Study Number: STUDY2025-00000283
IRB Approved
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RESEARCH PARTICIPANT CONSENT FORM FOR SCREENING

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

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Please read this document carefully. This document describes the screening process for a research study. You can choose not to participate at any time without any penalty. If you decide to participate in the screening visit, you will be asked to sign this *Consent Form for Screening*. If you are deemed eligible to join the study, you will be given the opportunity 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 screen 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% which will be determined during screening. Your participation is voluntary. You may choose not to participate or leave the screening or study at any time.

The purpose of this screening is to determine your eligibility to participate in a research study on the impact of slowly digestible carbohydrates on glucagon-like peptide-1 (GLP-1) secretion.

Your participation in the screening will last approximately 20-30 minutes. During which you will:

1) Choose whether to sign this Consent Form for Screening
2) Confirm your responses from the Pre-Screening Questionnaire
   Including measuring height and weight to calculate BMI
3) Have 3 mL (~0.61 teaspoons) of your blood drawn
4) Receive a full overview of the study and the Consent Form for Enrollment
5) Receive $25 if you complete the Screening Visit

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. Participation in this screening may be no direct benefit to you, other than compensation.

What is the study about that I am screening for?

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 will be screened to determine if you are nondiabetic with fasting blood glucose levels ≤100 mg/dL and HbA1c ≤ 5.7%.

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

What will I do if I choose to participate in screening?

At the screening visit, your height and weight will be measured to calculate body-mass index (BMI). A blood sample will be collected to assess fasting glucose and HbA1c levels. You will receive a copy of your blood results through FileLocker (if Purdue-affiliated) or as a printed copy, and you will be notified 1-2 weeks after the screening visit by your provided best method of contact whether you qualify.

If eligible, you may be 1 of 19 individuals invited to enroll and to the next visit. At that visit, we will review what the study entails, and we are happy to answer any questions you may have. You will sign the written Consent Form for Enrollment at the start of the next visit.

How long will this take?

Your participation in screening will last about 20-30 minutes.

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

Blood draws may cause bruising, pain, venous clots, and infection. Still, these risks can be reduced by cleaning the insertion site, following all good clinical practices, and having only an experienced, trained 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, outside of compensation. But the research study that you are screening for 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 the screening process. You will receive $25 upon completion of the screening visit. 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 in screening?

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.

What are my rights as a participant in this screening?

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, please notify the research member working with you about your decision as soon as possible.

How might the information collected in this screening 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 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, through screening, you are deemed ineligible, or you are eligible but choose not to enroll in the research study, your personal health information will be destroyed immediately. If the information is physical, it will be shredded. If it is digital, it will be permanently deleted. However, we will keep track of how many people were screened to compare to how many were enrolled, and a record of compensation.

If you enroll, yet withdraw from the study, your personal health information data will be removed and destroyed at the point of dropout. Upon withdrawal you may request that any identifiable or coded data and stored blood samples that have not yet been analyzed to be destroyed, and no further use be made of those materials. However, copies of the signed consent forms and a record of compensation will be retained for three years.

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 screening for 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 to Participate in the Screening Visit

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 the screening visit portion of this study

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date