

UK HEALTH FOLLOW-UP STUDY
Basic Consent to Participate in a Treatment Outcome Research Study
University of Kentucky Medical Center, Center on Drug and Alcohol Research

WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH? You are being asked to take part in a follow-up treatment outcome research study. You are being asked to do this because you are a client of a medication assisted treatment program. Your participation in this research project is completely voluntary. If you take part in this study, you will be one of about 200 people per year to do so. This research study is separate from your taking part in counseling services at the medication assisted treatment program. Your taking part in the study is not required to get treatment at the program.

WHO IS DOING THE STUDY? The Principal Investigator in charge of the study is TK Logan, Ph.D. who works for the University of Kentucky, and Jennifer Cole, Ph.D. also works with the study. Other professionals who work with the investigators may help them with the study.

WHAT IS THE PURPOSE OF THIS STUDY? The purpose of this study is to gather information about medication assisted treatment services and related behavioral health problems. It also studies employment, education, legal status, stress and health status and your use of treatment services. It is also for the purpose of learning more about your experience with medication assisted treatment.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST? When you come in for your treatment assessment at the clinic where you receive medication assisted treatment, your counselor will ask you questions about substance use and related behaviors. In addition, 6 months after you entered treatment, we will contact you by telephone for a follow-up interview. Not everyone is contacted for these follow-up interviews, but names are selected randomly for the calls. The follow-up interview takes about 20 minutes.

WHAT WILL I BE ASKED TO DO? You will be asked to answer questions about your treatment experience as well as your substance use and related behavioral health problems. You will also be asked about your employment, education, housing, legal status, stress, and your use of services. You will not be asked to take part in any experimental treatments or procedures.

You will also be asked to give contact information so that we can contact you in 6 months. We will ask you for names, addresses, and phone numbers of two persons who would be most likely to know how to reach you at the time of follow-up 6 months after the initial interview questions. We may call you to update your information so we can reach you for the follow-up. If you are called for a follow-up interview by telephone, you will be asked some of the same questions that are asked by your counselor. This telephone call interview takes about 20 minutes.

You are also asked to let the researchers use state information about the number, type and costs of state and Medicaid funded services you receive if your services were funded in part by the state. In addition, you are being asked to let the researchers collect information from public records of arrests and court events that have involved you. You or the people you list as contacts may be contacted by phone, mail, email, or through social networking sites such as Facebook in order to reach you to complete the follow-up interview. We may use publicly available databases to find updated information in order to contact you about completing the follow-up interview. In some cases, we may confidentially try to contact you

through addresses or phone numbers that are or have been linked to you in some way by mail or phone. When trying to contact you, the researchers will continue to keep your connection with the program confidential.

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.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS? There are no known risks to participating in these interviews. 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. 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 during the intake interview you can speak about it with your counselor or the treatment program's staff and at follow-up interview, you will be offered referral resources to national and local agencies.

WILL I BENEFIT FROM TAKING PART IN THIS STUDY? There are no direct benefits to you for taking part in the follow-up study. However, 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.

DO I 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 medication assisted 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 follow-up 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 have any cost for the follow-up interview.

WHO WILL SEE THE UK HEALTH FOLLOW-UP STUDY INFORMATION THAT I GIVE? Because of the steps we have taken to protect your privacy, the risk of unauthorized disclosure of information is minimal. Your information will be combined with information from other people taking part in the study. When we write about the study, we will write about the combined information we have gathered. You will not be identified in these written materials. When we publish the results of this study, 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. All information is stored in computers that are secure and under password protection. Files are encrypted to further protect your confidentiality.

In addition, we have obtained a Confidentiality Certificate (No. DA-11-141) 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 to anyone including judges, probation and parole officials. (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 is disclosed to us. In addition, the agency funding this research

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

WILL I RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY? You will receive \$20.00 for completing a follow-up interview 6 months after your first interview. In order to get the \$20.00 you must take part in the follow-up interview, and then payment will be mailed to you. If you are paid over \$600 in any year from various studies, the University of Kentucky has to report this as income to the IRS. There is no compensation for completing the intake interview.

WHAT IF I 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. TK Logan at 859-257-8248. 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. You may also contact the Cabinet for Health and Family Services Institutional Review Board (CHFS-IRB) at 502-564-5497 ext. 4102. 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 Use Disorder to better understand the treatment of substance abuse including medication assisted treatment. You will be told if any new information is learned which may influence your willingness to continue taking part in this study.

Now that you've read the consent form, choose the appropriate option below stating whether or not the client agrees to being contacted by telephone for a follow-up interview. At that time, a participant can decide again whether they do or do not want to participate in the follow-up interview.

Choose one of the following answers (entering information on the computer screen):

- I agree to be contacted for participation in the research study
- I do NOT agree to be contacted for participation in the research study

If client answers "Do NOT agree"

Thank you for answering these questions. Your information helps improve medication assisted treatment in Kentucky.

If client answers "Agree"

Thank you for agreeing to be in the follow-up study! The last part of the interview asks for some simple locator information that is important to help the UK Health Follow-up Study call you for the second interview. UK will use this information ONLY to locate you for a follow-up interview. Like all the rest of the responses you have just given, the locator information is stored encrypted in a password-protected file to which only approved study staff has access.