you are invited to participate is for research purposes only. The MRI scan is not a clinical scan intended for diagnostic or therapeutic purposes. The faculty and staff at the Center for Brain, Biology and Behavior are not neuroradiologists (physicians), and therefore, are not qualified to provide any medical comments on your brain scans.

However, structural scans obtained from all research participants in the course of research participation at the Center for Brain, Biology and Behavior will be sent to a consulting neuroradiologist for blind review (any means of identifying the participant removed), except in cases when a participant's scans were already sent for review as part of research participation at the Center within the previous 6 months. It is unlikely in normal, healthy individuals for brain images to reveal clinically significant findings. If the neuroradiologist believes that the brain images contain an abnormality that warrants medical follow-up, one of the Principal Investigators for this study (or their delegate) will notify you within three business days of the MRI scan. In these cases when medical follow-up is recommended, the Principal Investigator (or delegate) will offer you the images in digital format on a disk, as well as the initial report from the neuroradiologist. Images are only provided in cases when the neuroradiologist identifies an abnormality that warrants medical follow-up. Any follow-up medical care and associated costs will be your responsibility. Note that because the MRI scans are for research purposes only, there is no guarantee that the images will show an existing abnormality that may appear in a clinical scan. By signing this consent form, you consent to have your de-identified images shared with a neuroradiologist for review.

What are the possible risks of being in this research study?

MRI

Eligibility and cautions: To evaluate risks of participation and determine eligibility for inclusion in an MRI study, you will be given a CB3 MRI Safety Screening form. This must be filled out and reviewed with the MRI technician to determine risks of participation. This form must be filled out to the best of your knowledge as these risks may be serious and potentially life threatening. The CB3 screening form covers devices, illnesses, injuries and medical procedures that affect participant safety. If completion of the screening form leads you or the MRI technologist to have safety concerns, you may be ineligible to participate in the MRI portion of this study, or the MRI portion of the study may need to be rescheduled at a later date to allow the MRI technologist to gather additional information about your health status to inform the level of risk. This form must be signed and initialed where required.

Some people cannot have an MRI scan because they have internal or external metal devices in or on their body that cannot be removed. For instance, if you have a heart pacemaker, artificial heart valves, metal implants, chemotherapy or insulin pumps, or other such metal clips or rings, you will not be allowed to participate in the MRI portion. An internal metal device could potentially turn on or off inappropriately, or could move within you potentially damaging tissue or vessels resulting in injury or death. Not removing piercings could cause tissue damage, warming or burns.

Tattoos could cause warming, redness or burns around the tattooed body part. You will be informed to not make skin contact to the sides of the tunnel when in the MRI machine. In other words, we will tell you to stay as still as possible in the machine, and not to touch any other part of the machine. If your skin makes direct contact to the sides of the machine, this could potentially cause mild to severe burns. Certain medications could also enhance side effects such as dizziness, light-headedness, or nausea.

At this time, as a policy of the CB3, women who are pregnant or trying to get pregnant are excluded from participation in research projects involving an fMRI/MRI scan. Although there are no known negative effects on pregnant women or fetuses, very little is known of the possibility of any negative effects. This study may involve risks that we cannot predict.

If you are considered ineligible for the MRI portion of the study because of a safety issue, you may still choose to participate in the non-MRI portions.

Likely risks when following all security measures: None.

Less likely risks: During the MRI scan, potential discomforts may include: feeling cold, feeling warm, anxiety, body discomfort/stiffness, or you may experience a metallic taste. Lying still for a prolonged time may prove uncomfortable. Some individuals may have a claustrophobic response, which is fear of confined spaces, and some may experience stiffness from lying still. The MRI machine makes loud banging noises while taking measurements, so ear protection will be used to reduce the noise.

You will be in communication with the MRI technologist throughout the MRI scan. If you experiences any of these or other discomforts, you will be instructed to notify the MRI technologist immediately. You will be given a squeeze bulb to contact the MRI technologist, which may be used at any time before or during scanning.

Rare risks: An additional risk, though highly unlikely, is the possibility that metal objects could be pulled into the magnetic center of the MRI machine and hit you. To reduce this risk we require that all people involved with the study remove all metal from their clothing and all metal objects from their pockets. It is important to know that no metal can be brought into the magnet room at any time. Once you are in the magnet, the door to the MRI room will be closed so that no one from the outside accidentally goes near the MRI machine.

Eye Tracking
There are no known risks in the use of the eye tracking system. The eye tracking system used in the Center is completely non-invasive.

Questionnaires and Height/Weight Measurements
There are no known risks associated with the questionnaires or height/weight measurements.

In case of injury:
It is unlikely that you will be injured as a result of your participation in this study. However, if you are injured as a direct result from study participation, you should notify the investigator immediately, and we will ensure that treatment is sought at a location of your choice. However, you or your insurance carrier will be expected to pay for the costs of any treatment due to injury.

If injured in any part of the MRI procedure or another aspect of this project, an incident report will be completed and sent to both the Chairperson of the University of Nebraska-Lincoln Institutional Review Board and to the Director of the Center for Brain, Biology and Behavior. Identifiable information about your participation may be provided according to reporter and reviewer needs.

What are the possible benefits to you?
You are not expected to get any direct benefit from being in this study.

What are the possible benefits to other people?
The benefits to science and/or society may include better understanding of how young adults process information and how this affects their health.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be compensated for being in this research study?
To compensate you for your study participation, you will receive $125 in cash when you complete the study. (If you complete only the non-MRI parts of the study, either because you are deemed ineligible to complete the MRI portion or you decline the MRI portion, you will receive a prorated compensation of $50 cash.) All compensation will be provided by DCN Lab staff. For all compensation, you will be required to complete a receipt form upon receiving your cash which will include your name, address, telephone number, social security number, and signature. This receipt will be stored in a locked filing cabinet in our laboratory separate from any other information collected as part of your participation in the study. Upon request, the receipt may be shared with the University controller for accounting purposes only.

In addition to compensation for participation, participants who travel from outside of Lincoln and nearby areas (defined as more than a 2-hour drive to the lab) are eligible to request reimbursement of some travel costs. For participants who live outside of Lincoln and nearby areas but are willing to drive in for the session, mileage for travel to and from the session may be reimbursed at the UNL-approved rate following completion of paperwork required by the university.

What should you do if you have a problem during this research study?
Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact either the DCN Lab (402.472.2556) or the Principal Investigators (Timothy Nelson, Ph.D., 402.472.7707; Cary Savage, Ph.D., 402.472.0168).

How will information about you be protected?
Reasonable steps will be taken to protect your privacy and the confidentiality of your study data. Information pertaining to you will be recorded by study ID, with a master list linking names with ID numbers that will be stored separately from any study data.

Data on paper will be stored in a locked cabinet in the DCN Lab and will only be accessible by authorized members of the research team. Electronic data will be stored on a secure server and will only be accessible by authorized members of the research team.

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential. We may share individual-level data if needed as a part of publishing our research findings or if required by a funding agency; however, if we do share individual-level data, only de-identified data will be shared. That is, we will not share any information that would allow anyone outside of the research team to know that the data reported are yours.

Due to the ongoing longitudinal nature of the broader project in which you have been participating, we are unable to specify at this time an exact date for when the master list linking names and ID numbers will be destroyed; however, this list will be destroyed after all data have been collected and these records are no longer needed for research purposes.

To help us protect your privacy, this project has a Certificate of Confidentiality from the Federal Government. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use this Certificate to resist any demands for information that would identify you, except as explained below:

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written

consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or intent to harm self or others.

What are your rights as a research subject?

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.

For study related questions, please contact the DCN Lab or the Principal Investigators.

For questions concerning your rights or complaints about the research contact the Institutional Review Board (IRB):

- Phone: 1(402)472-6965
- Email: irb@unl.edu

Will the information collected be kept confidential?
Yes. All information provided by you will be kept confidential, except when we have concerns about your safety.

What will happen if you not to be in this research study or decide to stop participating once you start?
You can decide not to be in this research study, or you can stop being in this research study ("withdraw') at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigators, the DCN Lab, or with the University of Nebraska-Lincoln. You will not lose any benefits to which you are entitled.

Public Information about this Study
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Documentation of informed consent
You are voluntarily making a decision whether or not to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. You will be given a copy of this consent form to keep.

Participant Feedback Survey
The University of Nebraska-Lincoln wants to know about your research experience. This 14 question, multiple-choice survey is anonymous. This survey should be completed after your participation in this research. Please complete this optional online survey at: http://bit.ly/UNLresearchfeedback.

DOCUMENTATION OF INFORMED CONSENT

YOU ARE VOLUNTARILY MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THE RESEARCH STUDY. YOUR SIGNATURE CERTIFIES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ AND UNDERSTOOD THE INFORMATION PRESENTED. YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP FOR YOUR RECORDS.

CONSENT SIGNATURE

A. Participant's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and ask questions. I hereby consent to take part in this study.

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Signature of Participant & Date Signed

B. Person Obtaining Consent

I certify that I have explained the research, its purposes, and the procedures to the participant or his/her legal representation before requesting their signature. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved in participation and their signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding. **IN MY JUDGEMENT THE PARTICIPANT IS VOLUNTARILY AND KNOWINGLY GIVING INFORMED CONSENT AND POSSESSES THE LEGAL CAPACITY TO GIVE INFORMED CONSENT TO PARTICIPATE IN THIS RESEARCH STUDY.**

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Signature of Person Obtaining Consent & Date Signed

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Signature of Study Director, Date Signed