

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY**YALE UNIVERSITY**

Study Title: Developing e-Coverly: An App-Based Intervention to Support Recovery from Co-occurring Alcohol and Opioid Use

Principal Investigator (the person who is responsible for this research): *Trace Kershaw, 135 College Street, Suite 200, New Haven, CT 06510*

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to pilot test an app-based intervention to support individuals reporting both alcohol and opioid use in maintaining recovery after completing substance use treatment.
- Study activities will include: completing brief questionnaires, downloading software on to your phone that tracks your GPS information, testing an app-based intervention for four weeks (28 days), completing brief surveys on your phone daily, and participating in a recorded interview about your experience with the intervention.
- Your involvement will require 4 hours.
- There may be some risks from participating in this study. Participating in this study may unintentionally cause you to feel upset or to experience cravings to return to use. There is also an unlikely risk that the information you share with us could be inadvertently shared with other people outside of the research study. We have put measures in to place to prevent both of these situations from happening as much as possible.
- The study may have no benefits to you. Participants in other studies have indicated that they found the app useful as a means of reflection and accountability. Your participation will help us to develop an intervention to support individuals finishing treatment for substance use and entering early recovery. By joining this study, you may help our research and, in the future, may help in improving the health of those entering treatment for substance use.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you are currently attending or recently attended substance use treatment. We want to hear your thoughts about a preliminary version of a smartphone app that we have developed to provide ongoing support for individuals in early recovery. We are looking for 40 participants to be part of this research study.

Who is paying for the study?

This study is being funded by the National Institute on Alcohol Abuse and Alcoholism, which is a part of the U.S. National Institutes of Health, the government agency responsible for public health research.

What is the study about?

The purpose of this study is to pilot test an app-based intervention to support individuals reporting both alcohol and opioid use in maintaining recovery after completing substance use treatment. As part of this study, you will try a version of this app for 28 days and will then share your experience with us.

What are you asking me to do and how long will it take?

If you agree to take part, this is what will happen: We will ask you to do a brief interview with one of our staff members. During the interview we will ask you questions about the places you consider to be triggering of cravings to return to use. During part of the interview, you will use a computer that will ask you brief questions about you, your health, and experiences with substance use and substance use treatment. You will answer the questions by picking the choice that best fits what you think or how you feel on the computer screen. All of your answers are private. We will not share your answers with anyone else.

During this first interview, we will download software on your phone that will monitor GPS locations for the next four weeks and will also send messages whenever you encounter the triggering locations you identified. We are doing this to test an intervention to support individuals in maintaining their recovery as they encounter similar locations. Location services must be turned on for the entire duration of the study.

While participating in the intervention portion of the study, you will be asked to complete a brief 5-minute survey each day, including added questions if you visit any of the locations you identified during the study. In order to limit the amount of work you have to do, you will never get more than one brief survey per day, regardless of how many locations you visit. If you are not responsive to the survey questions for 48 hours and cannot be reached by text or phone, we will reach out to the contacts you provide during your initial interview.

After four weeks (28 days), we will ask you to do another brief interview to find out about your experience in using the app. We will also conduct a recorded verbal interview so that you can share more about your experience with the app. At this second interview, we will remove the app software from your phone and we will stop tracking your cell phone records. We will never see your cell phone records again.

We think that the study will take 4 hours of your time.

Are there any risks from participating in this research?

There is no physical risk for joining this study. If you decide to take part in this study, you may experience emotional distress or cravings to return to use. There is also an unlikely risk that the information you share with us could be inadvertently shared with other people outside of the research study.

We have put measures in to place to prevent both of these situations from happening as much as possible. We will keep all information strictly private and confidential. You do not have to

answer any questions you do not want to answer. Receiving messages may unintentionally cause you to feel cravings to return to use. If this occurs, you can turn off the app to stop receiving messages and notify one of the members of the research team.

How can the study possibly benefit me or others?

You may not benefit from taking part in this study. Participants in other studies have indicated that they found the app useful as a means of reflection and accountability.

We hope that our results will add to the knowledge about how to develop and refine an intervention to support individuals finishing treatment for substance use and entering early recovery. By joining this study, you may help our research and, in the future, may help in improving the health of those entering treatment for substance use.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs may include transportation and your time coming to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You will be paid up to \$80 for participating in the study. You will receive \$25 for completion of each of the in-person interviews. You will receive an additional \$30 for the data we receive via smartphone, including one brief mobile survey a day.

In addition to the above, you can also receive additional payment for referring friends or peers to the study. You will receive \$10 for each person who you refer who is screened and considered eligible for study participation. You can receive up to \$50 in this way.

You will be asked to initial a receipt log to confirm that you have received payment. This receipt log will be kept separately from your responses and will not be associated with your data in any way. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

How will you keep my data safe and private?

All of your responses will be held in confidence. Only the researchers and app developer involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

If you decide to take part in this research study, we will ask you to give us personal information about your health, health-related behaviors, and the places that you go. We will assign you a code number when you begin the study so the information you provide will be attached to the code number and not your name. The information we get will be used for the purposes of data

analysis and all analyses will be conducted by code numbers only. All files will be destroyed using a sophisticated program that permanently deletes all information from our computer.

We have obtained a Certificate of Confidentiality for this project from the Federal government. A Certificate of Confidentiality protects your privacy by allowing staff to refuse to disclose your name or other identifying information to anyone outside this research project. However, we cannot know for sure how much protection the Certificate provides because it has rarely been challenged in the courts. In the unlikely event of an audit by the funding agency, the National Institute on Alcohol Abuse and Alcoholism staff may have to reveal your name, but only to the agency's authorized representatives. The Yale University Human Investigation Committee may also inspect study records. However, if we learn about abuse of a child or elderly person, or that you intend to harm yourself or someone else, we must report that to the proper authorities.

The link to your personal information will be kept for the duration of this study, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

Identifiers will be removed from the identifiable private information you provide. After such removal, we may share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

You have the option to receive payment for study participation through a Bank of America reloadable debit card. If you decide to receive payment in this way, we will need to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the first payment. You will need to activate the card over the phone. Each additional payment will be automatically added to your card. You can receive payment in other ways if you do not feel comfortable with this option.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with any substance use treatment programs or other health and social service providers.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you *have* questions later or if you have a research-related problem, you can call the Principal Investigator at (203) 785-3441.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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

Documentation of Informed Consent

Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will give you a copy of this consent form.

_____	_____	_____
Participant Printed Name	Participant Signature	Date
_____	_____	_____
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date