COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL: SMILOW CANCER CENTER

Study Title: A photoplethysmography sensor-based personalized feedback intervention for heavy-drinking young adults targeting heart rate variability, resting heart rate, and sleep
Principal Investigator (the person who is responsible for this research): Lisa Fucito, Ph.D.
Phone Number: 203-200-1470

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to test a mobile health intervention for young adults who report heavy alcohol use.
- Study procedures will include: an initial, in-person intake appointment (Week 0), a 6- week intervention phase with a brief phone call check-in at week 3, and 2 follow-up visits (Weeks 6 and 10).
- 3 visits are required.
- These visits will take **3** hours total.
- There are some risks from participating in this study. There are no physical risks associated with this study. The OURA™ biosensor is safe and easy to use. We will work with you to select a ring size that is comfortable. However, there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.
- The study may have benefits to you. You will engage in self-monitoring that may help you learn more about your alcohol use, health, and/or sleep. If randomized to the Feedback group, you will receive personalized feedback about your health and behaviors as well as tailored, evidence-based advice, which may help you improve your drinking, health, and/or sleep. You will be provided compensation for your participation.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you are 18-25 years of age, reported ≥4 heavy drinking occasions in the last 4 weeks, and have a personal smartphone available for use along with the wearable sensor provided in the study**.** We are looking for about 60 participants to be part of this research study.

Who is paying for the study?

National Institutes of Health grant (R21AA028886)

Who is providing other support for the study?
The Connecticut Mental Health Center and the Connecticut Department of Mental Health and Addiction Services will provide research space for this study.

What is the study about?

The purpose of this study is to test a mobile health intervention for young adults who report heavy alcohol use. The health intervention includes: (1) alcohol use and other health self-monitoring including use of a wearable biosensor, (2) a mobile application, and (3) personalized feedback and tailored health tips about your health and alcohol use data.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen: Participation in this study will consist of an initial, in-person intake appointment (Week 0), a 6- week intervention phase with a brief phone call check in at week 3, and 2 follow-up visits (Weeks 6 and 10).

Your participation in the study will consist of:

Intake (Week 0):

Prior to attending the intake and upon arrival, you will be screened for COVID-19 symptoms. These include fever of 99.9°F or higher, cough, shortness of breath/difficulty breathing, fatigue, repeated shaking with chills, muscle pain or body aches, chills, headache, sore throat, new loss of taste or smell, congestion or runny nose, nausea or vomiting, or diarrhea. We will also discuss COVID-19 risks with you. You will then be asked to complete a number of questionnaires and self-assessments that will ask you about your sleep, alcohol use, health behaviors, mood, and psychological characteristics. We will also ask for demographic information including age, race, socioeconomic and marital status, and educational and occupational levels. A licensed clinical psychologist will conduct an interview with you to determine your substance use history and other relevant medical and psychiatric history. We will measure your height and weight. This visit will take about 1 hour.

Randomization (Week 0): You will be randomly assigned (like the flip of a coin) to 1 of 2 conditions: (1) Assessment or (2) Feedback.

If you are assigned to the Assessment group, you will wear the OURA™ ring and complete daily diaries for 6 weeks but will not have access to the OURA™ mobile app and will not receive any feedback about your health data. You will have an opportunity to receive this health data after you complete your final follow-up visit at Week 10.

If you are assigned to the Feedback group, you will wear the OURA™ ring and complete daily diaries for 6 weeks. During this time, you will have access to the OURA™ mobile app and will receive personalized feedback and tailored health tips about your data.

Treatment Phase (Intake-Week 6): You will begin wearing the OURA™ after the intake every day for a 6-week period. During these weeks, monitoring will occur continuously with the OURA™ and you will also complete daily diaries using the MEI Research application. We will

arrange to pick up the biosensor from you at the end of the 6-week monitoring period. If you are in the Feedback group, you will also receive health feedback and advice through the OURA™ mobile app and reports that are sent to you. The OURA™ app provides daily summaries of your resting heart rate, heart rate variability, and sleep that you can view on the app. The research staff will orient you to the OURA™ app health feedback and advice. In addition, every 2 weeks (i.e., Weeks 2, 4, and 6), we will send a written report via text/email that: (1) summarizes your alcohol use and the links with your heart and sleep health data and (2) provides health advice tailored to this data. The research staff will call you at week 3 for a brief phone conversation. You will get the opportunity to express any concerns with the device, and confirm the date and time of your week 6 appointment.

Follow-up (Week 6): You will complete the Week 6 follow-up visit remotely via ZOOM, which will be recorded using ZOOM with your consent. The research staff will conduct exit interviews and treatment evaluation surveys to understand the feasibility/acceptability of the health intervention program including wearing the biosensor. You will also complete questionnaires and interviews about your alcohol use, health characteristics, and the feasibility and acceptability of self-monitoring activities and health feedback/advice.

Follow-Up (Week 10): You will also complete the Week 10 follow-up visit remotely via ZOOM, which will be recorded using ZOOM with your consent. You will complete questionnaires and interviews about your alcohol use and health characteristics.

What are the risks and discomforts of participating?

There are no physical risks associated with this study. The OURA™ biosensor is safe and easy to use. We will work with you to select a ring size that is comfortable. However, there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

You will engage in self-monitoring that may help you learn more about your alcohol use, health, and/or sleep. If randomized to the Feedback group, you will receive personalized feedback about your health and behaviors as well as tailored, evidence-based advice, which may help you improve your drinking, health, and/or sleep.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of how to engage more young adults into alcohol prevention and treatment programs and reduce the substantial harms and healthcare costs associated with heavy alcohol use.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits. Standard text message rates will apply for the texts you receive from us.

Will I be paid for participation?

You will be paid $30 for completing the intake, $45 for completing the week 6 follow-up visit, and $60 for completing the week 10 follow-up visit, total=$135. You will also be compensated for at-home monitoring activities: (1) $1 per day for wearing the OURA (42 possible days for a total of $42)d (2) $1 per day for completing each daily diary (42 possible days for a total of $42). The total possible compensation for at-home monitoring is $94. Compensation will be paid weekly, meaning if you wear OURA daily and complete your diary each morning, you will get $14 for the week. For returning OURA at the end of the 6 weeks you will get $50. Therefore, the total possible compensation you could receive is $279.

We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. We will have to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the first payment. You will need to activate the card over the phone. Each additional payment will be automatically added to your card.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

I understand the Economic Considerations described above:

☐ Yes ☐ No Initials: _____

I agree to allow zoom interviews to be audiotaped:
☐ Yes ☐ No Initials: _____

What are my choices if I decide not to take part in this study?

Alternatives to treatment in this study include evidence-based web-based treatment programs for sleep and/or alcohol use, some of which are available at a cost to you.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

The researcher will have information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and street number and date of birth. This information will be kept for 7 years. After that time, it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected

members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

Paper records that include identifiable information will be kept in a locked research cabinet. Research records will also be stored on a secure server and your data and responses will be identified by a unique numerical code.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Records about phone calls made as part of this research
- Records about your study visits
- Research questionnaires
- Information obtained during this research regarding laboratory, and other test results

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those representatives at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator
- The study sponsor
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Other researchers through a shared data agreement through a required policy from NIAAA
- We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to

better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

We have obtained a Certificate of Confidentiality (CoC) issued by the NIH. Once granted, the researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. When the CoC is obtained, we will inform all active study participants.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

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.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing Lisa Fucito, Ph.D. at the Yale University School of Medicine: 20 York Street Fitkin Building F619, New Haven, CT 06510.
If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this consent form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. The study team may decide to take you out of the study without your agreement if:

- You do not follow the directions of the study team;
- The study team decides that the study is not in your best interest;
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Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale University or Yale-New Haven Hospital.

What will happen with my data if I stop participating?

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203-200-1470

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

OURA™ Policy Disclosure Notice

Your signature below indicates that you have received copies of the OURA™ Health Privacy Policy and the OURA™ Teams Privacy Policy and that you understand the information presented in both of these documents.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Consent for Forwarding Address

In the event that the investigators cannot contact me at my current address and phone number, I give consent for the following persons to be contacted to obtain my forwarding address and phone number. I will tell these persons that they may be contacted.

Name:_____

Relation: _____

Phone Number: _____

Address: _____

Name:_____

Relation: _____

Phone Number: _____

Address: _____

Consent to Recontact:

The research team may wish to contact you in the future, to clarify questions from the questionnaires or interviews, or to invite you to participate in other studies. Therefore, we ask your permission to contact you in the future. Giving your permission for the research team to contact you does not obligate you to answer any future questions, or to participate in any future research-- you always have the right to decline further participation in research. Please indicate your preference about future contact by writing your initials in one of the spaces below:

Initials:
_____ I give the research team permission to contact me in the future
_____ I DO NOT give the research team permission to contact me in the future