CALIBRATION STUDY OF A WEARABLE NONINVASIVE BLOOD ALCOHOL MONITOR

NCT: NCT03574181

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RESEARCH CONSENT FORM

Basic Information

Title of Project: CALIBRATION STUDY OF A WEARABLE NONINVASIVE BLOOD ALCOHOL MONITOR

IRB Number: **H-36914**

Sponsor: National Institute on Alcohol Abuse and Alcoholism (KWJ Engineering)

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Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to test the accuracy of a 'wristwatch' device that is designed to measure blood alcohol level through skin contact. If you agree, you will drink alcohol in a simulated living room while wearing a wristwatch on each arm. Researchers will measure your blood alcohol level (BAL) through these watches and also by an alcohol breath test. You will be asked to complete this drinking session two times during the study. You will be in the study for up to nine months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are loss of confidentiality and feeling intoxicated. You will find more information about risks later in this form.

Purpose

The goal of this study is to determine whether a wristwatch blood alcohol monitor will be sensitive and reliable when compared to a standard measure of blood alcohol taken by a breathalyzer.

What Will Happen in This Research Study

Each subject will complete 4-5 visits over a period of up to 9 months of participation. Study participation is comprised of a baseline assessment, Phase I BAL calibration session, Phase II eligibility screening session, and Phase II BAL validation session. Each visit is described below.

1. Baseline Assessment (Today):

If you decide to volunteer for this study, your first visit will take approximately 3 hours to complete. You may complete all of this today, or your visit may be split over two visits on different days. In this visit you will be evaluated to make sure that you can safely participate in the drinking sessions.

During this visit you will be asked to:

- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Undergo a physical exam, and review of your medical history to assess your overall health and wellness.
- Have an electrocardiogram (ECG). This is a test that measures the electrical activity of your heart. It involves placement of leads (wires) on your chest, arms and legs for about 15 minutes.
- Have vital signs (blood pressure and heart rate) taken.
- Provide a blood sample to assess how your liver is working.
- Provide a urine sample to test for drug use.
- Provide basic demographic information (e.g., age, occupation, and income).
- Provide the names of any prescription and “over-the-counter” medications you are taking.
- Answer questions about your mental health, substance use and alcohol withdrawal symptoms.
- Describe your daily alcohol use over the past 28 days.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).

You will provide addresses and telephone numbers for yourself and other people, such as family members or friends who will know how to contact you if you fail to show up for –study visits, or if study personnel have problems getting in touch with you. In doing so, you give study personnel permission to contact these people to find out how to contact you. Please be aware that telling others you are in this study could jeopardize your privacy.

If you test positive for any recreational drugs other than marijuana during this screening visit, you will be excluded from this study and will not be reimbursed. If we encounter anything else during the screening that would disqualify you from taking part in this study, we will end the interview and provide you with a pro-rated payment for the time you have spent in screening. You will receive a percentage of the payment based on the amount of time you have spent in screening. If your laboratory results disqualify you from taking part in the study, you will receive a telephone call from study staff prior to your next visit informing you of these results.

If you decide at any time during this study that you would like to cut back or quit drinking, please inform study staff immediately. Drinking alcohol in a laboratory could interfere with any effort you are making to change your drinking. If you purposefully abstain from alcohol with the intent of cutting back or quitting drinking, you will be excluded from study participation.

2. Phase I BAL Calibration session (Within 14 Days of Baseline Assessment visit)

The Phase 1 drinking session is expected to take **at least 8 hours**. For safety reasons, we ask that you arrange for transportation that does not involve you operating the vehicle (such as car, motorcycle, bicycle, etc) on the day of the drinking sessions. You will not be permitted to use nicotine during the drinking session. If you are unable to abstain from nicotine for periods of up to 8 hours, then you may not take part in this study.

During this visit you will be asked to:

- Wear one BAL wristwatch on each arm that measures your blood alcohol level
- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Have vital signs (blood pressure and heart rate) taken.
- Provide a urine sample to test for recreational drug use.
- Provide the names of any prescription and "over-the-counter" medications you are taking.
- Describe your daily alcohol use since your first visit.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).

You may be excluded from continuing in the study if you have become pregnant, if you test positive for recreational drug use, or if you have started a new medication that would make participation unsafe for you.

After completing surveys and interviews, you will be brought to a room that is furnished with a comfortable chair, side table, and television. Before the alcohol administration session occurs, you will be fitted with the BAL wristwatches and a 60 minute period of baseline observation will start to demonstrate that the wristwatches are working correctly. During this period you will be asked to blow into a breathalyzer every 15 minutes. You will have access to streaming entertainment during this period, but you are asked to limit use of personal electronics during this time.

After the 60 minute baseline observation, the drinking self-administration will begin. You will choose your alcohol of choice that exceeds 24% alcohol by volume. The study staff will pour you two drinks of this alcohol that are measured to raise your blood alcohol level to 0.05 g/dL. Drinks will be mixed with a sugary mixer (3:1 Mixer:Alcohol) to avoid possible low blood sugar. You will consume these drinks in 60 minutes. During this period you will be asked to blow into a breathalyzer every 15 minutes. To ensure that residual alcohol in your mouth doesn't provide a

false breath alcohol reading, you will be asked to eat saltine crackers and rinse your mouth with water before blowing into the breathalyzer. During the drinking session you will have access to Netflix, HBOgo and YouTube. You will be asked to limit your personal electronics (e.g. cellphone, laptop) during the drinking session. The estimated maximum BAC you will achieve is 0.05 g/dL. For reference, the legal limit in Massachusetts for driving after drinking is 0.08 g/dL.

The 60 minute drinking session will be followed by an observation period that could last up to five hours. Your blood alcohol level will be measured simultaneously using the transdermal sensors in the wristwatches and a breathalyzer, which you will blow into every 15 minutes during the observation period. You will be given a light meal (approximately 375 calories) four hours after you finish drinking. After the observation period you will be free to leave the lab provided your Blood Alcohol Level has reached 0.04 g/dL or less. Given the rate of alcohol elimination, you will likely have a BAL of 0.00 g/dL at the end of the observation period.

Your drinking session will be observed by study staff using a small video camera in the room where you are drinking. This drinking session will be recorded. The video will be stored on an encrypted hard drive with password protection. The video recording will be deleted upon completion of the study.

5. Phase 2 eligibility screening session

When 12 participants have completed Phase 1 of the study, you will be contacted by phone and invited back to the lab to complete phase 2. We will assess your eligibility again to ensure that it is still safe for you to continue before you start the second drinking session.

During this visit you will be asked to:

- Meet with a medical doctor to discuss your medical history
- Provide a blood sample to assess how your liver and kidneys are working.
- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Have vital signs (blood pressure and heart rate) taken.
- Provide a urine sample to test for recreational drug use.
- Provide the names of any prescription and “over-the-counter” medications you are taking.
- Describe your daily alcohol use for the past 28 days.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).
- Answer questions about your mental health

Phase 2 BAL validation session (Within 14 days of Phase 2 eligibility visit)

During this visit you will complete the second drinking lab session. The procedures for this second drinking session are the same, with a few exceptions:

- You will be wearing newer BAL wristwatch sensors
- The observation period will last only 3 hours (or longer if necessary to reach a BAL of 0.04 g/dL or less)

If you participate in this study, all visits will be completed within 9 months of your first visit.

The laboratory testing and ECG that you will have in this study are clinical tests that you will have for research purposes only. However, if we see something that could be important to your health, we will ask you if you want us to explain what we noticed. If you would like, we will also make copies of the results that you can bring to your doctor. You or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

Physical Discomforts:

I. The drawing of blood may cause pain, bruising, lightheadedness, and on rare occasions, infection. You may briefly feel the prick of the needle when it is inserted. You may feel dizzy or faint when blood is drawn. Trained phlebotomists will be used to minimize these risks.
II. ECGs may cause discomfort and/or irritation of the skin (redness and itching) from the adhesive electrodes. Hair on your chest may need to be removed using a razor in order to obtain the best electrical contact between the adhesive electrodes and your skin. Trained staff will be used to minimize these risks.

Risk of overconsumption

There is a risk that the amount of alcohol you drink during the study sessions could be more than what is comfortable for you. If you decide to be in this study you will drink two drinks that will have only enough alcohol to raise your BAL to 0.05 g/dL. Medical staff will be monitoring your participation and if you become intoxicated to a point of presenting some risk to yourself or others, your participation will be stopped. The study team will ask you to stay in the laboratory until your blood alcohol level reaches 0.04 g/dL or less. During this time you will have snacks, access to your personal electronic devices, and access to streaming electronic entertainment.

There may be unknown risks or discomforts involved.

If you get pregnant while you are in this study, it could be bad for the fetus. You must use birth control if you are a woman having sex with men during the period between screening and the

drinking session. Only some birth control methods work well enough to be safe while you are in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. You should not be in this study if you are a woman who has sex with men and cannot use one of these birth control methods.

Potential Benefits

You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn if a wearable wristwatch can accurately measure blood alcohol level. This device may help researchers measure drinking more accurately and also could be used as a tool to help people achieve a goal of less risky drinking.

Costs

There are no costs to you for being in this research study.

Payment

During this study you will receive the following payments for completion of study tasks:

Baseline assessment	$40 (split payment if two visits are needed)
Phase I Drinking session	$100
Phase II eligibility screening session	$40
Phase II Drinking session	$100
Completion Bonus	$60

In total, you may be compensated up to $340 if you complete all of the study activities.

Payments will be made by giving you a prepaid credit card. You must give us your Social Security Number or Individual Taxpayer Identification Number to receive this payment.
The research may lead to the development of a device that may have commercial value. You will not get any money if products are developed from the research.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality. This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in

connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

Confidentiality has some limits. If you are in immediate danger of hurting yourself or hurting another person at any time in the study, the study team would work with you to ensure a plan to keep you or another person safe. Because study staff have an ethical obligation to protect you (or another person), it is possible that your information will be shared as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Use and Disclosure of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or given out during this research includes:

- Information that is in your hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or given out to others are:

- To do the research described here.

- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to give out any information from you in the event that there is an immediate risk of you harming yourself or another person.

The people and groups that may use or give out your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
- Public health and safety authorities who may be involved in protecting people who have an immediate danger of harming themselves or others.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or giving out your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the

research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.

- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical DG-privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.

Compensation for Injury

If you think that you have been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. You can get treatment for the injury at Boston Medical Center, the BU School of Dental Medicine, or at any healthcare facility you choose. There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, Eric Devine at 617-414-1990. Also call if you need to report an injury while being in this research. Contact Eric Devine at 617-414-1990 if you are calling after normal business hours.

You may also call 617-358-5372 or email . You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Subject: _____

Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and release of information that may identify you as described, including your health information.

_____ _____

Signature of subject Date

Researcher: _____

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____

Signature of person conducting consent discussion Date

To be completed by witness if researcher reads this form to the subject

This consent form was read to and apparently understood by the subject in my presence.

_____

Printed name of witness (a person not otherwise associated with the study)

_____ _____

Signature of witness Date

BMC and BU Medical Campus IRB
IRB NUMBER: H-36914
IRB APPROVAL DATE: 04/12/2019