



CONSENT FORM

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

Head 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 case managers 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 a case manager may help mothers and their families. They want to learn what kinds of services are useful. They want to know if the PCAP program helps mothers become healthy and alcohol and drug free. This study is funded by the Washington State Health Care Authority.

The purpose of this consent form is to give you information to help you decide if you want to be in the PCAP research study. 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 will do a research interview with you before you start PCAP. After 3 years in the study, another 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.

If you decide to take part in the study, I will ask you questions while you are 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 2 hours. 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?"

During the program, the case manager 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 case manager 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

The case manager you work with or I will also ask you about your mental health. For example:

- Have you been feeling down, depressed or hopeless?
- Have you had trouble remembering parts of stressful events from your past?

After 3 years in PCAP, a UW researcher will interview you and ask you to fill out a form about your work with your case manager. You would be asked if you agree with statements such as, “My case manager 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?

There may not be a direct benefit to you, but being in this study might help researchers better understand how mothers 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 the PCAP research study if you don’t want to. If you don’t want to take part in the research study, you can still be in the PCAP program. If you decide not to be in the research study, we would still talk with you to find out how PCAP can help you and your family, but your answers **would not** be given to the UW study team. If you decide to be in the study, you don’t have to answer every question. You may leave the study at any time. If you want to leave, you can write to or 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. The UW study team would destroy all research information about you and wouldn’t contact you again.



If a court or Child Protective Services (CPS) orders you to be in PCAP, your case manager will provide all PCAP services to you and your family. If you don't want to take part in the PCAP research study you don't have to. You won't be penalized by CPS or the court if you are not in the PCAP research study. If you decide not to be in the research study, a member of the PCAP program will still interview you when you start the program to find out how your case manager can help you and your family, but your answers would not be given to the research study team.

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 case manager keeps about their 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 researchers from Washington State Health Care Authority (HCA), including your name and other information that could identify you. HCA 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 without your written consent. All researchers are required to keep study information confidential. If the research team writes any reports about the PCAP research program, we won't use your name or any other information that could identify you.

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 (the clinical supervisor and your case manager) 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 or give you a \$20 gift card 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 6 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. You may call the Washington State Institutional Review Board if you have questions, concerns, complaints, or to offer input about your rights in this research study. 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.

INVESTIGATOR SIGNATURE	DATE
<p><u>If you agree to participate:</u></p> <p>This study has been explained to me. The interviewer 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 researcher will pay me \$20 or give me a \$20 gift card 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, or if I want to report a research-related problem, I can call the head researcher at the 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.</p> <p>I have been told that PCAP staff may have to release program information about me, if a court orders them to.</p>	
PARTICIPANT SIGNATURE	DATE

Copies to: Participant
 Clinical supervisor's file