CONSENT FORM

PARENT-CHILD ASSISTANCE PROGRAM (PCAP)
University of Washington Department of Psychiatry & Behavioral Sciences

Researcher:
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PCAP is a program that offers 3 years of support and services to mothers who used alcohol or drugs during pregnancy. PCAP advocates offer home visits and connect clients with needed community services to help families become healthy and stable.

Researcher’s Statement:

Why is the research taking place?

The University of Washington is doing this research to learn how 3 years of working with an advocate may help women and their families. They want to learn what kinds of services are useful. They want to know if the program helps women become healthy and alcohol and drug free.

The purpose of this consent form is to give you information to help you decide if you want to be in the PCAP research. Please read the form carefully. You may ask questions about why the research is taking place, what you would be asked to do, the possible risks and benefits, your rights as a person in this study, and anything else that is not clear. When all your questions have been answered, you can decide if you want to be in the study. This is called ‘informed consent.’

What would I be asked to do?

If you agree to take part in the research, I, the clinical supervisor, will do a research interview with you before you start PCAP. After 3 years in the study, a University of Washington researcher would interview you. If you do the first interview and agree to take part in the study, your answers will be given to the study team at the UW. You don’t have to take part in the research.

If you don’t want to take part in the study, I will talk with you to find out how PCAP can help you and your family; your answers would not be given to the UW study team.

If you decide to take part in the study, I will ask you questions in the PCAP office or another place you choose, such as your home or in treatment. I will ask about your family, your use of drugs and alcohol, your pregnancy history, and your arrest history. The interview takes about 1 hour. Many questions are very personal. Examples of these questions are:

"Have you worked as a prostitute for either drugs or money?"
"Have you ever been arrested because of your drug use?"

I will ask you questions about childhood abuse. Examples of these questions are:

“Did a parent or other adult in the household ever hit you so hard that you had marks or were injured?
“Did an adult or person at least 5 years older than you ever try to or actually have oral, anal, or vaginal sex with you?

I will ask about your mental health. For example:
“I have felt scared or panicky for no good reason.”
“The thought of harming myself has occurred to me.”

The advocate you work with at PCAP will ask you about your children. For example:
“How old are you children?”
“Where do your children live?”
“Do any of your children have fetal alcohol syndrome?”

The advocate you work with will tell the UW researchers if certain things happen during your time with PCAP. This includes:
Having another baby
If you used alcohol or drugs during pregnancy
If a doctor says that you have a mental illness or that you or your child has fetal alcohol syndrome
If you or your child die

After 3 years in PCAP, a UW researcher will interview you, and ask you to fill out a form about your work with your advocate. You would be asked if you agree with statements such as, “My advocate helps me learn how to solve my problems.” The researcher would share the information on this form with PCAP staff so we can improve services. The researcher would take your code number off the form before sharing it.

You don’t have to answer every question they ask for the study.

What are the possible risks or harms if I take part?
Risks could include breaks in the privacy of information about you. If you say that you may harm yourself or others, we will report it to a mental health worker or the police. If we become aware of child abuse or neglect, we will report it to CPS. Some questions are very personal and you might be upset by them. You may have a hard time reading or understanding some questions. If this happens I will explain the questions to you.

What are the possible benefits?
Benefits of being in the PCAP study may include an increase in knowledge about how women can become healthy and alcohol and drug free.

What are my choices if I don’t take part?
You don’t have to be in this study if you don’t want to. You don’t have to answer every question. You may leave the study at any time. If you want to leave, you can call the head researcher at the toll free number listed at the top of this form. You won’t be penalized in any way if you decide not to take part, skip questions, or leave the study early. You can get PCAP services even if you don’t want to take part in
the study. The UW study team would destroy all research information about you and wouldn’t contact you again.

Who would see study information about me?

Three groups of people may see study information about you:

- **The research team at the University of Washington.** The research team will keep your study information confidential. Study forms use a code number, not your name. Your name will be kept separate from information about you that is collected for the study. The UW study team will not see your PCAP program information, such as notes that your advocate keeps about her work with you. The UW research team will only use information about you for their research. They won't give study information to CPS or your DSHS caseworker. They may give information about you to DSHS researchers, including your name and other information that could identify you. DSHS researchers may want to use your information to evaluate agency programs and services. The UW researchers may give study information that doesn’t identify you to other researchers. **All researchers are required to keep study information confidential.**

  The UW researchers have a Confidentiality Certificate (CC) from the US government. The Certificate adds special protections for your privacy. This means that the UW study team can't be forced to give research information to anyone, even if a court orders them to. But if you want them to give study information to other people or agencies, you would need to give the UW researchers permission in writing. If the study is audited, the auditor may see research information about you.

- **PCAP program staff.** PCAP program staff will collect and use information about you so we can help you get services. Information to help you get services is **not** protected by the Certificate of Confidentiality.

- **The courts.** You may be asked to sign a release form that gives permission for PCAP program staff to talk about you in court or to give information to a lawyer or probation officer. If you do this, the court might try to get other information about you. The court could try to get information the UW researchers collect for the study. Even if you don’t sign a release form, PCAP program staff might have to give information about you if a court orders us to.

**There are some exceptions to the protection of your privacy:** 1) PCAP could be ordered by a court to release your program records. 2) If you reveal that you may hurt yourself, we will call a mental health worker or the local Crisis Line. 3) If you threaten to hurt someone else, we will call the police. 4) If we become aware that a child is being abused or neglected, we will report it to Child Protective Services.

Would I be paid for my time? Will the study cost me anything?

You don’t have to pay to be in the study. The UW study team will pay you $20 for taking part in the second interview in 3 years.
What else do I need to know?

If you decide to be in this study, the UW study team will keep your research information for 7 years after the study ends. This includes your name and all research information. At the end of your 3 years in PCAP, a UW researcher will ask you if it is OK to get in touch with you in the future for a similar study.

You have rights as someone who takes part in research. If you have questions about these rights, or complaints about the UW study, you can call the Washington State Institutional Review Board. The Board oversees this study to protect your rights. You can call toll-free at (800) 583-8488. You don't have to give your name if you call.

If you agree to participate:

This study has been explained to me. The PCAP clinical supervisor told me that some questions may be very personal. I was told that if I plan to hurt others or myself, it will be reported to the police or to a mental health worker. If they are concerned about child abuse or neglect, they will report it to CPS. The UW researchers will pay me $20 for the 3-year exit interview. I freely agree to be in this study. I don’t have to answer every question and I can leave the study at any time, without penalty. I have had a chance to ask questions. If I have any questions about the study or want to leave the study I can call the head researcher at the toll free number listed at the top of this form. If I have any questions about my rights as a person in this study, I can call the Washington State Institutional Review Board.

I have been told that PCAP staff may have to release program information about me, if a court orders them to.

Copies to:  Participant
            Clinical supervisor’s file