

## **KY-Moms: Maternal Assistance Towards Recovery (MATR) Outcome Study Consent to Follow-Up Data Collection**

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

You are being asked to take part in a follow-up research study of the KY-Moms MATR program because you were involved with the program. Your participation in this telephone survey research project is completely voluntary. If you take part in this study, you will be one of about 200 women each year to do so.

### **WHO IS DOING THE STUDY?**

The Principal Investigator in charge of the study is TK Logan, Ph.D. Allison Scrivner, M.S. and Jennifer Cole, Ph.D. also work with the study. There may also be others involved in the study.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

The purpose of this study is to gather information about your health during and after your pregnancy. It also asks about your employment, education, legal status, stress and health status and your use of treatment and KY-Moms MATR services. This interview is part of the evaluation of the KY-Moms MATR program and helps us learn more about your program experiences.

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

The follow-up interviews are done by staff at the University of Kentucky who will contact you by telephone. The phone survey takes about 20 minutes to complete.

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

You will be asked to answer questions about your health during and after your pregnancy including substance use and related behavioral health. You will be asked about your employment, 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 about 6 months after you give birth. We will ask you for the names, addresses, and phone numbers for you and up to two persons who would be most likely to know how to reach you at the time of follow-up about 6 months after the baby is born. 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. You are also asked to let the researchers use state information about the number, types and costs of state and Medicaid funded services you receive and medical information about your health and birth outcomes at the time of the delivery of your baby.

### **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 express discomfort during the follow-up interview, you will be offered referrals to local and national resources.

**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 women find it helpful to be interviewed about their health and their pregnancies because it helps them see their health in a different light. Your opinion will also help provide information about how best to help pregnant women and how to improve the KY-Moms MATR program, and may also help obtain future funding for the program.

**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.

**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 participate.

**WHAT WILL IT COST ME TO TAKE PART IN THIS STUDY?**

You will not have any cost for participating in any part of this research 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 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, which means the data are scrambled so that only authorized viewers with a passkey are able to see it.

To further protect your information, we have a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. 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 a completed follow-up interview at 6 months after you have given birth. 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 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, Professor 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. You can ask for a copy of this consent form to take with you if you wish to do so.

**WHAT ELSE DO I NEED TO KNOW?**

This study is funded by the Kentucky Division of Behavioral Health to better understand the effects of the KY-Moms MATR program.

By choosing the appropriate option below, the client agrees to being contact by telephone approximately 6 months after giving birth 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.

- 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 prenatal services for other women in Kentucky like yourself.**

**If client answers "Agree"**

Thank you for agreeing to let us get in touch with you in the future. This last section asks you about some information to help us contact you. 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. We will only use this information to locate you in the future, and it will not be given to anyone else. One thing we will ask is whether we can contact someone you know (like your mother or grandmother) to reach you. If we do that, we will not tell that person anything except that you have been asked to take part in a **health program follow-up study**.