Consent to Participate in a Research Study

Targeted Assessment Program (TAP)
November 12, 2008

WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a follow-up study because you have been referred to the TAP program. If you take part in this study, you will be one of about 650 people to do so. This research study is separate from your taking part in services with the TAP program 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 Michele Staton Tindall, Ph.D., an Assistant Professor at the University of Kentucky, Carl Leukefeld, D.S.W., a Professor at the University of Kentucky, and Robert Walker, M.S.W., L.C.S.W., who is an Assistant Professor at the University of Kentucky. Other professionals who work with them as study staff may assist them and act for them.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to gather information about substance abuse, mental health, domestic violence, and learning difficulties, as well as the use of service referrals. This data will be used to learn more about changes that occur among TAP clients.

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

The research procedures are a part of your assessment process at the TAP program. When you first meet with your TAP worker, he or she will gather information. The assessment interviews may take place over one or more interviews and they may be conducted at the TAP office, in the community, or as part of a home visit. Six months after your assessment, we may re-contact you either in person or by telephone for a follow-up interview. Including the first data collection interviews and the follow-up interviews with you 6 months after assessment, the total amount of time you will be asked to volunteer for this study is about 2 hours over the next six months.
WHAT WILL I BE ASKED TO DO?

You will be asked to answer questions about substance use, mental health, domestic violence, and learning difficulties. 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 6 months after your assessment. 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.

Six months after your assessment, you may be randomly selected to participate in a follow-up interview where you will be asked some of the same questions that you were asked during intake. This interview will take approximately 30 minutes.

You are also asked to let the researchers use state of Kentucky 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 referred to the TAP program, you are eligible to take part 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 receiving TAP services, you can talk about this discomfort with your TAP worker. The assessment interviews are a part of your overall assessment for service needs and the TAP worker will refer you to services upon completing these interviews with you. Also, some people may be uncomfortable talking about confidential information. You do not have to answer any questions that you do not want to answer, and you can stop the interview at any time. 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 experiences because it helps them to see things in a different light. These questions about substance use, mental health, domestic violence, and learning difficulties might help you see a need for change and this can be a benefit. In addition, assessment of problems like substance abuse, mental health problems, learning difficulties and domestic violence may help DCBS plan more safely for your future. If you experienced problems in one these four areas, but have not previously disclosed these problems, you are not likely to have received services that could reduce the risk of harm to you or your
children. You may benefit from disclosing problems that can lead to referral to safe shelters, treatment programs, or other services as needed.

**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. It will not cause you any trouble with your ability to participate in the TAP program if you do not take part in this follow-up 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 DCBS and the TAP 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 be charged fees for any of the activities or procedures used 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. Someone from the University of Kentucky and the Cabinet for Health and Family Services may look at or copy pertinent portions of the records that identify you.

A Certificate of Confidentiality has been obtained 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. However, with the certificate, we may provide information to appropriate individuals or agencies if harm to you, harm to others, or child abuse or exploitation becomes a concern. The Certificate does not imply approval or disapproval of the project by the Secretary of DHHS. It adds special protection for the research information about you. In addition, the agency funding this research, the Cabinet for Families and Children, staff from the Center on Drug and Alcohol Research, and staff from the Office of Research Integrity may review records that identify you as part of their audit procedures.
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 Michele Staton Tindall, Ph.D., at 859-543-0078 x238 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 PAYMENT FOR TAKING PART IN THIS STUDY?

You will receive $20.00 for the follow-up interview 6 months after your assessment. In order to receive 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 Principal Investigator, Michele Staton Tindall, Ph.D., at 859-543-0078 x238. 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 Cabinet for Health and Family Services. 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

Printed name of person taking part in the study

Name of TAP Specialist providing information to participant

Signature of University of Kentucky Investigator