AUTOMATED REINFORCEMENT MANAGEMENT SYSTEM (ARMS):

PHASE 1 CLINICAL ANALOG TRIAL

National Clinical Trial (NCT) Identified Number: NCT 04656925

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Sponsor: NIH/NIAAA

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CONFIDENTIALITY STATEMENT

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STATEMENT OF COMPLIANCE

This trial will be conducted in compliance with International Conference on Harmonization Good Clinical Practice (ICH GCP) and the following:

United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

National Institutes of Health (NIH) funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Washington State University Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. Also, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator:

Signed: _____ Date: _____

Name*: Sterling McPherson, Ph.D.

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: **Automated Reinforcement Management System (ARMS)**

Grant Number: R41 AA0267993

Study Description:

Alcohol abuse remains a significant cause of preventable morbidity and mortality in the US, yet only 15% of those with alcohol use disorders receive treatment. Contingency Management (CM) is a cost-effective intervention for drug addiction where individuals are rewarded when they submit biological verification of drug abstinence. We propose to develop an integrated CM system capable of incorporating mobile device input and Electronic Medical Record (EMR) integration, that would allow us to deliver a CM intervention for problematic drinking to anyone who owns a smartphone. The mobile device input will incorporate ecological momentary assessments (EMA), geospatial mapping, and biomarker-based feedback from a portable measuring device. This novel approach will enable personalized CM goal setting and a new platform for clinician feedback and progress monitoring. The goal of the system will be to provide an end-to-end CM platform, which can aggregate and inform the understanding of mechanisms underlying the initiation, maintenance, and recovery from problematic drinking in both treatment and naturalistic settings with little to no required clinician involvement.

Objectives*:

Primary Objective: To develop and combine mobile technology, geospatial mapping, and biomarker measurement, with individual goal setting and EMA feedback to launch behavioral modification strategies and progress monitoring.

Secondary Objectives: To develop and consumer-test the mobile application component to help the patient alcohol-related treatment goals at home.

Endpoints*:	
	Primary Endpoint: Our primary endpoint is biochemically confirmed alcohol abstinence, measured thrice daily throughout the 8-week study. Secondary Endpoints: Secondary endpoints will include self-reported alcohol use measured by the Timeline Follow Back to assess the frequency and amount of daily drinking via multi-modal EMA data collection.
Study Population:	Twenty (20) subjects, male and female, between 18 and 65 years of age who have an Alcohol Use Disorders Identification Test (AUDIT) score of eight or higher. Subjects must read and speak English and have the ability to provide written informed consent. They must also live in the Greater Inland Northwest area (i.e., Spokane and Coeur d'Alene).
Phase* or Stage:	
	Phase I, Clinical Analog Trial with A-B-A phase design.
Description of Sites/Facilities Enrolling Participants:	
	This study will take place in Greater Inland Northwest area in cooperation with the Community Health Association of Spokane (CHAS) and other clinical referral entities throughout the Spokane region, including MultiCare Health System (MHS) and others.

Description of Study Intervention/Experimental Manipulation:	We will utilize an A-B-A, completely within-subject design with the intent of recruiting twenty (n=20) total participants. During the first A phase, participants will receive reinforcement for simply submitting breath samples three times per day between 4 and 6 hours apart. In this application, we will use a Bluetooth enabled breathalyzer developed by BACtrack, however our smartphone-based technological solution will interact with any alcohol monitoring device, such as BACtrack Skyn. 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 of reinforcers for simply submitting a breath sample during the designated windows of time. We will also collect EMA data on stress, anxiety, depression, and other brief measures daily through their smartphone. Each phase will last a total of four weeks (i.e., two weeks of the first A phase, four weeks of the B phase, and then two more weeks of the A-phase) each for a total of 8 weeks of participation. To the extent possible, we will use existing protocols, procedures, and equipment that we have used in previous A-B-A studies.
Study Duration*:	Eight to twelve months.
Participant Duration:	Two months for each participant to complete all study-related tasks.

1.2 SCHEDULE OF ACTIVITIES

Table 1. Schedule of study activities.

	Baseline Week 0	**A-B-A Week 1-8**
Informed consent	√	
M.I.N.I*. Research Psychiatric Diagnosis	√	
Medical history form	√	
Other inclusion/exclusion criteria	√	
Alcohol use (biochemical BAC**)	√	3x / day
Alcohol Timeline Follow Back (self-report)	√	3x / day
Addiction severity Index: ASI-Lite (self-report)	√	
Alcohol cravings and withdrawal: visual analog scale (self-report)	√	3x / day
Location and Activity at time of the report	√	3x / day
Other substance use (biochemical)	√	
Health-related quality of life (self-report)	√	
Tobacco dependence (Fagerström***)	√	
Alcohol dependence (AUDIT****)	√	
Adverse Events	√	weekly
Psychopathology (BSI*****)	√	
Follow-up phone call	√	weekly
Sleepiness Scale	√	Weekly

*The Mini-International Neuropsychiatric Interview (**M.I.N.I.**) is a short structured diagnostic interview, developed jointly by psychiatrists and clinicians.
**Blood Alcohol Concentration (BAC).
***The Fagerström Test for Nicotine Dependence is a standard instrument for assessing the intensity of physical addiction to nicotine.
****The Alcohol Use Disorders Identification Test (AUDIT).
*****The Brief Symptom Inventory (BSI).

2 INTRODUCTION

2.1 STUDY RATIONALE

Alcohol abuse remains a significant cause of preventable morbidity and mortality in the US, yet only 15% of those with alcohol use disorders receive treatment. Contingency Management (CM) is a cost-effective intervention for drug addiction where individuals are rewarded when they submit biological verification of drug abstinence.[1-7] We propose to develop an integrated CM system capable of incorporating mobile device input and Electronic Medical Record (EMR) integration, that would allow us to deliver a CM intervention for problematic drinking to anyone who owns a smartphone. The mobile device input will incorporate ecological momentary assessments (EMA), geospatial mapping, and biomarker-based feedback from a portable measuring device. This novel approach will enable personalized CM goal setting and a new platform for clinician feedback and progress monitoring. The goal of the system will be to provide an end-to-end CM platform, which can aggregate and inform the understanding of mechanisms underlying the initiation, maintenance, and recovery from problematic drinking in both treatment and naturalistic settings with little to no required clinician involvement.

2.2 BACKGROUND

In a recently completed randomized controlled trial (RCT; n=79) we used ethyl glucuronide (EtG), a urine-based biomarker capable of detecting heavy drinking for up to five days, as the basis for a CM intervention for alcohol use disorders in outpatients who suffered from comorbid mental illness (PI: McDonell, Co-I: McPherson; Am J Psychiatry). We found that participants randomized to CM were 3.13 times more likely than controls CI=2.18-4.50, p<0.01) to submit alcohol-negative urine samples during the 12-week treatment period. They also achieved longer duration of alcohol abstinence: 2.9 weeks (SD=3.30) versus 1.4 weeks in the control group (SD=2.10; p<.02). The CM group also had significantly:
1) lower average EtG levels,
2) fewer days of any drinking or heavy drinking during treatment, and
3) fewer days of drinking during the 6-month follow-up.
These results provide convincing evidence for the efficacy of CM in treating people who have an alcohol use disorder.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The risk to patients from digital intervention is negligible. However, as in all trials of this nature, there is the possibility of unauthorized disclosure of confidential information; discomfort, or embarrassment related to biologic sample collection or administration of questionnaires or assessments dealing with sensitive information. There may be unforeseen and unpreventable risks to participants of encountering friends or associates at the research laboratory study visits. These are acknowledged and will be reduced as much as possible.

2.3.2 KNOWN POTENTIAL BENEFITS

The potential benefit of this intervention is to decrease alcohol consumption during medication-assisted therapy. This benefit may occur by participating in the trial and the data collected may extend this benefit to future users of the technology. The application is expected to improve their self-awareness and understanding of their current alcohol use, cravings as related to their personal goals, and progress towards recovery goals.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

There is a small risk that information provided by a study participant will be seen by someone who is not supposed to see it. We will lower this risk by giving all the information provided by participants a unique identification number instead of their names. Participants are encouraged to discuss any distressing issues that may appear due to their participation in the study. If any identifiable information is released by accident, affected participants will be informed by the PI, apologies for the situation, and notified of steps the study team is taking to rectify the situation as best as possible.
Questions about the participant's habits and history may make them feel uncomfortable. There may be discomfort, social stigmatization, or embarrassment related to giving a urine sample or being seen at the research lab. Our research team will take the utmost caution to avoid creating distress, stigmatization, offending, or degrading participants and their families.

We anticipate that the intervention will lower the average alcohol levels, reduce the number of days of any drinking or heavy drinking during treatment, and decrease the number of days of drinking during the study.

3 OBJECTIVES AND ENDPOINTS

Primary Objective:
To develop and combine mobile technology, geospatial mapping, and biomarker measurement, with individual goal setting and EMA feedback to launch behavioral modification strategies and progress monitoring.

Secondary Objectives:
To develop and consumer-test the mobile application component to help the patient alcohol-related treatment goals at home.

Primary Endpoint:
Biochemically confirmed alcohol abstinence measured thrice daily throughout the 8-week study.

Secondary Endpoints:
The secondary endpoint will include self-reported alcohol use measured by the Timeline Follow Back to assess the frequency and amount of daily drinking via multi-modal EMA data collection.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This pilot study will utilize an A-B-A, completely within-subject design with the intent of recruiting twenty (n=20) total participants. During the first A phase, participants will receive reinforcement for simply submitting breath samples three times per day between 4 and 6 hours apart. In this application, we will utilize a Bluetooth enabled breathalyzer developed by BACtrack, but our smartphone-based technological solution will interact with any alcohol monitoring device, such as BACtrack Skyn. 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 second A phase (i.e., return to the baseline phase) will involve the delivery of reinforcers for simply submitting a sample during the designated windows of time. We will also collect EMA data on stress, anxiety, depression, and other brief measures daily through their smartphone. Each phase will last a total of four weeks (i.e., two weeks of the first A phase, four weeks of the B phase, and then two more weeks of the A-phase) each for a total of 8 weeks of participation. To the extent possible, we will use existing protocols, procedures, and equipment that we have used in previous A-B-A studies.

This study will take place in Greater Inland Northwest area in cooperation with the Community Health Association of Spokane (CHAS) and other outpatient entities, community recruitment, etc. under the auspices of the WSU Program of Excellence in Addictions Research and the Analytics and PsychoPharmacology (APPL).

We will recruit n=20 patients throughout Greater Inland Northwest area. We anticipate a five-month recruitment period, necessitating four recruited per month which is far below our normal recruitment rates. Flyers will advertise the study, and staff and providers will be aware of the study and will be asked to refer potentially interested participants to our investigation. Initial eligibility for a referral will be provided by AUDIT screen and Screen, Brief Intervention, and Referral to Treatment performed at the different treatment centers . Once the treatment center has completed its screening and intervention, they will utilize the AUDIT score to determine the patients that will be provided, the study Research Coordinator contact number for study screening. After an initial phone screening, eligible participants will be scheduled for an in-person study interview, during which they will provide informed consent and complete baseline data collection. During this time, participants will also receive a brief tutorial on how to use the BACtrack breathalyzer and how it integrates with the application on their smartphone. Participants who do not have a compatible iOS smartphone will be provided one for this study. The phones will be supplied from a testing inventory maintained by Managed Health Connections. Participant set-up instructions will also describe the time window for reporting, the definition of zones of use, and will be provided contact information for technical support to be used during the study.

During the A-B-A phase (2-4-2 weeks), participants will be asked to submit thee breath samples daily for 8 weeks. They will also be asked to fill out a weekly timeline follow back for alcohol, tobacco, and cannabis use during that period. At the end of the 8 weeks participation period, participants will bring back the phone and fill out the exit questionnaire.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

To be eligible to participate in this study, an individual must meet all the following criteria:
1) Age 18-65 years.
2) An Alcohol Use Disorders Identification Test (AUDIT) score of 8 or higher.
3) Ability to read and speak English.
4) Ability to provide written informed consent.
5) Breath alcohol of 0.00 during informed consent.
6) Operate a smartphone with an active service provider.

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:
1) Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) alcohol use disorder, severe type.
2) Significant risk of dangerous alcohol withdrawal, defined as a history of alcohol detoxification or seizure in the last 12 months and expression of concern by the participant about dangerous withdrawal.
3) Diagnosis of a psychotic disorder.
4) Lifetime suicide attempt or suicidality in the past year.
5) Any other medical or psychiatric condition that would compromise safe participation.

5.3

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in the study but are not subsequently assigned to the study intervention or entered in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria that are likely to change over time may be rescreened. Examples include the successful treatment of a previous affective DSM-5 alcohol use disorder, severe type, and overcoming the significant risk of dangerous alcohol withdrawal, defined as a history of alcohol detoxification or seizure in the last 12 months and expression of concern by the participant about dangerous withdrawal. Rescreened participants will be assigned the same participant number as for the initial screening.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We anticipate a 5-month recruitment period, necessitating n=4 recruited per month which is far below our normal recruitment rates. Flyers will advertise the study, and staff and providers will be aware of the study and will be asked to refer potentially interested participants to our investigation. As noted elsewhere, while

we will partner with clinics we will also recruit from the community. After an initial phone screening, those deemed eligible will be scheduled for an in-person study interview, during which they will provide informed consent and complete baseline data collection. During this time, participants will also receive a brief tutorial on how to use the BACtrack breathalyzer and how it integrates with the application on their smartphone. Participants who do not have a compatible iPhone Operating System (iOS) smartphone will be provided one for this study. The phones will be supplied from a testing inventory maintained by Managed Health Connections.

Participant set-up instructions will also describe the time window for reporting the definition of zones of use and will be provided contact information for technical support to be used during the study. During the baseline visit participants will receive a $30 gift cards for their time.

During the first A phase, participants will receive $2 per sample (regardless of being positive or negative for breath alcohol) submitted instantly, for a maximum payout of $6 per day.

During the B phase, participants will begin by receiving $2 per alcohol negative breath sample submitted, escalating by $0.25 per alcohol negative breath sample submission until a maximum value of $3.50 per sample is reached. Once this value is reached based on negative breath sample submissions, participants will continue to receive $3.50 per alcohol-negative breath sample submission. If a participant submits an alcohol positive breath sample, they will be reset to $2.00 per sample and will need to work up to receive $3.50 per sample again. Final onetime payment of $50 will be provided to participants upon return of study devices. Participants will receive electronic payment through a gift card. Payments will be loaded onto the card weekly.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

We will use 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 the participant's geospatial location data (via smartphone). As part of this CM system, participants will have the capability to receive multi-modal message reminders when they enter a new window of needed biochemical sample submission and additional reminders when the window of sample submission is about to close. While participants will receive information messages to this effect during the A phase, participants will receive additional personalized multi-modal message reminders once our CM platform can detect that they have entered a cold or hot zone. This will be based on the participant 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 they had 50% or greater likelihood of drinking in that zone during the A phase, they will receive a text message encouraging them to change surroundings in order better promote abstinence. Also, if the participant is within a window of time where they are eligible to submit a sample and receive a dose of reinforcement, this is another action that the individual can take to help bolster their attempt to remain abstinent. All of these data (e.g., biochemical results, location of sample submission, time of submission) will be warehoused in the individual's EMR to be presented in summary form on their primary care provider's dashboard. This will help the provider give counsel or otherwise devise an action plan if the patient's drinking behavior is proving impervious to intervention or if the patient's goals are being met, this is something the provider can encourage.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon their request.
An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance unless varying compliance is an aspect of the study objectives.
- Lost-to-follow up; unable to contact subject.
- Any event, medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

The reason for participant discontinuation or withdrawal from the study will be recorded on REDCap.
In this situation, participants will be asked to bring back the phone, fill out the exit questionnaire and received a $50 gift card.

7.2 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to return for a scheduled visit and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant, reschedule the missed visit, counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason for loss to follow-up.
- Study phone provided at baseline will be disable remotely.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Our primary outcome is biochemically confirmed alcohol abstinence, measured thrice daily throughout the 8-week study. Age and risky drinking will be determined based on self-report at the screening interview. Risky

drinking will be defined using the AUDIT and AUD diagnosis will be confirmed by administering the DSM-5 checklist. Research staff will also use this interview to assess for possible exclusionary cognitive or psychotic disorders using the MINI Neuropsychiatric Interview (M.I.N.I.). At baseline data collection, potential participants will complete a medical history form.

Secondary outcomes will include self-reported alcohol use measured by the Timeline Follow Back to assess the frequency and amount of daily drinking via multi-modal EMA data collection. The Addiction Severity Index and the quality of life in several domains (e.g., psychiatric, legal, medical) will be assessed at baseline. The EMA application will also collect data to assess craving and withdrawal for alcohol and tobacco by using a 1 to 5 Likert scale along with location and activity at the time of the report. Other substance use, including amphetamine, methamphetamine, cocaine, and marijuana, will be measured by urinalysis at baseline. We will characterize the psychiatric health of the participant sample by measuring psychopathology with the Brief Symptom Inventory, which assesses anxiety, depression, impulsiveness, and suicidality. We will also use the Fagerström Test of Nicotine Dependence to measure the severity of tobacco dependence and the Alcohol Use Disorders Identification Test to measure the severity of alcohol use disorder.
Our study variables and the schedule of data collection are summarized in **Table 2**.

Table 2. Data collection schedule

Measure	**Baseline Week 0**	**A-B-A Week 1-8**
Eligibility Criteria		
Demographics	√	
MINI Research Psychiatric Diagnosis	√	
Medical history form	√	
Other inclusion/exclusion criteria	√	
Primary Outcomes		
Alcohol use (biochemical BAC)	√	3 times per day
Secondary Outcomes		
Alcohol Timeline Follow Back (self-report)	√	
Addiction severity: ASI-Lite (self-report)	√	
Alcohol cravings and withdrawal: visual analog scale (self-report)	√	3 times per day
Location and Activity at time of the report	√	3 times per day
Other substance use (biochemical)	√	
Health-related quality of life (self-report)	√	
Tobacco dependence (Fagerström)	√	
Alcohol dependence (AUDIT)	√	
Psychopathology (BSI)	√	
Follow up phone call	√	Weekly
Sleepiness Scale	√	Weekly

8.2 SAFETY ASSESSMENTS

Qualified personnel will perform the study according to the WSU IRB-approved application.
The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
We will assess participants alcohol use three times daily through the Automated Reinforcement Management System (ARMS) which will provide the following functions: Breathalyzer recording, EMA responses, and eventually geospatial mapping Patient Dashboard, and a Clinician Dashboard. The participant will be provided with a BACtrack breathalyzer device. The setup process will pair their phone with the breathalyzer device and establish a profile including locations and time of day for reporting.
The mobile application will provide the participant user with the ability to input EMA information and control the breathalyzer function. It will utilize a hybrid iOS/mobile web application architecture for phase 1 enabling the integration of breathalyzer and geographic information with web-based dashboard information. The participant will be prompted to record EMA and breathalyzer samples based on their profile information and prior reporting. During a reporting window, the participant will receive a prompt to initiate breathalyzer measurement within the thirty (30) minute time window. The application will automatically record the location of the breathalyzer sample and categorize it as a "hot" or "non-hot" zone for future analysis. Following the breathalyzer report, the participant will be prompted to respond to EMA questions. Following the data entry, the participant will receive a multimedia message describing their progress and sample tailored messaging offering resources for additional information.
To support compliance, if a participant does not record substance use in real-time and does not respond to the daily check-in, the system will send reminders. The reminders are multi-modal as they can reach the user through different means based on user preference. For the study, we will rely on application delivered PUSH messages for the assigned smartphones with text message back up and the option for voice calls from Research Coordinator.
If the participant does not respond to the application and does not respond to reminders, their name and status will be communicated to the research coordinator. The research coordinator could place a personal call to the participant to follow up.
The application provides a dashboard for each patient to show how the EMA answers are related to substance use outcomes. It informs the patient of progress toward CM rewards and provides suggestions regarding which factors are most likely to be associated with craving and substance use.
Responses to EMA-assessed factors will provide the basis for creating a menu of customizable strategies to improve goal adherence for individuals and/or modify incentives. Certain patterns of responses will trigger the app to employ specific strategies to help the participant achieve his goal.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

According to the code of federal regulation title 21 of the Food and Drug Administration FDA, An Adverse event refers to any untoward medical occurrence associated with the use of a drug in humans, whether considered drug-related or not.

All AEs, whether volunteered, elicited, or noted on physical examination, will be recorded throughout the study (i.e., from signing of the ICF until completion).

All AEs will be collected in a proper case report form and recorded in REDCap.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization, prolongation of existing hospitalization, a persistent or significant incapacity/substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

Important medical events that may not result in death, though life-threatening or require hospitalization may be considered serious when, based upon appropriate medical judgment, they jeopardize the life or require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. SAEs are life-threatening adverse events or life-threatening suspected adverse reactions. An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

Each AE will be assigned a category by the Investigator as follows:
Mild: An AE that is easily tolerated by the subject, require minimal or no treatment and does not interfere with the participant's daily activities.

Moderate: An AE that results in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning. Intervention may be needed.

Severe: An AE that prevents everyday activities and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.
If there is a change in the severity of an AE, it must be recorded as a separate event.

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

The investigator will make every effort to assess the relationship of the AE, if any, to the study intervention. The investigator should use their knowledge of the subject, the circumstances surrounding the event, and

an evaluation of any potential alternative causes to determine whether an AE is related to the study treatment. Causality should be assessed using the categories presented below:
Related: The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
Not Related: There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

Action Taken
The investigator will describe the action taken in the proper section of the CRF, as follows:
- None
- Study procedure or the medication stopped
- Study medication temporarily interrupted
- Concomitant medication
- Other, specify.

8.3.3.3 EXPECTEDNESS

A provider with expertise in alcohol withdrawal syndrome will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The study coordinator will record events with start dates occurring any time after informed consent is obtained until seven (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

Investigators must report to the IRB as soon as possible, but in all cases within seven (7) working days after the reportable event had been made known to the investigator. All AEs occurring during the study must be documented on the relevant CRF pages. The following information should be documented for each AE:
- Description of the symptom event
- Classification of ‘’serious’’ or ‘’not serious’’
- Severity
- Date of first occurrence and date of resolution (if applicable)
- Action was taken
- Causal relationship
- The outcome of the event (unknown, recovered, not yet recovered, recovered with sequelae, death)

8.3.6 SERIOUS ADVERSE EVENT REPORTING

The SAE form must be completed as thoroughly as possible with all available details of the event, signed by the investigator (or appropriately qualified designee), and emailed or faxed to medical monitor within 24 hours of first becoming aware of the event. Such SAE will be reported to the Ringful and, the WSU IRB within 24 hours of first becoming aware of the event.

9 STATISTICAL CONSIDERATIONS

9.1 SAMPLE SIZE DETERMINATION

This is a minimum viability proof of concept trial. The samples size is determined to provide preliminary usability data as required by an R41 project.

9.2 POPULATIONS FOR ANALYSES

The dataset will consist of all enrolled subjects. This excludes all patients who failed the screening for this study or those who are eligible but uninterested in study participation.

9.3 STATISTICAL ANALYSES

9.3.1 GENERAL APPROACH

Raw data will be entered directly into the Research Electronic Data Capture (REDCap) system on a secure server by research staff at baseline and all subsequent data from participants via cell phone will flow directly into REDCap.

First, we will perform generalized estimating equations for the repeated binary outcome of alcohol abstinence. This model will include the variables of 1) Time (individually varying timestamp from when the breath sample was submitted) and 2) Phase (A, B, A).
Second, we will analyze the outcome of 1) self-reported heavy drinking days (4+ standard drinks per drinking day for women, 5+ standard drinks per drinking day for men), 2) self-reported craving, and 3) self-reported craving, all over time.

9.3.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Our primary outcome is biochemically confirmed alcohol abstinence, measured thrice daily throughout the 8-week study. Age and risky drinking will be determined based on self-report at the screening interview. Risky drinking will be defined using the AUDIT and AUD diagnosis will be confirmed by administering the DSM-5 checklist.[27] Research staff will also use this interview to assess for possible exclusionary cognitive or psychotic disorders using the MINI Neuropsychiatric Interview (M.I.N.I.). This variable will be analyzed as a repeated dichotomous variable.

If data are missing, missingness will be handled in a manner consistent with current expert recommendations, some of which have been established by our own team.[20,22,24,38-43] Our approach emphasizes 1) either maximum likelihood or multiple imputations, and 2) extensive sensitivity analyses, including missing not at random approaches, to examine the robustness of treatment effects across varying assumptions. Maximum likelihood and multiple imputations have both shown exceptional performance compared to other, more common methods of handling missing data when the assumption of "missing at random" can be safely satisfied.[39]

9.3.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary outcomes will include mobile usage, EMA bout completions, and self-reported alcohol use measured by the Timeline Follow Back [28] to assess the frequency and amount of daily drinking via multi-modal EMA data collection by time, date and location. The Addiction Severity Index and quality of life in several domains (e.g., psychiatric, legal, medical) will be assessed at baseline.

9.3.4 SAFETY ANALYSES

Medical coding will use MedDRA for the concomitant diseases (Medical History) and AEs and the World Health Organization (WHO) Drug Dictionary for medications.
Each AE will be counted once only for a given participant. The AEs expectedness, severity, frequency, and their relationship to the study intervention will be presented by System Organ Class (SOC) and preferred term groupings. Adverse events leading to premature discontinuation from the study intervention and serious treatment-emergent AEs will be presented either in a table or a listing.

9.3.5 BASELINE DESCRIPTIVE STATISTICS

We will initially run descriptive statistics across baseline variables to characterize the sample. All inferential results will be presented as point estimates with 95% confidence intervals, and we will use an alpha error rate of 0.05 as the threshold for statistical significance. Our approach is consistent with that of several similar RCTs involving tobacco smoking and alcohol use disorders.[12,13,24,34-37]

9.3.6 TABULATION OF INDIVIDUAL PARTICIPANT DATA

N/A

9.3.7 EXPLORATORY ANALYSES

N/A

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

NIH Clinical Trial Protocol

Human subjects research at WSU is coordinated through the WSU Institutional Review Board (IRB). The IRB is responsible for the review and approval of all research activities involving human subjects. The IRB is charged with protecting the rights and welfare of human subjects to ensure that all study participants are treated physically, psychologically, and socially in such a way as to minimize embarrassment and stress and to avoid harm or other negative effects.

All Research staff will complete online training through the Collaborative Institutional Training Initiative (CITI) https://about.citiprogram.org/en/homepage/, a web-based training program on Human Research Subject protections, before starting the study training.

All Research Coordinators and Research Associates will complete all the following before interacting with participants:

Thoroughly read the protocol and guidelines on consenting and safety procedures found below. Research Coordinator should be knowledgeable on all procedures and safety procedures. This includes HIPAA training. Documentation of course completion will be included in the study file.

Practice all study procedures & consenting with existing study personnel. All study staff should be able to answer frequent questions from participants.

Shadow and watch an approved Research Coordinator complete an entire study visit: recruiting, consenting, and enrolling a participant.

Receive approval by the Principal Investigator to conduct the consenting.

10.1.1 INFORMED CONSENT PROCESS

The process of obtaining informed consent is a basic ethical obligation and a required element of a human subject's research. The IRB will require that informed consent be documented using a written consent form approved by the IRB and signed and dated by the subject. The participant will be given ample time to read the consent document before it is signed. A copy of the document will be given to the person signing the form.

The informed consent form will be presented to allow potential participants to review facts about the study and what will be asked of them so that they can voluntarily choose whether to participate as a research subject.

Changes to the study protocol may result in the need for a new consent form. Only the current approved consent form will be used. The consent form document will have an IRB stamp of approval, version number, and date at the bottom of each page.

Please note: Unless you have the PI’s authorization, do not conduct the consenting process.

10.1.1.1 CONSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study procedures, and risks will be given to the participant and written documentation of informed consent will be completed before starting the study. The following consent materials are submitted with this protocol:

1- Printed written consent form
2- Web-based consent with an electronic signature
3- HIPAA Authorization form

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

The consenting process will be conducted consistently for every participant.
If a participant is eligible, the iPad that was used for screening will display the consent form. The research assistant (RA) or research coordinator (RC) will explain that this document will explain the details of the study they are being asked to take part in. Allow the participant plenty of time to read.
When the participant is done reading the consent, they will be asked if they have any questions about the study. If the answer to a question is not immediately obvious, the research coordinator or an investigator will be asked for their opinion, which must also be documented. The consent form will then be thoroughly reviewed to ensure that the participant understands what they are agreeing to.
Eligibility for the study is determined by study procedures. Signing the consent does not ensure eligibility to participate. That said, it will be made clear to the prospective participant that participation will not impact their care.
The key point to stress in the consenting process is that PARTICIPATION IS VOLUNTARY. Participants can choose not to consent to the study or discontinue at any time for any reason. They can choose not to answer any questions that make them feel uncomfortable.
The RA/RC will show the participant where to type their name and date the consent form. The participant must date and place their signature or initials on consent. The RA/RC will give a paper copy of the consent to the participant for their records.
Remember that consenting is an ongoing process.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending, or terminating party to study participants, investigators, funding agencies, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to the study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants.
- Demonstration of efficacy that would warrant stopping.
- Insufficient compliance with protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- The determination that the primary endpoint has been met.
- Determination of futility.

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies.

10.1.3 CONFIDENTIALITY AND PRIVACY

The risk to patients from digital intervention is negligible. All data is collected in a HIPAA-complaint manner. Private identifiable information will be encrypted and kept secure. A research coordinator who has been trained in the proper performance of these duties will obtain informed consent.
Study visits will be conducted in a manner to protect participant privacy. The consent process, administration of questionnaires, assessment and biologic sampling, medication dispensing, and CM draws will occur in a restricted area. To reduce the risk of unauthorized disclosure of confidential information all personal identifiers will be kept separate from participant files and a study-specific research identification number (key) will be assigned to each participant. Data will be collected, entered, and accessed by study personnel trained in issues of confidentiality related to human subject protection. The key will be kept separate and not in the same enclave component of the network. Data will be entered into a password-protected database that is encrypted and firewalled. All information provided by the participant will be kept private except in the case that this would immediately put the participant or someone else in danger. In that case, the Investigator would release information to keep the participant or another person safe. If the investigator learns about abuse to a child or an elder, that information must be reported to the proper authorities.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

No specimens will be stored for this study. All paper records be shredded, physical tapes are erased, and physically destroyed, and electronic media be scrubbed after the files are deleted. (Entirely de-identified data where all links to individual identity including any information that could identify participants will be retained.) See: WSU BPPM 90.01 - *https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/*

All research materials (consent forms, surveys, digital) will be kept for a minimum of three years after completion of the study. See: WSU BPPM 90.01 - https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/

10.1.5 SAFETY OVERSIGHT

The primary responsibility for monitoring the data and safety of the study will be with Dr. McPherson with the guidance and assistance of Mr. Johnson and Dr. McDonell. The study participants are at minimal risk from participation in the proposed research study. Comprehensive security measures will be deployed to protect participant data on the Managed Health Connections server and during transmission.

The participant database, web services and web applications will be hosted in a secure data center (PCI compliant and HIPAA compliant) in Austin, Texas. The data center physical building is under 24/7 video surveillance and is only accessible via two-factor authentication using both key cards and biometric sensors. The data center is connected directly to both the power grid and the fiber internet backbone. It is backed by diesel generators in case of power failure. All data on the server is continuously backed up to a centralized, hard drive-based storage system. The web site (dashboard) and web services API will be accessible from the Internet. All connections to the services will be encrypted with 256-bit SSL connection to maintain confidentiality. Except for the public web site and web service, the server is only accessible to authorized administrators via encrypted channels, such as VPN and SSH. Public and private access to the server is continuously monitored to detect any hacking or unauthorized access. When such attempts are detected, the system administrators are automatically alerted in real time. The databases will be password protected and only investigators and professionally trained and credentialed project staff on the study will have access to these files. Hard copies of signed consent forms and other study measures will be kept in a locked filing cabinet in a locked office accessible only to certified research staff. The master list that links participants' names to subject identification numbers will be kept in a password-protected file only accessible by certified research staff.

10.1.6 QUALITY ASSURANCE AND QUALITY CONTROL

The clinical site will perform internal quality management of study conduct, data, and biological specimen collection, documentation, and completion. Quality control (QC) procedure will be implemented, and Inspection may be conducted by regulatory authorities at their discretion.

10.1.7 DATA HANDLING AND RECORD KEEPING

10.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Washington State University will oversee activities with the data management of this study. This includes setting up a relevant database and data transfer mechanism, along with the proper validation of data and resolution of queries.

Study data will be collected directly at the study site into REDCap. Any data recorded directly on REDCap should be considered as a source document. Any changes in the data entered REDCap will be recorded and available for audit by the Food and Drug Administration (FDA) (CFR 21 part 11 compliant). Medical coding will use MedDRA for the concomitant diseases (Medical History) and AEs and the World Health Organization (WHO) Drug Dictionary for medications. Missing or inconsistent data will be queried within the REDCap system in writing to the Investigator for clarification. Any modification of the database will be documented.

10.1.7.2 STUDY RECORDS RETENTION

WSU's Business Policy & Procedures Manual requires that all research materials (consent forms, surveys, voice/video/digital/images, etc.) be kept for a minimum of three years after completion of the study.

See: WSU BPPM 90.01 - *https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/*

10.1.8 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonization Good Clinical Practice (ICH GCP). Noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance (QA) and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the principal investigator to use continuous vigilance to identify and report deviations.

At times, it may become clear to the researcher that acting in the best interest of a research participant will cause a deviation from an IRB approved protocol. The cause may be emergent (e.g. like present concerns involving the potential spread of a disease) or non-emergent (a chance occurrence). Potential issues that may be met in emergent situations include but are not limited to insufficient staff to conduct safely/effectively research or the research location becomes unsafe for the participants. Regardless of the cause, the IRB expectation is the same: always act (using your best judgment) to avoid unnecessary harm to research participants and staff. If doing so causes (or will cause) a deviation from the approved protocol, the following actions are recommended:

1. If deviation from the protocol is expected and became necessary and the investigators have time to submit an amendment to the IRB to address the expected deviation, they should do so. The IRB office will expedite the review of amendments intended to minimize (or decrease) risks to subjects.
2. If deviation from the protocol is expected but the investigators do not have time to submit the amendment, they should consider at least informing the IRB (phone or e-mail) that they anticipate they will need to deviate from the protocol. The IRB can provide guidance and document that notification was made in advance of the deviation and a reporting form can be submitted later (as soon as practicable).
3. If a deviation is required to avoid harming a participant and there is insufficient time to either submit an amendment or inform the IRB via other means, the expectation of the IRB is that the investigator will report the deviation as soon as it is practicable.
4. If deviation is expected to repeat, the IRB office will work with them to determine the best approach (including potentially amending your protocol) to address these potential exceptions.
5. Deviations from a protocol that are made, in good faith, solely for protecting research participants or others will rarely be considered non-compliance (e.g. only if the above guidance is not followed), these deviations will be classified as exceptions and the IRB office will collaborate with the PI to determine any future actions required to address the exception/deviation.

To simplify this process, the IRB /HRPP (Human Research Protection Program) has implemented a new consolidated IRB reporting**.** The form that can be used to report any protocol related event including

deviations, exceptions, adverse events and UPIRSOs (unanticipated problems involving risks to subjects and others). This form can be used to report any type of event, even if you are unsure how to classify the event, simply describe the event and IRB staff will assist you in classifying and handling of the event. To access the reporting form, please go to http://irb.wsu.edu/forms.asp and select the "IRB Reporting Form".

10.1.9 PUBLICATION AND DATA SHARING POLICY

This study will be published under the National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

All data collected for this research is the property of Managed Health Connection (MHC), which retains rights of access and ownership. *https://policies.wsu.edu/prf/index/manuals/45-00-contents/45-35-managing-research-records/ - "Ownership" Section.* Washington State University (WSU) may retain a copy of the data, but can also use the data as prescribed by MHC.

https://policies.wsu.edu/prf/index/manuals/60-00-personnel/60-74-employee-departure-procedures/ - "Facilities/Property" Section.

10.1.10 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by Managed Health Connection, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed (e.g., WSU employed individuals). Persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. If the economic interest is a "significant economic interest" as defined in WSU's Executive Policy #27, the management plan established with the Conflict of Interest Committee will be submitted.) See also: *https://research.wsu.edu/resources-researchers/operations-support/coi*

10.2 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ASI	Addiction Severity Index
AUDIT	Alcohol Use Disorders Identification Test
BAC	Blood Alcohol Concentration
CFR	Code of Federal Regulations
CHAS	Community Health Association of Spokane
CLIA	**Clinical Laboratory Improvement Amendments**
CM	Contingency Management
COC	**Certificate of Confidentiality**
CONSORT	**Consolidated Standards of Reporting Trials**
CRF	Case Report Form
DCC	**Data Coordinating Center**
DHHS	**Department of Health and Human Services**
DSMB	Data Safety Monitoring Board
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EMA	Ecological momentary assessments
eCRF	Electronic Case Report Forms
EMR	Electronic Medical Record
FDA	Food and Drug Administration
FFR	**Federal Financial Report**
GCP	Good Clinical Practice
GLP	**Good Laboratory Practices**
GMP	**Good Manufacturing Practices**
GWAS	**Genome-Wide Association Studies**
HIPAA	Health Insurance Portability and Accountability Act
HRPP	Human Research Protection Program
IB	**Investigator's Brochure**
ICH	International Council on Harmonization
ICMJE	**International Committee of Medical Journal Editors**
IDE	**Investigational Device Exemption**
iOS	iPhone Operating System
IRB	Institutional Review Board
ISM	**Independent Safety Monitor**
ITT	Intention-To-Treat
LSMEANS	**Least-squares Means**
MedDRA	Medical Dictionary for Regulatory Activities
MOP	**Manual of Procedures**
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	**NIH Institute or Center**
OHRP	**Office for Human Research Protections**
PI	Principal Investigator
QA	Quality Assurance

QC	Quality Control
RA	Research assistant
RC	Research coordinator
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SAP	**Statistical Analysis Plan**
SMC	**Safety Monitoring Committee**
SOA	Schedule of Activities
SOC	System Organ Class
SOP	**Standard Operating Procedure**
UPIRSOs	Unanticipated Problems involving risks to subjects and others
US	United States
WA	Washington State
WHO	World Health Organization
WSU	Washington State University

10.3 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is in the Protocol Title Page.

Version	Date	Description of Change	Brief Rationale

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12 APPENDICES

AUDIT

Place an "X" in one box that best describes your answer to each question.

Questions	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
3. How often do you have six more drinks on one occasion?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured because of your drinking?	No		Yes, but not during the last year		Yes, during the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not during the last year		Yes, during the last year
				Total:	

Addiction Severity Index *Lite* - CF

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Remember: This is an interview, not a test

≈Item numbers circled are to be asked at follow-up.≈
≈Items with an asterisk* are cumulative and should be rephrased at follow-up.≈
≈Items in a double border gray box are questions for the interviewer.

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.
There are two time periods we will discuss:

1. The past 30 days
2. Lifetime Data

Patient Rating Scale: Patient input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.
The scale is: 0 - Not at all
1 - Slightly
2 - Moderately
3 - Considerably
4 - Extremely
If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

INTERVIEWER INSTRUCTIONS:

1. Leave no blanks.
2. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions ofhis/her problems).
3. X = Question not answered.
   N = Question not applicable.
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.
6. Tutorial/clarification notes are preceded with "•".

HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

CONFIDENCE RATINGS: ⇒ Last two items in each section.
⇒ Do not over interpret.
⇒ Denial does not warrant misrepresentation.
⇒ Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:

1. Higher execs, major professionals, owners of large businesses.
2. Business managers if medium sized businesses, lesser professions, i.e., nurses, opticians, pharmacists, social workers, teachers.
3. Administrative personnel, managers, minor professionals, owners/proprietors of small businesses, i.e., bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent.
4. Clerical and sales, technicians, small businesses (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary).
5. Skilled manual - usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, policeman, plumber).
6. Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator).
7. Unskilled (attendant, janitor, construction helper, unspecified labor, porter, including unemployed).
8. Homemaker.
9. Student, disabled, no occupation.

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4, Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinal, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinal
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate, Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or Crack, and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Psilocybin (Mushrooms), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy
Inhalants:	Nitrous Oxide (Whippits), Amyl Nitrite (Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants,
Ulcer Meds = Zantac, Tagamet
Asthma Meds = Ventolin Inhaler, Theodur

ALCOHOL/DRUG USE INSTRUCTIONS:

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol /drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

⇒30 day questions only require the number of days used.
⇒Lifetime use is asked to determine extended periods of use.
⇒Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
⇒Alcohol to intoxication does not necessarily mean "drunk", use the words felt the effects", "got a buzz", "high", etc. instead of intoxication. As a rule of thumb, 5+ drinks in one setting, or within a brief period of time defines "intoxication".
⇒ "How to ask these questions:
→ "How many days in the past 30 have you used....?
→ "How many years in your life have you regularly used....?"

Addiction Severity Index *Lite* - Training Version
GENERAL INFORMATION

G1. Study ID: ☐☐☐☐☐☐☐☐☐☐

G2 . N/A ☐☐☐ - ☐☐ - ☐☐☐☐

G3. Program No: ___ ____ ____

G4. N/A: ☐☐ / ☐☐ / ☐☐☐☐

G5. Date of Interview: ☐☐ / ☐☐ / ☐☐☐☐

G8. Class: 1. Intake 2. Follow-up ☐

G9. Contact Code: 1. In person
2. Telephone (Intake ASI must be in person)
3. Mail ☐

G10. Gender: 1. Male 2. Female ☐

G11. Interviewer Code No.: ☐☐

G12. Special: 1. Patient terminated
2. Patient refused
3. Patient unable to respond ☐

Name

Address 1

Address 2

City State Zip Code (____) Tel. No.

G14. How long have you lived at this address? ☐☐ Years ☐☐ Months

G16. Date of birth: (Month/Day/Year) ☐☐ / ☐☐ / ☐☐☐☐

G17. Of what race do you consider yourself? ☐
1. White (not Hisp) 5. Asian/Pacific 9. Other Hispanic
2. Black (not Hisp) 6. Hispanic-Mexican
3. American Indian 7. Hispanic-Puerto Rican
4. Alaskan Native 8. Hispanic-Cuban

G18. Do you have a religious preference? ☐
1. Protestant 3. Jewish 5. Other
2. Catholic 4. Islamic 6. None

G19. Have you been in a controlled environment in the past 30 days? ☐
1. No 4. Medical Treatment
2. Jail 5. Psychiatric Treatment
3. Alcohol/Drug Treat. 6. Other: _____
•A place, theoretically, without access to drugs/alcohol.

G20. How many days? ☐☐
•"NN" if Question G19 is No. Refers to total number of days detained in the past 30 days.

(Clinical/Training Version)

MEDICAL STATUS

M1.* How many times in your life have you been hospitalized for medical problems? ☐☐
- Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications). Enter the number of ***overnight*** hospitalizations for medical problems.

M3. Do you have any chronic medical problems which continue to interfere with your life? 0 -No 1 - Yes ☐
- ***If "Yes", specify in comments.***
- A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

M4. Are you taking any prescribed medication on a regular basis for a physical problem? 0 - No 1 - Yes ☐
- ***If Yes, specify in comments.***
- Medication prescribed by a MD for medical conditions; ***not psychiatric medicines***. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability? 0 - No 1 - Yes ☐
- ***If Yes, specify in comments.***
- Include Workers' compensation, exclude psychiatric disability.

M6. How many days have you experienced medical problems in the past 30 days? ☐☐
- Do not include ailments directly caused by drugs/alcohol.
- Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.).

For Questions M7 & M8, ask the patient to use the Patient Rating scale.

M7. How troubled or bothered have you been by these medical problems in the past 30 days? ☐
- Restrict response to problem days of Question M6.

M8. How important to you *now* is treatment for these medical problems? ☐
- Refers to the need for ***new*** or ***additional*** medical treatment by the patient.

CONFIDENCE RATINGS

Is the above information <u>significantly</u> distorted by: ☐

M10. Patient's misrepresentation? 0 - No 1 - Yes ☐

M11. Patient's inability to understand? 0 - No 1 - Yes ☐

MEDICAL COMMENTS

(Include question number with your notes)

EMPLOYMENT/SUPPORT STATUS

E1.* Education completed:
- GED = 12 years, note in comments.
- Include formal education only.

Years ☐☐ Months ☐☐

E2.* Training or Technical education completed:
- Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.

Months ☐☐

E4. Do you have a valid driver's license?
- Valid license; not suspended/revoked.

0 - No 1 - Yes ☐

E5. Do you have an automobile available?
- If answer to **E4** is "**No**", then **E5** must be "**No**". Does not require ownership, only requires availability on a regular basis.

0 - No 1 - Yes ☐

E6. How long was your longest full time job?
- Full time = 35+ hours weekly; does not necessarily mean most recent job.

☐☐ / ☐☐
Yrs / Mos

E7.* Usual (or last) occupation?
(specify) _____
(use Hollingshead Categories Reference Sheet) ☐

E9 Does someone contribute the majority of your support?

0 - No 1 - Yes ☐

E10. Usual employment pattern, past three years? ☐

1. Full time (35+ hours)
2. Part time (regular hours)
3. Part time (irregular hours)
4. Student
5. Service
6. Retired/Disability
7. Unemployed
8. In controlled environment

- Answer should represent the *majority* of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents more current situation.

E11 How many days were you paid for working in the past 30 days? ☐☐
- Include "under the table" work, paid sick days and vacation.

EMPLOYMENT/SUPPORT COMMENTS
(Include question number with your notes)

Page 3

EMPLOYMENT/SUPPORT (cont.)

For questions E12-17: How much money did you receive from the following sources in the past 30 days?

E12 Employment? ☐☐☐☐☐
- Net or "take home" pay, include any "under the table" money.

E13 Unemployment Compensation? ☐☐☐☐☐

E14 Welfare? ☐☐☐☐☐
- Include food stamps, transportation money provided by an agency to go to and from treatment.

E15 Pensions, benefits or Social Security? ☐☐☐☐☐
- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

E16 Mate, family, or friends? ☐☐☐☐☐
- Money for personal expenses, (i.e. clothing), include unreliable sources of income (e.g. gambling). Record ***cash*** payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.).

E17 Illegal? ☐☐☐☐☐
- ***Cash*** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. ***Do not*** attempt to convert drugs exchanged to a dollar value.

E18 How many people depend on you for the majority of their food, shelter, etc.? ☐☐
- Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc.

E19 How many days have you experienced employment problems in the past 30 ? ☐☐
- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For Question E20, ask the patient to use the Patient Rating scale.

E20 How troubled or bothered have you been by these employment problems in the past 30 days? ☐
- If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems.

E21 How important to you *now* is counseling for these employment problems? ☐
- The patient's ratings in Questions E20-21 refer to Question E19.
- Stress help in finding or preparing for a job, not giving them a job.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

E23 Patient's misrepresentation 0-No 1-Yes ☐

E24 Patient's inability to understand? 0-No 1-Yes ☐

EMPLOYMENT/SUPPORT COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS

Route of Administration Types:
1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

• *Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe.*

		Past 30 Days	Lifetime (years)	Route of Admin
D1	Alcohol (any use at all)	☐☐	☐☐	■
D2	Alcohol (to intoxication)	☐☐	☐☐	■
D3	Heroin	☐☐	☐☐	☐
D4	Methadone	☐☐	☐☐	☐
D5	Other Opiates/Analgesics	☐☐	☐☐	☐
D6	Barbiturates	☐☐	☐☐	☐
D7	Sedatives/Hypnotics/ Tranquilizers	☐☐	☐☐	☐
D8	Cocaine	☐☐	☐☐	☐
D9	Amphetamines	☐☐	☐☐	☐
D10	Cannabis	☐☐	☐☐	☐
D11	Hallucinogens	☐☐	☐☐	☐
D12	Inhalants	☐☐	☐☐	☐
D13	More than 1 substance per day (including alcohol)	☐☐	☐☐	■

D17. How many times have you had Alcohol DT's? ☐☐

• ***Delirium Tremens*** (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake, shaking, severe disorientation, fever, , hallucinations, they usually require medical attention.

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS (cont.)

How many times in your life have you been treated for :

D19*. Alcohol abuse? ☐☐

D20*. Drug abuse? ☐☐

- Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period).

How many of these were detox only:

D21. Alcohol? ☐☐

D22. Drugs? ☐☐

- If D19 = "00", then question D21 is "NN"
  If D20 = '00', then question D22 is "NN"

How much money would you say you spent during the past 30 days on:

D23. Alcohol? ☐☐☐☐☐

D24. Drugs? ☐☐☐☐☐

- Only count actual ***money*** spent. What is the financial burden caused by drugs/alcohol?

D25. How many days have you been treated as an outpatient for alcohol or drugs in the past 30 days? ☐☐ • Include AA/NA

For Questions D28-D31, ask the patient to use the Patient Rating scale. The patient is rating the need for additional substance abuse treatment.

How many days in the past 30 have you experienced:

D26. Alcohol problems? ☐☐

How troubled or bothered have you been in the past 30 days by these

D28. Alcohol problems? ☐

How important to you *now* is treatment for these:

D30. Alcohol problems? ☐

How many days in the past 30 have you experienced:

D27. Drug problems? ☐☐

- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

How troubled or bothered have you been in the past 30 days by these

D29. Drug problems? ☐

How important to you *now* is treatment for these:

D31. Drug problems? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

D34. Patient's misrepresentation? 0-No 1-Yes ☐

D35. Patient's inability to understand? 0-No 1-Yes ☐

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

Page 6

LEGAL STATUS

L1. Was this admission prompted or suggested by the criminal justice system? 0 - No 1 -Yes ☐
- Judge, probation/parole officer, etc.

L2. Are you on parole or probation? 0 - No 1 -Yes ☐
- Note duration and level in comments.

How many times in your life have you been arrested and charged with the following:

L3 * Shoplift/Vandal	☐☐	L10* Assault	☐☐
L4 * Parole/Probation	☐☐	L11* Arson	☐☐
L5 * Drug Charges	☐☐	L12* Rape	☐☐
L6 * Forgery	☐☐	L13* Homicide/Mansl.	☐☐
L7* Weapons Offense	☐☐	L14* Prostitution	☐☐
L8* Burglary/Larceny/B&E	☐☐	L15* Contempt of Court	☐☐
L9 * Robbery	☐☐	L16* Other: _____	☐☐

- Include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult.
- Include formal charges only.

L17* How many of these charges resulted in convictions? ☐☐
- If L03-16 = 00, then question L17 = "NN".
- Do not include misdemeanor offenses from questions L18-20 below.
- Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.

How many times in your life have you been charged with the following:

L18* Disorderly conduct, vagrancy, public intoxication? ☐☐

L19* Driving while intoxicated? ☐☐

L20* Major driving violations? ☐☐
- Moving violations: speeding, reckless driving, no license, etc.

L21* How many months were you incarcerated in your life? ☐☐
- If incarcerated *2 weeks or more*, round this up to 1 month. List total number of months incarcerated.

L24 Are you presently awaiting charges, trial, or sentence? 0 - No 1 - Yes ☐

L25 What for? ☐☐
- Use the number of the type of crime committed: 03-16 and 18-20
- Refers to Q. L24. If more than one, choose most severe.
- Don't include civil cases, unless a criminal offense is involved.

L26 How many days in the past 30, were you detained or incarcerated? ☐☐
- Include being arrested and released on the same day.

LEGAL COMMENTS
(Include question number with your notes)

LEGAL STATUS (cont.)

L27 How many days in the past 30 have you engaged in illegal activities for profit? ☐☐
- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with Question E17 under Employment/Family Support Section.

For Questions L28-29, ask the patient to use the Patient Rating scale.

L28 How serious do you feel your present legal problems are? ☐
- Exclude civil problems

L29 How important to you *now* is counseling or referral for these legal problems? ☐
- Patient is rating a need for ***additional*** referral to legal counsel for defense against criminal charges.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

L31 Patient's misrepresentation? 0 - No 1- Yes ☐

L32 Patient's inability to understand? 0 - No 1 - Yes ☐

LEGAL COMMENTS
(Include question number with your notes)

FAMILY/SOCIAL RELATIONSHIPS

F1. Marital Status:
1-Married 3-Widowed 5-Divorced
2-Remarried 4-Separated 6-Never Married
• Common-law marriage = 1. Specify in comments.

F3. Are you satisfied with this situation?
0-No 1-Indifferent 2-Yes
• Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

F4.* Usual living arrangements (past 3 years):
1-With sexual partner & children
2-With sexual partner alone
3-With children alone
4-With parents
5-With family
6-With friends
7-Alone
8-Controlled Environment
9-No stable arrangement
• Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement.

F6. Are you satisfied with these arrangements?
0-No 1-Indifferent 2-Yes

Do you live with anyone who:

F7. Has a current alcohol problem? 0-No 1-Yes

F8 Uses non-prescribed drugs? 0-No 1-Yes

F9. With whom do you spend most of your free time? 1-Family 2-Friends Alone
• If a girlfriend/boyfriend is considered as family by patient, then they must refer to them as family throughout this section, not a friend.

F10. Are you satisfied with spending your free time this way? 0-No 1-Indifferent 2-Yes
• A satisfied response must indicate that the person generally likes the situation. Referring to Question F9.

Have you had significant periods in which you have experienced serious problems getting along with:

	0 - No 1 - Yes Past 30 days	In Your Life
F18 Mother		
F19 Father		
F20 Brother/Sister		
F21 Sexual Partner/Spouse		
F22 Children		
F23 Other Significant Family (specify)_____		
F24 Close Friends		
F25 Neighbors		
F26 Co-workers		

• "Serious problems" mean those that endangered the relationship.
• A "problem" requires contact of some sort, either by telephone or in person.

Did anyone abuse you?

	0- No 1-Yes Past 30 days	In Your Life
F28. Physically? • Caused you physical harm.		
F29. Sexually? • Forced sexual advances/acts.		

FAMILY/SOCIAL COMMENTS
(Include question number with your notes)

FAMILY/SOCIAL (cont.)

How many days in the past 30 have you had serious conflicts:

F30. With your family? ☐☐

For Questions F32-34, ask the patient to use the Patient Rating scale.

How troubled or bothered have you been in the past 30 days by:

F32. Family problems ? ☐

FHow important to you now is treatment or counseling for these:

F34. Family problems ☐

- Patient is rating *his/her* need for counseling for family problems, not whether the family would be willing to attend.

How many days in the past 30 have you had serious conflicts:

F31. With other people (excluding family)? ☐☐

For Questions F33-35, ask the patient to use the Patient Rating scale.

How troubled or bothered have you been in the past 30 days by:

F33. Social problems? ☐

How important to you now is treatment or counseling for these:

F35. Social problems ☐

- Include patient's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems.

CONFIDENCE RATING

Is the above information significantly distorted by:

F37. Patient's misrepresentation? 0-No 1-Yes ☐

F38. Patient's inability to understand? 0-No 1-Yes ☐

FAMILY/SOCIAL COMMENTS
(Include question number with your notes)

PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problems:

P1.* In a hospital or inpatient setting? ☐☐

P2.* Outpatient/private patient? ☐☐

- Do not include substance abuse, employment, or family counseling.

Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.

- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? ☐

0-No 1-Yes

Have you had a significant period of time (that was not a direct result of alcohol/drug use) in which you have:

0-No 1-Yes

		Past 30 Days	Lifetime
P4.	Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	☐	☐
P5.	Experienced serious anxiety/ tension, uptight, unreasonably worried, inability to feel relaxed?	☐	☐
P6.	Experienced hallucinations-saw things or heard voices that were not there?	☐	☐
P7.	Experienced trouble understanding, concentrating, or remembering?	☐	☐

For Items P8-10, Patient can have been under the influence of alcohol/drugs.

P8.	Experienced trouble controlling violent behavior including episodes of rage, or violence?	☐	☐
P9.	Experienced serious thoughts of suicide? • Patient seriously considered a plan for taking his/her life.	☐	☐
P10.	Attempted suicide? • Include actual suicidal gestures or attempts.	☐	☐
P11.	Been prescribed medication for any psychological or emotional problems? • Prescribed for the patient by MD. Record "Yes" if a medication was prescribed *even if* the patient is not taking it.	☐	☐

P12. How many days in the past 30 have you experienced these psychological or emotional problems? ☐☐

- This refers to problems noted in Questions P4-P10.

For Questions P13-P14, ask the patient to use the Patient Rating scale

P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? ☐

- Patient should be rating the problem days from Question P12.

P14. How important to you *now* is treatment for these psychological or emotional problems? ☐

CONFIDENCE RATING

Is the above information significantly distorted by:

P22. Patient's misrepresentation? 0-No 1-Yes ☐

P23. Patient's inability to understand? 0-No 1-Yes ☐

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

Page 11

Fagerström

1. How soon after you wake up do you smoke your first cigarette?
   - Within 5 minutes (3 points)
   - 5 to 30 minutes (2 points)
   - 31 to 60 minutes (1 point)
   - After 60 minutes (0 points)
2. Do you find it difficult not to smoke in places where you shouldn't, such as in church or school, in a movie, at the library, on a bus, in court or in a hospital?
   - Yes (1 point)
   - No (0 points)
3. Which cigarette would you most hate to give up; which cigarette do you treasure the most?
   - The first one in the morning (1 point)
   - Any other one (0 points)
4. How many cigarettes do you smoke each day?
   - 10 or fewer (0 points)
   - 11 to 20 (1 point)
   - 21 to 30 (2 points)
   - 31 or more (3 points)
5. Do you smoke more during the first few hours after waking up than during the rest of the day?
   - Yes (1 point)
   - No (0 points)
6. Do you still smoke if you are so sick that you are in bed most of the day, or if you have a cold or the flu and have trouble breathing?
   - Yes (1 point)
   - No (0 points)

Scoring: 7 to 10 points = highly dependent; 4 to 6 points = moderately dependent; less than 4 points = minimally dependent.

Brief Symptom Inventory (BSI)

I**NSTRUCTIONS**: Below is a list of problems and complaints that people sometimes have. Read each one carefully and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST MONTH INCLUDING TODAY. Write that number next to the question. Do not skip any item.

Descriptors:

0. Not at all
1. A little bit
2. Moderately
3. Quite a bit
4. Extremely

HOW MUCH WERE YOU DISTRESSED BY:

1. Nervousness or shakiness inside _____
2. Faintness or dizziness _____
3. The idea that someone else can control your thoughts _____
4. Feeling others are to blame for most of your troubles _____
5. Trouble remembering things _____
6. Feeling easily annoyed or irritated _____
7. Pains in heart or chest _____
8. Feeling afraid in open spaces _____
9. Thoughts of ending your life _____
10. Feeling that most people cannot be trusted _____
11. Poor appetite _____
12. Suddenly scared for no reason _____
13. Temper outbursts that you could not control _____
14. Feeling lonely even when you are with people _____
15. Feeling blocked in getting things done _____
16. Feeling lonely _____
17. Feeling blue _____
18. Feeling no interest in things _____
19. Feeling fearful _____
20. Your feelings being easily hurt _____
21. Feeling that people are unfriendly or dislike you _____
22. Feeling inferior to others _____
23. Nausea or upset stomach _____
24. Feeling that you are watched or talked about by others _____

25. Trouble falling asleep _____
26. Having to check and double check what you do _____
27. Difficulty making decisions _____
28. Feeling afraid to travel on buses, subways, or trains _____
29. Trouble getting your breath _____
30. Hot or cold spells _____
31. Having to avoid certain things, places, or activities because they frighten you _____
32. Your mind going blank _____
33. Numbness or tingling in parts of your body _____
34. The idea that you should be punished for your sins _____
35. Feeling hopeless about the future _____
36. Trouble concentrating _____
37. Feeling weak in parts of your body _____
38. Feeling tense or keyed up _____
39. Thoughts of death or dying _____
40. Having urges to beat, injure, or harm someone _____
41. Having urges to break or smash things _____
42. Feeling very self-conscious with others _____
43. Feeling uneasy in crowds _____
44. Never feeling close to another person _____
45. Spells of terror or panic _____
46. Getting into frequent arguments _____
47. Feeling nervous when you are left alone _____
48. Others not giving you proper credit for your achievements _____
49. Feeling so restless you could not sit still _____
50. Feelings of worthlessness _____
51. Feeling that people will take advantage of you if you let them _____
52. Feelings of guilt _____
53. The idea that something is wrong with your mind _____

Personal Health Questionnaire Depression Scale (PHQ-9)

How often during the past 2 weeks were you bothered by?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure, or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
	Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
10. If you checked off any problems, how difficult these problems made it for you to do your work, take care of things at home, or get along with other people?	0	1	2	3

Alcohol Urge Questionnaire

Listed below are questions that ask about your feelings about drinking. The words "drinking" and "have a drink" refer to having a drink containing alcohol such as beer, wine, or liquor. Please indicate how much you agree or disagree with each of the following statements by ***selecting one number*** *for each question between STRONGLY DISAGREE and STRONGLY AGREE. The closer you select a number to one end or the other indicates the strength of your disagreement or agreement. Please complete every item. We are interested in how you are thinking or feeling* ***right now*** *as you are filling out the questionnaire.*

RIGHT NOW

1. All I want to do now is have a drink.

STRONGLY AGREE 1[] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

2. I do not need to have a drink now.

STRONGLY AGREE 1[] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

3. It would be difficult to turn down a drink this minute.

STRONGLY AGREE 1[] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

4. Having a drink now would make things seem just perfect.

STRONGLY AGREE 1[] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

5. I want a drink so bad I can almost taste it.

STRONGLY AGREE 1[ ] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

6. Nothing would be better than having a drink right now.

STRONGLY AGREE 1[ ] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

7. If I had the chance to have a drink, I don't think I would drink it.

STRONGLY AGREE 1[ ] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

8. I crave a drink right now.

STRONGLY AGREE 1[ ] 2[ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] STRONGLY DISAGREE

Scoring Procedure and Interpretation

Each item is scored on a 1 to 7 scale (Strongly Disagree = 1 and Strongly Agree = 7). Items 2 and 7 are reverse scored. A total score is computed by averaging the item scores. Higher scores reflect greater craving.

Alcohol Withdrawal Assessment Scoring Guidelines (CIWA - Ar)

Nausea/Vomiting - Rate on scale 0 - 7

0 - None
1 - Mild nausea with no vomiting
2
3
4 - Intermittent nausea
5
6
7 - Constant nausea and frequent dry heaves and vomiting

Tremors - have patient extend arms & spread fingers. Rate on scale 0 - 7.
0 - No tremor
1 - Not visible, but can be felt fingertip to fingertip
2
3
4 - Moderate, with patient's arms extended
5
6
7 - severe, even w/ arms not extended

Anxiety - Rate on scale 0 - 7
0 - no anxiety, patient at ease
1 - mildly anxious
2
3
4 - moderately anxious or guarded, so anxiety is inferred
5
6
7 - equivalent to acute panic states seen in severe delirium or acute schizophrenic reactions.

Agitation - Rate on scale 0 - 7
0 - normal activity
1 - somewhat normal activity
2
3
4 - moderately fidgety and restless
5
6
7 - paces back and forth, or constantly thrashes about

Paroxysmal Sweats - Rate on Scale 0 - 7.
0 - no sweats
1- barely perceptible sweating, palms moist
2
3
4 - beads of sweat obvious on forehead
5
6
7 - drenching sweats

Orientation and clouding of sensorium - Ask, "What day is this? Where are you? Who am I?" Rate scale 0 - 4
0 - Oriented
1 – cannot do serial additions or is uncertain about date

2 - disoriented to date by no more than 2 calendar days

3 - disoriented to date by more than 2 calendar days
4 - Disoriented to place and / or person

Tactile disturbances - Ask, "Have you experienced any itching, pins & needles sensation, burning or numbness, or a feeling of bugs crawling on or under your skin?"
0 - none
1 - very mild itching, pins & needles, burning, or numbness
2 - mild itching, pins & needles, burning, or numbness
3 - moderate itching, pins & needles, burning, or numbness
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Auditory Disturbances - Ask, "Are you more aware of sounds around you? Are they harsh? Do they startle you? Do you hear anything that disturbs you or that you know isn't there?"
0 - not present
1 - Very mild harshness or ability to startle
2 - mild harshness or ability to startle
3 - moderate harshness or ability to startle
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Visual disturbances - Ask, "Does the light appear to be too bright? Is its color different than normal? Does it hurt your eyes? Are you seeing anything that disturbs you or that you know isn't there?"
0 - not present
1 - very mild sensitivity
2 - mild sensitivity
3 - moderate sensitivity
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Headache - Ask, "Does your head feel different than usual? Does it feel like there is a band around your head?" Do not rate dizziness or lightheadedness.

0 - not present
1 - very mild
2 - mild
3 - moderate
4 - moderately severe
5 - severe
6 - very severe
7 - extremely severe

Procedure:

1. Assess and rate each of the 10 criteria of the CIWA scale. Each criterion is rated on a scale from 0 to 7, except for "Orientation and clouding of sensorium" which is rated on scale 0 to 4. Add up the scores for all ten criteria. This is the total CIWA-Ar score for the patient at that time. Prophylactic medication should be started for any patient with a total CIWA-Ar score of 8 or greater (ie. start on withdrawal medication). If started on scheduled medication, additional PRN medication should be given for a total CIWA-Ar score of 15 or greater.
2. Document vitals and CIWA-Ar assessment on the Withdrawal Assessment Sheet. Document administration of PRN medications on the assessment sheet as well.
3. The CIWA-Ar scale is the most sensitive tool for assessment of the patient experiencing alcohol withdrawal. Nursing assessment is vitally important. Early intervention for CIWA-Ar score of 8 or greater provides the best means to prevent the progression of withdrawal.

Assessment Protocol a. Vitals, Assessment Now. b. If initial score ≥ 8 repeat q1h x 8 hrs, then if stable q2h x 8 hrs, then if stable q4h. c. If initial score < 8, assess q4h x 72 hrs. If score < 8 for 72 hrs, d/c assessment. If score ≥ 8 at any time, go to (b) above. d. If indicated, (see indications below) administer prn medications as ordered and record on MAR and below.	**Date**												
	Time												
	Pulse												
	RR												
	O_2 sat												
	BP												
Assess and rate each of the following (CIWA-Ar Scale):	**Refer to reverse for detailed instructions in use of the CIWA-Ar scale.**												
Nausea/vomiting (0 - 7) 0 - none; 1 - mild nausea ,no vomiting; 4 - intermittent nausea; 7 - constant nausea , frequent dry heaves & vomiting.													
Tremors (0 - 7) 0 - no tremor; 1 - not visible but can be felt; 4 - moderate w/ arms extended; 7 - severe, even w/ arms not extended.													
Anxiety (0 - 7) 0 - none, at ease; 1 - mildly anxious; 4 - moderately anxious or guarded; 7 - equivalent to acute panic state													
Agitation (0 - 7) 0 - normal activity; 1 - somewhat normal activity; 4 - moderately fidgety/restless; 7 - paces or constantly thrashes about													
Paroxysmal Sweats (0 - 7) 0 - no sweats; 1 - barely perceptible sweating, palms moist; 4 - beads of sweat obvious on forehead; 7 - drenching sweat													
Orientation (0 - 4) 0 - oriented; 1 - uncertain about date; 2 - disoriented to date by no more than 2 days; 3 - disoriented to date by > 2 days; 4 - disoriented to place and / or person													
Tactile Disturbances (0 - 7) 0 - none; 1 - very mild itch, P&N, ,numbness; 2-mild itch, P&N, burning, numbness; 3 - moderate itch, P&N, burning ,numbness; 4 - moderate hallucinations; 5 - severe hallucinations; 6 – extremely severe hallucinations; 7 - continuous hallucinations													
Auditory Disturbances (0 - 7) 0 - not present; 1 - very mild harshness/ ability to startle; 2 - mild harshness, ability to startle; 3 - moderate harshness, ability to startle; 4 - moderate hallucinations; 5 severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous.hallucinations													
Visual Disturbances (0 - 7) 0 - not present; 1 - very mild sensitivity; 2 - mild sensitivity; 3 - moderate sensitivity; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations													
Headache (0 - 7) 0 - not present; 1 - very mild; 2 - mild; 3 - moderate; 4 - moderately severe; 5 - severe; 6 - very severe; 7 - extremely severe													
Total CIWA-Ar score:													
PRN Med: (circle one) Diazepam Lorazepam	**Dose given (mg):**												
	Route:												
Time of PRN medication administration:													
Assessment of response (CIWA-Ar score 30-60 minutes after medication administered)													
RN Initials													

Scale for Scoring: Total Score = 0 – 9: absent or minimal withdrawal 10 – 19: mild to moderate withdrawal more than 20: severe withdrawal	**Indications for PRN medication:** a. Total CIWA-AR score 8 or higher if ordered PRN only (Symptom-triggered method). b. Total CIWA-Ar score 15 or higher if on Scheduled medication. (Scheduled + prn method) Consider transfer to ICU for any of the following: Total score above 35, q1h assess. x more than 8hrs required, more than 4 mg/hr lorazepam x 3hr **or** 20 mg/hr diazepam x 3hr required, or resp. distress.

Patient Identification (Addressograph)

Signature/ Title	Initials	Signature / Title	Initials

Alcohol Withdrawal Assessment Flowsheet (revised Nov 2003)

Name/ID#: _____ Date: _____

TIMELINE FOLLOWBACK CALENDAR: 2020

One 12 oz can/bottle

1 Standard Drink is Equal to

One 5 oz glass of regular (12%)

1 ½ oz of hard liquor (e.g. rum, vodka,

1 mixed or straight drink with 1 ½ oz hard liquor

Complete the Following

Start Date (Day 1): **End Date** (yesterday):

2020	SUN	MON	TUES	WED	THURS	FRI	SAT
				1 New Year's Day	2	3	4
J	5	6	7	8	9	10	11
A	12	13	14	15	16	17	18
N	19	20 M. King Day	21	22	23	24	25
	26	27	28	29	30	31	1
F	2	3	4	5	6	7	8
E	9	10	11	12	13	14 Valentine	15
B	16	17 Pres. Day	18	19	20	21	22
	23	24	25	26	27	28	29
M	1	2	3	4	5	6	7
A	8	9	10	11	12	13	14
R	15	16	17 St. Patrick	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31	1	2	3	4
A	5	6	7	8	9	10 Good Friday	11
P	12 Easter	13	14	15	16	17	18
R	19	20	21	22	23	24	25
	26	27	28	29	30	1	2
M	3	4	5	6	7	8	9
A	10 Mother's Day	11	12	13	14	15	16
Y	17	18	19	20	21	22	23
	24	25 Memorial Day	26	27	28	29	30
	31						

2020	SUN	MON	TUES	WED	THURS	FRI	SAT
J		1	2	3	4	5	6
U	7	8	9	10	11	12	13
N	14	15	16	17	18	19	20
	21 Father's Day	22	23	24	25	26	27
	28	29	30	1	2	3	4 Independence Day
J	5	6	7	8	9	10	11
U	12	13	14	15	16	17	18
L	19	20	21	22	23	24	25
	26	27	28	29	30	31	1
A	2	3	4	5	6	7	8
U	9	10	11	12	13	14	15
G	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
S	30	31	1	2	3	4	5
E	6	7 Labor Day	8	9	10	11	12
P	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30	1	2	3
O	4	5	6	7	8	9	10
C	11	12 Columbus Day	13	14	15	16	17
T	18	19	20	21	22	23	24
	25	26	27	28	29	30	31 Halloween
N	1	2	3 Election Day	4	5	6	7
O	8	9	10	11 Veterans Day	12	13	14
V	15	16	17	18	19	20	21
	22	23	24	25	26 Thanksgiving	27	28

D	29	30	1	2	3	4	5
E	6	7	8	9	10	11	12
C	13	14	15	16	17	18	19
	20	21	22	23	24	25 Christmas	26
	27	28	29	30	31		

Unified Theory of Acceptance and Use of Technology (UTAUT)

		Strongly Disagree			-			**Strongly Agree**
	Question	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1	I find the system useful for the course.							
2	Using the system will enable me to accomplish tasks more quickly.							
3	Using the system will increase my productivity.							
4	If I use the system, I will increase my chances of getting a raise.							
5	My interaction with the system will be clear and understandable.							
6	It will be easy for me to become skilful at using the system.							
7	I find the system easy to use.							
8	Learning to operate the system is easy for me.							
9	Using the system is a good idea.							
10	The system will make work more interesting.							
11	Working with the system is fun.							
12	I like working with the system.							
13	People who are important to me think that I should use the system.							
14	People who influence my behaviour think that I should use the system.							
15	The Doctor has been helpful in the use of the system.							
16	In general, the organization has supported the use of the system.							
17	I have the resources necessary to use the system.							
18	The system is not compatible with other systems I use.							
19	I have the knowledge necessary to use the system.							
20	A specific person (or group) is available for assistance with system difficulties.							
21	I could complete a job or task using the system...							

21.a	If there was no one around to tell me what to do as I go.							
21.b	If I could call someone for help if I got stuck.							
21.c	If I had a lot of time to complete the job for which the software was provided.							
21.d	If I had just the built-in help facility or assistance.							
22	I hesitate to use the system for fear of making mistakes I cannot correct.							
23	It scares me to think that I could lose a lot of information using the system by hitting the wrong key.							
24	I feel apprehensive (anxious) about using the system.							
25	The system is somewhat intimidating to me.							
26	I plan to use the system in the next <n> months.							
27	I predict I would use the system in the next <n> months.							
28	I have used the system a lot in the past 4 weeks.							
29	I have been using the system regularly in the past 4 weeks.							

Phone Screening Script:

Research staff will call potential participants and will greet and present themselves to participants. When appropriate in the conversation, they will use the following script:

"We have a research Study that is testing the usefulness of an application based psychosocial treatment called Contingency Management that uses a mobile application to see if it can improve alcohol secession treatment response by reducing the days of heavy alcohol use. This intervention involves sending remote alcohol breathalyzers samples (via mobile phone) and getting paid if samples have alcohol levels below (Blood Alcohol Concentration ''BAC'') 0.08. The study is titled: **"Automated Contingency Management System for Reduction of Alcohol Use.** The **National Institute on Alcohol Abuse and Alcoholism** funded this study, and the Washington State University Institutional Review Board has approved it. The study looks at the ability of this technology to help individuals to reduce the number of days of heavy alcohol use for eight weeks. If you are interested and qualify, we will set a 2 hours in-person interview in a date and time that is convenient for you. People who take part will receive up to $536.75 for 8 weeks of participation to compensate for their time.
Would you be interested in answering a few questions to see if you qualify for the study?
➔ ***If no*** "Thank you so much for your time, have a wonderful day"

➔ ***If yes*** "Great! Do you have time now to go over the screening questions"?

➔ ***If no "***Can I call you another time?"
Write the number here*:* _____

➔ ***If yes* (Handoff to the research recruiting team)**
Great! Now I am going to ask you the screening questions. Some of the questions might be sensitive in nature because they are about your current alcohol use behavior. We ask that you be as honest and accurate as possible. You do not have to answer any question that you do not wish to answer. However, if you choose not to answer some questions, you may not be eligible to take part in the study, because your answers are needed to determine if you are a match.

SD1. How old are you? _____ years
If under 18 or older than 65 years → ineligible, stop screening
SD2. Do you know how to use a smartphone ?
If no→ ineligible, stop screening
If yes→ Do have an iPhone?
If yes→ is your iPhone an iPhone 7 or newer version with an iOS 13.5?
If no→ *If you do not have an iPhone 7 or newer, we can loan you one if you know how to use it, but it must be returned at the end of the study. Upon completion of or withdrawal from the study AND return of the phone you will receive a $50 Amazon gift card.*
If yes→ Do you have an active and consistent service provider?
If no→ ineligible, stop screening

SD3. What is your gender?
(0) Female
(1) Male
(2) Non-binary
SD4. What is your race?
(0) African American
(1) Asian
(2) Caucasian
(3) American Indian or Alaska Native
(4) Native Hawaiian or Other Pacific Islander
(5) Multiple
SD3m. Specify: _____
(6) Other
SD3o. Specify: _____

SD5. Are you of Hispanic origin?
(0) No
(1) Yes

SD6. What is your current employment status? Circle all that apply
(0) Fulltime (36 hours or more)
(1) Part-time
(2) Homemaker
(3) Student
(4) Disabled
(5) Unemployed

SD7. What is your marital status?

(0) Single
(1) Married or cohabitating with a partner
(2) Divorced or separated
(3) Widowed

SD8. How often do you drink alcohol beverages in a month?
If less than 5→ ineligible, stop screening

SD9. How many drinks containing alcohol do you have in a typical day when you are drinking?
If less than 3 → ineligible, stop screening

SD10. In the last 12 months, did you have seizure due to alcohol withdrawal?
If yes→ ineligible, stop screening

SD11. Can you read in English?
If no→ ineligible, stop screening

- ➔ ***If not eligible*** "I am sorry but based on your answers, you are not currently a good match for our study. However, we appreciate your interest in our study and thank you for taking the time to answer our questions."

- ➔ ***If eligible*** "Great thank you, it looks like you may be a good match for the study."

If you are interested in taking part in this study would it be ok for us to set an appointment next week?

- Schedule appointment.

Ok great I will see you then. Thank you again for your interest in our study!

Individual Exit Interview ARMS Phase I study

1. What are your general thoughts about the application?
    a) Was it easy?
    b) Was there anything frustrating about it?

2. What are your general thoughts about the BACTrack device?
    a) Was it easy?
    b) Was there anything frustrating about it?

3. Which features of the application did you use most? Why?

4. Prompt for response to “Record BAC”

5. Prompt for response to “Snooze function”

6. Prompt for feelings about EMA questionnaire response ease of use, frequency

7. Prompt for “Rewards”

8. Prompt for “Reports”

9. Prompt for “Daily messaging”

10. Was there anything else that would have helped you?

11. Do you think the application helped you understand or manage your alcohol use?

12. What would you absolutely change about the application?

13. Would you recommend the application to others trying to manage their alcohol use? Why or why not?

Karolinska Sleepiness Scale (KSS). How sleepy are you?

Rate	Verbal Descriptions
1	Extremely alert
2	Very alert
3	Alert
4	Fairly alert
5	Neither alert nor sleepy
6	Some signs of sleepiness
7	Sleepy, but no effort to keep awake
8	Sleepy, some effort to keep awake
9	Very sleepy, great effort to keep awake, fighting sleep

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), 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-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, Co-Investigator.

Sponsor: NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

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 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 4-6 hours 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, 4-6 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, 4-6 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, 4-6 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 to return the study phone. 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. Examples of withdrawal symptoms are feeling like you need another drink to make you feel better. Delirium Tremens, shakes, and other physiological 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.

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)

Day2, sample1 ($3.50), sample2 ($3.75), sample3 ($3.75)
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

Follow-up screening script.

Hello, my name is …….. I am calling from Washington State University.

May I please speak to ……?

[If the participant is available to continue if not thank the person who answered and call again later]

I am calling to follow-up on your participation in the ARMS study. Is this a proper time to talk about it?

[If yes]: Great. How are you doing today?

We are conducting the weekly follow-up today. It will take about 2-3 minutes.

[If no] What is the best time to call you back? [Note the time and politely end the call].....

[Complete the participant's weekly follow-up questionnaire with them. After filling out the questionnaire, ask,]

Do you have any concerns about your study participation?

[If Yes, note concerns and contact study PI as necessary] …….

Thank you for taking the time to talk with me today. If you have any additional questions or concerns, please feel free to contact me. My name is …… and I can be reached at phone number……. and/or [email address……].