

PCAP Clients as Human Subjects: Special Considerations (“ABCs of IRB”) for Participation

PCAP currently operates under Washington State Institutional Review Board (IRB) oversight because some PCAP data is collected for the purpose of research in addition to evaluation. There are special considerations and protections for people (“human subjects”) who participate in research, especially vulnerable people such as our clients. This is why all PCAP staff at hire are required to understand their role in the protection of human subjects.

A. Who can participate in the PCAP research?

Only mothers who are able to give voluntary consent can participate in the PCAP research. Therefore, we DO NOT conduct any research activities with a client who is:

- In prison, jail, on furlough, in a work release program, under house arrest, electronic home monitoring or in a Community Parenting Alternative (CPA), or being detained in treatment or other setting as an alternative to criminal prosecution (e.g., Drug Offender Sentencing Alternative “DOSA”) and Family & Offender Sentencing Alternative (“FOSA”) or as part of a court order, or legally restricted in her freedom of movement (*see exceptions, below**);
- mentally incapacitated due to intoxication or severe mental illness; or
- under the age of 18; or
- unable to understand and speak English.

Mothers under these restrictive conditions do not have total freedom of movement and therefore cannot give voluntary consent. They may feel that by agreeing to participate in research, they may garner special treatment (e.g., by the courts).

**Women who do have freedom of movement are considered by IRB to be able to give voluntary consent. For example, women on probation/parole; in drug/family treatment/mental health courts; or who has a restraining order against her at the time of referral, is able to give voluntary consent.*

B. Who collects PCAP data for research, and what forms do they use?

- Site supervisors or UW ASI interviewers administer the **Intake ASI interview** (research pre-test).
- Site exit interviewers or UW ASI interviewers administer the **Exit ASI interview** (research post-test).

The ASI Interviewers are the ones who can determine if the mother can voluntarily consent to participate in these two types of PCAP research interviews.

Case managers do not collect PCAP data for research. Case managers fill out evaluation forms that are used for documenting client progress. The forms case managers fill out (e.g., Monthly Update, Goals, Biannuals, etc.) are not administered as interviews, nor are they used for research. Case Managers also fill out the DLC, Difference Game, Biological Children at Enrollment, and Subsequent Birth forms, but should never do so while visiting a client in jail, because these forms may be used in the research.

C. What are the IRB Rules for PCAP Research Recruitment, PCAP Research Intake, and PCAP Research Exit?

IRB Rules For PCAP Research Recruitment

The supervisor uses the approved **Research Study Recruitment Script** to talk to a potential client about the PCAP research study. This IRB script is built into the Community Referral Screening Questionnaire (CRSQ) and includes the following language:

“The University of Washington is conducting a study to learn how three years of help from a case manager may help women and their families. We want to know if the program helps them become healthy and alcohol and drug free.”

IRB Rules For PCAP Research Intake

The supervisor or UW ASI interviewer guides potential study subjects through an IRB-approved consent process. The mother then decides for themselves whether or not they agree to take part in the study. If they agree, they sign an IRB-approved **Intake Consent Form** prior to taking part in the intake research interview.

IRB Rules For PCAP Research Exit

Under no circumstances may any PCAP staff member:

- talk with a client who fits any of the criteria in Section A (on page 1) about arranging a PCAP exit interview; or**
- intervene with a client’s legal counsel for the purposes of arranging an exit interview.**

Any PCAP staff who approach their PCAP clients about taking part in a research exit interview must use the appropriate IRB-approved [Exit Interview Script for Case Managers](#). This script includes the following language:

“The researcher would like to give you information to help you decide if you want to participate in the study exit interview. If you decide to take part, she will interview you for about an hour and ask you to fill out a form. She’ll pay you \$20 for taking part in the interview. You don’t have to be in the study if you don’t want to. You won’t be punished in any way if you decide not to take part.”

There is another version of the exit script for case manager to use when a client is missing and being traced. That script is called [Exit Interview Locator Script for Case Managers](#). All IRB scripts and consent forms are located on the PCAP website intranet, under Protocols and Forms > IRB forms.

After determining that the client is able to voluntarily consent, the exit ASI interviewer guides the PCAP client through the IRB-approved consent process. The client then decides whether or not she agrees to take part in the exit/follow-up interview. If she agrees, the interviewer has her sign an IRB-approved Follow-Up/Exit Interview Consent Form prior to the interview.

Printed Name

Signature

Date

For questions about any of this, please contact Stacy Dimmich @ sdimmich@uw.edu.