V. 6-2020

#PBRC 2020-039

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

Title of Study: **A Cross-over Pilot Trial to Determine the Effect of an LSU Patented Dietary Herbal Supplement on Quality of Life**

Study Sponsor: LSU Lift Grant

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 evaluate the effect of a combination of 3 food components to improve the quality of life in people who have trouble sleeping
  - Your expected time in this study will be 1 month consisting of 4 study visits.
    - The procedures involved in this study include:
    - Questionnaires
    - Blood tests
    - Sleep study done in the Pennington Sleep Center (requiring 4 overnight stays in the Sleep Center at PBRC)
    - Wearing a watch that records your level of activity
    - Wearing a device on your finger 1 night to measure blood oxygen using light
    - Keeping a diary of your sleep
    - Drinking 2 ounces of a combination of three food components at bedtime for 1 week and a placebo (inactive liquid) at bedtime for 1 week
    - Measuring your height, weight, blood pressure and pulse rate.
- **What are the possible risks and discomforts?**
  - The drawing of blood could possibly result in infection and/or pain and bruising at the vein on the arm where the needle is inserted. Aseptic (sterile) technique and trained personnel minimize these risks.
  - 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?**
  - You may experience a better quality of life during the week taking the supplement with 3 food components, but 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:
    - Getting no treatment

Detailed Information

1- Who is doing the study?

Investigator Information:

Principal Investigator:	Frank Greenway, MD 225-763-2578
Medical Investigator:	Frank Greenway, MD 225-763-2578 24-hr. Emergency Phone Nos.: 225-763-2578 (Weekdays 7:00 a.m.-4:30 p.m.) (225) 765-4644 (After 4:30 p.m. and Weekends)
Sub Investigators:	Prachi Singh, PhD

Dr. Frank Greenway directs and provides medical supervision for this study. We expect about ten people from one site will be enrolled in this study. The study will take place over a period of 3 months. Your expected time in this study will be one month. This study is part of a Pennington Biomedical Research Center study.

2- Where is the study being conducted?

This study takes place in the Pennington Biomedical Research Center Outpatient Clinic and in the Sleep Center in the Inpatient Metabolic Unit.

3- What is the purpose of this study?

The purpose of this research study is to evaluate the effect of a combination of 3 food components on the quality of life in people who have trouble sleeping.

4- Who is eligible to participate in the study?

You are eligible to participate in this study if:

- You are a healthy male or female
- You are 50 years of age or older
- You are willing to have blood stored for future research.
- Your usual bedtime is between 9pm and mid-night
- You meet the International definition for insomnia (trouble falling or staying asleep)

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?

This study tests a supplement containing 3 food components taken before bedtime for 1 week or a placebo. You will be asked to come to the PBRC Sleep Lab on 4 occasions for overnight sleep testing. You will come for baseline sleep test, be provided with the study supplement or placebo to take for 1 week then will return for a sleep test while taking the supplement/placebo. This testing will be followed by a 2-week washout period and a second test period with a baseline test and then 1-week period taking the supplement or placebo that was not taken in the first testing period. Questionnaires and polysomnography (sleep study) will be done at the beginning and end of each of the two treatment weeks. The details are described below.

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

Schedule of Events

		Visit 1	Visit 2	Visit 3	Visit 4
Week	Screening	Baseline	Week 1	Week 3	Week 4
Informed Consent	X				
Medical Questionnaire	X				
Vital Signs	X	X	X	X	X
Height	X				
Weight	X	X	X	X	X
Sleep Study		X	X	X	X
Oximetry (R/O Sleep Apnea)	X				
Questionnaires		X	X	X	X
7-Day Actigraphy (activity monitoring) and Sleep Diary	X	X		X	
Actigraphy During Sleep Test		X	X	X	X
Overnight Stay for Sleep Test		X	X	X	X
Blood Work	X		X		X
Adverse Events Assessed			X		X
Dispense/Collect Test Material		X	X	X	X

Screening visit: *Approximately 1 hour. Fasting for 10 hours except for water*
You will be asked to give informed consent, have blood pressure, pulse rate, height and weight measured, have blood (two teaspoons) drawn for assessment of overall health, complete a health questionnaire and a questionnaire relating to quality of life and sleep.

You will be given an oximeter, a small electronic device that measures oxygen in your blood using a light. You will be asked to wear this device on your finger overnight in your home. This procedure is called oximetry and will help the investigators rule out sleep apnea (condition that causes your breathing to stop and start irregularly during sleep) as the reason for your sleep problems. You will be asked to return the device the following business day in order for the study staff to determine if you are eligible for the test days.

You will be given an actigraphy (accelerometer) which is a device that is worn like a wristwatch to monitor activity and motion throughout the day and night. You will be asked to wear this activity monitor the next 7 days. In addition, you will also be given a 7 day sleep diary to record your sleep and wake times. You will be asked to return the actigraphy and diary for review prior to scheduling the next visit.

Those passing the screening visit and determined to not have sleep apnea, will be scheduled for study visit one.

Study Visit 1:
Approximately 12 hours; Non-Fasting – Overnight Stay at PBRC Sleep Lab
After your evening meal, you will come to the Sleep Lab at PBRC for an overnight sleep study (or polysomnography). Your arrival time should be approximately 7:00 pm. Polysomnography records your brain waves, the oxygen level in your blood, heart rate and breathing, as well as eye and leg movements during the night. Sticky patches will be applied to your head, chest, and legs, a loose band will be placed around your chest and stomach and you will be allowed to sleep in a dark, quiet room. You will be instructed to sleep from 10:00 pm until approximately 6:00 am the next morning. Your sleep study will be video-recorded. At this time, movements will also be recorded using a device that is worn like a wristwatch only it measures movement (actigraphy). The following morning you will complete 5 questionnaires that will assess your sleep, quality of sleep and how tired you felt. Unless a specific cause like sleep apnea is identified as the reason for your trouble sleeping, you will be given a week's supply of the dietary supplement or placebo with instructions to take 2 ounces one hour before bedtime. The study supplement order will be assigned randomly, like flipping a coin.

At the end of the visit, you will be sent home with the Actigraphy (wrist watch that monitors activity and motion throughout the day and night) and sleep dairy for the next seven days as well. You will be asked to wear the activity monitor all day, each day during the week and record your sleep times each night for the week.

Study Visit 2:
Approximately 12 hours; Non-Fasting – Overnight Stay at PBRC Sleep Lab
You will return in 1 week for a repeat sleep study. You will be asked to come at 7:00 pm again and bring your supplement with you. The study staff will administer the supplement 1 hour before bedtime (approximately 9:00 pm). You will complete the sleep test as described in Study Visit 1. Upon awakening the next morning, you will have blood drawn (approximately 2 tablespoons) for assessment of health, protein and for storage in the event further testing is needed. You will be asked to complete the same 5 questionnaires completed at Visit 1.

After a **2-week washout period** you will return for visit 3.

Study Visit 3:
Approximately 12 hours; Non-Fasting – Overnight Stay at PBRC Sleep Lab
This visit occurs after a 2-week washout period, and is the same as Visit 1. After completing the sleep study, you will be provided with one week of supplement (or placebo) that you were not assigned at study visit 1.

Study visit 4:
Approximately 12 hours; Non-Fasting – Overnight Stay at PBRC Sleep Lab

This visit is the same as visit 2, and will be the end of the trial.

The results of the study will be shared with you at the end of the study. Your blood tests or other tests that you had during the study will be shared with you and with your physician, if you want your physician to have that information.

6- What are the possible risks and discomforts?

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

Questionnaires: There are no known risks to completing the questionnaires. You do not have to answer any questions you do not want to answer.

Measuring height, weight, blood pressure and pulse rate has no known risks

Actigraphy is wearing a wrist watch-like device that measures motion. Actigraphy has no known risks

Sleep Diary is to keep track of your sleep habits and experiences. There are no known risks in keeping a sleep diary.

Oximetry is a device that is worn on the finger like a thimble that measures the oxygen in your blood using a light. There are no known risks to wearing an oximetry device

Sleep study involves gluing many small surface electrodes on scalp and face. You may have some discomfort with the application of the electrodes to your scalp. You may also experience some claustrophobia because of the monitoring equipment that is applied to your head and face. It is also possible that you may wake up at night feeling a little disoriented. To obtain the polysomnographic measurements, it may be necessary to glue many small wires on your scalp and face. The adhesive used to attach these wires has a strong smell, and you may feel a scratching sensation when the wires are applied.

Dietary Supplement is a mixture of 3 foods, a component of chicory, decaffeinated green tea powder and another component of green tea. The supplement has no known risks.

Unforeseeable Risks Involving Pregnant Women

Although the supplement is a combination of 3 food components and is unlikely to cause damage to a developing fetus, the supplement has not been tested for safety in pregnant women. If you are pregnant or become pregnant, dietary supplement may involve risks to the embryo or fetus, which are currently unforeseeable. Since the effects of the study medication on an unborn child are not known, use of the supplement may be associated with risks to a fetus. If you are a woman who is sexually active and capable of becoming pregnant, you must use an effective form of birth control throughout the study. You should inform the study coordinator immediately if you have any reason to believe that you may be pregnant. Medically acceptable methods include oral contraceptive medication, an intrauterine device (IUD), an implantable contraceptive (such as Implanon), an injectable contraceptive (such as Depo-Provera), abstinence, exclusive sexual relations with a vasectomized partner, same-sex relations or a barrier method (such as condom or diaphragm with spermicide).

Questionnaires

You do not have to answer any questions you do not want to answer.

Will I be notified if my blood test information 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?

You may experience an improvement in your quality of life in the week you take the supplement. If that does occur, the effect is likely to go away after you are off the supplement for a day or two. We cannot promise any benefits from your being in the study. If you take part in this study, you 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. 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 Frank Greenway at 225-763-2578. If you think you have a research-related injury or medical illness, you should call 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, someone from the Pennington Biomedical Research Center and Louisiana State University (the sponsor) 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 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 white blood cells or serum may be used to develop new drugs or other products that may result in commercial profit that will not be shared with you.

Your white blood cells and serum that are collected for this research study will not include whole genomic, germline, somatic or exome sequencing. This means that the researchers have no plans to look at or try to “read,” the protein information that makes up your genes (DNA) from your sample.

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

Dr. Frank Greenway or the study sponsor can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include a situation where for some medical reason, remaining in the study would not be in your best interest. You could also be withdrawn if you are unwilling or unable to comply with the study requirements. The sponsor of the study may also end the study early.

You may withdraw from the study at any time without penalty; however, information Pennington Biomedical that has previously been collected cannot be removed from the study. If you decide you would like to withdraw your consent, you must provide a written request to the Principal Investigator at:

Frank Greenway
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808

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 $200 for completion of the study. If you do not complete the entire study, you will be compensated $50 for each sleep stay that 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

Frank Greenway, MD
Principal and Medical Investigator

17- What you need to know about future research with your biospecimens.

Research with your biospecimens (blood white blood cells and serum) can help to find out more about the effect of the food components in the supplement on inflammation and its effect on your quality of life. Your white blood cells or serum may be sent to researchers outside of the Pennington Biomedical Research Center. Any personal information that could identify you will be removed before the white blood cells or serum 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.

Withdrawal of Consent

If you decide you would like to withdraw your consent, you must provide a written request to the Principal Investigator as outlined in Section 11 of this consent form.