Title of Project:

Effect of Pulsatile Pressure and Long Sleep Duration on Cerebral Vascular Function

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Consent Form

TITLE OF STUDY
Effect of Pulsatile Pressure and Long Sleep Duration on Cerebral Vascular Function

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WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?
You are between the ages of 40-59 years without a personal history of diabetes, heart disease, stroke, or sleep disorders. You do not smoke or vape, nor do you take medications for blood pressure or sleep. You are not considered to be obese, have uncontrolled blood pressure, or have high fasting blood sugar (glucose). Lastly, you are considered to have normal sleep habits.

WHAT IS THE PURPOSE OF THIS STUDY?
The objective of this research is to examine the effect of long sleep duration on overnight blood pressure and brain health.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?
This research study will take place in room 119 of the Kinesiology and Sport Management building at Texas Tech University. This study will involve one 1-hour visit and four 2-hour visits. It should take you about 3 weeks to complete all the visits.

WHEN WILL THE VISITS BE SCHEDULED?
The visits will be scheduled in the morning hours (between 6:00 and 10:00am) since we ask that you arrive for the visit after an overnight fast.

WHAT WILL I BE ASKED TO DO?
A member of the research team will fully explain each procedure that applies to your participation. Please sign your initials after each section to show that you understand the procedures, measurements, and risks. The study and its procedures are outlined below:

- You will be asked to avoid food, caffeine and supplements (vitamins, aspirin, health or workout supplements) for at least 8 hours prior to each visit.

- You will be asked to wear loose-fitting shorts for each visit. If you do not own such shorts then we will provide a pair for you to wear during the study.

- **Visit 1 (Screening Visit).** After reviewing and signing this consent form, you will be asked to complete a medical history and sleep questionnaire. Next, your resting blood pressure will be measured along with height and weight. One of your fingers will then be pricked for blood in order to measure fasting blood glucose with a hand-held device. After being familiarized with the cognitive and vascular test(s) that you will perform in later visits, you will be given a physical activity/sleep tracker to wear for 19 days and instructions to pick-up blood pressure monitor to wear the day and night before your next visit. The blood pressure monitor will take measurements every 20 minutes during the day and every 30 minutes throughout the night.

- **Sleep Prescription.** After visit #1, you will be asked to follow strict instructions on how much time to spend in bed throughout the remainder of this study. First, you will be asked to spend 8 hours in bed for two consecutive nights. This will be followed by six consecutive nights of either 8 or 11 hours in bed each night. After a 3 day break of unrestricted sleep, you will be asked to repeat this process again at either 8 or 11 hours time in bed each night. We ask that you change the time you go to bed at night to achieve these times in bed rather than changing when you wake-up in the morning. Please note that you will be asked to keep a sleep diary to track when you go to sleep, when you awake during the night and morning, and when you take off the sleep tracker. We will also ask you to download data from your physical activity/sleep tracker each morning from home so we can confirm that you wore the device and are meeting the prescribed sleep times. Failure to comply with our instructions will lead us to exclude you from the study.

- **Visits 2 and 4.** You will be asked to sit while 20 millilitres (1.3 tablespoons) of blood is collected from an arm vein. You will then be asked to complete a sleep questionnaire then a series of cognitive function tests performed on a computer. Next, you will lie down on your back for testing of blood pressure waveforms at your neck, wrist, and leg. The blood vessel in your neck and upper leg will also be imaged during this time to determine its size and blood flow characteristics. Following this test, blood pressure cuffs will be placed around your forearm and wrist. The cuff around your forearm will inflate to a high pressure for 10 minutes then deflate rapidly as blood flow is measured. The cuff around your wrist will inflate and deflate repeatedly during the blood flow measurement. Next, you will be asked to rebreathe your expired air for 3 minutes (like breathing in a paper bag) as blood flow is measured in your brain using transcranial Doppler. Oxygen will be leaked into the bag so your body remains relaxed. Lastly, you will be given a blood pressure monitor to wear for 24 hours including the night. The blood pressure monitor will take measurements every 20 minutes during the day and every 30 minutes during the night during the 24-hour period.

- **Exercise Prescription.** On the same day as visits #2 and #4, you will be asked to perform three 10-minute bouts of brisk walking or jogging at 50-60% heart rate reserve. We will show you the pace of walking/jogging that you need to achieve in order to reach this intensity. These exercise sessions can be performed anywhere you wish during the day, however, we ask that you spread them out such that the first bout of exercise is performed before noon and the last between 5:00-7:00 pm in the evening.

- **Visits 3 and 5.** We will ask that you return the morning after visits #2 and #4. At these visits, we will repeat all the measurements described above for visits #2 and #4 except for blood collection which will not be performed at these visits.

The following measurements are involved in this study:

- **24-hour Blood Pressure.** A small device worn at the hip that is connected to a blood pressure cuff worn on the upper arm will measure blood pressure after you leave visits #2 and #4. Measurements will be taken every 30 minutes while you are awake and asleep for a 24-hour period. During each measurement you are asked to keep your arm still, relaxed, and fully extended.

- **Blood Flow Measurement**. Blood flow will be measured using a commonly used instrument. A transcranial Doppler ultrasound probe will be placed firmly against the skin between your eyebrows and ear (over middle cerebral artery). The probe will be fixed and

held in place using a headband strap to prevent subtle movement. The probe produces sound waves that are used to measure the velocity of blood. Another Doppler ultrasound machine will also be used to measure blood flow at your neck (carotid artery) and leg (femoral artery) as you rest lying down. Lastly, blood flow during the cuff protocol will be measured using flexible strings wrapped around your forearm that will measure the change in size of your forearm as blood flows into the tissue.

- **Blood Measurements.** Blood will be collected by pricking your finger during visit #1 for measurement of glucose levels in your blood. Only a drop of blood will be needed for the test strip. The test may be repeated if errors are given by the machine. Blood will be collected by the lead investigator from an arm vein at rest during visits #2 and #4. The total amount of blood collected throughout the entire study is 40 milliliters or approximately 2.6 tablespoons. Blood will be stored and used to measure markers of inflammation and oxidative stress. Collected blood will not be used for any other purpose. All blood samples will be destroyed after analysis which we plan to perform at the end of the study.

- **Blood Pressure and Pressure Waveform Measurements.** Blood pressure will be measured with an automated device that requires a blood pressure cuff around your finger and upper arm. We will also hold a pencil-like sensor on your skin at your wrist, neck, and leg. You will be asked to breathe normally and remain still as a machine measures the blood pressure waves moving through your blood vessel.

- **Cognitive Function.** Standard neuropsychological tests will be administered using a computer and special software to assess the impact of the varied sleep times on attention, psychomotor speed, critical thinking, and memory.

- **Heart Rate Measurement.** For some of the tests, we will place three sticky electrodes on your chest (two just below your shoulder and one below your lowest left rib). The electrodes will be connected by wires to a computer that allow us to monitor heart rate.

- **Physical Activity/Sleep Measurement.** You will be asked to wear a small instrument (accelerometer) on wrist of your nondominant hand. The instrument records physical activity including the intensity and time spent physically active. In addition, the instrument can measure sleep characteristics like time in bed and sleep time.

- **Rebreathing Test.** You will be asked to breathe through a mouthpiece while wearing a noseclip that will allow us to collect your expired air. The expired air will then be used for you to inspire for 3 minutes while oxygen is leaked into the bag at your own metabolic rate to ensure your body remains relaxed. Oxygen saturation of your blood will be monitored with a finger device throughout the test to ensure enough oxygen is being delivered. During this test, brain blood flow will be measured along with carbon dioxide levels in your expired air.

WHAT WILL HAPPEN TO MY DATA?
Your information and blood samples collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
The researcher(s) have taken reasonable safeguards to minimize any known potential risks.

- **Blood Sampling.** The risk associated with blood sample collection includes one or all of the following: local discomfort at the puncture site, dizziness and nausea, and bruising. Infections such as cellulitis are very rare, but are also potential risks. If you present with skin that is red, swollen, and painful or warm to the touch then seek medical attention contact the researcher. **_____ (your initials)**

- **Blood Pressure Cuff Inflation.** There is a risk of temporary discomfort at the site where the blood pressure cuff is inflated. The discomfort might be greater the longer the cuff is inflated. In addition, you may feel a tingling sensation in your fingers while the cuff is inflated; however, this feeling goes away quickly after the cuff is deflated. **_____ (your initials)**

- **Doppler Ultrasound.** There is a minimal risk that the ultrasound probe will irritate your skin. **_____ (your initials)**

- **Heart Rate.** There is a minimal risk that an allergic reaction could occur from the adhesive on the ECG electrodes. **_____ (your initials)**

- **Rebreathing Test.** Discomfort associated with this test may include anxiety as breathing in your expired air may increase your drive to breathe. This may present as a desire to breathe faster or take larger breathes during the test. Tingling sensations in your limbs towards the end of this test are also a common feeling, but these sensations go away quickly after returning to breathing room air. *You can also stop the test early (before the 3 minutes are complete) if you feel uncomfortable by giving a 'thumb down' motion during the test.* **_____ (your initials)**

WILL MY HEALTH BENEFIT FROM TAKING PART IN THIS STUDY?
There are no direct health benefits to you in participating in this study. However, you will be given your blood pressure and fasting blood glucose level.

DO I HAVE TO TAKE PART IN THE STUDY?
Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time.

CAN MY TAKING PART IN THE STUDY END EARLY?
Your participation in the study could end early if you find any of the study procedures too difficult, you do not follow instructions on wearing the physical activity/sleep device or blood pressure monitor, or if you miss scheduled visits.

WHAT WILL IT COST ME TO PARTICIPATE?
There is no cost to you for participating except that associated with your transportation to our research facilities at Texas Tech University.

WHO WILL SEE THE INFORMATION THAT I GIVE?
Your information will be combined with information from other participants taking part in the study. In the event of any scientific publication resulting from the research, no personally identifiable information will be disclosed. Your name will be kept separate from your research records which will be given a code number. Your name and the associated code number will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THE STUDY?
Yes. Participants will be paid a total of $200 cash for their participation in the entire study. If for some reason you do not complete the study, you will be paid for the visits you did complete ($50 each for visits #2, #3, #4, and #5). There is no payment for visit #1 as it serves as a 'screening visit'. This study is funded by the American Heart Association.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH?
If this research project causes injury (physical, psychological, social, economic, legal, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409.

WHAT IF I HAVE QUESTIONS?
Drs. Joaquin Gonzales (806-834-5944) will answer any questions you have about the study. Questions about your rights as a research participant can be directed to the Human Research Protection Program (HRPP), Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, 806-742-2064.

_____	_____
Participant Signature	Date
_____	_____
Printed name of person agreeing to take part in the study	Name of Person Providing Consent