Interventions for Unemployed Hazardous Drinkers

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CONSENT FORM

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PI Phone Number: (860) 679-4556

Title of Research Study: Health Behaviors and Employment

Expected Duration of Subject's Participation: 12 months

IRB Number: 15-041-2

Funding Source: National Institutes of Health

Name of Research Participant:_____

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This research is being done to improve employment outcomes in people who drink alcohol. This study lasts about 12 months. This study consists of weekly visits with a research assistant for 3 months to discuss job-related activities as well as breathalyzer submissions. There will also be 6 interviews over 12 months. During the interviews, you will be asked about your employment, alcohol and drug use, gambling, legal, medical and mental health history, and you will give breath and urine samples that will be tested for substance use.

There are no serious risks of participating in this study. Some of the questions during the interviews may cause you discomfort. Risks are described in more detail later in this form. There may be benefits from participation. You will receive treatment that may help you find a job. A more detailed description of this research follows.

What Is The Purpose Of This Research Study?

The purpose of this study is to look at how unemployment and alcohol use relate. The results could lead to better methods of helping unemployed people who drink find jobs.

Why Am I Invited To Participate?

You are invited to participate in this study because you reported drinking alcohol and problems with unemployment.

How Many Other People Will Participate?

Up to 280 people will take part in this randomized study.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully. Discuss any questions you have with the research assistant. If you decide to participate in the study, you are free to withdraw at any time. If you decide not to participate or you withdraw from the study, your choice will not affect your present or future relationship with this agency or your present or future care at UConn Health. There will be no penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?

This study lasts about 12 months. This study consists of brief daily phone calls and weekly visits with a research assistant for 3 months. There will also be 6 interviews over 12 months.

What Will I Be Asked To Do?

Interviews: If you take part in this study, you will be interviewed by the research assistant six times: today and about 1, 3, 6, 9 and 12 months from today. During the interviews, you will be asked about your employment, alcohol and drug use, gambling, legal, medical and mental health history. You may give a breath sample that will be tested for alcohol use and a urine sample that will be tested for alcohol,

marijuana, stimulants, opioids, and benzodiazepine use. The interviews will take about three hours. For completing today's interview, you will be paid $25 in gift cards. You will receive $50 in the form of a check or gift cards for interviews about 1, 3, 6, 9 and 12 months from today. If you do interviews by mail rather than in person, you will receive $25.

Completing Breathalyzer Tests and Weekly Visits: At the end of today's interview, the research assistant will lend you a study cell phone and a breathalyzer. A breathalyzer tests your breath for alcohol. It is a little larger than a cell phone. You will be asked to carry the cell phone and breathalyzer wherever you go, in your purse, or in your pocket, or within close reach at all times. Before giving these to you, we need a copy of a state-issued identification card (for example, a driver's license). The breathalyzer and cell phone are state-owned equipment. We cannot lend them until we have proof of your name and address. If you have your own cell phone that can receive texts, you may use your own cell phone for the study. If you use your own phone, you will receive $35 per month to pay study-related charges on your cell phone bill, up to $105.

For the next 12 weeks, you will receive up to 3 requests for samples per day (up to 21 requests per week). These prompts will occur between 8 a.m. and 11 p.m. Times can be adjusted if you get a job, so that you are not prompted when you are working. The prompts will ask you to complete a breathalyzer test. This process will take about 2 minutes. You will get training on how to use the breathalyzer and cell phone. For up to the first 5 days, the research assistant may call you after a sample is requested to see if you need help. You may also call the research assistant if you need help with the breathalyzer any time during the study.

Breathalyzer tests must be completed within one hour of the prompt. The research assistant will verify timing and quality of the test before you will receive earnings. The research assistant will email, text or phone you (your choice) to tell you how much you earned for completing the tests. You will receive $2 for each valid on-time test you complete. You will also receive a $26 bonus for every 7-day period that you complete all requested tests on time. On average, you can earn about $46 per week, or about $552 in total over 12 weeks. You will receive your earnings in the form of a check or gift cards (your choice). You can collect earnings weekly.

If you do not complete at least 50% of the tests we ask for each week, then your study cell phone service will be stopped. If you are using your own cell phone, you will not receive $35 toward your cell service that month. The research assistant will let you know if you are missing too many tests and are at risk of losing cell service or payments. If your study cell phone service is ended, you need to submit an unprompted breathalyzer test to re-start your service, typically within 1 business day. Study cell phone service will only be re-started once during the 12 weeks. If you miss more than half of your tests in a week more than one time, you will no longer be paid for submitting tests for the rest of the 12 weeks. If this happens, we still encourage you to complete study interviews. Interviews are a very important part of the study. To stay in touch with you, the research assistant will ask you to give contact information of at least three people you expect to have regular contact with over the next 12 months. Research staff needs this information so they can find you. No information about you will be given to these people.

If you return the breathalyzer and cell phone to the research assistant in working condition when you finish the 12 weeks, you will receive $50. Even if your cell phone service is stopped, you can return the phone and breathalyzer and receive the $50.

Two weeks before your 12-month interview, you will come back for a brief re-training on the breathalyzer and cell phone. You will then again receive up to 3 daily requests for breathalyzer tests for 14 days. You will receive the same payments for making them as described above. If you return the equipment in working order at the 12-month interview, you will receive $25.

The study interviews and weekly visits (described in more detail below) may be audiorecorded. Only study staff will listen to these audiorecordings. Staff members listen to make sure the research assistant is doing the interviews and interventions correctly. If you decide you do not want to be audiorecorded, you can still take part in the research study. Please make a choice by initialing one option below.

Initials: _____ **Yes**, I agree. My interviews and study treatment can be audiorecorded.

Initials: _____ **No**, I do not want my interviews and study treatment to be audiorecorded.

If you are incarcerated during the study, you can still complete the questionnaire portion of the follow-up interviews. The interviews can be delivered to you. A stamped and addressed return envelope will also be provided. If you complete and return the interview, you will get $25 in the form of a check or gift cards for the interviews at months 1, 3, 6, 9 and 12. You will get your payment after your release from incarceration, or you may designate a person to whom it should be sent during your incarceration. Your participation in this study while incarcerated will have no effect on your eligibility for parole. Please indicate your preference by initialing the appropriate box below.

Initials: _____ **Yes**, if I become incarcerated during the study, I would like the interview delivered to me in prison.

Initials: _____ **No**, if I become incarcerated during the study, I do not want the interview delivered to me in prison.

You can also earn up to $100 for helping us find other people for this study. We will give you cards that describe the research study. The cards will include the research assistant's contact information. You can give these cards to people you know who are unemployed and drink alcohol and may be interested in the study. If a person you give a card to calls us and is invited to and attends an interview, you will receive $20 in your choice of gift cards. You can receive $20 for up to 5 people, for a total of $100. If you choose not to pass on the cards, it will not affect your study participation.

After today's training, you will be assigned randomly (like the flip of a coin) to one of four groups. The reason you will be randomly assigned to a group, rather than you choosing one, is so that researchers can compare all the groups. No matter which group you are randomly assigned to, you will meet weekly with the research assistant. At the weekly meetings, you will give a breath sample that will be tested for alcohol and asked about recent substance use. During periods of elevated risk due to COVID, we may ask you to use your assigned breathalyzer or skip the in-office breathalyzer. Every other week, you will give a urine sample that will be tested for alcohol, marijuana, stimulants, opioids, and benzodiazepines. You will also complete breathalyzer tests for 12 weeks, as described above.

Group A (70 participants): If you are randomly assigned to Group A, you will complete a job-related activities contract at your weekly meetings with the research assistant. Each week, you will select 3 activities plus 1 alternate activity to complete in the upcoming week. These activities will help you work toward your employment goals. They may include attending a job club, meeting with a vocational training specialist, completing a resume, or filling out a job application. The research assistant will choose whether or not to approve your activities. Some types of activities will not be approved. These include activities that do not support your employment goals or activities that have no proof of completion. Also, you may not be allowed to choose some activities again and again during the study. The purpose is to encourage you to take steps to find a job. If you get a job, your activities may involve going to the job. We hope to help you complete activities and find a job. We will review your progress each week. See a sample activity contract below.

Activity	**Best day and time**	**Problems that may interfere**	**Verification**
1. Attend a mock interview	Wed 2-3:00	Won't feel like it	Appointment slip
2. Attend job club	Thurs 10 am	Oversleep	Signed meeting slip
3. Fill out a job application at Stanley Works	Mon am	Need to figure out bus route	Card or brochure from company
4. (alternate) Library—research job options	Friday	Raining and don't feel like walking	Take out book or print out from internet

Group B (70 participants): If you are randomly assigned to Group B, you will complete everything described above for Group A. In addition, you will earn a chance to win a prize for each breathalyzer test

that reads negative for alcohol (<0.02 g/dl). For each valid, on-time, negative sample you submit, you will get to draw once from a prize bowl at your weekly visit with the research assistant.

The prize bowl contains 500 cards. Of these, 164 are cards for small prizes (for example, your choice of $1 gift certificates, food items, or bus tokens/tickets). There are 35 cards for large prizes, worth up to $20 in value (for example, your choice of movie theater tickets, kitchen supplies, or a watch). One card is for a jumbo prize worth up to $100 (for example, your choice of small stereo, television, or five large prizes). A variety of prizes will be available. You can also suggest prizes. All cards are returned to the bowl after drawings so your chances to win do not change.

You will also earn bonus draws for each week that you submit all negative samples. You will earn 5 bonus draws after the first week of negative sample submissions. The bonus will go up by 2 for each week of negative samples in a row, for a maximum of 15 bonus draws. Your tests need to be verified by the research assistant before you can draw for your prizes. At your weekly visit, you will be able to draw for the previous week's earnings. On average, if you submit all negative samples over the next 12 weeks, you will earn about 266 draws.

If you submit a positive sample or you do not submit a sample during the one-hour timeframe, then the number of draws you earn will be re-set. For your next negative sample, you will earn one draw. After 7 days in a row of negative samples, you will earn 5 bonus draws. Bonus draws will increase by 2 for each week in a row you submit negative samples.

Group C (70 participants): If you are assigned to Group C, you will complete everything described in Group A. In this group, you will earn the chance to win prizes for each activity you complete on your weekly contracts. For each activity that you provide proof of completing in the one-week period, you will get 3 draws from the prize bowl. You will draw from the same bowl described in Group B. You will also get bonus draws each time you complete 3 activities in one week. You will start at 6 bonus draws. The number of bonus draws you earn will increase by 2, up to a maximum of 16 bonus draws. For example, if you complete 3 activities during week 1, you will earn 6 bonus draws, for a total of 15 draws that week. If you then complete 3 activities in week 2, you will get 8 bonus draws that week, for a total of 17 draws. Bonus draws keep going up if you do 3 activities a week. If you do not complete (or cannot verify) 3 activities in a week, bonus draws will reset to 6. You can earn up to 270 draws for completing activities throughout the 12 weeks.

Group D (70 participants): If you are randomly assigned to Group D, you will complete everything as described above in Groups A, B and C. You will be able to earn draws from the prize bowl for both completing activities and submitting negative breath samples. You can earn up to 536 draws if you submit all negative samples and complete 3 activities each week.

Are There Possible Risks?

(a) You may be disappointed if you are not put in the group you wanted. If you are unhappy with your group, you may withdraw from the study.
(b) You may feel uncomfortable when asked questions about employment histories and problems, alcohol and drug use, medical problems and histories, psychosocial problems and submitting urine and breath samples. If you feel uncomfortable during an interview, you may take a break or not answer a question. You should record all breath samples in a private location. You are given one hour to complete the breathalyzer test so you can find a private spot.
(c) You may have difficulties if your study cell phone service is disconnected for not submitting breath samples. Research staff will let you know if you are in danger of losing service. They will try to contact you if you have been disconnected to remind you that your service may be re-started if you submit an unprompted breathalyzer test.
(d) The information you provide for this study, including breathalyzer tests, may become available to people who are not involved in this research. Every effort will be made to protect your confidentiality. The next section describes steps to protect your personal information.

How Will My Personal Information Be Protected?

Confidentiality: Every effort will be made to protect confidentiality of information we gather from you. We cannot guarantee 100% confidentiality. The following steps will be taken to protect the confidentiality of your records in agreement with state and federal laws. A study number, not your name, will code your study information. Study numbers will be derived from a letter code identifying the study and site, followed by a 3 digit number that is a sequential indicator of the number of patients that have been enrolled in the study. Your study information will be kept in a locked file cabinet. A master key, which links your name and study number, will be kept in a separate and secure location. We encourage you to password protect your cell phone, complete your tests in private and delete texts related to this study, in case your phone is lost or stolen. The breathalyzer uses facial recognition technology which means an image of your face is validated by an automated system. Your image is encrypted (translated into a code) which makes it very difficult for someone not associated with this study to see your face, however, we cannot guarantee your privacy with this technology. Only research staff, the funder and agencies responsible for research compliance will have access to your study information. At the end of this study, the researchers may publish their findings. Information will be presented in summary format. You will not be identified in any presentations or publications.

If you decide to take part in this research study, you will be asked to give us information about your substance use. We have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). The CoC is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. However, they will not be given access to your study information, except as required by state or federal law.

Even when a CoC is in place, you must still continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information. If you become incarcerated and share your information with anyone, then the CoC will not be able to protect your privacy.

Also, because this research is sponsored by NIH, staff from that and other Department of Health and Human Services (DHHS) agencies may review records that identify you only for audit or program evaluation. They can't report anything that would harm the research subjects. This Certificate, however, does not imply that the Secretary, DHHS, approves or disapproves of the project.

A description of this trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Results of the Study

You may not be provided with overall results of the study. You will be provided with individual results from sample submission. Samples will be destroyed after results are recorded. You will be contacted if there are significant findings that may impact your willingness to continue to participate in the study.

What Are The Benefits Of Participating In This Study?

(a) You may receive an intervention that may help you find a job and/or decrease heavy drinking.
(b) You will receive careful evaluation of your alcohol use.
(c) You may help us learn how to better assist people who are looking for work.

Will I Be Paid For Participating In This Study?

(a) You will get $25 in gift cards for completing the intake interview and $50 for each interview at months 1, 3, 6, 9, and 12.
(b) You will receive $2 for each valid on-time test completed and $26 per 7-day period that you submit all breath samples. You can earn about $46 per week for 12 weeks, and again in the two weeks before the 12-month interview.

(c) You will get $50 for returning the breathalyzer and cell phone in working order at week 12, and $25 for returning them at your 12-month interview. If you use your own cell phone instead of the study cell phone, you may receive up to $35 per month to cover study costs of your phone.
(d) If a person you tell about the research study is eligible and attends an intake interview, you will receive $20 in your choice of gift cards. This can happen up to 5 times, for a total of $100.
(e) You may receive bus passes for transportation to study visits.

If you are in group B you may receive up to $513 in prizes. If you are in group C you may receive up to $521 in prizes. If you are in group D you may receive up to $1,033 in prizes.

If cumulative payments for research participation total $600 or more in a calendar year, the payments must be reported to the IRS as income.

What If I Decide To Stop Participating In The Study?
You are free to stop taking part in this study at any time. If you decide to stop taking part in the study, your relationship with this agency and UConn Health will not be affected. If you decide to withdraw, please call the research team at 860-679-4556. Or, send a written notice to Dr. Rash or Dr. Alessi, 263 Farmington Avenue, Farmington, CT 06030-3944.

Can Someone Else Make Me Stop Participating In This Study?
The investigators may end your study participation. If this happens, it will not affect present or future care with this agency or at UConn Health. The investigators would end your participation only if they feel it is in your best interest or if you are not following the instructions given by the research staff.

What If I Have Questions?
The Principal Investigators, Dr. Rash or Dr. Alessi, are willing to answer any questions you have about the study. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call Drs. Rash or Alessi at 860-679-4556. For questions about your rights as a research subject you may contact the Institutional Review Board (IRB) at 860-679-1019, 860-679-8729, or 860-679-4849. You may also call the IRB if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies. Do not call the IRB number for medical issues or for appointment scheduling.

Consent To Participation:
By signing this form you acknowledge that you 1) have read, or have had read to you, this consent document, 2) have talked with research staff about this study and have been given the opportunity to ask questions and have them satisfactorily answered, 3) and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the participant and that a copy of this document signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Participant's Printed Name	Participant's Signature	Date

Name of Investigator or Person Obtaining Consent	Signature of Investigator or Person Obtaining Consent	Date