IRB-Approved Parental Consent Form for

Lunchtime Meal Feeding Study for Preschool Children

ClinicalTrials.gov Protocol ID: ChildFood402

ClinicalTrials.gov ID Number: NCT03926065

Principal Investigator: Dr. Barbara J. Rolls

Sponsor: The Pennsylvania State University

Grant Title: Strategies to Moderate Energy Intake for the Prevention of Obesity in Children

Grant Number: R01DK082580

Funded by: National Institute of Diabetes and Digestive and Kidney Diseases

Institutional Review Board
The Pennsylvania State University

IRB ID: STUDY00012358
Initial Approval Date: 10 May 2019

IRB Protocol Document version 0.03
Approval Date: 26 February 2020

CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: *Lunchtime Meal Feeding Study for Preschool Children*
Principal Investigator: *Barbara J. Rolls, PhD*

Address: *226 Henderson Building University Park, PA 16802*

Telephone Number: *814-863-8482*

Subject's Printed Name: _____

We are asking you to be in a research study. This form gives you information about the research.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you and there will be no penalty or loss of benefits to which you are entitled.

Please ask questions about anything that is unclear to you and take your time to make your choice.

Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study, and we may ask them to agree (give assent) to take part. Throughout the consent form, when we say "you" we mean you or your child.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information provided above.

1. **Why is this research study being done?**
   The purpose of this research is to test how children respond to differences in vegetable appeal in a lunchtime meal.

   Approximately 60 children, and their parents will take part in this research study in the community.

2. **What will happen in this research study?**

   Please fill out the provided Screening Questionnaire. This questionnaire will be used to determine your child's eligibility for this study. If eligible, the following study procedures will be followed.

   If you agree to allow your child to take part in this research, your child will have lunch for 4 different testing sessions that are provided by the Laboratory for the Study of Human Ingestive Behavior.
   Lunch will take place during the child's regularly scheduled lunch period in his or her pre-school classroom at your childcare center. The test meal will include foods that are normally served in the child care center

and will meet Child and Adult Care Food Program (CACFP) recommendations. Each test meal will consist of fish sticks, ketchup, rice, broccoli, corn, applesauce, and milk. Study staff will observe these test meals.

At the end of the study, children will meet with a research assistant for a brief visit that includes the Tasting Game, which will involve assessing the child's preference of the foods used in the study. Your child's height and weight will also be measured once during the study by a trained lab staff member. We may take a photograph of the children during a test session to be used in poster or slide presentations of this study at scientific meetings. If you do not wish your child to be included in a photograph, there is a place for you to indicate such at the end of this consent form.

Parents will be asked to complete a set of questionnaires (4 total), a background questionnaire and behavioral questionnaires, which will be distributed toward the end of the study. We will schedule appointments around a parent's pick up of their child from the center for the parents to return the questionnaires and receive payment information.

Teachers will also be asked to complete a questionnaire in which they will be answering questions about children enrolled in the study. There is a place for you to indicate whether or not questions about your child may be answered by teachers at the end of this consent form.

3. What are the risks and possible discomforts from being in this research study?

There are minimal risks involved in eating the meals. The foods served will be commonly served items at the child care center. It is possible that investigators will discover a participant's previously unknown food allergy during the course of the study. If this occurs, the parent(s) of the child will be notified immediately so that a quick decision about medical care can be made and action can be taken.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to you?

There are no direct benefits for participating in this research.

4b. What are the possible benefits to others?

You will be aiding in our understanding of human eating behavior.

5. What other options are available instead of being in this research study?

Participation in research is completely voluntary. You can decide to participate or not to participate. You may choose not to take part in this research study.

6. How long will you take part in this research study?

The total time you will spend participating in this project, including meals, the game, and height and weight measurements, will be roughly 3 hours (30 minutes for each meal and 30 minutes for obtaining height and weight and the tasting game).

The total time for parents will be roughly 30 minutes to complete the questionnaires.

Total time of child and parent participation will be approximately 3 hours.

7. How will your privacy and confidentiality be protected if you decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information.

A list that matches your child's name with your code number will be kept in a locked file in a locked closet in the lab manager's office. Parents will not have their own identifiers - we will use your child's three digit number and letter to label parent data.

Children's research records will be labeled with a number and letter of the alphabet and will be kept in a locked room in the lab office.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsor, National Institutes of Health
- The Institutional Review Board (a committee that reviews and approves research studies) and
- The Office for Research Protections.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to The National Institutes of Health in order for it to evaluate or audit the research. For

additional information ask the principal investigator or a member of the study team or contact the Office for Research Protections at (814) 865-1775.

If parents agree to the use of photographs in poster or oral presentations, facial images may be recognizable, but no names or other identifiable information will be included.

7b. What will happen to my research information and/or samples after the study is completed?

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

8. What happens if you are injured as a result of taking part in this research study?

In the unlikely event you become injured as a result of your participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By signing this document, you are not waiving any rights that you have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators.

9. Will you be paid or receive credit to take part in this research study?

Parents will receive $20.00 after participation in all test meals (4 total) and $40.00 for return of questionnaires. Total payment will be $60.00.

If, for any reason, you do not complete the entire 4 meals, payment will be pro-rated at $5 per meal. You will be paid $10 per questionnaire returned.

Payments will be given in cash.

10. Who is paying for this research study?

This research is funded by the National Institutes of Health.

11. What are your rights if you take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Your participation and parents' participation are voluntary. You can stop at any time. You can choose not to answer any questions you don't want to answer. You do not have to eat any foods or beverages that you do not want to eat. Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would receive otherwise.

Persistent inability to adhere to protocol or blatant intentional lack of compliance can result in removal from the study.

If you are dropped for any reason, you will be compensated for any time that you have already given to the study.

12. If you have questions or concerns about this research study, whom should you call?

Please call the lab manager, Christine Sanchez, at 814-863-8482 if you:

- Have questions, complaints or concerns about the research, including questions about compensation.
- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, IRB-ORP@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Office for Research Protections' website at https://www.research.psu.edu/irb/participants for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the ORP at (814) 865-1775.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions the subject or subject representative has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____
Signature of Subject	Date	Printed Name

Signature of Parent(s)/Guardian for Child

Child's Name:_____ Date of Birth:_____

☐ My child's photograph **MAY** be used in presenting the results from this research in a poster or oral presentation.

☐ My child's photograph **MAY NOT** be used in presenting the results from this research in a poster or oral presentation. NOTE: Images will be destroyed within 3 years of completing this research.

Teacher Questionnaire Consent

☐ My child's teacher **MAY** answer questions about my child.

☐ My child's teacher **MAY NOT** answer questions about my child.

By signing this consent form, you indicate that you permit your child to be in this research and agree to allow his/her information to be used and shared as described above.

_____	_____	_____
Signature of Parent/Guardian	Date	Printed Name