

PARENT OF RESEARCH PARTICIPANT

STUDY CONSENT FORM

Benefits of Breakfast in the Classroom

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This consent may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

This is a research study being conducted by Dr. Heather Leidy at Purdue University.

Research studies include only people who choose to participate. As a parent of a study participant, you have the right to know about the tasks and activities that will be used in this research study so you can make the decision whether or not to participate. The information presented here is simply to make sure you understand so that you may give your approval for your child to participate in this research study. Please take your time to make your decision and talk about it with your family and friends.

Your child is being asked to take part in this study because your child attends Center Middle School which will be implementing a 'Breakfast in the Classroom' program. In order for your child to participate in this study, you must give your written assent.

Please note: regardless of whether your child participates in this study, your child will still be able to participate in 'Breakfast in the Classroom.'

What is the purpose of this study?

The purpose of this study is to determine whether 'Breakfast in the Classroom' increases breakfast consumption and improves overall health and well-being. In addition, we want to determine whether different foods provided at breakfast improve these outcomes.

This research is being done because we currently do not know whether school breakfast programs that allow the students to consume breakfast in their classrooms is beneficial for overall health and well-being.

How many people will take part in the study?

We expect that up to 550 students will take part in the study.

What will my child do if I choose to allow his/her to be in this study?

At school your child will complete the following tasks **at the beginning and end** of the study. The study is 8 weeks in duration. Also, all questionnaires will be completed using either student Chromebooks or as paper forms.

1) Body Weight, Height, and Body Composition: (ESTIMATED TIME: 5 min/time) For one day at the beginning and end of the study, your child will have his/her body weight and percent body fat measured using a research scale in a private room. Also at this time, height will be measured using a wall-mounted ruler in a private room.

2) Characteristics and Breakfast Habits Questionnaires: (ESTIMATED TIME: 5 min/time) For one day at the beginning and end of the study, your child will complete a questionnaire that ask some questions about his/her age, gender, ethnicity, race, and breakfast habits.

At school your child will complete the following tasks **at the beginning, middle, and/or end of the study.**

3) Appetite & Mood Questionnaires: (ESTIMATED TIME: 30 sec/questionnaire) For 3 days at the beginning, middle, and end of the study, your child will complete questionnaires that asks about his/her feelings of hunger, fullness, food cravings, mood, and energy levels. The questionnaires are completed before breakfast, immediately after breakfast, 1 h and 2 h after breakfast, and right before lunch.

4) Snacking Questionnaires: (ESTIMATED TIME: 5 min/questionnaire) For one day at the beginning , middle, and end of the study, your child will complete a questionnaire that asks about his/her snacking behavior and foods that are typically eaten at school and at home.

5) Cognitive Performance: (ESTIMATED TIME: 20 min/questionnaire) For one day at the beginning and end of the study Your child will complete a series of 'computer games' that estimate attention, memory, decision making, and the ability to multi-task.

6) Breakfast in the Classroom Questionnaires: (ESTIMATED TIME 30 sec/questionnaire) For 5 days at the beginning, middle, and end of the study, your child will complete a questionnaire that ask some questions about how much breakfast was eaten and thoughts on breakfast foods.

At school your child will complete the following tasks **at the middle and end of the study.**

7) Breakfast in the Classroom Waste: (ESTIMATED TIME 5 sec/task) For 5 days at the end of the study, your child will eat breakfast (as normal). However, when he/she is finished, he/she will place all containers and uneaten foods into a Ziploc bag and will place these into the classroom bin to assess waste.

How long will my child be in the study?

We expect your child to be in the study for 9 weeks. This will include Baseline (Week 0);4-weeek mid-study; and 8-week post-study measures.

You can stop your child from participating at any time. Your decision to withdraw your child from the study will not affect in any way your child's medical care and/or benefits. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom.

What are the possible risks or discomforts?

The only potential risk is feeling uncomfortable or nervous in having body weight and height measures completed or answering questions about himself/herself. All information is confidential and will not be shared with anyone other than the study staff.

Are there any potential benefits?

If you agree to allow your child to participate in this study, there may or may not be direct benefit to your child. He/she may expect to benefit to the extent that he/she is helping with increases in health knowledge. We hope the information learned from this study will benefit other schools considering serving 'Breakfast in the Classroom.' Your child may receive benefits from this study by understanding why his/her current eating habits are unhealthy and might lead to increased overeating, weight gain, and obesity. This study may show your child which eating habits might be beneficial in order to reduce these unhealthy and unwanted behaviors. There is no guarantee that participating in this project will improve your child's eating habits.

What alternatives are available?

An alternative is to not participate in this research study.

Will I receive payment or other incentive?

Your child will be compensated with a \$25 gift card for participating in the study. The gift card will be given to you at the end of the study.

Are there costs to me or my child for participation?

There is no cost to you or your child for participating in the study.

What happens if my child becomes injured or ill because he/she took part in this study?

If you feel your child has been injured due to participation in this study, please contact Heather J. Leidy, PhD. (Primary Investigator) at 573-825-2620 or email: hleidy@purdue.edu. Purdue University will not provide medical treatment or financial compensation if your child is injured or become ill as a result of participating in this research project. This does not waive any of your or your child's legal rights nor release any claim you might have based on negligence.

Will information about my child and his/her participation be kept confidential?

The project's research records may be reviewed by the departments at Purdue University responsible for regulatory and research oversight.

The project's research records may be reviewed by the Purdue University Institutional Review Board, the Purdue Office for Human Research Protection, Office for Human Research Protections, by departments at Purdue University responsible for regulatory and research oversight.

Original paper copies of all identifiable data will be kept indefinitely in locked storage cabinets and rooms which are only accessible by Dr. Leidy, her research staff, and selected members of her department's information technology resources staff. All data will be de-identified prior to data entry and statistical analyses. There is a risk of breach of subject confidentiality but safeguards are in place to minimize this risk as outlined above.

What are my child's rights if he/she take part in this study?

Your child's participation in this study is voluntary. You may choose not to allow your child to participate or, if you agree to allow him/her to participate, you can withdraw your consent at any time without penalty or loss of benefits to which your child is otherwise entitled. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact Heather J. Leidy, PhD at 573-825-2620 or email: hleidy@purdue.edu.

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University
Ernest C. Young Hall, Room 1032
155 S. Grant Street,
West Lafayette, IN 47907-2114

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to allow my child to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

Participant Name (print)

Participant Parent

Date

Investigator

Date