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IRB Approved
4/14/2026

RESEARCH PARTICIPANT CONSENT FORM FOR ENROLLMENT

Slowly Digestible Carbohydrates for GLP-1 Secretion
IRB # 2025-00000283

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Please read this document carefully. This document describes a research study. You can choose not to participate at any time without any penalty. If you decide to participate in the study, you will be asked to sign the *Consent Form for Enrollment*. Please be sure you understand what participation involves, including possible risks and benefits.

Key Information

You are being asked to participate because you are a healthy adult male or female aged 18–45 years, can read and speak English, do not have diabetes, and do not have allergies or intolerance to gluten or dairy. Eligibility includes fasting blood glucose ≤100 mg/dL and HbA1c ≤5.7%.

Your participation is voluntary. You may choose not to participate or leave the study at any time.

The purpose of this research is to study the impact of slowly digestible carbohydrates on glucagon-like peptide-1 (GLP-1) secretion. We will measure plasma GLP-1 concentration, blood sugar, insulin, and feelings of hunger and fullness.

Your participation will last approximately 5 weeks and includes: 1 screening visit, 2 free preliminary lunches, and 4 morning through lunch study visits. You will be asked to fast overnight for 12 hours before each visit.

During study visits, you will:

1) Consume either a control or carbohydrate-containing beverage
2) Have an IV placed for periodic blood sampling
   Please do not donate blood during participation in this study.
3) Complete questionnaires about your feelings of hunger and fullness
4) Receive lunch at the end of the visit and compensation

Risks include possible mild gastrointestinal discomfort (such as bloating or gas), but these are no greater than those typically encountered in daily life. Other risks include possible slight discomfort during the blood draw. Bruising, venous clot, or infection are risks for any blood draw. Also, some people feel weak or light-headed at the thought or sight of blood. No adverse events or weakness, even slight, is anticipated based on the low volume of blood taken. There may be no direct benefit to you, other than compensation. The study may benefit society by helping identify dietary strategies to naturally activate metabolic pathways for weight management.

What is the study about?

The goal of this study is to determine the potential use of slowly digestible starch as a food-based agent for weight loss. You are being asked to participate because you are a healthy adult male or female aged 18–45 years, can read and speak English, and have no allergies or intolerances to gluten or dairy. You are nondiabetic with fasting blood glucose levels ≤100 mg/dL and HbA1c ≤ 5.7%.

During this study, we will measure plasma GLP-1 concentration, blood sugar, insulin, and feelings of hunger and fullness. We will also collect descriptive information like your biological sex, height, weight, and lifestyle patterns.

What will I do if I choose to be in this study?

At the screening visit, your eligibility was determined. You are1 of ~19 individuals invited to enroll. We will discuss everything the study entails and will happily answer any questions you may have. You will sign the written Consent Form for Enrollment during the start of the first free lunch visit, which you will read about below.

If enrolled, you will be asked to participate in 5 weeks of study visits. We are happy to work with you to accommodate the best day of the week for your study visit. You will be randomly assigned to a treatment schedule by chance, like flipping a coin. Neither you nor the research team will know the treatment (starch or carbohydrate control) you are consuming.

Week 1 – Free Lunch Visits

During Week 1, you will attend two free lunch visits at noon on separate days at the Clinical Research Center (CRC) in Stone Hall on Purdue West Lafayette's campus. You will eat lunch and receive compensation ($25 ea). Then, you will repeat once more during the same week. After this second free lunch, you will pick up a packaged dinner for the next week.

Week 2 – Week 5 – Study Visits

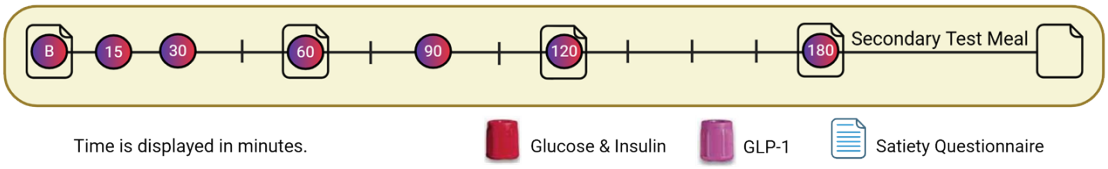
Once per week during Weeks 2–5, you will be asked to come to the CRC at 8:45pm. Please plan your morning walk or commute to arrive on time. You will consume a packaged dinner the night before and fast for at least 12 hours overnight with only water. (You may eat the packaged meal up until 8:59 pm.)

When you arrive at 8:45 am, you will complete a satiety questionnaire. Next, a trained phlebotomist will place a small IV line to collect blood samples periodically over three hours without repeated needle sticks. Approximately 56 mL (~11.4 teaspoons) of blood will be collected at each visit. (This is a little more than 1/10 pint. The standard volume for blood donation is 473 mL.) Across the entire study, approximately 227 mL (~46 teaspoons) of blood will be collected. Please do not donate blood for the duration of this study.

After the first blood draw, you will be given a beverage to drink (control or test). For the next 180 minutes, you will not eat or drink, and your blood will be drawn at 15, 30, 60, 90, 120,

and 180 minutes for a total of 7 tubes (baseline and 6 time points). You are encouraged to relax during the study visit, whether that means reading, watching movies, or studying. The blood collected will be analyzed for plasma GLP-1, insulin, and glucose.

At 60, 120, and 180 minutes, you will complete another satiety questionnaire then be provided lunch. After lunch, you will complete a final satiety questionnaire and receive compensation before leaving. A sample collection timeline is below:



There will be at least 7 days between study visits (washout period). You will follow your normal routine during this break; there is no data collection. After completing all four visits, your participation is complete.

How long will I be in the study?

Your participation will last about 5 weeks, unless you request a longer washout period. This time will include 7 visits to the Clinical Research Center (1 screening, 2 lunches, 4 study visits). The screening visit will take about 20 minutes. The lunches will take about 30-45 minutes. Each study visit will last no longer than 4 hours (8:45am-12:45pm).

Please consider the risks of taking part in this study before you decide to participate.

The risks of being in this study are like those in your normal life. Some people might feel bloated or have gas after eating slowly digestible carbohydrates. These symptoms typically resolve on their own within a short period and do not usually require medical attention, but they may cause short-term discomfort during the study period.

Blood draws may cause bruising, pain, venous clots, and infection. These risks can be reduced by cleaning the insertion site, following good clinical practices, and having only a trained, experienced phlebotomist draw blood.

There is a small chance of a privacy breach, even though all your information will be kept secure. Your records, if physical, will be behind two locks in a safe place, and any HIPAA-protected information will be stored in a HIPAA-protected folder on Purdue Box on a password-protected computer.

Are there any benefits?

There are no direct benefits for you. But this study may help us to understand how slowly digestible carbohydrates affect GLP-1 secretion, blood sugar, and satiety. This could help decrease the risk of diseases like obesity and diabetes for others in the future.

How will the researchers protect my information and who will see the information collected in this research?

Your identifiable information will be stored securely. Any data considered protected under HIPAA will be de-identified using a numeric code and stored in a HIPAA-protected folder or in a locked filing cabinet in a secure location on Purdue's campus. Only the research team will have access to your records. We will keep copies of the signed consent forms, screening information, and study progress for three years after the study's termination. At that time, they will be destroyed. If the documents are physical, they will be shredded. De-identified data may be shared with the research community or in journals in which study results are published. No identifiable information will be published. Efforts will be made to limit the use and disclosure of your data to people who need it. We cannot promise complete secrecy. Information about you may be used or seen by the US DHHS Office for Human Research Protections because they are responsible for regulatory and research oversight.

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

Will I receive payment or other incentive?

You will be compensated for your time and involvement in this study. You have the potential to make $425 for 100% participation. This is a cross-over study, which means it is important that participants complete the study in its entirety. To incentivize 100% attendance, we will pay more in the last two weeks. See the compensation breakdown below:

Screening Visit - $25
Two free lunch visits (Week 1) - $25 each = $50
Study Visit (Week 2) - $75
Study Visit (Week 3) - $75
Study Visit (Week 4) - $100
Study Visit (Week 5) - $100

If you desire to leave early, you will still be compensated for your time, as described above. All subjects will be required to fill out and sign a payment log with the Food Science Department Business Office after each payment. The researcher onsite will have this log.

Are there costs to me for participation?

If you choose to participate in this study, the only potential cost to you is parking when coming to the Clinical Research Center. This will not be reimbursed. Please plan your commute accordingly so that you arrive to the Clinical Research Center at Stone Hall on time for each study visit at 8:45am.

What are my rights as a research participant in this study?

Participation is voluntary. You may stop at any time without penalty. Your relationship with the investigators will not be affected. If you choose to leave the study, please notify the research member working with you about your decision as soon as possible.

How might the information collected in this study be shared in the future?

If, through screening, you are deemed eligible and voluntarily choose to enroll in the research study, we will keep a copy of the signed consent form, screening information, and study progress including all data collected for three years after termination of the study. At that time, they will be destroyed. If the documents are physical, they will be shredded.

If you enroll, yet dropout from the study, your personal health information data will be removed and destroyed at the point of dropout. However, copies of the signed consent forms and a record of compensation will be retained for three years after termination of the study; then, they will be destroyed. If you choose to withdraw your consent at any time, you will be given the opportunity to request the destruction of any identifiable, coded data, and unanalyzed stored blood samples. Please note that de-identified data or data incorporated into completed analyses may not be able to be withdrawn. If you withdraw and request the withdraw of your data, then no further use will be made of those materials, nor will data be retained for research purposes. Your data will be destroyed.

During the study, blood samples will be coded and kept in freezer a locked laboratory in the Department of Food Science on Purdue's West Lafayette campus. Samples will be accessible only to the research team. As a reminder, your identifiable information has been replaced by a numerical code. Your data will not be used for anything other than what is approved by the Institutional Review Board (IRB) and detailed in the IRB protocol.

Conflict of Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in the research study.

Two of the researchers on this study, the Principal Investigator, Dr. Bruce Hamaker, and Dr. Thaisa Cantu-Jungles (who serves as Co-PI) are co-founders and part owners of RiteCarbs, LLC, a start-up company that develops science-based carbohydrates to promote human health. Some of the data on the effects of raw corn starch on activating the GLP-1 system collected as part of this study might be used to support product development for RiteCarbs, LLC.

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

If you have questions, comments, or concerns about this research project, your first point of contact is Erica de Jong. Her contact is listed below. If you reach out, indicate that you are a research participant and provide Erica the best method of follow-up contact. You may also contact the principal investigator, Dr. Bruce Hamaker. To report anonymously via Purdue's Hotline, see www.purdue.edu/hotline

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
Seng Liang Wang Hall
516 Northwestern Ave
West Lafayette, IN 47906

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Consent for Enrollment

By signing this consent form, I confirm I have read the information in this consent form and have had the opportunity to ask questions. I will be given a signed copy of this consent form. I voluntarily agree to take part in this study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date