Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Using Wearable Technology to Develop Biomarker-Driven Intervention for Alcohol-Facilitated Intimate Partner Violence

Concise Summary

Your consent is being sought for a research study. Participation is voluntary. The purpose of the study is to examine the usability, feasibility, and acceptability of wearable activity trackers (like a smart watch) and use of a cell phone application (app) among couples. We are also testing how the use of this device and app will affect alcohol use and couple conflict.

This study will involve a screening phase with will include 1-2 appointments. Participants will complete questionnaires and interviews privately apart from their partner and complete some tests to measure alcohol/drug use and pregnancy. If eligible and enrolled, the research study will last 28 days, and participants will be asked to wear the smart watch for the length of the study. Location and heartrate will be monitored. Participants will also be asked to complete several surveys throughout the study. There are risks of participating in this study that are described in this document, including loss of confidentiality, inconvenience, and increased risk of couple conflict.

Everyone enrolled in the study will receive contact with research staff, access to additional mental health and substance use information, and referrals to other treatment services if needed. Your alternative is to not participate in this study.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making you decision. As the study staff discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

The purpose of this observational study is to examine the usability, feasibility, and acceptability of wearable activity trackers (like a smart watch) and use of a cell phone application (app) among couples experiencing couple conflict and alcohol use disorder. We are testing the use of this device and app to see if it will reduce alcohol use and couple conflict. This study will use **Ecological momentary assessment** (EMA), also knows as 'the daily diary method or 'experience sampling', which takes repeated samples of participants' current experiences (location, alcohol use, conflict) in real time in an individual's natural environment. Throughout the course of this 28-day research study, we will collect data on you such as your heartrate and location. Your heartrate will be collected so we can learn more about when and how you experience you stress. In addition, the app will remind you randomly to complete a few questions on drinking and drug use, conflict behaviors, and mood and feelings.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate because you are between the ages of 21-70 years of age, you are in a romantic relationship with at least one instance of couple conflict in the last six months, and either you or your partner has an alcohol use disorder. The study is sponsored by the National Institute on Alcohol Abuse and Alcoholism. The investigator in charge of this study at MUSC is Julianne Flanagan, PhD. The study is being done at the Medical University of South Carolina. Approximately 50 couples or 100 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. Screening Visit
    a. The first visit includes screening for study eligibility and will take approximately 1.5 hours. You have the option to complete this in 1 or 2 visits. During that time, you will be asked to answer some questions about yourself such as your age, health, relationship with your partner, and your use of alcohol and drugs to determine if you are eligible to participate.
    b. If you have recently started taking a prescription medication, you may be asked to wait 4 weeks until you participate in the study so that the effects of the medication will be stable and won't affect the study results.
    c. If you meet initial eligibility criteria and you choose to participate, you and your partner will begin the assessment portion of the screening visit. If you are a woman, you will be asked to complete a urine pregnancy test. The urine pregnancy test must be negative in order to participate. If your pregnancy test is negative, or if you are male, you will be asked to provide a urine sample to test for drug use. You will also complete a breathalyzer test.
        i. We are testing for pregnancy because sometimes it can cause changes in heartrate, which may affect study data. If you become pregnant over the course of the study, please notify staff. You will still be able to continue participating in the study.
    d. The study team will also conduct short interviews with you to assess your overall health and relationship status. The study team will ask about conflict and aggression in your relationship by going through a calendar asking if and when conflict events occurred.
    e. You will also be asked questions and given questionnaires to complete about your use of alcohol, drugs, and tobacco, mood, behaviors, and sleep.
2. Demonstration Session
    a. If you are eligible and wish to participate, research staff will contact you via phone or text for the remainder of your participation in the study. Following the screening visit, you will be contacted to schedule a short demonstration session (demo session).
    b. Before your demo session, the study team will ship all necessary study supplies to you, including a Garmin Vivosmart 4 activity tracker and charger, as well as an iPhone Gen 3,

charger and protective case. If you have a personal iPhone with data connection, you may use your own device. If you have an Android or other mobile device, or wish not to use your personal device, the study team will provide an iPhone for you to use over the course of the study.

c. Once you have the necessary equipment, the study team will guide you through downloading and setting up two applications on your iPhone. One of these applications costs approximately $10. You will be reimbursed for this cost. You will be asked to return all equipment at the end of the study.

d. You will then complete the demo session (in person or via telehealth) with research staff to learn how to use the iPhone, smartwatch, and mobile apps. This session will last approximately one hour.

e. You will also be trained on a breathing technique that you will be prompted to use in week 4. Once prompted to complete the breathing task, you will look at the app, which will have an oscillating bar that will guide you to inhale and exhale at a rate of about 6 breaths per minute.

3. Observational period

a. You will be asked to wear the study issued Garmin Vivosmart 4 activity tracker (or 'smart watch') and carry the mobile device at all times while you are awake during the 28-day research study. The smart watch will collect information about your location and heart rate.

b. Four daily EMA reports will be requested via mobile app notification and will take 2-3 minutes each (Days 1-28; one morning report plus three additional reports at random times over the following 12 hours). You will have the ability to select the time you receive the morning assessment and provide a daily window for start and end times. Both you and your partner will be assigned to the same assessment schedule. You will have 2 hours to complete the morning report and 1 hour to complete the additional reports.

c. During the 28-day period of this research study you will also be asked to complete event-specific reports if alcohol use or partner conflict takes place. These reports will include questions about drinking and drug use, conflict behaviors (when and where did verbal or physical aggression happen), and mood and feelings.

d. Research staff will contact you by phone or text if the first two EMA entries on any particular day are missed. You will have the opportunity to contact research during normal business hours over the course of your participating, should you have any questions.

4. Intervention Period

a. During days 22-28, you will be randomly prompted once per day (by your mobile device) to complete the breathing task taught during the demonstration session. This should take only a few minutes and the app will use an oscillating bar to guide your breathing pattern.

b. You will also be prompted to complete the EMA reports just like the first three weeks.

c. You will have access to the app so that you can use the breathing technique more often if you like, but you will only get prompted once per day.

5. Exit Interview
    a. After you have completed the 28-day research study, you will be asked to meet with research staff to complete an exit interview, which will take approximately 30-60 minutes. You will be asked questions about your experience in the trial, recent alcohol use and conflict behaviors.
    b. You will also be given instructions on how to return the smart watch and any other study materials. If you used a study-issued iPhone for your participation, the study team will also provide instructions on how to remove any personal information from the phone prior to returning it.
6. Technology Use Expectations
    a. The smartwatch and iPhone, if applicable, is that of a loan and is the **property of MUSC**. It is expected to be returned to the study team immediately after all study tasks that require the equipment has been completed. In the event you wish to terminate your study participation, you are to contact the study team return the loaned equipment as soon as possible. We also ask you to keep the study equipment in good working order.
    b. In the event study equipment is not returned to the study staff at MUSC or returned in poor working order, this will affect your compensation by not receiving the equipment return bonus.
    c. Refrain from completing sessions on the mobile devices at a time when it may be unsafe to do so (e.g., while driving).
    d. Refrain from using the study devices for any purposes other than participating in the study (e.g., taking photos, calling/ texting, or browsing the internet).

TELEHEALTH

This research study can be conducted virtually, or through home-based telehealth (HBT). In order to complete sessions via HBT, you will need to have internet or cellular access in your home and a computer, tablet, or smartphone capable of accessing the internet. If you complete this study via telehealth pregnancy tests, urine drug screens and all study supplies will be shipped to you via trackable UPS or Fedex shipment. Females will be required to provide verbal and photo (of dipstick) confirmation of a negative pregnancy test at the screening visit.

You will be asked to find a private room, away from your partner for portions of the screening visit and any additional visits. The study team can also work with you and your partner to schedule these portions individually and separately in order to maintain protection of your privacy.

If you and your partner do not live together study supplies may be shipped to one (agreed upon) residence.

We would like your consent to ship study supplies the address provided on your contact information form.

Please indicate your choice below, or scroll down to the bottom of the screen and select your choice electronically:

____Yes, I would like study supplies shipped to my residence.

____No, I would not like study supplies shipped to my residence.

C. DURATION

Participation in the study will take about 3 visits (about 3.5 hours) over a period of about 6 weeks.

D. RISKS AND DISCOMFORTS

Interviews and Surveys: The questions that will be asked may be sensitive in nature and may make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer.

Risk of Loss of Confidentiality
There is a chance that your personal information may inadvertently not be kept confidential. Some answers you give during the research visits (like whether you use illegal drugs) may put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records to the extent allowed by law by keeping all your materials in locked file cabinets only accessible by research staff and all computer files will be secure password-protected files only accessed by research staff. Your research records are kept separate from your clinic records and will not be shared with your clinical counselor. Only research staff will have access to your private information. Data collected through the smart watch and app will be stored on a cloud based system but will not be linked to you. No identifiable information will be stored on the cloud based system used in this project.

Participants in this project might have instances of psychological and/or physical couple conflict during the 28-day study period. However, we estimate the risk of couple conflict occurring, or couple conflict increasing in frequency or severity to research participation to be very low.

Limits of Confidentiality:

Suspected or known abuse or neglect of a child, disabled or elder abuse, or threatened violence to self or others may be reported to appropriate authorities.

If you are or become pregnant and test positive for illegal drugs, it is a law that the South Carolina Department of Social Services (DSS) must be notified. You and your family will be evaluated by the agency. You could be ordered to mandatory drug treatment, lose custody of your children, or possibly be jailed.

Unknown Risks: The study procedures may have unknown risks. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFIT

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours and will help the researcher learn more about alcohol use disorder and conflict among couples.

G. COSTS

You will be asked to purchase a mobile app (HRV4Biofeedback) for approximately $10. The study team will reimburse you for this cost. Since this study involves use of a mobile phone and app, standard mobile and data rates will apply to if you choose to use your own device.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid up to $262 for participation in this study. You will receive:
$50 for the screening visit
$10 for the purchase of HRV4Biofeedback mobile app
$1 per completed EMA report (maximum 4 per day for 28 days, $112 in total)
$10 bonus for each week that you complete at least 80% of EMA reports (4 weeks, $40 maximum)
$25 for completing all 4 weeks of participation

$25 for returning borrowed equipment (*return mailers provided*).

Participants will be compensated for survey completion on a weekly basis. All participants will be compensated for weekly survey completion on a scheduled day.

Payment types may include checks and Clincard.

If you refer other participants to this trial, you will receive $10 per enrolled referral.

You may receive payment in the form of a ClinCard, a pre-paid debit card. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. Should you choose this payment option, you will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Compensation may also be provided in the form of check. In order to receive compensation, you will be asked to fill out a W9.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study. The study team will provide you with referrals for other treatment options.

J. DATA SHARING

No information about you that is collected as part of this research (whether or not it is identifiable) will be used or distributed for future research studies under any circumstances.

K. NIAAA DATA ARCHIVE

Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests

your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NIAAADA. The study data provided to NIAAADA may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAADA data. You will not be contacted directly about the study data you contributed to NIAAADA.

You may decide now or later that you do not want your study data to be added to the NIAAADA. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAADA. If you know now that you do not want your data in the NIAAADA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NIAAADA, call or email the study staff who conducted this study, and they will tell NIAAADA to stop sharing your study data. Once your data is part of the NIAAADA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

Please indicate your choice below, or scroll to the bottom of the screen and select your choice electronically.

____Yes, I agree to share my study data with the NIAAADA.

____No, I do not agree to share my study data with the NIAAADA.

L. DISCLOSURE OF RESULTS

Study data will not be shared with participants to maintain confidentiality.

M. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.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.

Q. COLLECTION OF SPECIMENS

Urine specimens will be collected in this study. We will collect specimens in order to measure drug use. and test for pregnancy. If you are a woman, you will provide a urine sample at the screening visit. If you are not pregnant, all participants will provide a urine sample during the screening visit to conduct a urine drug screen. These specimens will be used solely as part of this research study and will not be shared with other investigators. All specimens will be coded with your numeric study code to protect your confidentiality.

R. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

S. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please indicate your choice below, or scroll down to the bottom of the screen and select your choice electronically:

____Yes, I agree to be contacted.

____No, I do not agree to be contacted.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board

for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions. If your participation is ended for medical reasons, you will be referred to a doctor or other health professional for care. You will be responsible for the cost of these services.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Julianne Flanagan at (843) 792-5569. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date