WASHINGTON STATE UNIVERSITY

Elson S. Floyd College of Medicine,
Program of Excellence in Addictions Research/Analytics and PsychoPharmacology Laboratory

Research Study Consent Form

Study Title: Automated Reinforcement Management System (ARMS): Phase I study

Researchers:

Sterling McPherson, Ph.D., Associate Professor, and Director, Washington State University Elson S. Floyd College of Medicine, (509-324-7459), Principal Investigator.

Michael G. McDonell, Ph.D., Associate Professor, Washington State University Elson S. Floyd College of Medicine, (509-324-7444), Clinical Psychologist, Co-Investigator.

Crystal Lederhos Smith, Ph.D., Assistant Research Professor, and Research Supervisor, Washington State University Elson S. Floyd College of Medicine, (509-324-7235), Co-Investigator.

Ron Kim Johnson, General Manager/COO, Managed Health Connections, (512) 657-0675, Co-Principal Investigator.

André Miguel, Ph.D., Assistant Research Professor, Elson S. Floyd College of Medicine, Program of Excellence in Addictions Research, (509-368-6896), Co-Investigator.

Paul Kamate, M.D., Clinical Research Coordinator/Scientific Assistant, Washington State University Elson S. Floyd College of Medicine, 509-368-6928, Research Coordinator.

Sponsor: NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
- The study purpose is to develop an integrated Contingency Management (CM) system capable of incorporating mobile device input, that would allow us to deliver a CM intervention for problematic drinking to anyone who owns a smartphone. The primary goal is to combine mobile technology, geospatial mapping, and biomarker measurement, with individual goal setting and ecological momentary assessments (EMA) feedback to launch behavioral modification strategies and progress monitoring. We will utilize an A-B-A (“A” represents the initial unaltered behavior, and that becomes a baseline for the study. The letter “B” is the introduced intervention. So, in the A-B-A model, the

initial behavior is replaced by the intervention and then the intervention is withdrawn to see if the behavior returns to the baseline level), completely within-subject design with the intent of recruiting twenty total participants from the Community in Spokane. During the first A phase, you will receive reinforcement for simply submitting breath samples 3 times per day between 4 and 6 hours apart. In this application, we will utilize a Bluetooth enabled breathalyzer developed by BACTrack. During the B phase, the delivery of reinforcers will be contingent upon the submission of an alcohol negative breath sample on an escalating schedule. The A phase or return to the baseline phase will involve the delivery reinforcers for simply submitting a breath sample during the designated windows of time. We will also collect other EMA data on stress, anxiety, depression, and other brief measures daily through your iPhone.

- Major Activities of Subject Participation – Activities you will have to complete or avoid. You will be asked to submit 3 breath samples per day. Test results for breath alcohol will be available instantly to you and uploaded to the CM response system almost immediately. The cutoff for an alcohol positive breath test will be 0.00. Your location will be recorded through your iPhone each time you submit a breath sample. We will utilize that information during the first A phase of data collection to define personalized 'cold' (i.e., lower than 50% probability of drinking) and 'hot' (i.e. greater than 50% probability of drinking) spots using your geospatial location data (via iPhone). As part of this CM system, you will have the capability to receive multi-modal message reminders when you enter a new window of needed breath sample submission and additional reminders when the window of sample submission is about to close. While you will receive information messages to this effect during the A phase, you will receive additional personalized multi-modal message reminders once our CM platform can detect that you have entered a ‘cold’ or ‘hot’ zone. This will be based on you entering a 2/10s (i.e., approximately 1,000 feet) of a mile radius near a ‘cold’ or ‘hot’ zone. For example, upon entering a ‘hot’ zone radius during the B phase wherein you had a greater 50% likelihood of drinking in that zone during the A phase, you will receive a text message encouraging you to change surroundings in order to better promote abstinence. Also, if you are within a window of time where you are eligible to submit a sample and receive a dose of reinforcement, this is another action that you can take to help bolster your attempt to remain abstinent. All these data (i.e., breath results, location of breath sample submission, time of submission, and other bits of data) will be collected and be presented in summary form to the research team. This will help the team devise an action plan if your drinking behavior is proving impervious to intervention or if your goals are being met, this is something the research can encourage about.
- Duration of Participation - 8 weeks of participation.
- Significant Risks - You may continue to use alcohol. This study may not help you stop drinking or you may experience alcohol withdrawal symptoms if your drinking decreases during the study.
- Potential Benefits - This may potentially help you reduce your alcohol drinking or not.
- Alternative Procedures - We provide referrals to other treatment providers.

- This is a clinical trial and should not be considered medical treatment.

What you should know:
You are being asked to take part in a research study conducted by Dr. Sterling McPherson. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully. Take as much time as you need. Ask the researcher to explain anything you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is the purpose of this study?
The purpose of this study is to evaluate the effectiveness of a phone application when paired with a behavioral method in increasing alcohol abstinence. This behavioral approach, known as contingency management, means that a person is rewarded for not using alcohol or reducing their alcohol use. In this study, we will ask you to provide urine and breath samples at study visits to assess whether you are drinking. The breath sample measures recent alcohol use. We will ask you to fill out questionnaires during the study.

You are being asked to take part because during our screening interview you indicated that you are between 18 and 65 years old, you regularly drink 3 or more drinks at least 4 times a week.

If you decide to take part. There will be an initial visit called a baseline interview after filling out this consent form. We will ask you to provide urine and breath samples to assess your drinking status and fill out questionnaires.

You cannot be in this study if you are under 18 years old or over 65 years old. You also cannot be in the study if you are pregnant or trying to get pregnant. You cannot be in this study if you have attempted suicide in the past or you were suicidal in the past 12 months. Also, you cannot be in the study if you have a psychotic disorder or severe alcohol use disorder, or if the researchers determine that your safety may be in danger.

What will I be asked to do if I am in this study?
If you take part in the study, you will be asked to do the following:

- Complete the baseline interview after you fill out this consent form. This will take about 2 hours. You will be asked to fill out questionnaires and to provide urine, and breath samples. A urine test, ethyl glucuronide (EtG), will be used to detect the presence of alcohol. We will ask that you supply about half a cup of urine into a cup. The sample will be labeled with a unique study ID number to protect your

privacy and we will evaluate your urine at our lab. Providing samples is a condition of taking part in the study.
You will be asked to sign a release of health information that allows us to get information about your substance use. The locations of frequently used resources, and your physical and mental health. You will be asked to fill out questionnaires about your alcohol, tobacco, and drug use.
You will be provided with instruction on the phone application and how to use the breathalyzer. The application will track your location at the time you provide the breath sample. The application works only on iPhone 7 or newer version with an (iPhone Operating System) iOS 13.5. If you do not have an iPhone 7 or newer version, we can loan you one if you know how to use it, but it must be returned at the end of the study.
You will receive a $30.00 Amazon electronic gift card for completing this visit.
After the baseline interview, you will be asked to log into the phone application every 4 to 6 hours ‘’three times a day’’ and provide a breath sample via the BACtrack breathalyzer. This takes 2 to 3 minutes each time.

- Complete 2 weeks of introduction period. You will be asked to provide 3 breath samples a day, 4 to 6 hours apart via your BACtrack breathalyzer, and the phone application. You will receive $2.00 for each sample submitted, regardless of what if that sample is positive or not, for a total of $6.00 a day.

- Complete 4 weeks of the contingency management period. You will be asked to submit 3 samples a day, 4 to 6 hours apart. You will be rewarded for submitting negative samples (a breathalyzer of 0.00). You will begin at $2.00, but rewards will escalate by $0.25 per alcohol negative breath sample submission until a maximum value of $3.50 per sample is reached.
    - If you submit a positive sample your rewards will reset back to $2.00.

- Complete the 2 weeks follow up phase. You will be asked to provide 3 breath samples a day, 4 to 6 hours apart via your BACtrack breathalyzer, and the phone application. You will receive $2.00 for each sample submitted, regardless of if it is positive or not, for a total of $6.00 a day.

- At the end of the 8 weeks. You will be asked to fill out a questionnaire and if a phone was provided, you will be required to return it even though it will be disabled cleared of all data and unable to be used. This will take 2 to 3 minutes. Upon completion of or withdrawal from the study and return of the iPhone, you will receive a $50 Amazon electronic gift card.

- Supplying samples is a condition of participating in the study. At any time, you may decide not to provide samples, however, this may result in you not receiving the full amount of rewards.

- We will call you weekly to fill out a survey about your alcohol, tobacco, and cannabis use and your sleepiness.

- Follow study safety procedures. For safety purposes, we ask that you do not attempt to drive to your appointment if you are intoxicated or under the influence. If you provide a breath sample greater than .08, or team members observe overt behaviors of intoxication, you will be asked to remain in our laboratory or office until your blood alcohol level returns to below legal limit. If your blood alcohol level is above the legal limit one hour before our office closes you will be asked to either call a friend or family member or a cab to pick you up. No funds are allocated for transportation while you are intoxicated. If you are experiencing symptoms of alcohol withdrawal, you may be asked to be evaluated by a medical professional or by the research team, Dr. McDonell. These procedures are to make sure that you and others are safe. Should a medical emergency occur at a study visit, Dr. McDonell (509-324-7444), will be contacted to assess medical treatment needs. The study team may call 911. Dr. McDonell may also be contacted about medical referral information. There are no funds allotted for compensation for study-related injuries. There are no funds for transportation, but you are provided with free parking.

- The total time of this study is estimated to be 09 hours 30 minutes spread out over 8 weeks of participation.
- You are not waiving any legal rights by consenting to take part in this study.

Are there any benefits to me if I am in this study?

The potential benefits to you for taking part in this study are that you may decrease or stop using alcohol. If you take part in this study, you may help others in the future. It is hoped that the results from this study will help develop effective treatment strategies for alcohol use disorders.

Are there any risks to me if I am in this study?

The following are some potential risks that may occur because of taking part in this study and explanations of how we have tried to minimize these risks.

- You may continue to use alcohol. This study may not help you stop drinking. We provide referrals to other treatment providers.

- There is a small risk that the information you provide to the study will be seen by someone who is not allowed to see it. We will try to lower this risk by assigning all data you provide with a unique identifier.

- There is a small risk that you may encounter another study participant in the clinic which would result in a loss of your confidentiality. We will attempt to schedule participants at times that would prevent this from occurring.

- You may be asked some questions about your habits and history that make you feel uncomfortable. Likewise, you may feel uncomfortable providing urine or

breath samples. We selected questionnaires and sample collection procedures that are like those that you might encounter if you went to a medical or treatment facility.

- You may experience alcohol withdrawal symptoms if your drinking decreases during the study. Some examples of withdrawal symptoms are:
  - The feeling like you need another drink to make you feel better.
  - The Delirium Tremens usually starts two to five days after the last drink, and it can be fatal. Shaking, confusion, high blood pressure, fever, and hallucinations are some symptoms.

  We will try to lower this risk by evaluating the withdrawal symptoms at every study contact. If you score higher than 10 points on our withdrawal scale you will be evaluated by Dr. McDonell.
  Depending on the severity of the withdrawal symptoms, the investigators may decide to terminate your study participation for your safety.

  Researchers will contact 911 or Dr. McDonell should a medical issue arise during any study visit or study contact, depending on the severity of the reported issue. If a serious medical issue should arise outside of your visits, you should contact 911 immediately. There is no compensation being offered through this investigation should a medical emergency occur while being part of this study. There will be no cost for you for Dr. McDonell's services.

- We will follow Washington State University guidelines to decrease your chance of exposure to the 2019 coronavirus disease (COVID-19). We will ask you to keep 6 feet apart and wear masks.

Will my information be kept private?

Yes. The data for this study will be kept confidential to the extent allowed by law. You will be assigned a unique identification number. This number is stored separately from your personal information. All recorded data will be kept in a locked file cabinet in a locked research office that is only accessible by members of the research team. Only research team members will have access to the study database storing participants' information, which is saved on a firewall-protected computer. The computer is under password protection. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. The data for this study will be kept for 3 years.

If keeping any information private would immediately put you or someone else in danger. The investigators would release that information to keep you or another person safe. If investigators learn about abuse to a child or an elder, we will report that information to the proper authorities. Also, if the safety procedures described in this consent form are not followed, campus security or local police may be notified.

Are there any costs or payments for being in this study?

There are no costs to you for taking part in this study. There are free parking spots outside of the facility for study visits. The payment for study participation is based on rewards. If you choose to take part. You will be eligible to receive a $30 Amazon electronic gift card for completing the baseline.
You will receive a total of $168.00 during the first 2 weeks of the introduction period and the last 2 weeks of the follow-up period. The payment will be $42.00 weekly.

During the 4 weeks of the contingency management period. You will begin by receiving $2.00 per alcohol negative breath sample submitted. This will be escalating by $0.25 per alcohol negative breath sample submission until a maximum value of $3.50 per sample is reached. For instance:
Day1, sample1 ($2.00), sample2 ($2.25), sample3 ($2.50)
Day2, sample1 ($2.75), sample2 ($3.00), sample3 ($3.25)
Day3, sample1 ($3.50), sample2 ($3.50), sample3 ($3.50)
Once this value is reached based on negative breath sample submissions. You will continue to receive $3.50 per alcohol-negative breath sample submission. If you submitted an alcohol positive breath sample. You will be reset to $2.00 per sample and you will need to work up to receive $3.50 per sample again. If you submitted all negative samples during this period. You will receive a total of $288.75. This will be paid weekly ($68.25 the first week, and then $73.5/week the second, third, and fourth week).
A final onetime payment of $50.00 Amazon electronic gift card will be given to you upon return of study iPhone.
During the 8 weeks study, if you submitted all negative samples and returned the study phone, you will receive a total of $536.75.

If you decide to quit the study, you will not receive any payment beyond any rewards already earned for any completed study visits.

Who can I talk to if I have questions?

If you have questions about this study or the information in this form. Please contact the researcher, Dr. Sterling McPherson at 412 East Spokane Falls Blvd, WA 99202-2131; 509-324-7459; sterling.mcpherson@wsu.edu.
If you have questions about your rights as a research participant or would like to report a concern or complaint about this study. Please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at Neill 427, PO Box 643143, Pullman, WA 99164-3143.

What if I have a study-related injury or want to withdraw?

If you have a study-related injury, illness, distress, or want to withdraw please contact Dr. Sterling McPherson.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part.

You may choose not to answer specific questions or to stop taking part at any time. You will be given a copy of the consent form for your records.

What does my signature on this consent form mean?
Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- You are giving your voluntary consent to take part in the study.

Statement of Consent

Yes, I agree	**No, I disagree**	
		This is the proof of my "intent" to sign the consent document to take part in this research.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Printed Name of Participant Date