Pennington Biomedical IRB FWA 00006218
Approved March 4, 2022

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT INFORMED CONSENT - PART I

Title of Study: Safety and Tolerability of Soy Fiber in the Elderly: A Dose Escalation Study

Study Sponsor: National Institute of Aging

Key Information

- **Why am I being asked to review this form?**
  - You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.

- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this study is to determine the maximum tolerated dose of dietary fiber from soybean flour made from whole soybean pods.
  - Your expected time in this study will be approximately four weeks consisting of four study visits.
  - The procedures involved in this study include:
    - Measurement of weight, height, blood pressure, heart rate, and temperature.
    - Blood draws.
    - Nutrition counseling.
    - Diet intervention for three weeks.

- **What are the possible risks and discomforts?**
  - **Blood Draws/IV Procedure**
    There is a possibility of infection and/or pain and bruising at the vein on your arm where the needle is inserted. Aseptic (sterile) technique and trained personnel minimize these risks.
  - **Study Foods**
    There are no known risks from consuming the foods provided during the study. They are foods that are ordinarily consumed by people and are cooked and stored using methods common in food preparation. The research dietitians and staff of the research kitchen are experienced in developing, preparing, storing, and dispensing study-specific food products developed to meet the needs of the study. You will be asked to complete a questionnaire informing staff about any food allergies or intolerances.

- **Soybean**
  There are no known risks from consuming the soybean flour. Since soybean is a legume (such as chickpeas, navy beans, and black beans) it could cause an allergic reaction in people who are allergic to legumes. Therefore, we ask that you inform us if you have legume allergies.

A more comprehensive and detailed description of reasonably foreseeable risks to subjects are included later in Section 6 of the informed consent.

- **What are the possible benefits?**
  - If you take part in this study, you will learn how to increase the dietary fiber content of your diet.
  - You may also see improvements in your bowel movements. This information will help others in the future.

- **If you choose not to participate in the study, are there other choices?**
  - You have the choice at any time not to participate in this research study.
  - If you decide not to participate in this study, your other choice may include:
    - Taking part in another study

Detailed Information

1- Who is doing the study?

Principal Investigator:	Candida Rebello, Ph.D., R.D. 225-763-3159
Medical Investigator:	Frank Greenway, M.D. 225-763-2576 24-hr. Emergency Phone Nos.: (Weekdays 7:00 a.m.-4:30 p.m.) 225-765-4644 (After 4:30 p.m. and Weekends)
Co-Investigator:	John Kirwan, Ph.D. 225-763-2513
Co-Investigator:	Jeffrey Keller, Ph.D. 225-763-3190

Dr. Candida Rebello directs this study, which is under the medical supervision of Dr. Frank Greenway. We expect about ten people from one site will be enrolled in this study. The study will take place over a period of four months. Your expected time in this study will be one month. This is a Pennington Biomedical Research Center study.

2- Where is the study being conducted?

This study takes place at the Outpatient Unit of the Pennington Biomedical Research Center**.**

3- What is the purpose of this study?

The purpose of this study is to determine the maximum tolerated dose of dietary fiber from soybean. The result of this study will enable us to define the optimal dose of dietary fiber from soybean for testing of its effects in the elderly.

4- Who is eligible to participate in the study?

Inclusion Criteria

- Have a body mass index (BMI) in the range 30 kg/m^2 to 40 kg/m^2 (a number calculated from your height and weight).
- Are between 70 and 85 years of age.
- Have no evidence of diabetes (fasting blood sugar <126 mg/dL).
- Have no clinically significant gastrointestinal malabsorption syndromes such as chronic diarrhea, or celiac disease.
- Willing to consume the study foods supplied by Pennington for three weeks.

You may not qualify for this study based on other eligibility criteria not listed. The study coordinator will go over this information in detail.

5- What will happen to you if you take part in the study?

After passing the screening, your participation in the research study will be three to four weeks. You will have four study visits all at the Pennington Center. You will be provided with foods for three weeks and you will be required to eat these foods everyday along with foods you usually eat. Each visit will be for approximately one hour. During this time blood will be collected for testing which is explained later in this consent. At the study visits, you will be given foods for each week and you will meet or speak over the phone with a registered dietitian who will help you to incorporate the foods into your usual diet.

You will provide a stool sample each week that was collected within 72 hours prior to your study visit. We will measure a type of fat in the stool as a measure of the response to the study foods that you eat during each week.

CLINIC VISITS

Please note that all times provided for procedures are the total times for each clinic visit and are approximations that may vary depending on circumstances. Table 1 shows what will happen at each study visit:

Screening Visit (2 hours), Before visit fast for at least 10 hours, which means eat or drink nothing except water

We ask you to report to the Pennington Biomedical Clinic in the morning following an overnight fast (except for water) that began no later than 10 hours prior to the study

appointment. If you agree to the procedures by signing the consent form the following procedures will be performed:

- Completion of a brief personal and family medical history questionnaire.
- Completion of questionnaires to assess cognition and general well-being.
- Measurement of height, weight, and vital signs (blood pressure, pulse, and temperature).
- Recording of medication use.
- Collection of blood (less than one tablespoon) to measure your electrolytes (for example, salts), cholesterol, triglycerides, iron, immune cell function, glucose, insulin and other standard health measures.

After this visit, if you meet the inclusion/exclusion criteria you will be contacted by the study coordinator. You will have four study visits at the Pennington Center. Prior to the baseline visit you will be given a stool collection kit by the study coordinator.

Table 1. Schedule of Assessments for Dose Response Study

Procedure	Screening 1	Baseline	Visit 1	Visit 2	Visit 3
Infromed Consent	x				
Height	x				
Weight, and Vital Signs	x	x	x	x	x
Blood Draw	x				x
Medical History Questionnaire	x				
Mental Health questionnaires	x				
Medications	x	x	x	x	x
Adverse Events			x	x	x
Tolerability Questionnaires		x	x	x	x
Nutrition Counseling		x	x	x	
Food Dispensation		x	x	x	
Compliance with Study Foods			x	x	x
Stool Sample Collection		x	x	x	x

Baseline Visit (1 hour to 1½ hours), non-fasting

To start the study, you will visit the Pennington Biomedical clinic in the morning. We will perform the following procedures:

- You will provide a stool sample collected within 72 hours prior to the visit.
- Measurement of weight and vital signs (blood pressure, pulse, and temperature).
- You will receive nutrition counseling from a registered dietitian.
- You will complete a tolerability questionnaire.
- You will be given the study foods for one week with instructions on storage and handling.

Visits 1 and 2 (1 hour to 1½ hours), non-fasting

On the day prior to the visit, you will receive a phone call from the dietitian who will provide you with nutrition counseling, and assess your tolerance to the study foods you

ate over the past week. We ask you to report to the Pennington Biomedical clinic for your study visit and the following procedures will be performed:

- You will provide a stool sample collected within 72 hours prior to the visit.
- Measurement of weight and vital signs (blood pressure, pulse, and temperature).
- You will be required to return all food containers and any leftover foods that were provided to you at the last visit.
- If you tolerate the foods, you will be given the study foods for the following week with instructions on storage and handling.
- If you do not tolerate the foods you will be instructed to fast for at least 10 hours prior to your visit and blood will be drawn (less than one tablespoon) to measure your electrolytes (for example, salts), cholesterol, triglycerides, iron, immune cell function, glucose, insulin and other standard health measures.

Visits 3 (1 hour to 1½ hours), Before visit fast for at least 10 hours, which means eat or drink nothing except water

On the day prior to the visit, you will receive a phone call from the dietitian who will assess your tolerance to the study foods you ate over the past week. We ask you to report to the Pennington Biomedical Clinic in the morning following an overnight fast (except for water) that began no later than 10 hours prior to the study appointment. The following procedures will be performed:

- You will provide a stool sample collected within 72 hours prior to the visit.
- Measurement of weight and vital signs (blood pressure, pulse, and temperature).
- Collection of blood (less than one tablespoon) to measure your electrolytes (for example, salts), cholesterol, triglycerides, iron, immune cell function, glucose, insulin and other standard health measures.
- You will be required to return all food containers and any leftover foods that were provided to you at the last visit.

Following completion of the study procedures at Visit 3, your participation in the study will end.

DESCRIPTION OF PROCEDURES

Study Foods

You will be given foods containing soybean flour that is high in dietary fiber for each day. You will be required to consume these foods everyday along with your usual diet. Each week the dose of dietary fiber from soybean will be increased as follows:

- In the first week you will receive foods containing 4 g of dietary fiber from soybean.
- If you tolerate 4 g of dietary fiber, you will be given foods containing 8 g of dietary fiber from soybean for the second week.
- If you tolerate 8 g of dietary fiber, you will be given foods containing 12 g of dietary fiber from soybean for the third week.

Nutrition Counseling

You will receive nutrition counseling from a registered dietitian to guide you on including these foods in your daily diet. Eating dietary fiber is recommended for health but your body may take time to adjust to increased dietary fiber in the diet. The dietitian will help you to overcome any discomfort you may have from increasing the dietary fiber content of your diet.

Tolerability Questionnaire

You will be required to answer questions about how you feel after eating the study foods and the dietitian will evaluate your tolerability to the dose of dietary fiber. If you tolerate the dose of dietary fiber, you will be given the study foods for the next week

Adverse Events

You will be asked about any medical problems you may have experienced since your participation in this study.

Stool sample

You will be given a triangular piece of plastic that fits under the toilet seat and that accommodates a plastic dish with a screw top. You will be required to collect your stool samples at home no more than 72 hours prior to your visit. You will be provided with instructions for collection of the stools. ***Turn the stools in at the Pennington Center within 24 hours of collection.***

Blood Collection for Health Measures

Following a fast which began no later than ten hours before the appointment, blood will be drawn for standard health and safety measures. Total blood drawn will be less than two tablespoons.

6- What are the possible risks and discomforts?

Blood Draws

There is a possibility of infection and/or pain and bruising at the vein on your arm where the needle is inserted. Aseptic (sterile) technique and trained personnel minimize these risks.

Stool Sample

There is no risk associated with collecting a stool sample except for the distasteful odor.

Study Foods

There are no known risks from consuming the foods provided during the study. The meals provided during the study are foods that are ordinarily consumed by people and are cooked and stored using methods common in food preparation. The research dietitians and staff of the research kitchen are experienced in developing, preparing, storing, and dispensing study-specific food products developed to meet the needs of the

study. You will be asked to complete a questionnaire informing staff about any food allergies or intolerances.

Soybean Flour

There are no known risks from consuming the soybean flour. The soybean being tested in the study is a food which will be grown at the Louisiana State University (LSU) Agricultural Center and milled to a flour at the United States Department of Agriculture (USDA, New Orleans, LA.). This research examines an approach that mimics soybean consumption from parts of the world where its health benefits are known. You may experience some symptoms from increasing dietary fiber in your diet such as flatulence and mild gastrointestinal stress but these symptoms usually resolve as your body gets used to the increase in dietary fiber in your diet.

Food Allergies

Because of the way our meals are prepared for research, and the possibility that the ingredients in the foods we get from commercial vendors could change at any time without our knowledge, it cannot be guaranteed that allergens will be identified and removed from the foods used in our research studies. If you have a food allergy, and you are participating in a study where foods are provided, there is a risk that you could have an allergic reaction. All participants with known life-threatening food allergies must inform staff of their allergies.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

Will I be notified if my blood samples result in an incidental finding?
During a research study, a researcher may notice something that he or she was not looking for. This is called an “incidental” or “unexpected” finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.

Researchers may share some or all of their findings with you. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by the medical investigator or trained study personnel and referred to a treatment facility for further testing and/or treatment.

Risks: It can be very upsetting to learn unexpected information about your health. This is especially true if you learn that you have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. You might need more tests and procedures to find out what the information really means. It’s also possible that the information might be incorrect, so you would worry without cause.

7- What are the possible benefits?

If you take part in this study, you will learn about increasing the dietary fiber content of your diet. You may also experience an improvement in your bowel movements. This information may help others in the future.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Dr. Candida Rebello at 225-763-3159. If you think you have a research-related injury or medical illness, you should call Dr. Frank Greenway at 225-763-2578 during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, the sponsor or someone from the Pennington Biomedical Research Center, may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

Identifiable Private Information or Identifiable Biospecimens

Any identifiers might be removed from your identifiable information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or given to another investigator for future research without additional informed consent from the subject or legally authorized representative.

ClinicalTrials.gov

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. 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.

Biospecimens and Commercial Profit

Your biospecimens may be used to develop new drugs or other products that may result in commercial profit that will not be shared with you.

11- Can your taking part in the study end early?

Dr. Candida Rebello, Dr. John Kirwan, Dr. Jeffrey Keller, Dr. Frank Greenway, or the study sponsor can withdraw you from the study for any reason or for no reason. You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study. Possible reasons for withdrawal include an inability to comply with the study requirements or

medical concerns that would make continued participation not in your best interests. The sponsor of the study may end the study early.

12- What if information becomes available that might affect your decision to stay in the study?

Significant New Findings

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

Clinically Relevant Research Results

In this study, you will be informed of any clinically relevant research that may be discovered.

13- What charges will you have to pay?

None

14- What payment will you receive?

If you agree to take part, we will compensate you $125 for completion of the study. If your participation in the study ends early, you will receive $25 for each visit that you complete. You will not be compensated for the screening visit. Your check will be requested from the LSU payroll department when you complete the study. It usually takes about 3-4 weeks for it to arrive at the Pennington Biomedical Research Center.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You will need to provide your social security number to receive payment.

You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU are required to report this income to the IRS.
Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa and 1-94 for payment to be processed.

I authorize that all information on this Informed Consent form and HIPAA Authorization form, including any personal and financial data may be shared with Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely.

15- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require

ongoing medical treatments, they must be provided by community physicians and hospitals.

16- Signatures

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

_____
Printed Name of Volunteer

_____ _____
Signature of Volunteer Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Candida Rebello, Ph.D., R.D., LDN
Principal Investigator

Frank Greenway, M.D.
Medical Investigator

17- What you need to know about future research with your data, biospecimens or imaging.

You are being asked to allow some of your blood to be stored and used for research at a later time. This bodily material is called a biospecimen. The donation of biospecimens in this study is optional. No matter what you decide to do, it will not affect your study participation. You will still be allowed to take part in the study even if you don't want your specimens to be collected and used for future research

Your blood may be sent to researchers outside of the Pennington Biomedical Research Center. Any personal information that could identify you will be removed before the blood samples are shared.

What you should know about your biospecimens:

- The samples will be stored indefinitely.
- If you agree to have your samples stored, you can change your mind later.
- For privacy and confidentiality, your samples will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your samples with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.
- The future research may or may not take place at Pennington Biomedical and may or may not involve Pennington Biomedical Researchers.
- You will not be compensated for any research studies that might be conducted in the future.
- You will not be informed of the details of any specific research studies that might be conducted in the future.
- The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.
- The research done with your specimens may also help to develop new products in the future, or may be used to establish a cell line or test that could be patented or licensed. You will not receive any financial compensation for any patents, inventions, or licenses developed from this research.

Stools

If you give permission, a part of the stool sample will be collected and stored by this study. Your stored samples may be tested at Pennington Biomedical Research Center or other locations used in future research.

Do you give permission for your stool to be used in future research?

Yes, I give permission _____ _____
Signature Date

No, I do not give permission _____ _____
Signature Date

Withdrawal of Consent

If you decide you would like to withdraw your consent to use your biospecimens you must provide a written request to have your samples destroyed. In the event you withdraw your consent, it will not be possible to destroy the data, samples or imaging that have already been given to researchers.

For destruction of your biospecimens you can send a request to the Principal Investigator at:

Candida Rebello
Pennington Biomedical Research Center
6400 Perkins Road Baton Rouge, LA 70808.