Study Title: Fear, Gastrointestinal Distress, and Interoception: Physiological and Psychological Mechanisms in eating Disorders.

NCT ID: 05382702

Date Approved By IRB: 12/2/2024

Ohio University Research Consent Form

Title of Research: Taste, Psychological, and Physiological Responses to Food Intake Associated with Disordered Eating
Researchers: K. Jean Forney, Ph.D., Chunmin Lo, Ph.D., & Brett Peters, Ph.D.
IRB number: FY25-330

You are being asked by an Ohio University researcher to participate in a research study. Before deciding whether you want to participate in this study, you should understand what the study is about, and know the possible risks and benefits in order to make an informed decision. This process is called informed consent. This document describes the purpose, procedures, possible benefits, and risks of the research project. It also explains how your personal information will be used and protected.

Once you have read this form and your questions about the study are answered, you will be asked to indicate your consent by signing the form before participating in this study. You will receive a copy of this document to keep.

Key Study Information

This study is being done to understand differences in taste perception and the psychological and biological response to food intake among people with disordered eating behaviors. This is a screening survey to determine preliminary eligibility for a larger study. If you are eligible for the larger study, you will first complete an eligibility appointment where you will complete interviews and questionnaires. If you are eligible and wish to participate, you will be asked to visit the lab on two separate mornings and to consume approximately ¾ cup of yogurt on each morning. You will be randomized into one of three conditions: 1) consuming two high fat yogurts; 2) consuming two low fat yogurts; or 3) consuming one high fat and one low fat yogurt. You will find out which condition you are randomized to after you consent to participate. You will be asked to wear skin conductance sensors, consume yogurt, have blood draws completed, and fill out questionnaires at both visits.

Purpose of Study

This study is being done because it is unknown how taste perception is related to psychological and biological responses to food intake.

You are being asked to participate in this study because you completed a phone screen suggesting you are eligible and said that you were interested in participating.

We expect to enroll 152 participants in this study.

You should not participate in this study if you are pregnant or breastfeeding or have a medical condition that impacts your appetite or weight (e.g., diabetes). You should not participate if you participated in the study “Taste Perception and Body Image Concerns” (IRB 19-F-33 and IRB-FY24-233).

Study Procedures

If you agree to participate, you will be asked to complete interviews and questionnaires about your eating attitudes and behaviors, common mental health problems, and related topics and have height and weight assessed to determine your eligibility for the second two study visits. For the next two study visits, you will attend a lab session on two separate mornings to consume a yogurt on each morning. You will be randomly assigned to one of three conditions: 1) consuming two high fat yogurts; 2) consuming two low fat yogurts; or 3) consuming one high fat and one low fat yogurt. You will find out which condition you are assigned to after you consent to participate. You will be asked to refrain from eating or drinking anything other than water before both visits from 10 pm the evening before. You will be asked to not take any medications other than hormonal contraceptives, prescribed medications or daily over the counter medications for three days before your visit. You will be asked to wear a skin conductance sensor, consume yogurt, and fill out questionnaires assessing taste, eating attitudes and behaviors, and bodily perceptions at both visits. You will also be asked to have an indwelling IV catheter inserted to complete 6 repeated blood draws at both study visits. The IV catheter will be inserted for approximately 1 hour and 45 minutes. Approximately 4 tablespoons of blood will be taken, in total. To minimize risk, the procedure will be performed with sterile technique by qualified personnel using established procedures at the Ohio University Clinical and Translational Research Unit.

Your participation in the study will last approximately 8 hours. Study Visit 1 will take about 3 hours and can occur at any time. Study Visits 2 and 3 will take approximately 2.5 hours each and must occur in the morning. In unusual circumstances, a participant may be asked to repeat a partially completed study visit; however, this is optional.

We would like to audiorecord your interview for the purposes of determining whether or not our interviewers rate answers the same way and to provide training to research staff. This is optional and will not affect your ability to participate. May we record your interview?

- ☐ Yes, you may audio record my interview
- ☐ No, you may not audio record my interview

Risks and Discomforts You May Experience

Risks or discomforts that you might experience are feeling uncomfortable when completing questionnaires about sensitive topics. We will conduct all study visits in a private location to maximize your privacy. You may choose to skip any questions you wish or discontinue at any time. We will mark your records with a unique ID number. In order to minimize the risk that your confidentiality is breached, the only link between your identifying information and unique ID will be stored in a secure, web-based application, REDCap. For more information, please see “Confidentiality and Records.”

You may feel some pain during the insertion of the needle catheter by the research nurse. As with any blood sampling, possible risks include hypoglycemia, dizziness,

fainting, nausea, bruising, and a small chance of infection. To minimize risk, the procedure will be performed with sterile technique by qualified personnel using established procedures at the Ohio University Clinical and Translational Research Unit.

The study involves consuming two strawberry yogurts. may be randomized to eat one or two high fat yogurts. Some people respond to high fat food with diarrhea due to malabsorption or lactose intolerance. If you are allergic to dairy, strawberries, or honey, you are not eligible to participate.

Please indicate if you are allergic to dairy, strawberries, or honey:

- ☐ Yes, I am allergic to dairy, strawberries, and/or honey
- ☐ No, I am not allergic to dairy, strawberries, and/or honey
- ☐ I am not sure if I am allergic to dairy, strawberries, and/or honey

In the Event of a Research Related Injury

Ohio University does not offer reimbursement for medical expenses or other compensation for research-related injuries. Emergency services will be called for injuries occurring on the Ohio University campus. You or your medical insurance will be billed for this service. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. No other medical treatment or financial compensation for injury from participation in this research project is available. By signing this form, you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact Dr. Forney at 740-593-1085. Should you experience a medical emergency, please call 911 or seek immediate medical attention.

Possible Benefits

This study is important to science/society because it will provide information about how psychological and biological factors influence reactions to food intake. This will inform future treatment development.

You are not expected to benefit personally by participating in this study.

Confidentiality and Records

The information below describes how the confidentiality of your research records will be protected in this study.
Your study information will be kept confidential by removing your name from the data you provide. Hard copies of your data (e.g., paper questionnaires) will be stored in locked filing cabinets in Dr. Forney's locked research office and your blood samples will be stored in a locked research space. Your data will be identified with a unique code, and your name will only be linked to your unique code in a secure, web-based application, REDCap. REDCap follows the Health Insurance Portability and Accountability Act (HIPAA) guidelines. The digital record in REDCap will be destroyed

after the completion of data collection, which will be completed by April 2026. These links may be destroyed earlier.

If we have concerns about your immediate safety (e.g., imminent risk of suicide), we may break confidentiality to alert the appropriate authorities (e.g., 9-1-1).

If you choose to be audio recorded, these audio recordings will be stored on encrypted flashdrives in locked research offices using your unique code or saved in encrypted files on a password-protected shared drive. These recordings will be deleted following the completion of interrater reliability, which is anticipated in April 2026.

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

- Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
- Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU

Compensation

As compensation for your time/effort, you will receive $50 for the first study visit and $63 each for the second and third study visits. Compensation will be prorated for degree of completion. For example, Study Visit 1 is made up of three components (first interview and height/weight compensated at $20, second interview compensated at $20, questionnaires compensated at $10). If you only completed one of the interviews at the first study visit, you would be compensated $20. If you completed both interviews, you would be compensated $40. Your participation for the second and third study visits will be prorated for degree of completion at the rate of $25 per hour.

Please be aware that certain personal information, such as name, email address, phone number, tax ID/social security number (for a W-9/W-8) and address may be provided to the Ohio University Finance Office to document that you received payment for research participation. However, your study data will not be shared with Finance.

Cost to Participate in the Research

There is no cost to you for participating in this research.

National Institute of Mental Health Data Archive

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH).

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Please indicate if you are willing to have your data submitted to the National Institute of Mental Health Data Archive (NDA)

- ☐ Yes, I am willing to have my data submitted to NDA
- ☐ No, I am not willing to have my data submitted to NDA

Future Use Statement

Data/samples collected as part of this research may be used for future research without your additional consent, but only after all identifying information has been removed. We may share the de-identified data with other researchers as part of this future research. This is a separate process from the National Institute of Mental Health Data Archive.

Voluntary Participation

Your participation in this research is completely voluntary, and you may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you or your relationship with Ohio University, and you will not lose any benefits to which

you are otherwise entitled.

Withdrawal from Study
The investigators conducting the study may need to remove you from the study for a number of possible reasons, such as failure to follow directions or to protect you from excessive risk. If you leave the study early, either by voluntarily withdrawing or because the investigators remove you, data you provided up to that point will remain in the study database unless you explicitly request to withdraw your identifiable data.

Conflict of Interest Disclosure
The researchers have no relevant conflicts of interest to disclose.

Contact Information
If you have any questions regarding this study, please contact the investigator Dr. Jean Forney at forney@ohio.edu or 740-593-1085.

If you have any questions regarding your rights as a research participant, please contact the Director of Research Compliance, Ohio University, (740) 593-0664 or compliance@ohio.edu.

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By signing this document, you are agreeing that:

- you have read this consent form (or it has been read to you) and you have been given the opportunity to ask questions and have them answered;
- you have been informed of potential risks and they have been explained to your satisfaction;
- you understand Ohio University has no funds set aside for any injuries you might receive as a result of participating in this study;
- you are 18 years of age or older;
- your participation in this research is completely voluntary.

_____ _____
Signature of Person Consenting to Participate in Research Date

_____
Printed Name

_____ _____
Signature of Study Team Member Obtaining Consent Date

_____
Printed Name