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

Title of Study: Pilot Study Evaluating the Hedonic Acceptability and Absorption of the Bioactive Compounds of a 5011-Nutrasorb Bar (Russian Tarragon Nutrasorb) – Phase 1

Study Sponsor: Botanical Research Center, Pennington Biomedical

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 research study is to make a bar from 5011-Nutrsorb that is safe and acceptable for consumption.
  - Your expected time in this study will be 1 day consisting of 1 study visit.
- The procedures involved in this study include:
  - Measurement of your height, weight and vital signs (blood pressure and heart rate)
  - Taste test of the study bar.
  - Completing questions regarding the taste, smell, appearance, texture and pleasantness of the bar.
- W**hat are the possible risks and discomforts?**
  - There are minimal risks involved in eating the bar.
  - 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?**
  - We cannot promise any benefits from your being in the study. Your participation may help us gain knowledge that may help people 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 choices may include:
    - Taking part in another study

Detailed Information:

1- Who is doing the study?

Investigator Information:

Principal Investigator: Jennifer Rood, Ph.D.
(225) 763-2524

Medical Investigator: Daniel Hsia, M.D.
(225) 763-2831
24-hr. Emergency Phone Nos.:
(225) 763-2672 (Weekdays 7:00 a.m.-4:30 p.m.)
(225) 765-4644 (After 4:30 p.m. and Weekends)

Dr. Jennifer Rood directs this study, which is under the medical supervision of Dr. Daniel Hsia. We expect about 10 people will be enrolled in this study at a single site. The study will take place over a period of 2 months. Your expected time in this study will be 1 day. This is a Pennington Biomedical Research Center study.

2- Where is the study being conducted?

This study will take place in the Clinical Trials Unit at Pennington Biomedical Research Center.

3- What is the purpose of this study?

The purpose of this study is to make a bar from the soy-protein Russian Tarragon (5011) complex *(5011-Nutrasorb)* that is safe and acceptable for consumption. The 5011-Nutrasorb comes from a plant source called Artemisia drancunculus. This plant has a long history of medicinal (health) and culinary (food) use and has been reported as effective as a traditional treatment for diabetes in various parts of the world.

4- Who is eligible to participate in the study?

You may be eligible to participate in this study if you meet the following criteria:

- Male or female between the ages of 18 and 50, inclusive
- BMI (calculation of height to weight ratio) of 20-30 kg/m^2
- Taking no prescription medications
- Willing and able to stop taking any over the counter medications for the test day.

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?

You will be asked to come in for one test day for this study. You will be assessed for eligibility following the consent and then complete the test day procedures.

The following table shows what will happen at each study visit:

Procedures	Test Day
Informed Consent	x
Height/Weight	x
Vital Signs	x
Taste Test	x
Questions about Bar	x
Adverse Events	x

Test Day Fasting Visit (nothing to eat or drink other than water beginning at 10:00 pm the night before your test day), Visit will be approximately 1 ½ hours

The following procedures will be done on the Test Day:

- Sign this informed consent if you agree to participate
- Body weight and height will be measured (your body mass index will be calculated from these measures)
- Provide a list of any medications that you are currently taking.
- Blood pressure and pulse will be measured
- Taste test of the study bar.
- Complete questions regarding the taste, smell, appearance, texture and pleasantness of the bar.

Note: You could be asked to return 2 additional times just to complete the taste test and questions. This will occur if the product is found unacceptable and be completed after a new bar is produced.

6- What are the possible risks and discomforts?

There are minimal risks involved in participating in this study.

Consumption of the bar: You may not know that you are allergic to components of the bar and you may develop a reaction. We will inform you of the ingredients of the bar prior to consumption.

7- What are the possible benefits?

We cannot promise any benefits from your being in the study.

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. You have the right to take part now and change your mind later on.

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. Rood at 225-763-2524. If you think you have a research-related injury or medical illness, you should call Dr. Hsia at 225-763-2831 during regular working hours. After working hours an-d 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, someone from 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.

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

Dr. Rood or Dr. Hsia can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include being unable to complete the study procedures.

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.

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 results, including your individual results, 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 $35 *completion of the study.* If you are asked to come in for additional taste tests, you will receive $20 for each additional taste test you complete. Your check will be requested from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their 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 will 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 provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data may be shared with the 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

By signing this consent form, I agree to participate in the study as it is described. 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

Jennifer Rood, Ph.D.
Principal Investigator

Daniel Hsia, M.D.
Medical Investigator

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

Title of Study: Pilot Study Evaluating the Hedonic Acceptability and Absorption of the Bioactive Compounds of a 5011-Nutrasorb Bar (Russian Tarragon Nutrasorb) – Phase 2

Study Sponsor: Botanical Research Center, Pennington Biomedical

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 research study is to assess certain blood levels after consumption of the 5011-Nutrasorb bar along with assessing taste and acceptability.
  - Your expected time in this study will be 1 month consisting of 2 study visits.
  - The procedures involved in this study include:
    - Measurement of your height, weight and vital signs (blood pressure and heart rate)
    - Questionnaire to collect health history
    - Blood Work
    - Taste test of the study bar.
    - Completing questions regarding the taste, smell, appearance, texture and pleasantness of the bar.

- **What are the possible risks and discomforts?**
  - There is the possibility of infection and/or pain and bruising at the vein on your arm following blood draws and IV line insertion.
  - 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?**
  - We cannot promise any benefits from your being in the study. Your participation may help us gain knowledge that may help people 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 choices may include:
    - Taking part in another study

Detailed Information:

1- Who is doing the study?

Investigator Information:

Principal Investigator: Jennifer Rood, Ph.D.
(225) 763-2524

Medical Investigator: Daniel Hsia, M.D.
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24-hr. Emergency Phone Nos.:
(225) 763-2672 (Weekdays 7:00 a.m.-4:30 p.m.)
(225) 765-4644 (After 4:30 p.m. and Weekends)

Dr. Jennifer Rood directs this study, which is under the medical supervision of Dr. Daniel Hsia. We expect about 10 people from 1 site will be enrolled in this study. The study will take place over a period of 6 months. Your expected time in this study will be approximately 1 month. This is a Pennington Biomedical Research Center study.

2- Where is the study being conducted?

This study will take place in the Clinical Trials Unit of Pennington Biomedical Research Center.

3- What is the purpose of this study?

The purpose of this study is to test the blood levels of soy-protein Russian Tarragon (5011) complex *(5011-Nutrasorb)* that is contained in a bar and to assess the acceptability of the bar. The 5011-Nutrasorb comes from a plant source called Artemisia drancunculus. This plant has a long history of medicinal (health) and culinary (food) use and has been reported as effective as a traditional treatment for diabetes in various parts of the world.

4- Who is eligible to participate in the study?

You may be eligible to participate in this study if you meet the following criteria:

- Male or female between the ages of 18 and 50, inclusive
- BMI (calculation of height to weight ratio) of 20-30 kg/m^2
- Taking no prescription medications
- Willing and able to stop taking any over the counter medications for the test day.
- You did not participate in the 1st phase of this study.

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?

You will be asked to come to the Center for a screening visit. Following successful completion of the screening visit, you will return for a test day within 30 days of screening.

The following table shows what will happen at each study visit:

Procedures	Screening Visit	Test Day
Informed Consent	x	
Height/Weight	x	
Vital Signs	x	
Blood Work	x	
Medical History Questionnaire	x	
IV Procedure		x
Taste Test		x
Questions about Bar		x
Adverse Events		x

Screening Visit (Fasting visit – nothing to eat or drink other than water after 10:00 pm the night before your visit), approximately 1 ½ hours

- Sign this informed consent if you agree to participate
- Body weight and height will be measured (your body mass index will be calculated from these measures)
- Blood pressure and pulse will be measured
- You will complete a medical history questionnaire.
- You will have blood drawn to assess your overall health (approximately 2 teaspoons)

Test Day - (Fasting visit – nothing to eat or drink other than water after 10:00 pm the night before your visit), approximately 4 hours

- You will have an IV line placed in your arm. Blood will be drawn to assess the level of nutrients, blood sugar levels and insulin levels from the study bar before you eat the bar, immediately after eating the bar and 30, 60, 120 and 180 minutes after eating the bar. A total of approximately 6 teaspoons of blood will be drawn for this test day.
  IV Procedure (Intravenous Procedure): Fast for 10 hours before the test
  - An IV line will be placed in your arm vein for blood draw purposes and will remain there throughout the testing. Blood will be drawn at specific times. **During your IV procedure, a small amount of your own blood (less than 1 teaspoon) will immediately be returned into your vein through the IV after each specimen is collected.**
- Taste test of the study bar.
- Complete questions regarding the taste, smell, appearance, texture and pleasantness of the bar.
- You will be asked about any side effects and how you feel throughout the test day.

6- What are the possible risks and discomforts?

Risk for study procedures:

Consumption of the bar: You may not know that you are allergic to components of the bar and you may develop a reaction. We will inform you of the ingredients of the bar prior to consumption.

Blood Draws: There is the 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.

IV Procedure: There is a possibility of pain, bruising, or infection at the site of the needle insertion for the IV line. Trained personnel minimize this risk.

Will I be notified if my blood test result(s) 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.

Unknown Risks

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

7- What are the possible benefits?

We cannot promise any benefits from your being in the study.

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. You have the right to take part now and change your mind later on.

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. Rood at 225-763-2524. If you think you have a research-related injury or medical illness, you should call Dr. Hsia at 225-763-2831 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, 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.

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

Dr. Rood or Dr. Hsia can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include being unable to complete study procedures.

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.

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 results, including your individual results, 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 $75 for completion of the test day. You will not be compensated for the screening visit. Your check will be requested from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their 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 will 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 provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data may be shared with the 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.

V. 12-2019

#PBRC 2020-022

16- Signatures

By signing this consent form, I agree to participate in the study as it is described. 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

Jennifer Rood, Ph.D.
Principal Investigator

Daniel Hsia, M.D.
Medical Investigator