Consent for Research Participation

Research Study Title: Foods within a Meal and Food Liking Study

Researcher: Dr. Hollie Raynor, PhD, RD, LDN, University of Tennessee, Knoxville

Why am I being asked to be in this research study?

We are asking you to be in this research study because you are of a healthy weight according to medical standards, an adult between the ages of 18 and 35, and do not have any foods you must avoid to prevent you from taking part in this study.

What is this research study about?

The purpose of the research study is to evaluate how different types of food within a meal influence your liking of these foods.

How long will I be in the research study?

If you agree to be in the study, your participation will involve one screening session and four meal sessions, which will occur over 2 to 8 weeks. These meetings will occur in-person.

What will happen if I say "Yes, I want to be in this research study"?

If you agree to be in this study, procedures and activities are conducted in-person. Due to COVID-19, health safety procedures may be put in place during your participation in the study. This could involve social distancing, wearing a face covering, and completing health screening prior to an appointment.

1) When/if social distancing is in place, Research staff will maintain 6 feet of distance between themselves and participants.

2) When/if the use of face coverings is in place, Research staff will wear a face covering over their nose and mouth at all times participants are in the lab. Participants will also be asked to wear face coverings while in the laboratory and in the same room as the research staff. Face coverings will be provided to participants if needed.

3) When/if health screenings are in place, Research staff will text the participant the online health screening survey early on the day of their appointment. If the participant has not completed the health screen 30 minutes prior their appointment, the link will be resent. If the participant does not complete the survey before their visit, research staff will verbally administer the screening upon the participant's arrival. Appointments should be rescheduled if the participant fails the health screen. Ask the following questions:

    a. Have you traveled outside the country in the past two weeks?
    b. Have you been told to quarantine/isolate by a medical provider or the health department?

c. In the last 14 days, have you had face-to-face contact for 10 minutes or more with someone who has or is suspected of having COVID-19?
d. Do you have any of the following symptoms?
    i. Fever or chills
    ii. Cough
    iii. Achiness
    iv. Shortness of breath or difficulty breathing
    v. New or worsening cough
    vi. Loss of smell, taste, or appetite
    vii. Sore throat
    viii. Vomiting or diarrhea

If you agree to be in this study, we will ask you to come to the Healthy Eating and Activity Laboratory (HEAL) for 1, 60-minute screening session and 4, 30-minute meal sessions. During the first screening session you will be asked to complete questions about your demographic information (age, race, education, etc.) and your height and weight will be measured. In addition, you will be asked to taste test the foods to be used in the study. Then you will be scheduled for 4 meal sessions. For these 4 meal sessions, you will be asked to not change your normal eating habits and to not do physical activity for 24 hours before your appointment. Additionally, you will be asked to eat before 10am on the meal session days, but not to eat within 3 hours of the meal session. At the meal sessions you will be asked to recall all of the foods and drinks you consumed and any physical activity you may have completed in the previous 24 hours. If you have eaten any foods or drinks (other than water) within 3 hours of your appointment, did not eat any food before 10am, or have completed any physical activity within 24 hours of the scheduled appointment, your appointment will be rescheduled. Next, you will be asked to rate your level of hunger and fullness, and liking of the foods prior to being served the meal. Then, you will be served a meal consisting of a variety of items, which could include chicken soup or tomato soup, sugar-free chocolate pudding, grapes, blueberry yogurt, macaroni and cheese, vanilla ice cream, pretzels, and honey graham snacks. You will have 25 minutes to eat as much or little as you wish. After eating the meal you will rate your level of hunger and fullness, and your liking of the foods. You will need to complete all sessions within 8 weeks. Please call Dr. Hollie Raynor at (865) 974-9216, ext. 1 if you have any questions about these procedures for the study.

What happens if I say "No, I do not want to be in this research study"?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

What happens if I say "Yes" but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

If you decide to stop before the study is completed, you may contact the HEAL lab at 865-974-0752 to let us know you would no longer like to participate. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

Possible risks of this research study are considered minimal. It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. The confidentiality procedures are described later in this form. You may be allergic to the foods used in this investigation, but you have been phone screened on this criterion.

Are there any benefits to being in this research study?

We do not expect you to benefit from being in this study. Your participation may help us to learn more about the prevention and treatment of obesity. We hope the knowledge gained from this study will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by storing it securely. Only persons conducting the study will have access to your information unless you specifically give permission in writing to do otherwise.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information we collect about you. These include:

- People at the University of Tennessee, Knoxville who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- A description of this study will be posted on a public website, **http://ClinicalTrials.gov**, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this study is over?

Your research information may be used for future research studies or shared with other researchers for use in future research studies without obtaining additional informed consent from you. If this happens, all of your identifiable information will be removed before any future use or distribution to other researchers.

Will I be paid for being in this research study?

If you complete all procedures in this research study, you will receive a $50 Walmart gift card at your final session. You will not receive any payment if you withdraw from the study before completing all of the activities.

What else do I need to know?

We may need to stop your participation in the study without your consent if you no longer meet the study's eligibility requirements.

The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researchers,

Dr. Hollie Raynor
336 Claxton 37996-3400
The University of Tennessee, Knoxville
Knoxville, TN 37996-1920
Phone: (865) 974-9126, ext. 1

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
2240 Sutherland Ave., Suite 2,
Knoxville, TN 37919-2333
Phone: 865-974-7697
Email: utkirb@utk.edu

STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member	Signature of Research Team Member	Date