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OMB control Number 0990-0421
Expiration Date: October 12, 2020

Community Burden Substudy Informed Consent Parents/Caregivers

What is the purpose of this study?

ICF is a research company and we are working with the Centers for Disease Control and Prevention (CDC) to learn about how opioid use is impacting families across the country. As part of this work, we are conducting [interviews with parents, interviews and focus groups with family caregivers and foster parents who have cared for children affected by a parent's substance use issues] to understand how opioids and other substance use has affected children and families. We are also interested in learning about the support services available to families and caregivers, and how improvements can be made to help families struggling with opioid/substance use.

What will I have to do if I participate?

You have been invited to participate in this discussion because you were identified as a [parent who; kinship caregiver/foster parent caring for a child whose parent] has struggled with opioid/drug use and you live in one of the counties that we are conducting interviews in. If you agree to participate, we will ask you some question related your experiences [as a parent struggling with opioid/substance; caregiver/foster parent caring for a child whose parent has struggled with opioid/drug use.] Our discussion today will last about [60, 90] minutes.

We will reimburse you \$50 for the costs associated with your participation, such as child care and/or transportation.

Is my participation voluntary?

Your participation in this discussion is completely voluntary and you can choose not to participate. If you do participate you can stop at any time or choose to not answer a question for any reason. Refusal to participate will not involve any penalties or loss of benefits to which you are entitled.

What are the risks to participating?

During our discussion, I will ask about [your; the parent's] struggles with opioid/drug use and how those struggles may have impacted [your, the] children. It can be difficult to talk about these experiences, and you may feel some discomfort sharing this information. You can choose to not answer any questions that might make you feel uncomfortable. In addition, you are free to take a break or stop participating at any time.

What are the benefits to participating?

While you may not directly benefit from being in the study, the insights gained from your participation may help CDC and its partners identify resources that might be effective at preventing opioid misuse while also providing safe, stable, and nurturing environments for children and their families.

Will information about me and my participation be kept private?

We will keep your information private. We will not include any information in our reports that will make it possible to identify you and you will not be identified by name or description in any reports. If we tape-record the interview, we will destroy the tape after it has been transcribed. We will also not ask for your name during the interviews. As a further protection, we will not attribute any information directly to you. All information will be reported as a group summary.

To help us protect your privacy, we have obtained a Certificate of Confidentiality¹ from the Centers for Disease Control and Prevention. With this Certificate, the researchers for this study can legally refuse to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

An exception to the Certificate of Confidentiality is that we are required to report any evidence of child abuse or intent to hurt yourself or others.

What if I have questions about the study?

We will do our best to answer any questions you have about the study before we begin the interview/focus group.

If you have any additional questions about the study, you may contact the project director, Gary Chovnick, at (206) 801-2814 or gary.chovnick@icf.com. If you have any questions about your rights as a research study participant, you may contact Dr. Carole Harris (IRB Chair) at (404)321-3211 or IRB@icf.com.

For Focus Group Participants

As part of this study, you will be placed in a group of about 6 individuals. A moderator will ask you several questions while facilitating the discussion. Please note that there are no right or wrong answers to focus group questions. We also want to hear the many different viewpoints and would like for everyone to contribute their thoughts. Out of respect, please refrain from interrupting others. However, feel free to be honest even when your responses are different from those of other group members.

Should you choose to participate, you will be asked to respect the privacy of other focus group members by not repeating what was shared in the focus group to others outside of the group. Researchers will take every precaution to maintain confidentiality of the data, however, the nature of focus groups prevents us from guaranteeing confidentiality from other members.

Audio Recording and Consent

With your permission, we would also like to audio record the discussion to ensure we accurately capture the information shared. You will not be identified by name on the recordings and all recordings will be destroyed after the data has been collected and reviewed. Your name will not be stored or connected with any of your responses or used in any reports.

¹ Under the authorization of CFR 5 Part 1320 Section 1320.8.