

**Corrections/Detention Consent to Participate In a Treatment Outcome Study
University of Kentucky Medical Center
Center on Drug and Alcohol Research****UK HEALTH FOLLOW-UP STUDY****WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH?**

You are being invited to take part in a follow-up treatment outcome study because you are a client of a state-funded treatment program for substance use disorders in a correctional facility, local detention center, community custody or intensive outpatient program while under Kentucky Department of Corrections supervision. If you take part in this study, you will be one of about 4,000 people per year to do so. This research study is separate from your taking part in counseling services in the treatment program and your taking part in the study is not required for admission to the program.

WHO IS DOING THE STUDY?

The Principal Investigator in charge of the study is Dr. Michele Staton, who is a Professor at the University of Kentucky. Robert Walker, M.S.W., L.C.S.W., Dr. Carl Leukefeld, Erin McNeas Winston, M.P.A. and Jeb Messer also work with the study. Other professionals who work with the investigators as study staff may assist them or act for them.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to gather information about substance use disorder and related mental health problems, employment, education, legal status, and previous use of health and treatment services. It is also for the purpose of evaluating the outcomes of the services that you receive.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

When you are being interviewed early in the admission to the treatment program for substance use disorders, your counselor will collect clinical information from you. Part of the information for this study will be collected during one of those interviews. The other part is collected approximately 12 months after your release from the correctional facility. We may contact you by telephone, or Wi-Fi audio (such as using Facebook), or videoconference (such as using Zoom) if you request, for a follow-up interview using the contact information you give us in your counselor interview. For both the counselor interview and our call to you, the total amount of time for this study is about 1 hour over the next year.

If you are invited to participate in a one-time study voluntary focus group, the group will take place in the corrections-based treatment program for substance use disorders and will last about 1 hour.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to answer questions about related mental health problems, employment, education, legal status, and previous use of health and treatment services. Your counselor will ask you these questions, but you will not be asked to take part in any experimental treatments or procedures.

You will also be asked to give the names, addresses, and phone numbers of two contact persons who would be most likely to know how to reach you at the time of follow-up 12 months post-release. In addition, we may attempt to contact your community social service clinician for your updated address or phone number after you are released. You may be contacted while you are still in the corrections facility to update your locator information so we can reach you 12 months post-release. The research team may also use other internet searches and social media sites like Facebook to try to find you for the follow-up. Your decision to enroll in any study related social media site is completely voluntary and your contact information will not be shared with any other study participant. Sites like Facebook (if you are a member) will just be used to send you notifications about your follow-up interview. Twelve months after release, you may be called for a follow-up interview by telephone, or Wi-Fi audio (such as using Facebook), or videoconference (such as using Zoom) if you request, and you will be asked some of the same questions that are asked by your counselor. This telephone call interview takes about 30 minutes. In general, we usually contact about 20% of the persons who agree to participate in the follow-up study so your chances are about one in five of being contacted 12 months post-release.

You also may be invited to take part in a one-time voluntary focus group where you will be asked general questions about drug use, mental health, family, service options, and how helpful the program may be in addressing these issues, as well as how it may be improved. The groups will consist of a series of open-ended questions and will be audio recorded, if you agree, to ensure that we capture all the responses in the group. If you are invited to participate in the one-time study voluntary focus group, the group will take place in the corrections-based treatment program for substance use disorders and will last about 1 hour.

You are also asked to let the researchers use state information (DOC KOMS files, behavioral health service records) about the number and types of state-funded services that you received, court dates and actions, result of urine screens, time incarcerated,

and other criminal activity in the study. In addition, you are being asked to let University of Kentucky researchers look at public records of arrests and court events that have involved you. This information will help researchers evaluate the services you receive.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

There are no conditions that would keep you from taking part in this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no known risks to your health or mental health associated with these interview procedures. It is perhaps possible that the questions will cause you some emotional discomfort since they might cause you to remember times when you were unhappy or under stress. For your first interview, you can talk about this discomfort with your treatment counselor. Also, some people may be uncomfortable talking about confidential information. Because of the steps we have taken to protect your privacy, the risk of unauthorized disclosure is minimal. If you have some discomfort, you will be offered referral to counselors in your area.

However, if you are living in a treatment facility, institution or prison when contacted for a follow-up interview there is always a risk that your interview could be overheard by facility staff. University of Kentucky researchers will make every effort to minimize this risk by asking that the follow-up interview be conducted in a confidential setting over a secure phone line.

Your participation or non-participation will not be reported to the parole board or court to affect your parole or status.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Some people find it helpful to be interviewed about their lives and their substance use because it helps them see their health in a different light. Also, these questions about substance use might help you see a need for change and this can be a benefit. However, there are no direct benefits to you for taking part in the follow-up study.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in this follow-up study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still be in good standing with the treatment program for substance use disorders.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the follow-up study, there are no other choices except to not take part in the study.

WHAT WILL IT COST YOU TO TAKE PART IN THIS STUDY?

You will not be charged fees for any of the activities or procedures used in this study. The fees for your participation in the treatment program for substance use disorders will not be increased or reduced because of your taking part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

Because of the steps we have taken to protect your privacy, the risk of unauthorized disclosure of follow-up interview information is minimal. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. Your counselor will ask for your social security number but it will be encrypted to keep it secure and protected. This number helps us match all information clearly to your file; however, if you do not want to give us your social security number, you can still take part in the study. When we contact you 12 months after release, your personal information will not be shared with the Department of Corrections or the Parole Board.

We have obtained a Confidentiality Certificate from the US Department of Health and Human Services (DHHS) to protect the researchers from being forced, even by a court order or subpoena, to identify you. (The Confidentiality Certificate does not imply approval or disapproval of the project by the Secretary of DHHS.) You should know, however, that we may provide information to appropriate individuals or agencies if harm to you, harm to others or child abuse becomes a concern. In addition, the agency funding this research (Kentucky Department of Corrections), staff from the University of Kentucky, the Center on Drug and Alcohol Research, and DHHS agencies (SAMHSA) may review records that identify you as part of their audit procedures.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You have the right to skip questions, terminate your participation at any time, and skip any part of the study, including the focus group. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study

may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is of more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of reasons.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or become ill because of something that is done as a part of participating in the follow-up interviews you should call Dr. Michele Staton at 859-257-2483 immediately. It is important for you to understand that the University of Kentucky will not pay for the cost of any care or treatment that might be necessary because you get hurt or become ill as part of participating in this study. That cost will be your responsibility. Also the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. Health care providers are not allowed to bill your insurance company, Medicare, or Medicaid for these costs without first getting permission. If you have questions about any aspect of evaluation-related costs, you should ask the insurer or party who covers the costs of your treatment. The party that covers these costs may be the state of Kentucky and your counselor can answer questions about this source of treatment funding.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

If you are selected for participation in a 12-month follow-up interview, you will receive \$30.00. In order to get the \$30.00 you must take part in the follow-up interviews, and then payment will be mailed to you. If you choose to participate in any interview but do not complete the interview, your payment will be based on the time of participation.

If you are invited and actually participate in a one-time voluntary study focus group, you will be paid an additional \$10.

WHAT IF YOU HAVE QUESTIONS?

Before you decide whether to participate in this follow-up study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, Dr. Michele Staton at 859-257-2483 or the Study Director, Erin McNees Winston at 859-257-1720. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll-free at 1866-400-9428. We will give you a copy of this consent form to take with you.

WHAT ELSE DO YOU NEED TO KNOW?

This study is funded by the Kentucky Department of Corrections to better understand the treatment of substance use disorders in state-funded programs. You will be told if any new information is learned which may influence your willingness to continue taking part in this study.

Signature of person agreeing to take part in the study

Date

Printed name of person taking part in the study

Name of clinician or clinical staff providing information to participant

Date

Signature of University of Kentucky Investigator

FOLLOW-UP CONDITIONS

I also understand that 12 months post-release, when the University is contacting me for a follow-up interview, I may be living in a treatment facility, institution, or prison. I consent to being contacted in any of these facilities if the University has located me for an interview.

(Check One) _____ Yes _____ No

If there are any other studies being conducted by the University of Kentucky in your area following release from custody, please check here if you'd like to be contacted to hear more about the studies.

(Check One) _____ Yes _____ No