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

Title of Study: ***The Diet composition and Energy Balance Pilot Study (The DEB Pilot Study)***

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help people in the future.
- You have the right to refuse to take part, or agree to take part now and change your mind later on.
- Please review this consent form carefully and ask any questions before you make a decision.
- Your participation is voluntary.
- By signing this consent form, you agree to participate in the study as it is described.

1- Who is doing the study?

Investigator Information:

Principal Investigator: John W. Apolzan, PhD
225-763-2827

Medical Contact/Sub Investigator: Kishore M. Gadde, MD
225-763-2552
24-hr. Emergency Phone Nos.:
225-763-2552 (Weekdays 7:00 a.m.-4:30 p.m.)
225-765-4644 (After 4:30 p.m. and Weekends)

Sub Investigators: Corby K. Martin, PhD
Owen T. Carmichael, PhD
Nicole N. Fearnbach, PhD

Dr. Apolzan and Dr. Martin direct this study, which is under the medical supervision of Dr. Gadde. We expect about 20 people will be enrolled in this study. The study will take place over a period of about 1 year. Your expected time in this study will be 6 weeks.

2- Where is the study being conducted?

This study takes place in the outpatient clinic and neuroimaging center at Pennington Biomedical Research Center in Baton Rouge, LA.

3- What is the purpose of this study?

This study will assess the effects of the consumption of sugar in beverage vs. solid form on bodily systems. The main objectives are to determine if persons can consume the solid sugar daily, demonstrate our ability to perform brain scans, and determine the effects on bodily systems.

4- Who is eligible to participate in the study?

- Age 21-65 years old, BMI 20.0-40.0 kg/m^2
- Be willing to consume study foods
- Be willing to fast for at least 10 hours prior to the clinic visits
- Be able to undergo MRI scans and store for possible future use
- Be willing to archive brain scans and eye tracking data

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?

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

Table 1. Schedule of Procedures

		Intervention Period				
Visit Assessments	**Screening Visit**	**Week 0**	**Week 1**	**Week 2**	**Week 3**	**Week 4**
Informed Consent	X					
Anthropometrics (height, body weight)	X					
Anthropometrics (body weight, waist and hip circumference, and bioelectrical impedance)		X				X
Brief Lifestyle Interview and non-quantified food record	X					
Contact and Demographic Information	X					
Food Taste Test	X					
Food Craving Inventory (FCI), Yale Food Addiction Survey (YFAS) , Liking and Wanting Procedure, Retrospective Visual Analogue Scales (RVAS) , Barratt Impulsiveness Scale, and Delayed Discounting Task, and Food Familiarity and Liking Procedure		X				X
Urine Pregnancy Test		X				X
fMRI (fasting and fed state)		X				X
Randomization		X				
Study Product Dispensed		X	X	X	X	
Adherence check/calculations (self-report and container return), provision of study foods			X	X	X	X

Once the screening visit is complete, and it has been determined you are qualified to participate, you will be randomized to the solid or beverage treatment. Randomization is like flipping a coin.

Screening Visit: About 1.5 hours –Fasting (nothing to eat or drink other than water for at least 10 hours prior to visit)
This visit will take place in the Outpatient Clinic Department of Pennington Biomedical. The testing this day includes the following procedures:

- Informed Consent
- Current medication and supplement use
- Demographic and Lifestyle Questionnaire (including contact information)
- Lifestyle Interview
    - To discuss your understanding of the study and for the study staff to know what kinds of barriers may make it difficult for you to participate in the study. Such lifestyle barriers include your work or school schedule, outside activities, and other responsibilities may prohibit your from enrolling.
- Height

- Weight
- Food Taste Test

Week 0: About 4 hours – Fasting (nothing to eat or drink other than water for at least 10 hours prior to visit) after at least 7 hours of rest the previous evening
Note: Women who have menstrual cycles will be scheduled for their Week 0 visit during the luteal phase of their cycle.
This visit will take place in the Outpatient Clinic Department of Pennington Biomedical.
The testing this day includes the following procedures:

- Anthropometric Measurements – (body weight, waist and hip circumference, and bioelectrical impedance)
- Psychological and Behavioral Questionnaires
- Females of child-bearing potential will have a urine pregnancy test
- MRI/fMRI – fasting and fed state
- Treatment consumption – fed state fMRI
- 2 week supply of study product dispensed

Week 1: About 30 minutes – Non-Fasting

- Adherence check
- 1 week supply of study product dispensed

Week 2: About 30 minutes – Non-Fasting

- Adherence check
- 1 week supply of study product dispensed

Week 3: About 30 minutes – Non-Fasting

- Adherence check
- 1 week supply of study product dispensed

Week 4: About 4 hours – Fasting (nothing to eat or drink other than water for at least 10 hours prior to visit) after at least 7 hours of rest the previous evening
This visit will take place in the Outpatient Clinic Department of Pennington Biomedical.
The testing this day includes the following procedures:

- Anthropometric Measurements – (body weight, waist and hip circumference, and bioelectrical impedance)
- Psychological and Behavioral Questionnaires
- Females of child-bearing potential will have a urine pregnancy test
- MRI/fMRI – fasting and fed state
- Treatment consumption – fed state fMRI
- Adherence check

6- What are the possible risks and discomforts?

This study does not involve major risk to study participants.

- **Fasting for 10 hours:** There is a possibility that fasting for 10 hours may make you feel nauseous.
- **Self-reported Questionnaires:** There are no anticipated risks from completing self-report questionnaires. Due to the sensitive nature of the questionnaires, you may skip any questions that you do not wish to answer.
- **Bioelectrical Impedance Analysis (BIA) Measurement:** You will be asked to change into a gown and to remove all footwear and socks/stockings. Once changed and barefoot, you will be asked to stand on a scale (similar to a large gym scale), and you may be asked to hold on to hand electrodes on each side of the scale. You will be asked to step off of the scale once the measurement is complete (less than one minute).
    - There is no risk associated with the BIA measurement. **However, subjects with medical implants such as a pacemaker or metal joint replacements cannot be measured on the machine.**
- **Weight Gain:** There is a possible chance that the Calories will slightly increase body weight.
- **Brain MRI:** This scan is performed to measure the size of your brain and activation. You will change into a hospital gown and remove all objects containing metal from your body. During the scan, you will lie on your back on the scanner table with your head in a cradle. The scanner table will then move you into the magnet. During the scan, you will hear loud tapping noises. You will be given head phones and/or earplugs for protection from the scanner noise. You will also be given a call button should you need the MRI tech during the exam. This scan is for research purposes only and not for diagnostic treatment.

- **MRI Risks:**
  There are no known biological risks associated with magnetic resonance scanning. It has been used routinely for over 20 years. It produces side effects in very few situations. Those situations include:

  Metal: Because the magnetic resonance machine uses a magnetic field, it can move any metallic objects that are inside the body. This disruption of metal inside the body is extremely dangerous to you and may even be life threatening. If you think you may have a cardiac stent, metallic implant, metallic piercings, shrapnel, or any other metallic material in your body, it is of utmost importance that you alert the study coordinator or MR technician. If you have metallic materials in your body that cannot be removed, we will exclude you from this study for your safety.

  Electronics: Magnetic resonance imaging involves the use of radio frequency energy that can disrupt the functioning of electronic devices. If you think you might possess a pacemaker or any other electronic medical device inside your body, it is of utmost importance that you inform the study coordinator or MR technician. If you have any such electronic devices we will exclude you from this study for your safety.

Tattoos and cosmetics: Some tattoos and cosmetics contain metallic materials that can heat up during scanning, especially if they are located on the part of the body being scanned. If the metallic material heats up enough, you may feel an uncomfortable burning sensation, and a skin burn may develop. If you have any tattoos or cosmetics that might contain metallic materials, please alert the study coordinator or MR technician. If you feel a burning sensation on your skin, alert the study coordinator or MR technician. In some cases, the amount of metallic material in the area being scanned is so excessive that the scan must be stopped. In other cases, a cold compress placed over the metallic material will be used to prevent the burning sensation.

Confinement: During the MR scan, you will be lying down on a table inside of a metal tube. The metal tube is a confined place. This might produce a feeling of claustrophobia, which can be distressing. If you have experienced claustrophobia in the past, you might become too distressed to complete the scan. If you become distressed during the scan due to confinement in the scanner tube, please alert the MR technician and the scan will be halted.

Noise: The MRI machine creates a loud, rhythmic noise that sounds like grinding or churning. This can be distressing to those who are sensitive to loud noises. You will be provided with headphones and/or earplugs to reduce the noise. But if you find the machine noises distressing, alert the MR technician and the scan can be halted.

Peripheral nerve stimulation: During the MR scan, the magnetic field around your body goes through rapid changes. These changes are all within safety limits set by the Food and Drug Administration. But, some people experience twitching in the nerves of their arms or legs as a result of these magnetic field changes. This twitching is generally not painful, and it stops at the end of the MR scan. But the feeling of inadvertent muscle twitching may make you feel disoriented or uncomfortable. If you experience this and wish to stop the scan as a result, please tell the MR technician.

Physical frailty: The MR technologist performing the scan has received extensive training in how to position all participants, including elderly ones, in the MRI machine safely and comfortably. However, some older people have a more difficult time walking or moving their bodies due to arthritis and other conditions. There is a slight chance that these individuals could feel discomfort or fall during transitions into or out of the MRI scanner. The technologist will ensure that the walkway to the scanner is safe for you to walk on, will place cushioning on the scanner table for your comfort, and will carefully guide your movements around the scanner to minimize this risk.

Venous thromboembolism: In some elderly or obese individuals, lying down perfectly still for multiple hours can slightly increase the risk that blood clots develop in the blood vessels. These blood clots can be hazardous to your health. The technologist will make every effort to keep your time in the MRI machine as short as possible to reduce this risk. Also, you will have breaks during your time in the MRI machine, and during these breaks the technologist

will ask you to move your arms and legs and reposition your body to get comfortable. Moving around in this way reduces your risk of blood clots.

7- What are the possible benefits?

There are no direct benefits for subjects for participation in the study. However, 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.

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 John Apolzan at 225-763-2827 or Corby Martin at 225-763-2585. If you think you have a research-related injury or medical illness, you should call Dr. Kishore Gadde at 225-763-2552 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.

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.

What are the risks to your privacy? There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

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

Dr. John Apolzan, Dr. Corby Martin, or Dr. Kishore Gadde 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. The sponsor of the study may end the study early.

Some possible reasons for withdrawing a participant from the study:

- Failure to follow study directions
- Other administrative reasons

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

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.

13- What charges will you have to pay?

None.

14- What payment will you receive?

If you agree to take part, we will pay you up to $230. Subjects will be compensated $230 upon successful completion of the study. Subjects will receive $75 for completing clinic visit 1 (baseline; week 0) and $125 for completing clinic visit 2 (week 4 follow-up). Lastly you will receive $30 for successfully attending your weeks 1-3 adherence visits. 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.

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- Data Storage for Future Research

You are being asked to allow your MRI scans to be stored and used for research at a later time.

The use of MRI scans for future use is not optional. If you do not want your MRI scans stored for future research, you may not participate in this study.

The MRI scans will be stored and used for the study and also stored for future studies. The collection of scans may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. If you agree to have your samples stored, you can change your mind later.

The scans will be stored indefinitely. If you agree to donate your samples, they may be given to other investigators for future research as well. The future research may or may not take place at Pennington Biomedical and may or may not involve Pennington Biomedical Researchers in this study. For privacy and confidentiality, your MRI scans will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your MRI scans with this unique identifier and the minimum number of personal identifiers. You will not receive any financial compensation for any patents, inventions or licenses developed from this research.

If you decide you would like to withdraw your consent to use your samples, 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 samples that have already been given to researchers.

For destruction of your samples, you can contact the Principal Investigator at:
John Apolzan, PhD
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808

17- 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

John W. Apolzan PhD
Principal Investigator

The study volunteer has indicated to me that the volunteer is unable to read. I certify that I have read this consent form to the volunteer and explained that by completing the signature line above the volunteer has agreed to participate.

_____ _____
Signature of Reader Date