Effect of Varying Proportions of Low- and High-Energy-Dense Foods Over 5 Days in Preschool Children

ClinicalTrials.gov Protocol ID: ChildFood503

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Principal Investigator: Dr. Barbara J. Rolls

Sponsor: The Pennsylvania State University

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CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: 5 Day Preschool Study - 3

Principal Investigator: Barbara J. Rolls, Ph.D.

Address: 226 Henderson Building, University Park, PA 16802

Telephone Number: 814-863-8482

Subject's Printed Name: _____

Subject's Email: _____

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.

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, "you" always refers to the person who takes part in the research study.

1. Why is this research study being done?

We are asking you to be in this research because you meet the preliminary criteria for participation in this study.

The purpose of this research is to test how children respond to different meals over 3 five day periods.

2. What will happen in this research study?

If you agree to take part in this research, you will be provided breakfast, lunch, dinner and two snacks (afternoon and evening) over 3 periods of 5 consecutive days (Monday – Friday). There will be 3 study weeks (5 consecutive days), with a minimum 1 week break in between each study week.

All meals are provided by the Laboratory for the Study of Human Ingestive Behavior. Breakfast, lunch, afternoon snack and dinner will take place during the child's regularly scheduled meal periods in a pre-school classroom at your childcare center. Meals served will be similar to those served by the pre-school (see attached food list). These meals and snacks meet the USDA and Child and Adult Care Food Program (CACFP) recommendations for calorie and nutrient content for pre-school aged children. Trained research staff will observe these meals. Evening snack will be packed out for the child to take home along with an

Evening Report Form which is to be filled out and returned with the evening snack the next morning. We ask that no foods outside of those provided by this study are consumed during each test week.

In the event of unexpected events (i.e. unscheduled child care center closure, inclement weather, etc.), researchers may decide that a meal, or meals, may be packed out for consumption outside of the child care center and be returned to study staff the following day. If this should occur, you will be notified in advance. Applicable instructions for serving/reheating will be provided.

Physical activity levels will also be measure over the 3 periods of 5 consecutive days using accelerometers. The accelerometers will be worn while the children are present at the daycare center (from before breakfast to after dinner). Research staff will attach a device to the child's waist upon arrival at the center each morning and remove the device upon the child's departure from the center each evening.

At the end of the study, children will meet with a research assistant for a brief interview that includes The Tasting Game, which will involve assessing the child's preference of the foods used in the study and reasons they stop eating at a lunchtime meal. 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 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. Questionnaires will be distributed toward the end of the study. You are free to skip any questions you do not wish to answer. Payment information will be obtained during the last week of study participation, as well.

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 no risks involved in eating the meals. The foods served will be commonly served items at the day 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.

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?

You may decide to not participate in this 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 37.5 hours (30 minutes for each meal and 15 minutes for obtaining height and weight and the tasting game). The duration of the study will be 5 consecutive days, and you will be completing three of these 5 day periods for a total of 15 days.

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

Total time of child and parent participation will be approximately 39 hours.

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

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 name with your code number will be kept in a locked file in a locked closet in the lab manager's office.
- Your research records will be labeled with a number, color, and letter of the alphabet and will be kept a locked file in a locked closet in the lab manager's 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 most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

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.

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 anytime.

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 $225.00 upon completion of all test days (15 total) and $40.00 for return of questionnaires. Total payment will be $265.00.

If, for any reason, you do not complete the entire 15 days, payment will be pro-rated at $15 per day. You will be paid $10 per questionnaire returned.

Payments will be made in the form of a check. Your Social Security Number may be required to receive this payment.

Total payments within one calendar year that exceed $600 will require the University to report these payments to the IRS annually. This may require you to claim the compensation that you receive for participation in this study as taxable income.

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.

Missing 3 or more days in 1 study week or 2 meals per day for 3 or more days in 1 study week can also 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.
- 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, ORProtections@psu.edu if you:

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

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 and have answered any questions he/she 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.

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
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. Please keep the second copy of this consent form for future reference.

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.

	YES	NO
Does your child have any food allergies?	☐	☐
If YES, how does this affect his/her diet? _____		
Does your child suffer from lactose intolerance?	☐	☐
If YES, how does this affect his/her diet? _____		
Does your child have a special diet (anything that will affect what he/she can eat)?	☐	☐
If YES, please specify _____		

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