

Attachment F. Informed Consent Form

Form Approved
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BIRCH Study Informed Consent Form

Title: Building Indigenous Resilience in Communities and Homes (BIRCH) Study

Protocol No:

Sponsor: Centers for Disease Control and Prevention, National Center on Injury Prevention and Control

Investigator: Erica Roberts, PhD, MHS
James Bell Associates, Inc.
3033 Wilson Blvd
Arlington, VA 22201

Study-Related

Phone Number(s): (703) 842-0964

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

This purpose of this research is to learn about the community supports and resources available to children and families in Native communities affected by opioid and other substance use. As part

of this work, we are conducting small group discussions and individual interviews in different Native communities across the U.S. The Centers for Disease Control and Protection (CDC) is funding the project. About 120 people will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will involve completing a survey and participating in a 2-hour focus group or interview. The research team may reach back out to you after the focus group or interview to confirm or further understand the information you shared during the discussion. Once those steps are complete, your time in the study will be done.

What happens to me if I agree to take part in this research?

If you agree to participate, you will be asked to:

- Complete a short survey and
- Participate in a small focus group discussion or an individual interview.

The survey and focus group discussion/interview cover many topics, such as childhood experiences positive community supports, and how adverse childhood experiences and substance misuse are affecting children and families in your community. You may be contacted after the focus group or interview discussion to confirm or further understand the information you shared.

Could being in this research hurt me?

As a research participant, there are a few possible risks to you. Although the research team will keep all data files in secure locations, there is the chance that someone who should not see your information might see it. You might feel uncomfortable with some parts of the study. For example, some questions we ask are personal and you may feel some discomfort sharing personal information. You are free to say “no” to any part of the project and 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.

Will it cost me money to take part in this research?

It may cause you money to travel to the site of the interview or focus group.

Will being in this research benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, this research may help CDC and its partners identify resources that might be effective at providing safe, stable, and nurturing environments for children, and their families, in Native communities. You can be part of this important research. Many people find it helpful to think and talk about their lives, their families, and other information about themselves. Being in the study gives you a chance to do this.

What happens to the information collected for this research?

Your personal information will not be stored or connected with any of your responses and your responses will not be linked to you personally. Research staff will use a study number instead of your name on all of your data and will analyze data from everyone in the study as a group. When research staff share project results and data, they will not identify any one person. Project data are for research and education purposes only. All information and data are stored in safe, locked

areas. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the CDC. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, tribal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if the researchers hear reports of child abuse and neglect or harm to self or others. Researchers are mandatory reporters and will be legally obligated to make a report to appropriate authorities.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Is participation voluntary?

Your participation in this research is completely voluntary and you can choose not to participate. You have the right to change your mind about being in the study at any time and can choose to skip or not answer any question(s) for any reason.

Will I be paid for taking part in this research?

For taking part of this research, you will be paid \$75 for the costs associated with your participation, such as childcare and/or transportation, as well as your time and knowledge.

Will the discussion be recorded?

With your permission, we would also like to audio record the focus group discussion/interview to ensure we accurately capture the information shared. You will be identified by first name only on the recordings and all recordings will be destroyed after they are transcribed and reviewed. When the recording is transcribed (meaning it is written as a script), your name will not be written. Instead, the researchers will use a study number (such as Participant 1) in the place of your name. Prior to starting the group discussion/interview, research staff will request verbal consent to audio record. If any participant declines to be audio recorded, the focus group/interview will not be recorded, and research staff will take detailed notes during the discussion.

My consent

I have read and I understand the information on this consent form. I have had all my questions answered. I agree to take part in the project.

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent

Date

Signature of person obtaining consent

Date