SUPPORTING STATEMENT: PART B

Formative Research on Community-Level Factors that Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Misuse Among Children, Youth, and Families in American Indian and Alaska Native (AI/AN) Communities

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

This proposed data collection will consist of a series of semi-structured focus groups/interviews and a brief demographic survey to understand the impact of the opioid epidemic among American Indian/Alaska Native (AI/AN) populations in the U.S. The research study will collect and analyze data that will identify AI/AN community resources or supports that might be effective at preventing adverse childhood experiences (ACEs) and opioid misuse at the community level while also providing safe, stable, and nurturing relationships and environments for all AI/AN children and their families. The respondents for this data collection are individuals in the U.S. aged 18 years and older affected by the opioid epidemic from urban and rural Tribal communities in two diverse geographic regions. The data collection will involve well-established methods which include semi-structured in-depth individual interviews and focus groups. A brief demographic survey will be included and will be collected using pen and paper surveys in person (or through an online platform the mail if necessary).

There will be a total of four Tribal communities that participate in the study: one urban and one rural/reservation community in the Pacific Northwest region (e.g., Washington state) and one urban and one rural/reservation community in the Great Lakes region (e.g., Minnesota). Academic partners familiar with the tribal communities in these areas will act as liaisons to confirm the level of confidentiality that each Tribal community requests.

Protections of Tribes and Confidentiality
On January 26, 2021 the White House issued a Memorandum for the Heads of Executive Departments and Agencies titled "*Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships"*. This memorandum acknowledged and recommitted federal agencies to respect "tribal sovereignty and self-governance, commitment to fulfilling Federal trust and treaty responsibilities to Tribal nations…". Moreover, the memo states that, "we best serve Native American people when Tribal governments are empowered to lead their communities, and when Federal officials speak with and listen to Tribal leaders in formulating Federal policy that affects Tribal Nations." (Biden, 2021). This memo is supported by Executive Order No. 13175.

CDC's Tribal Consultation Policy was last updated in 2013 and states that "Indian Tribes have an inalienable and inherent right to self-government. As sovereign nations, Indian Tribes exercise inherent sovereign powers over their *members* [emphasis added], territory, and lands. As a Federal organization, CDC recognizes its special commitment and unique relationship with Indian Tribes and is committed to fulfilling their critical role in promoting the health and safety of Indian Tribes." (CDC, 2013).

The sovereign status of Federally Recognized Indian Tribes (FRTs) is further recognized in Title 45 Public Welfare Department of Health and Human Services, Protection of Human Subjects - also known as the *Common Rule.* For example, Subpart A, §46.101 states that Tribal laws must be followed and such laws may include additional protections in human subjects research (45 CFR 46.101(f), Subpart A).

There are currently 574 FRTs. The listed Indian entities are acknowledged to have the immunities and privileges available to federally recognized Indian Tribes by virtue of their government-to-government relationship with the United States as well as the responsibilities, powers, limitations, and obligations of such Tribes. A full list of FRTs can be found at: *https://www.federalregister.gov/documents/2021/01/29/2021-01606/indian-entities-recognized-by-and-eligible-to-receive-services-from-the-united-states-bureau-of*

The target audience for this research study includes adults from four respondent groups (i.e., parents/caregivers; Tribal Elders, Tribal Leaders, and traditional healers; community leaders and service providers; and young adults). Eligibility for participation will be determined using telephone screening (see **Attachment D**). Inclusion criteria includes 18 years or older; being affected by the opioid epidemic; self-identified AI/AN among Tribal Elders/Tribal Leaders/traditional healers, and young adults; and parents/caregivers of AI/AN children or community leaders/service providers (see additional inclusion criteria in **Table 1. Focus Groups or Interviews for the Study**). In each of the four communities, three focus groups (one with each type of respondent group) will be conducted for a total of 12 focus groups (see **Table 1. Focus Groups or Interviews for the Study**). The expected response rate for participation is 75% or greater of eligible individuals (see **Table 2. Total Number of Respondents for the Assessments Over a Three-Year Period**).

Table 1. Focus Groups or Interviews for the Study

Respondent group and number of focus groups/interviews	**Inclusion criteria**
Parents/caregivers, 4 focus groups (up to 8 parents/caregivers each; up to 32 total)	18 years or older; being affected by the opioid epidemic; have at least one AI/AN child who is under the age of 17 years
Tribal Elders/Tribal Leaders/Traditional healers, 4 focus groups (up to 8 Tribal Elders/Tribal Leaders/Traditional healers each; up to 32 total) and up to 12 interviews	18 years or older; being affected by the opioid epidemic; self-identified AI/AN
Community leaders and service providers, Up to 12 interviews	18 years or older; being affected by the opioid epidemic; Must represent public health, behavioral health, clinical health, and/or other service provider in the community or a community leader who provides indirect services to the local Tribal community.
Young adults, 4 focus groups (up to 8 young adults; up to 32 total)	Age 18 to 24 years; being affected by the opioid epidemic; self-identified AI/AN; prior experiences disruptive to youth's environment including involvement in the foster care system, residential Indian boarding school, youth regional treatment center, justice system involvement, or being placed out of the home and into in a kinship care situation

Table 2. Total Number of Respondents for the Assessments Over a Three-Year Period

Numbers and Cooperative Rates	Three Year Total
Number of potential respondents to be contacted	160
Expected cooperative rate	75%
Number of completed data collections*	120

*Computed based on anticipated respondents in focus groups

B.2. Procedures for the Collection of Information

The research team will conduct site visits to urban and rural Tribal communities within two diverse geographic regions to complete the in-person focus groups or interviews, depending on what is most culturally appropriate and feasible for recruitment, scheduling, and data collection for the community. For example, A recruitment/informational flyer **(Attachment O)** will be posted at local community organizations (e.g. health clinic, community center) and provide study and contact information for potential participants. Potential participants will contact the research team and the screener **(Attachment D)** will be implemented for individuals who show interest in participating. Due to COVID-19, at the time of the focus groups/interviews, social distancing and public health safety measures will be implemented, including considerations for phone/virtual meetings instead of in-person sessions. The research team will work with each of the four communities to provide respondents with a plain language letter reminding them about the project and where and when the focus group/interview will take place (see **Attachment C**). This letter includes defining what a focus group/interview is and is not, how it may resemble certain cultural practices (e.g., talking circles) and how it differs from those practices, how information is confidential and other ground rules and norms for the focus group or face-to-face interview in order to protect human subjects. Telephone screening of interested individuals will be used to determine eligibility for participation (e.g., affected by the opioid overdose epidemic), assess whether support is needed for reading through the consent form and survey ahead of the interview or focus group, and to further identify and recruit potential respondents (see **Attachment D**). If the potential participant need assistance with reading the consent form, then the screener will offer to read the consent form and survey over the phone now or schedule a separate call, or ask that they arrive at the focus group/interview 15 minutes early, where a researcher will help them read through the documents in person. After the research team has determined eligibility potential respondents will be asked if they are interested in participating in the focus group/interview at the designated date, time, and location. If yes, they will be sent a reminder to confirm their participation approximately one week prior to the scheduled session (see **Attachment E**). Respondents will also receive a reminder 24 hours prior to the focus group/interview (see **Attachment G**). In the event it is necessary to conduct the focus group or interview virtually, respondents will be asked to travel to a facility where internet access can be obtained. The aim is to conduct all data collection in person during site visits to each of the four communities. However, it is anticipated that scheduling conflicts may necessitate conducting some interviews over the phone after the site visit to complete all data collection. For recruitment and scheduling purposes, contact information (e.g., address, personal phone, email address) for

each respondent and additional contact information for a secondary contact person will be contained at the contractor site in a secure dataset. This will only be used for recruitment purposes. PII will not be collected when the demographic survey is administered. This information will not be shared with the Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) and will be deleted upon completion of data collection.

Unless completed beforehand for those who need an accommodation, respondents will sign a written consent form at the scheduled session (**Attachment F)**. The informed consent will include an explanation of the study, the goals of the discussion, confidentiality, voluntary nature of participation, risks and benefits of participation, duration of participation, contact person for the research including the chair of the IRB, permission to create an audio recording, option to decline to answer any question they do now wish to answer either in the focus group/interview or the survey, the right to withdraw without penalty, and provide an opportunity for respondents to ask questions. If respondents choose to participate and sign the consent form, they will be given a copy of the form for their records.

The data collection will take place at a time and place that is convenient for the respondents. Locations will be private (e.g., local tribal health clinic). The aim is to conduct all data collection in person during site visits however, due to COVID-19, the focus groups/interviews, may involve phone/virtual meetings instead of in-person sessions. If COVID-19 restrictions and protections are implemented, then participants will need to travel to a private safe location with broadband internet access. The focus groups/interviews will be audio-recorded with the consent of the respondents, and transcribed. Locations will be selected based on low ambient sound when possible so as not to interfere with the recording quality. The research team will also collect data with pencil and paper, including situations where audio recordings are not feasible. Two recording devices will be used to ensure no data are lost secondary to an inferior recording. All materials will be kept in locked cabinets in secure locations. Transcripts of the focus groups/interviews will be scrubbed to exclude such personal identifiable information (PII). Recordings will be kept in locked secure areas. PII required to recruit for the study, such as contact information, will be kept in separate locked cabinets from the data collection (e.g., surveys, recordings).

Respondents will complete a written survey (**Attachment I**) that includes questions about demographic characteristics (e.g., level of education, annual income, and others) that will take about 25 minutes. The survey contains items validated and used in multiple research settings.

Discussion guides are developed to help ensure that the research team systematically covers each topic of interest while allowing the questions to be open-ended so respondents can reply freely of their own accord. The trained data collector will guide the discussion with probing questions as needed. The absence of a structured script helps develop rapport between the research team and respondents, which increases the completeness of the data. Probes for the focus groups/interviews will be tailored to the respondent group (e.g., parent/caregiver) (see **Attachments J - L**).

Prior to starting the focus group/interview discussion, the research team will request verbal consent to audio record. If a respondent declines to be audio recorded, the focus group/interview will not be recorded, and the research team will take detailed notes during the discussion. While collecting information for research analysis purposes, the research team will inform respondents that although their names will not be used in summaries or reports, a goal of the study is to disseminate information about promising strategies which may necessitate naming the community's geographic location. Respondents will also be informed that they may skip any question or stop the data collection at any time without penalty. Focus groups/interviews will last two hours. Focus groups/interview discussions will include positive aspects of growing up in the Tribal community, community supports and resources that may help prevent opioid and other substance misuse and ACEs, and prevention strategies being implemented to prevent ACEs and address opioid and other substance misuse, including for the next generation. The research team will be trained and instructed on crisis procedures should one arise and instructions for when respondents become uncomfortable, distressed, or wish to discontinue. All respondents will be provided with a community-specific list of mental health care referral services that they may consult as needed (**Attachment H**).

Following each collection, the research team will immediately check the quality of the recordings and written notes. If any issues are found, the research team will immediately fill out the notes from memory to supplement the audio recording (e.g., for parts of the audio recording that could not be heard due to background noise). All audio recordings from the discussions will be stored on a secure network. Only the research team will have access to this network and only those working directly on the project will have access to the project folder on the network where recordings will be saved. The research team will be responsible for uploading the audio files from each site to the secure network. A secure FTP site will be used to transfer audio files to a sub-contracted professional firm for transcription. The firm will sign a confidentiality agreement. The contractor will instruct the firm to scrub names and any other PII from the transcripts prior to sending back via the FTP site. Audio files will be deleted upon approval of project deliverables.

Analysis will include descriptive demographic characteristics of respondents and other relevant data obtained from structured response questions. The bulk of the analysis will be done as traditional qualitative analysis, describing how respondents with different characteristics (e.g. demographics, geographic location) inform the research questions.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

The study will be carried out in ways sensitive to and respectful of the diverse nature of Tribal communities. CDC NCIPC contracts with a Native (8a) owned small business that has extensive knowledge and experience or can sub-contract for conducting qualitative research in Tribal communities and a high capacity for specific Tribal community engagement due to existing relationships, which will help to maximize community response to the data collection activities. AI/AN populations experience a disproportionate burden of ACEs and substance misuse and may be particularly vulnerable. As such, the research team will take great care to recruit individuals in a manner that respects and protects their privacy, while also honoring their dignity. When recruiting, they will highlight the overarching goals of the project and shared priority to

improve services for children, youth, and families in Tribal communities. The confidentiality of all individuals and the Tribe will be strictly maintained. No individuals or Tribes will be identified in the reporting of study findings. The following procedures described below are designed to maximize cooperation and to achieve the desired high response rate:

- The information collection activities described in the Information Collection Request (ICR) are for a one-time data collection.

- Telephone screening of interested individuals will be used to determine eligibility and to further identify and recruit potential respondents. Screening questions will be used to determine eligibility (see **Attachment E**).

- No individual will be asked to participate in more than one focus group/interview or complete more than one survey.

- The data collection protocol is designed to collect only the minimum information necessary for the purposes of the project to minimize burden and maximize response.

- The research team will call/email all respondents 24 hours prior to their scheduled focus group/interview to confirm participation (see **Attachment G**). We recognize that some respondents may have unexpected, last-minute conflicts with their scheduled session due to varied demands, stress, and busy schedules.

- If a respondent is unavailable at the scheduled time, the research team will work with the individual to reschedule the session if possible. If a respondent does not show for his/her scheduled session unexpectedly and does not respond to follow up communications, the research team will aim to recruit another individual in his/her place.

- The research team will seek to "oversample" by recruiting two extra respondents for each focus group anticipating that two to four respondents will not attend.

- When working with vulnerable populations, oftentimes recruitment is prolonged. If the length of time to recruit enough respondents for a full focus group is prolonged, the research team will consider conducting triads or mini-focus groups with three individuals to avoid losing respondents to attrition and to provide greater flexibility.

  Lastly, the research team will provide respondents with tokens of appreciation to encourage participation and convey appreciation for contributing in the research study. All respondents will receive $75 at the conclusion of the focus group/interview.

B.4. Tests of Procedures or Methods to be Undertaken

The research team will include experts with the targeted populations and rapid assessment methods, including screening and data collection development and implementation. Prior to beginning data collection, the research staff will receive training on the aims of the study, session protocols, and the discussion guides that will include leading/assisting/observing a pilot of the

focus group/interview with 9 or fewer representatives of the study population. After the first pilot focus groups/interviews using the discussion guides, the research team will assess how well the discussion guide facilitated information to meet the needs of the study. Each site visit to a community will include an experienced senior researcher and a more junior researcher. Senior researchers will have expertise in qualitative methods in Tribal communities and will oversee all data collection, analysis activities, and summary of findings for each community, ensuring that focus groups/interviews collect relevant data. Junior researchers will assist with scheduling, data collection, and analysis.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC NCIPC consulted with the following CDC and non-CDC agencies and entities (see **Table 3. Consultation)** for the development of the ICR and recommendations were incorporated into the study design and methodology.

Table 3. Consultation

Agency	Entity
CDC	NCIPC: Molly Evans, MD, MPH, Medical Officer Division of Overdose Prevention: Andrew Terranella, MD, MPH, Sarah Bacon, PhD, Behavioral Scientist, Office of the Director, Center for State, Tribal, Local, and Territorial Support (CSTLTS): Delight Satter (Confederated Tribes of Grand Ronde), MPH, Senior Health Scientist, Tribal Research Program and Jessica Damon, MLS, MPH, Senior Program Management Officer National Center for Chronic Disease and Health Promotion, Division of Diabetes Prevention: Dawn Satterfield, PhD, Health Education Specialist
ACF	Office of Planning, Research and Evaluation: Aleta Meyer, PhD, Senior Social Service Research Analyst and Team Lead for Community-Engaged and American Indian/Alaska Native Research in the Division of Family Strengthening
Indian Health Services	Division of Behavioral Health: Captain Andrew Hunt, MSW, LICSW (Lumbee) Acting Deputy Director
Johns Hopkins Bloomberg School of Public Health	The Johns Hopkins Center for American Indian Health: Melissa Walls, PhD, (Boise Forte Ojibwe), Director of Great Lakes Hub and Jessica Elm, PhD, Postdoctoral Researcher (Oneida Nation and Stockbridge-Munsee Band of the Mohicans)

NIH	Division of Program Coordination, Planning, and Strategic Initiatives: David Wilson, PhD, Director, Tribal Health Research Office (Navajo)
University of North Dakota	School of Medicine and Health Sciences: Donald Warne, MD, MPH, Professor of Family and Community, the Associate Dean of Diversity, Equity and Inclusion as well as the Director of the Indians Into Medicine and Master of Public Health Programs (Oglala Lakota)

References

Biden, J. (2021). White House Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/*

CDC (2013). CDC/ATSDR Tribal Consultation Policy (Updated 11/12/2013).

Exec. Order No. 13175, Fed. Reg. Vol. 65, No. 218 (November 6, 2000) https://www.federalregister.gov/d/00-29003