



**Basic Consent to Participate In a Treatment Outcome Study
University of Kentucky Medical Center
Center on Drug and Alcohol Research**

**UK HEALTH FOLLOW-UP STUDY
JANUARY 2005**

WHY AM I 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 substance abuse treatment program. 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 at the substance abuse treatment center and your taking part in the study is not required for admission to the program.

WHO IS DOING THE STUDY?

The persons in charge of the study are Dr. Carl Leukefeld, D.S.W., a professor at the University of Kentucky and Mr. Robert Walker, M.S.W., L.C.S.W., who is an Assistant Professor at the University of Kentucky. Ms. Michele L. Goltz and Ms. Erin Stevenson are research analysts at the University of Kentucky and they will be analyzing data related to this study and will be involved in writing reports on study data. Dr. Tom Jackson is a programmer and systems administrator with the study and he will help in analyzing data and producing reports. Other professionals who work with them as study staff may assist them or act for them. In addition, The University of Kentucky Survey Research Center conducts telephone interviews for this study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to gather information about substance abuse and related issues including mental health problems, employment and education information, arrest information and previous treatment contacts. 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?

The research procedures are a part of your intake at the substance abuse treatment center. When you come in for your intake visits, your counselor will meet with you to gather information. The intake interviews for treatment programs generally take up to three interviews. The information for this study will be collected during one of those interviews. Twelve months after you entered treatment, we will re-contact you by telephone for a follow-up interview. In between the intake and follow-up interview we may contact you and the other people whose names you gave as contacts to keep your contact information as updated as possible. Including the first interviews and the follow-up telephone interviews with you 12 months after treatment, the total amount of time you will be asked to volunteer for this study is about 1 hour over the next year.

**WHAT WILL I BE ASKED TO DO?**

You will be asked to answer questions about substance use and related issues including employment, education, mental health, arrests, and previous treatment contacts. If you are over 18 years old, you will be asked about recent sexual activity related to HIV risk as well as a question about the use of needles or other HIV risk practices with drug use. Your counselor will ask you these questions, but you will not be asked to take part in any experimental treatments or procedures. These questions will be a part of your first interviews with a counselor. 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 after treatment. You may be called to update your locator information so we can reach you 12 months after treatment.

Twelve months later and after treatment, you will be called for a follow-up interview by telephone and you will be asked some of the same questions that you were asked during intake at the substance abuse treatment program. This telephone call interview takes about 20 minutes.

You are also asked to let the researchers use state information about the number and types of state-funded services that you received. This will help researchers examine what types of services are most heavily used by participants 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 I SHOULD NOT TAKE PART IN THIS STUDY?

There are no conditions that would keep you from taking part in this study. If you have been admitted to the substance abuse treatment program, you are eligible to take part in the study. If you are getting only detoxification services or only DUI education, you should not be in the 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. Since you are taking part in this study while you are in treatment, you can talk about this discomfort with your counselor at substance abuse treatment program. The intake interviews are a part of your overall assessment for service needs and your counselor will provide services upon completing these interviews with you. 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.

WILL I 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. Since this study only involves asking questions and not offering experimental treatments, there are no specific benefits to taking part in the study.

DO I HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in this study, it should be because you really want to volunteer. It will not cause you any trouble with your ability to participate in the substance abuse treatment program if you do not take part in this study. 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 substance abuse treatment program.



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

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

WHAT WILL IT COST ME 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 substance abuse treatment program will not be increased or reduced because of your taking part in this study.

WHO WILL SEE THE INFORMATION THAT I GIVE?

Because of the steps we have taken to protect your privacy, the risk of unauthorized disclosure 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 will help 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.

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 (The Kentucky Division of Substance Abuse) and the staff of the University of Kentucky may also see your information if necessary.

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

If you believe you are hurt or become ill because of something that is done during the study, you should call Professor Robert Walker at 859-257-6623 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 while taking part 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.

Usually, medical costs that result from research-related harm cannot be included as regular medical costs. Health care providers are not allowed to bill your insurance company, Medicare, or Medicaid for these costs without first getting permission. You should ask your insurer if you have any questions about your insurer's willingness to pay under these circumstances. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility.

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

You will receive \$20.00 for the follow-up interview at 12 months after treatment. In order to get the \$20.00 you must take part in the follow-up interview, and then payment will be mailed to you.



WHAT IF I HAVE QUESTIONS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the Study Director, Professor Robert Walker at 859-257-6623 or the investigator, Professor Carl Leukefeld at 859-257-2355. 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 1-866-400-9428. We will give you a copy of this consent form to take with you.

WHAT ELSE DO I NEED TO KNOW?

This study is funded by the Kentucky Division of Substance Abuse to better understand the treatment of substance abuse 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 after treatment, 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