

Investigator Name: Erica Roberts, PhD, MHS	Board Action Date: 04/08/2021
Investigator Address: 3033 Wilson Blvd, Suite 650 Arlington, VA 22201, United States	Approval Expires: 04/08/2022 Continuing Review Frequency: No CR Required
Sponsor: Centers for Disease Control and Prevention Institution Tracking Number:	Sponsor Protocol Number: None Amended Sponsor Protocol Number:
Study Number: 1305769	IRB Tracking Number: 20211382
Work Order Number: 1-1416627-1	
Protocol Title: Building Indigenous Resilience in Communities and Homes (BIRCH) Study: Formative Research on Community-Level Factors that Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Use Among Children, Youth, and Families in Tribal American Indian and Alaska Native (AI/AN) Communities	

THE FOLLOWING ITEMS ARE APPROVED:

Investigator
 Advertisement - Flyer - Seeking Participants for Research Study #30405951.0 - As Submitted
 Protocol (03-2021)
 Consent Form [S0]
 Consent Information Sheet - Oral Consent [S0]
 Tribal Communities Study Information Letter #30405949.0 - As Submitted

Please note the following information:

WaiveDoc 46.117risk-both rules - The Board found that this research meets the requirements for a waiver of documentation of consent under 45 CFR §46.117(c)(1)(ii) [2018 Requirements] 45 CFR 46.117(c)(2) [Pre-2018 Requirements] for subjects who are consented over the phone. In-person subjects will provide written consent.

The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

Under the revised common rule (effective 1-21-2019), continuing review by the Board of the above referenced research is not required; however, the IRB will maintain our records and continue responsibility for exercising administrative and regulatory oversight of this research. The IRB will automatically charge an Ongoing Oversight fee for this administrative effort unless we are notified the research is closing. To avoid unnecessary fees due to closure, a closure form must be submitted for each site 30 days prior to expiration.

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

James Bell Associates, 3033 Wilson Blvd, Suite 650, Arlington, Virginia 22201

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT WCG IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



- Submit proposed modifications to the IRB prior to their implementation.
 - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- For research subject to continuing review, submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
 - The protocol is permanently closed to enrollment
 - All subjects have completed all protocol related interventions and interactions
 - For research subject to federal oversight other than FDA:
 - No additional identifiable private information about the subjects is being obtained
 - Analysis of private identifiable information is completed
- For research subject to continuing review, if research approval expires, stop all research activities and immediately contact the IRB.
- Promptly (within 5 days) report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.

If the IRB approved an e-consent process that involves uploading the approved consent form to an e-consent platform, please ensure that the consent form(s) approved for your site is the version of the consent form that gets uploaded to the platform. If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by WCG IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. "

For research subject to continuing review, you will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

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Contact, Company

Erica Roberts, PhD, MHS, James Bell Associates