V. 6-2020

#PBRC 2020-033

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

Title of Study: Metabolic Effects of Metformin Therapy in Obstructive Sleep Apnea (METOSA)

Study Sponsor: Pennington Biomedical Research Center
Nutrition Obesity Research Center (NORC)

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 compare the effects of metformin (a drug that prevents and treats diabetes) versus a placebo on metabolism in patients with obstructive sleep apnea using positive airway pressure (PAP) therapy. Metabolism is a process where your body converts what you eat and drink into energy that your body needs to function. For the purpose of this study, metformin is considered investigational, since it is not approved for use in patients with obstructive sleep apnea.
  - Your expected time in this study will be up to 4 months consisting of 6 study visits.
  - The procedures involved in this study include:
    - Overnight sleep study
    - Standard treatment of obstructive sleep apnea using PAP
    - Taking metformin or placebo
    - Blood draws
    - Fat and muscle biopsy
    - Measurement of body composition
    - Measurement of glucose metabolism
    - 24 hour blood pressure monitoring

- **What are the possible risks and discomforts?**
  - **Metformin:** There are some common side-effects related to metformin use including diarrhea, gas, and upset stomach. Uncommon or rare side effects might include metformin-associated lactic acidosis. This extremely rare side

effect may be severe enough to cause death, hypothermia, hypotension, and resistant bradyarrhythmias. We will not include you in this study if your chances to develop this rare side effect are high.

- **Fasting for 10 hours:** There is a possibility that fasting for 10 hours may make you feel nauseous.
- **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.
- **Fat and muscle biopsies:** Mild to severe pain, soreness, and bruising, and a small scar are common risks. There is a small risk of a hematoma (collection of blood in the tissue) or infection at the biopsy site. A sterile technique will be used to minimize these risks and the biopsy site will be monitored closely.
- **Body composition by DXA scan:** The amount of radiation used for this procedure is very small. The radiation dose for this scan is equivalent to the radiation you are naturally exposed to in the environment in less than one day.
- **Glucose tolerance test:** 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. The glucose drink may cause nausea, vomiting, abdominal bloating, or a headache.
- 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, any health benefits to which you are entitled will not be affected in any way.

Detailed Information

1- Who is doing the study?

Investigator Information:

Principal Investigator:	Prachi Singh, Ph.D. (225) 763-3151
Medical Investigator:	Kishore Gadde, M.D. (225) 763-2552 24-hr. Emergency Phone Nos.: (225) 763-2500 (Weekdays 7:00 a.m.-4:30 p.m.) (225) 765-4644 (After 4:30 p.m. and Weekends)
Sub Investigator:	Edward C. Mader, Jr., MD, FAASM LSU Health Sciences Center – New Orleans Department of Neurology

Dr. Prachi Singh directs this study, which is under the medical supervision of Dr. Kishore Gadde. We expect about 20 people from the greater Baton Rouge area will be enrolled in this study. The study will take place over a period of 1 year. Your expected time in this study will be up to 4 months.

2- Where is the study being conducted?

This study takes place at Pennington Biomedical Research Center in Baton Rouge, LA.

3- What is the purpose of this study?

The purpose of the study is to see if metformin improves metabolism in patients with obstructive sleep apnea (OSA) using positive airway pressure (PAP) therapy.

Metformin is approved by the Food and Drug Administration (FDA) for the treatment and prevention of diabetes. It is not approved for use in patients with OSA.

4- Who is eligible to participate in the study?

You may qualify for this study if you:

- Are aged 35-65 years
- Are **not** diabetic
- Have a body mass index (BMI) between 30 and 50 kg/m^2 (inclusive)
- Have moderate to severe sleep apnea
- Are willing to participate in study procedures including video recorded in-lab sleep studies, regular use of PAP therapy to treat OSA, and taking the study drug regularly)

- Are willing to have fat and muscle tissue collected
- Are willing to have blood, as well as fat and muscle tissue stored for future use
- Are willing to use appropriate contraceptive to avoid pregnancy throughout the study, if needed.

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?

Your participation in the study will last up to 4 months. If you agree to participate, you will be asked to come to Pennington Biomedical Research Center for two screening visits to determine if you are eligible to participate. The first screening visit will last for approximately 2 hours and the second screening visit will require an overnight stay for the sleep study. If you qualify and choose to participate, the study will include 4 study visits approximately one month apart. You will be provided with a positive airway pressure (PAP) therapy for treatment of sleep apnea. You will be allowed to keep the PAP equipment for continued use once your participation in the study is complete. You will also be asked to take a study drug, which we will provide to you, for the next 3 months. The study drug will be either metformin or placebo.

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

Table 1: Clinic Visits and Assessments

Assessment	Screening Visit 1	Screening Visit 2	Study Visit			
			#3 Baseline	#4 Month 1	#5 Month 2	#6 Month 3
Informed consent	X					
Health questionnaire	X					
Physical examination	X					
Medication reporting	X					
Blood pressure and heart rate	X					
Weight and Height	X					
Blood draw	X		X			X
Overnight oximetry (at home)	X					
Overnight sleep study		X				
Weight, waist, hip, neck measure			X			X
Glucose tolerance test			X			X
Urine Pregnancy testing (if needed)			X			X
Questionnaires			X			X
Dietary assessment (food record)			X			X

Body composition (DXA)			X			X
Fat biopsy			X			X
Muscle biopsy			X			X
24 h blood pressure (at home)			X			X
Study drug provided			X	X	X	
PAP provided			X			
Side effects monitoring				X	X	X
PAP and study drug use monitoring				X	X	X

Screening visit 1 (2 hours); Fasting (avoid food and drinks besides plain water for at least 10 hours before this visit):
You will be asked to come to Pennington Biomedical Research Center to complete this visit to determine if you are eligible to participate in this study. This visit will take approximately 2 hours. The following will happen during this visit:

- Consent: The study will be explained and you will be asked to sign a form to show that you agree to participate.
- Health Questionnaire: You will be asked to answer questions related to your general health.
- Medication reporting: You will be asked about your current and most recent use of medicines and supplements.
- Measurement of weight and height
- Vital signs: Your blood pressure and heart rate will be obtained.
- Blood draw: You will have a small amount of your blood drawn from your arm so that we can make sure you are healthy enough to participate in this study.
- Oximetry: You will be given a device (oximeter) that attaches to your wrist and index finger and measures oxygen levels in your blood during sleep for one night. This tells us about your sleep quality. You will be provided with clear instructions on how and when to use the device. You will be asked to drop-off the device after you have recorded your sleep quality. If the data is incomplete, you may be asked to repeat this measure.

Screening visit 2 (overnight stay, 12 hours): If you qualify based on screening visit 1, you will be asked to come to Pennington Biomedical for an overnight visit to monitor your sleep after having dinner. You will be asked to avoid consuming any caffeine and alcohol at least 10 hours prior to this study visit. You will also be asked to avoid any vigorous physical activities for at least 10 hours prior to the study visit.

- Sleep study: You will undergo an overnight sleep study where 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. Your sleep study will be video-recorded. We will then review the results of your sleep study and let you know if you have a sleep disorder. This test is only for research purpose.

- You will be woken up from sleep at 6:00 am and the wires and patches from the sleep study will be removed.

If you qualify based on this screening visit and are interested in participating:
You will complete 4 study visits over the coming 3 months. Additional visits may be required if you have difficulties with PAP treatment or study drug.

Study visit 1 (4 ½ hours); Fasting (avoid food and drinks besides plain water for at least 10 hours before this visit):
This visit will take approximately 4.5 hours. The following will happen during this visit

- Measurement of weight
- Measurement of waist, hip, arm and neck circumference
- If needed, you will be asked to provide a urine sample: Women of childbearing potential will be asked to provide a urine sample for a pregnancy test to make sure it is safe to continue in the study.
- Body composition measurement by DXA scan (about 10 minutes): This scan measures the amount of bone, muscle, and fat in your body. The scan will be performed using a whole-body scanner. You will be required to wear a hospital gown, to remove all metal-containing objects from your body, and to lie down on the table. You will be carefully positioned on the table, and your legs will be placed together using two Velcro straps. A scanner emitting low energy X-rays and a detector will pass along your body. You will be asked to remain completely still while the scan is in progress. The scan takes approximately ten minutes. This scan is for research purposes only and not for diagnostic treatment.
- Oral glucose tolerance test (about 2 hours): An IV line will be placed in your arm vein for blood draw purposes and will remain there throughout the testing. A blood sample will be drawn, and then you will drink a sugar solution consisting of 75 grams of glucose. Blood will be drawn at specific times after you consume the drink. Each blood sample will be about 1 teaspoon. (5 tablespoons total for the test). **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**. You will be provided lunch after the fasting procedures have been completed.
- Fasting blood draw: Using the IV line placed on your arm for the oral glucose tolerance test we will draw approximately 1.5 tablespoon blood to be archived for future use.
- Fat Biopsy: This procedure is used to sample fat cells from underneath the abdominal skin after cleansing the skin with iodine and using a local anesthetic. After cleansing the area, the doctor or nurse practitioner will make a small incision in the skin and introduce a needle under the skin to remove fat cells. About 1.5 to 2 grams (less than half a teaspoon size) of fat will be removed. After the biopsy is completed, the skin will be held closed with a sterile adhesive bandage; an antibiotic ointment will be applied.
- Muscle Biopsy: This procedure is used to sample muscle cells from underneath the skin of the leg. After cleaning the skin with iodine and using a local

anesthetic, the doctor or nurse practitioner will make a small incision in the skin and introduce a needle under the skin to remove muscle cells. About 500 milligrams (less than a teaspoon size) of muscle will be removed. After the biopsy is completed, the skin will be closed with a sterile adhesive bandage and an antibiotic ointment will be applied.

- Blood Pressure Monitoring: You will be given an ambulatory blood pressure monitor to wear for the next 24 hours. This procedure records your blood pressure and heart rate. You will wear a device the size of a small camera connected to a blood pressure cuff on your arm for 24 hours. The cuff of this device inflates automatically every 30 minutes during the day and night. Upon inflation, the device will make a quiet noise and will cause pressure on your arm. At the end of the 24 hours, you will return to the clinic to return the monitor. Depending upon the amount of data collected, you may be asked to wear the monitor for an additional day.
- Sleep quality and physical activity survey: You will be asked to fill out a few brief surveys about your habitual sleep and physical activity.
- 3-day dietary record: You will be asked to record your food and drink intake for three non-consecutive days including one weekend day. Detailed instructions to fill the daily log will be provided.
- Positive Airway Pressure (PAP) therapy: We will provide you with detailed instructions on how to use PAP equipment for sleep apnea treatment. The device is designed to keep the airway open while a person sleeps by gently pressurizing the air that they breathe. You will be encouraged to use PAP daily for the entire sleep duration. We will monitor your PAP usage during the study duration and will contact you if the PAP usage is not ideal.
- Study drug: We will assign you by chance (like a coin toss) to metformin or the placebo group. Neither you or the Principal Investigator can choose your study group. You will have an equal chance of being assigned to the metformin group. This study uses a placebo. A placebo looks exactly like the study drug, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study drug. You and the Principal Investigator will not know which study drug (metformin or placebo) is being given to you. However, in case of an emergency, this information will be available.
    - You will be provided the study drug along with detailed instructions for how and when to take the capsule. Each capsule will contain either 500 mg of metformin or 500 mg of placebo. You will be asked to take one capsule daily for the 1st week, 2 capsules daily for the 2nd week, 3 capsules daily for the 3rd week, and 4 capsules daily for the 4th week until the end of the study. We will also tell you about the potential side effects and reactions.
    - You will be asked to stop taking the study drug and to contact the study team within 24 hours if you feel cold in your hands or feet, feel dizzy or lightheaded, feel weak or tired, have a slow or irregular heartbeat, have unusual (not normal) muscle pain, have trouble breathing, or feel unusually sleepy or drowsy.

- During the study, we will ask you that you do not change any medication or supplements that you may be taking prior to the start of the study. The study team needs to be informed promptly of any planned changes in medications. The study team will decide if these changes will prevent you from continuing participation in the study.

Study visit 2 (45 minutes): (within 25 to 30 days of visit 1)
This visit will take approximately 45 min. You will be asked to bring the bottle of study drug for this visit. The following will happen during this visit

- Study drug: We will ask you questions to find out if you may have experienced any side effects related to study drug. We will provide you study drug for the next month.
- PAP use: We will check how often you use PAP and provide advice if needed.

Study visit 3 (45 minutes): (within 25 to 30 days of visit 2)
This visit will take approximately 45 min. You will be asked to bring the bottle of study drug for this visit and all measures for visit 2 will be repeated.

Study visit 4 (4 ½ hours); **Fasting (avoid food and drinks besides plain water for at least 10 hours before this visit):** (within 25 to 30 days of visit 3)
This visit will take approximately 4.5 hours. All procedures from study visit 1 will be repeated and an additional 1 tablespoon of blood will be drawn for routine health check at this visit. We will also ask you questions to find out if you may have experienced any side effects related to study drug and any remaining study capsules will be returned to study staff.

The study will end after the blood pressure monitor has been returned.

6- What are the possible risks and discomforts?

Study Procedures

- **Fasting for 10 hours:** There is a possibility that fasting for 10 hours may make you feel nauseous. Light snacks will be provided for you to eat once the fasting procedures are completed.
- **Surveys/Questionnaires**: You do not have to answer any questions you do not want to answer.
- **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.
- **Overnight Oximetry:** There are no significant risks related to overnight oximetry other than temporary discomfort while wearing the device.
- **Overnight Sleep study:** 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.

- **Oral glucose tolerance test:** 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. The drink may make cause nausea, vomiting, abdominal bloating, or a headache.
- **Fat Biopsy:** Mild to severe pain, soreness, and bruising, and a small scar are common risks. There is a small risk of a hematoma (collection of blood in the tissue) or infection at the biopsy site. Sterile technique will be used to minimize these risks and the biopsy site will be monitored closely.
- **Muscle Biopsy:** Mild to severe pain, soreness, bruising, and a small scar are common risks. There is a small risk of a hematoma (collection of blood in the tissue) or infection at the biopsy site. There is a slight risk that a superficial nerve may be cut; the nerve may heal, or it may result in a permanent loss of sensation in the skin at the biopsy site.
- **Body Composition by DXA Scan:** The amount of radiation used for this procedure is very small. The radiation dose for this scan is equivalent to the radiation you are naturally exposed to in the environment in less than one day. Scans will not be performed on any subject who is pregnant. A pregnancy test will be performed within 72 hours before the scan on females of child-bearing potential.
    - Lifetime radiation exposure: We are exposed to radiation in the environment on a daily basis; however, some scientists have suggested that humans have a lifetime maximum exposure limit. Exposure to radiation is not without risk, but it is difficult to quantify the exact amount someone is exposed to. By participating in this study you will be exposed to radiation that will add to this lifetime maximum exposure limit. If you believe you have been exposed to a significant amount of radiation as part of your occupation or due to treatment for a specific medical condition, you should notify the study team to discuss whether or not this study would be appropriate for you.
- **Blood Pressure Monitoring:** There are no known risks associated with the blood pressure monitor. You may experience some discomfort having the cuff inflate every 30 minutes around the clock.
- **Metformin:** The most common side effects of metformin include nausea, headaches, diarrhea, vomiting, bloating, excessive gas, loss of appetite, and an unpleasant taste in the mouth. These are more common when the medication is first started and lessen or disappear over time. About 10 out of 100 people using metformin may experience these symptoms to some degree. However, these side effects are rarely severe enough to result in needing to stop the medication. Other side effects include lower-than-normal levels of vitamin B12 in the blood, which may rarely lead to anemia (low blood count), although it is unlikely to happen in this study because of the short duration of treatment. Hypoglycemia (low blood sugar) rarely occurs when metformin is taken by itself, but it can occur when metformin is combined with some other diabetes medications.

In very rare instances (fewer than 3 in 100,000), a condition called lactic acidosis has been reported in patients taking metformin. When lactic acidosis occurs, it is usually in persons who have other severe medical problems, such as kidney disease, liver disease, or severe circulatory problems. We will analyze your blood and ask you about symptoms to make sure it is safe for you to take this medication. In addition, you must notify the study team immediately if you experience any of the following symptoms which could be signs of lactic acidosis: feeling cold in your hands or feet, feeling dizzy or lightheaded, feeling weak or tired, having a slow or irregular heartbeat, having unusual (not normal) muscle pain, having trouble breathing, or if you feel unusually sleepy or drowsy.

You should talk to the study team before you undergo any surgery, X-ray procedures, or CT scans that use any type of injection (such as dye that makes X-rays easier to see), as you will need to stop taking your study drug during the time of the procedure. Alcohol should not be used in excess while taking metformin. Inform your study doctor if you currently have (or develop during the course of the trial) kidney or liver disease, heart failure or severe infections.

- **Confidentiality of Data:** Taking part in this research may involve providing information that one considers confidential or private. Our staff are trained in how to maintain your confidentiality but there is a slight risk that data could be revealed inappropriately or accidentally.

Unforeseeable Risks Involving Pregnant Women

If you are pregnant or become pregnant, metformin may involve risks to the embryo or fetus, which are currently unforeseeable.

Will I be notified if my blood draws, DXA scan, sleep study or blood pressure 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. 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 Dr. Prachi Singh at 225-763-3151. 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?

Your sleep study data will be sent to researchers and vendors outside of the Pennington Biomedical Research Center. The data that are sent to these researchers may contain identifiable information. Identifiable information is being sent to these researchers and vendors because based on this information, they will be able to provide PAP prescription and equipment.

Every effort will be made to maintain the confidentiality of your study records. However, someone from the National Institutes of Health, the Pennington Biomedical Research Center, Louisiana State University or 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 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 blood, fat and muscle samples may be used to develop new drugs or other products that may result in commercial profit that will not be shared with you.

Whole Genomic Sequencing

Your blood, fat, and muscle samples collected for this research will be analyzed for the study. As part of the analysis, the research might include exome sequencing. This means that the researchers might look at your sample to learn about your genes (DNA). There are different ways to look at your DNA. Researchers often use a technology called sequencing to look at your DNA. Sequencing "reads" each letter of the DNA and finds changes (also called "variations" or "mutations") in your genes that may cause disease or affect how your body reacts to a certain disease. Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without asking for more samples from you. Each cell contains your complete DNA.

Genetic Information

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

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

Dr. Prachi Singh, Dr. Kishore Gadde, or the study sponsor can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include emergence of significant safety concerns which, in the opinion of the investigator, warrants withdrawal or significant change in medications while participating in the study. The sponsor of the study may also end the study early.

If your participation in the research ends early because of the investigator or by your choice or a reason listed above, termination procedures may need to be completed or follow-up data may need to be obtained to ensure your safety. These procedures include returning study drug and providing information related to side effects faced and reason for withdrawal. The study staff will go over the details with you.

You may withdraw from the study at any time without penalty; however, information Pennington Biomedical has previously 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:

Dr. Prachi Singh
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. These include your risk for sleep disorders and high blood pressure.

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 up to $300 upon completion of the study. If you do not complete the entire study, you will be compensated $100 for completing the first study visit, $25 each for completing the second and third study visit, and $150 for completing the final visit (Visit 4). You will also be allowed to keep the PAP equipment once the study has ended for continued OSA treatment. However, you will need to follow-up with your primary care provider for continued clinical care.

You will not be compensated for any screening 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.

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

Prachi Singh, PhD
Principal Investigator

Kishore Gadde, MD
Medical Investigator

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

This research study will store some of your blood, as well as fat and muscle tissue samples to be used for research at a later time. These bodily materials are called biospecimens. The storing of biospecimens in this study is not optional. If you do not want your biospecimens stored for future research, you may not participate in this study. Research with your biospecimens can help to find out more about understanding the causes of obesity, diabetes, cardiovascular disease, cancer, and dementia in patients with sleep apnea.

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

Your sleep study data will be sent to researchers and vendors outside of the Pennington Biomedical Research Center. The data that are sent to these researchers may contain identifiable information. Identifiable information is being sent to these researchers and vendors because based on this information, they will be able to provide PAP prescription and equipment.

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.