Informed Consent

Please read this informed consent carefully before you decide to participate in the study.

Consent Form Key Information:

- Complete an online screening survey
- Complete a home-and-clinic-based sleep, body weight, and cardiovascular health assessment
- No information collected that will connect identity with responses
- Study incentives include $200.00 US compensation for completion of the full study; free access to health screening services

Purpose of the research study: The overarching aim of this proposal is to acquire a more comprehensive understanding of the relationship between adiposity, sleep, and cardiometabolic factors by investigating whether normal weight subjects differ from overweight and obese subjects on these outcomes.

What you will do in the study: For the study, subjects must be 18 years of age and older and in general good health. Subjects may come from a variety of backgrounds and must reside in Tuscaloosa. All subjects will complete an internet-based screening survey. Eligible subjects will complete a two-phase study. Phase 1 will include the collection of the following data in a laboratory environment: adiposity indices (body mass index [BMI], air displacement plethysmography, anthropometrics); and cardiometabolic measures (blood pressure; pulse wave velocity and analysis, a blood draw for biomarkers including atherogenic lipoproteins and glucose. Phase 2 will include collection of the following sleep and socioecological measures: home sleep apnea screening, one week of actigraphy and sleep diaries, and a battery of questionnaires.

Time required: The study will require about 8.5 hours of your time. Screening survey: 30 minutes; home-based assessment: 4 hours; clinic-based assessment: 2 hours. The screening survey can be completed in one sitting. The home-based assessment will include maintaining a sleep diary for 1 week as well as a 1-night home sleep testing kit. The clinic-based assessment will take approximately 2 hours to complete.

Risks:

- Screening survey. There are minimal risks associated with completion of the online screening survey. The primarily risk pertains to confidentiality, rather than safety risks.
- Air-Displacement Plethysmography. There is minimal risk with air-displacement plethysmography. Mild discomfort due to the small dimension of the chamber is possible.
- Pulse wave velocity/analysis. There is minimal risk associated with the device as it is applied externally.
- Home sleep testing. There is minimal risk associated with home sleep recording. Mild discomfort from wearing the device is possible.
- Blood pressure. There is minimal risk associated with blood pressure measurement. Discomfort from the cuff and bruising is possible.
- Sleep diary and actigraphy. There is minimal risk associated with completing sleep diaries and actigraphy.
- Anthropometrics. There is minimal risk associated with collection of anthropometric data.
- Cardiometabolic biomarkers. There is minimal risk associated with the fingerstick to collect a drop of blood. Infection, bruising, fainting, and a small amount of bleeding is possible. As the
subject will be in a fasted state, there are some health risks associated, including dizziness, decreased alertness, and symptoms associated with low blood sugar.

- Questionnaires. There are minimal risks associated with completion of the online screening survey. The primarily risk pertains to confidentiality, rather than safety risks.

**Benefits:** Subjects may gain satisfaction knowing they contributed to a scientific study which may someday result in better diagnostic and treatment options for obesity and sleep. They will receive a health screening related to their body composition and sleep. In addition, all subjects will receive the opportunity to schedule 1-hour appointments with the Principal Investigator to review their scores and receive some interpretation of study questionnaires and assessments.

**Confidentiality:** Every effort will be made to ensure participant privacy. Whenever feasible, identifiers will be removed from study-related information. All blood samples will be identified by a barcode generated by a computer in place of identifiable information. Data obtained for the proposed study will be used for this research project only. Review of informed consent documents for Phase 1 and 2 of the study will occur face-to-face with subjects behind closed doors in a private interview room located within the Nutrition and Metabolism Research Lab. In-lab data will be collected in patient rooms (behind closed doors with no windows in the room) located within the Nutrition and Metabolism Research Lab. All paper records will be kept in locked filing cabinets located within the Principal Investigator’s locked office (doubly locked) and will only be accessible to personnel involved in the study. All interactions, including phone calls and e-mails to and from subjects will comply with HIPPA regulations. E-mails to and from participants may be kept in archives but may only be sent to and from e-mail addresses in the ua.edu domain, where all correspondences are encrypted.

**Voluntary participation:** Your participation in the study is completely voluntary.

**Right to withdraw from the study:** You have the right to withdraw from the study at any time without penalty.

**How to withdraw from the study:** If you want to withdraw from the study, please tell the researcher and leave the room. There is no penalty for withdrawing. You will still receive compensation for the completed parts of the study (please see compensation section). If you would like to withdraw after your materials have been submitted, please contact Dr. Adam Knowlden.

**Compensation:** You can receive up to $200.00 US compensation for completion of the full study. Compensation is pro-rated as follows: $100.00 for the in-lab component of the study (Phase 1) and $50.00 US for the in-home. component of the study (Phase 2). A $50.00 bonus will supplement compensation for subjects that provide complete data.

**Using data beyond this study:** The researcher would like to make the information collected in this study available to other researchers after the study is completed. Your information will be stored, used and shared for future research studies, including but not limited to secondary analyses and meta-analyses. Researchers of future studies will not ask your permission for each new study. However, the information you provide will be combined with the information provided by others to create a large data set. Your name and other information that could potentially identify you will not be connected to the information shared with other researchers nor will they attempt to identify you.
If you have questions about the study or need to report a study related issue please contact, contact:
Name of Principal Investigator: Adam Knowlden, Ph.D.
Title: Associate Professor
Department Name: Health Science
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Faculty Advisor’s Name: John Higginbotham, Ph.D.
Department Name: Community Health Science
Telephone: 205-348-7259
Email address: jhigginb@ua.edu

If you have questions about your rights as a participant in a research study, would like to make suggestions or file complaints and concerns about the research study, please contact:
Ms. Tanta Myles, the University of Alabama Research Compliance Officer at (205)-348-8461 or toll-free at 1-877-820-3066. You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://ovpred.ua.edu/research-compliance/prco/. You may email the Office for Research Compliance at rscompliance@research.ua.edu.

Agreement:

☐ I agree to participate in the research study described above.
☐ I do not agree to participate in the research study described above.
☐ I agree to video (audio, photograph) in the research study described above.
☐ I do not agree to video (audio, photograph) in the research study described above.

__________________________________________________
Signature of Research Participant

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Print Name of Research Participant

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Signature of Investigator or other Person Obtaining Consent

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Print Name of Investigator or other Person Obtaining Consent