**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 clicking "I consent" 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 responded to an advertisement and you are a cisgender female aged 18-40 with body image concerns and a body mass index (BMI) between 18.5 and 26.5 $kg/m^2$.

We expect to screen 4000 participants for the study and enroll 152 women in the main 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).

**Study Procedures**

If you agree to participate in this screening survey, you will be asked to complete a series of online questions to determine your eligibility for the in-person study. The online survey will take 5-10 minutes to complete. If you appear to be eligible, you will be asked to do a 15-minute phone interview scheduled at your convenience.

If you appear to be eligible for the in-person study, you will be asked to visit the lab on three occasions. At the first study visit, you will 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 or anti-depressants 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 8.5 hours. The screening process (survey and phone interview) will take up to 30 minutes. 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.

In completing this screening survey, you will also be considered for a study that is investigating the relationship between taste perception and body image concerns ("Taste Perception and Body Image Concerns" IRB-FY24-233). This study involves completing study visits on two different mornings and consuming a yogurt on each morning. You will be randomly assigned 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 have an equal chance of being assigned to one of these conditions and will find out which condition you are assigned to after you consent to participate. You will be asked to wear a skin conductance sensor, consume yogurt, and fill out questionnaires at both visits. You will only receive compensation for participating in this in-person study, if you are eligible.

**Risks and Discomforts You May Experience**

Risks or discomforts that you might experience are feeling uncomfortable when answering questions about your behaviors and attitudes. You may choose to skip any question you wish or discontinue at any time without any penalty to you. We have sought to minimize the risk that confidentiality is broken by using a secure web platform and application. Only members of the research staff will have access to the online survey. For maximum confidentiality, please clear your browser history and close the browser before leaving the computer.

If you are eligible and choose to enroll in the larger study, you will be asked to have an indwelling IV catheter inserted on two occasions. 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.

**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 research staff. If you are not eligible or not interested in the in-person study, we will not collect your name or other identifying information. You will only be asked for your name and contact information if you appear eligible for the in-person study and you are interested in participating in the in-person

study. Only staff involved in the study will have access to your name and contact information. Your contact information will be stored 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.

For maximum confidentiality, please clear your browser history and close the browser before leaving the computer or exiting the application on your mobile device.

The results of this study could be published, but we would not disclose any information that could identify you.

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**
The current study will be used to determine eligibility for an in-person study. Only eligible participants will be invited into the lab to complete the in-person study, where participants may be compensated up to $176. You will not receive compensation for the current online screening survey.

**Cost to Participate in the Research**
There is no cost to you for participating in this research.

**Future Use Statement**
Data 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.

**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 clicking "I consent," 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.