# Southwest Hub for American Indian Youth Suicide Prevention Research

**NCT03543865**

**Study Protocol**

**3 February 2023**

**JHSPH IRB Research Plan for New Data Collection**

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**Study Title:** **Southwest Hub for American Indian Youth Suicide Prevention Research**
**IRB No.:** **00008138**
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**Introduction:** *We were awarded an administrative supplement that will include two additional aims within the existing scope of work of the protocol to strengthen critical gaps in our scientific knowledge of the overlap between opioids and suicide in Native American communities***. The opioid supplement is a data collection sub-study within our parent grant intervention study. The diversity supplement involves geospatial analysis of parent grant data that will improve knowledge to address co-morbid opioid and suicide.**

*When we use the term opioid use, we mean any use of heroin, methadone or suboxone, as well as prescription pain medicines such as oxycontin, percocet, vicodin, morphine, dilaudid, and fentanyl (we will also use local slang terms verbally with participants) without a prescription from a doctor.*

**I. <u>Aims of the Study</u>:** Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

Primary Aim:

1. To use a SMART design to evaluate which of four sequences of New Hope (NH), Elders Resilience (ER) and Case Management (CM) have the greater effects on immediate and longer-term suicidal ideation (primary outcome) and resilience (secondary outcome) among American Indian (AI) adolescents ages 10-29 identified at risk for suicide.

   Hypotheses:

   i. New Hope vs. CM alone will significantly reduce participant suicidal ideation.
   ii. Elders Resilience vs. CM alone will significantly improve participant resilience.
   iii. New Hope followed by Elders Resilience will have the strongest effects on suicidal ideation and resilience.
   iv. CM alone will have the weakest effects of all combinations.

*Opioid Data Collection Sub-Study Aim: To use a mixed methods approach to examine opioid use among our SMART trial participants through addition of a quantitative opioid related measure and qualitative interviews (N=30) with a subset of those who endorse recent or current use.*

*Economic Evaluation Supplement Aim: To understand the economic impact of the Southwest Hub interventions. We hypothesize that both the NH and ER interventions' reduction in participant suicidal ideation and improved resilience will reduce participant healthcare and other community and personal costs compared to the standard of care of CM alone.*

1. *Administer a time use survey (e.g. time-logs) and conduct in-person interviews among the project staff and health workers. Using these tools, we will ask staff to recall how they allocated their time and what resources (e.g. supplies, equipment, etc.) they used.*
2. *Analyze Celebrating Life Apache surveillance system (CL) data for related data points for study participants, including intake and follow-up case management visits. This data counts the number of times study staff visited or attempted to visit study participants, and is key in accounting for the time and financial costs of conducting study visits with participants.*

*Diversity Supplement Aim: To assess individual characteristics (age, gender, substance use history, mental health status, educational and employment status, family composition) associated with co-occurrence of suicide ideation or attempts and history of opioid use compared with suicide risks alone*

Secondary Aims:

2. To examine mediators and moderators of treatment effectiveness and sequencing in order to determine which types and sequence of interventions is best suited for which youth.
3. To assess the acceptability, feasibility and capacity for sustainability of the Hub's key intervention components (Surveillance/Case Management, New Hope and Elders' Resilience) from the perspective of multiple stakeholders as they are implemented across different tribes. This will also include identifying, prioritizing and testing strategies aimed at enhancing the sustainability of tribally implemented suicide prevention programs.

*Opioid Data Collection Sub-Study Aim: Explore community beliefs about: a) correlates of risk (i.e., other substance use, mental health status, family, demographic and social factors), b) protective factors (cultural and spiritual factors) and c) behavior functions (i.e., emotional regulation, reinforcement patterns) of opioid abuse in Native American youth through focus groups with the existing Community Advisory Boards from the Hub partners.*

*Diversity Supplement Aim: To assess geospatial factors (neighborhood, and distances to opioid sources, treatment facilities or traditional care providers, school or workplace, or others in the sample with co-occurring disorders) associated with co-occurrence of suicide and opioid use.*

**II. <u>Background and Rationale</u>:** Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

American Indian and Alaska Native (AIAN) youth bear a much greater burden of suicidal behavior compared to other U.S. youth.[1] **Mental health problems** such as depression, trauma, substance use (including opioids), impulsivity, self-injury, low self-esteem and hopelessness are key risk factors.[2] **Health system barriers**, including scarcity of mental health services and service providers, particularly Native ones, and lack of tribal-specific data for informing intervention development also negatively impact AIAN suicide rates.[3] However, unique AIAN cultural understanding of mental health, culturally-informed protective factors, and a preference for culturally-based healing modalities might not align with Western models of care.[4] A balanced **risk-reduction/resilience-focused and culturally-grounded approach** that addresses community risk factors and promotes protective factors holds promise for reducing suicide among AIAN youth.

The overall goal of the research component of the NIMH-funded Southwest Hub for American Indian Youth Suicide Prevention Research is to identify effective, feasible and sustainable interventions to prevent suicide and promote resilience among American Indian (AI) youth. The proposed study will **build on 20+ years of behavioral and mental health research and partnerships** undertaken by the Center for American Indian Health (CAIH) at Johns Hopkins with the White Mountain Apache Tribe (WMAT).

Our primary research aim, to be undertaken with the White Mountain Apache, includes: 1) **identification and voluntary enrollment of youth 10-29 years old using the WMAT established surveillance and case-management (CM) system** who recently had a validated suicide attempt, ideation, or binge substance use

episode with recent suicidal ideation (i.e., index event); and 2) **implementation of a Sequential Multiple Assignment Randomized Trial (SMART)** to inform how to combine and tailor two brief interventions delivered by paraprofessional community mental health workers (CMHWs), with promising pilot data, to prevent further suicidal thoughts and behavior and promote resilience (and decrease long-term risk both due to suicidal behaviors and substance use including opioids); and 3) evaluate what are the cost savings per study participant with the implementation of the Southwest Hub interventions: *NH, ER, NH and ER*. A secondary aim will be to evaluate the acceptability, feasibility and sustainability of the two brief interventions with other Southwest Hub partners, **including the Navajo, San Carlos Apache, Hualapai, and Cherokee nations**, who will have support from the Administrative Core of the Southwest Hub to implement their own local tribal suicide surveillance systems for community-based identification of at-risk youth.

*Background on economic evaluation supplemental aim:* Little is known about the cost-effectiveness of mental health interventions for Native Americans. Lack of cost-effectiveness evidence is primarily due to lack of scientific evidence on intervention impact as well as obstacles in quantifying the disability burden for suicide ideation using standard metrics. A recent literature review on the cost-effectiveness of suicide and self-harm prevention interventions shows six studies provided high quality evidence and all six interventions were cost-effective. However, none of these focused on addressing suicidality in Native American populations and none included culturally appropriate interventions for this population. Our partners from the White Mountain Apache Tribe have indicated a strong interest in learning about the economic burden of suicide and costs of addressing it in order to inform policy decisions and future implementation and dissemination of these programs in other tribal settings.

As part of the *economic evaluation supplemental aim* we will administer a time use survey (e.g. time-logs) and conduct in-person interviews to assess the costs of the intervention. The rationale for these activities is doing quality control and capturing all the program resources needed to run the HUB interventions.

Different staff will specialize in different activities and the amount of time and resources that they devote to coordinating programs and/or providing services will fluctuate depending on changes to their roles (e.g. research tasks, non-research tasks, etc.), the programs' capacity (e.g. counts of staff, resources available to staff to provide services, and demand for services), and staff's level of expertise (i.e. staff become more experienced and efficient overtime).

To estimate the range of non-research staff time (i.e. costs) needed for Hub interventions, we will use time use surveys (i.e. time-logs). These time logs will help us capture the time that staff devote to different activities overtime, at different levels of capacity and expertise. To capture the range of type and amount of resources needed to provide services we will conduct in-person informal semi-structured interviews throughout the HUB study period.

**III. <u>Study Design:</u>**

A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives. Details will be requested later. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for <u>Secondary Data Analysis of Existing Data/Specimens</u>).

**Aim 1: To use a SMART design to evaluate which of four sequences of New Hope (NH), Elders Resilience (ER) and Case Management (CM) have the greater effects on immediate and longer-term suicidal ideation**

**(primary outcome) and resilience (secondary outcome) among AI adolescents ages 10-29 identified at risk for suicide.**

We will employ a SMART design (see diagram in Section C, page 8) to evaluate the effectiveness of New Hope (NH), Elders' Resilience intervention (ER), Case Management (CM) and the combination of these approaches on reducing suicidal thoughts and promoting resilience among AI youth ages 10-29 who are confirmed by surveillance case managers to have recently experienced suicide ideation, attempt or a binge substance use and ideation. Youth who assent will complete the baseline (case management visit 1 and will be referred to mental health care—the standard protocol for the Apache system). During the same visit, youth will be randomized 1:1 to either New Hope (NH) plus Case Management (CM), or CM alone, using a blocked randomized design, stratifying participants by age and event type. All youth will complete another study assessment after 30 days. The 30-day time frame will allow ample time to complete the NH intervention with participants and assess any changes in youth's mental health status for all study arms. Following another 30-day period, all participants will be re-assessed and re-randomized, using the same blocking and 1:1 ratio to either the Elders' Resilience (ER) intervention plus CM, or CM alone. To track long term outcomes, all youth will complete a final assessment 3 month later (6 months post-enrollment). This study will occur on the White Mountain Apache Tribe's Fort Apache reservation.

***For the Opioid Data Collection Sub-Study,*** *we will use the opioid use questions added to the SMART trial assessment battery (see Assessment Table and Appendix) as a screener for sub-study participation to identify those who are currently using opioids. If current or recent opioid use is identified, an additional qualitative interview (~60-90 mins; see Appendix for guide) among a subset of participants (n = 30). This interview will be recorded and transcribed. Note: The opioid questions are not a screener for the intervention study.*

***For the economic evaluation supplement****, we will use all healthcare claims data for each intervention participant (from one year prior to the study period to 12 months post-enrollment--for a total of 2 years of participant claims data) requested from the Indian health Service's electronic health records to assess healthcare expenditures. We will also ask participants about their school performance and work attendance, as well as, some additional items related to time spent participating in the interventions. These new items for participants are included in the assessment battery.*

*As part of the economic evaluation supplement, we will collect data from staff about their time use and resources use. For this aim, we will ask all project case managers and health providers to collect daily time-logs. The design of the time-log may vary overtime to better fit program needs or activities. But in general, this tool will ask staff to select which of a pre-defined list of activities they conducted each day and for how many hours each activity. In-person interviews with staff will follow a semi-structure design. A survey tool will be used to guide open ended questions and the survey will be modified over-time to fit program activities.*

> *We will also analyze CL data for related data points for study participants, including intake and follow-up case management visits. This data counts the number of times study staff visited or attempted to visit study participants, and is key in accounting for the time and financial costs of conducting study visits with participants.*

***For the diversity supplement****, we will compare individual characteristics associated with co-occurrence of suicide ideation or attempts and opioid use vs. suicide ideation/attempt without concurrent opioid use risk. We will use*

*baseline measures of age, gender, mental health status, education, employment, academic status, income, and family composition already being collected by the parent grant.*

**Aim 2: To examine mediators and moderators of treatment effectiveness and sequencing in order to determine which types and sequence of interventions is best suited for which youth.**

Due to anticipated sample sizes, proposed mediation and moderation models are hypothesis generating. Potential moderators such as gender or age will be evaluated by including them at the appropriate level of measurement in the models detailed in Section C (page 10) and interactions terms will be specified between moderator and intervention terms of interest.

***For the diversity supplement**, we will use spatial data collected as part of the parent grant data collection, including home addresses and GPS stamp, and information about the specific location where the index event took place using geographic code to pin major locations across the reservation. We will capture an ID (from registry) from the Celebrating Life Surveillance System to link participants to parent grant data and the location of the index event (from registry) that triggered their involvement with the parent grant study. In addition to data that is currently being collected, we will work with study team members, community stakeholders via parent grant community advisory board (CAB) to identify and add geographic data points of potential interest—such as health facilities, treatment centers, schools, police stations, and community gathering locations to help understand the interplay of geography and spatial clustering of suicide risk and opioid use to inform future place-based intervention design.*

*United States Census data will be merged in our data sets to identify tracts in which individuals live to inform the spatial statistical models. Two additional geographical questions will also be added to the parent grant survey for all assessment periods to assure that we are capturing relevant information for those that indicate recent opioid use: 1) where do individuals acquire opioids?, and 2) where do individuals use opioids?*

**Aim 3. To assess the acceptability, feasibility and capacity for sustainability of the Hub's key intervention components (New Hope, Elders Resilience Curriculum, and CM) from the perspective of multiple stakeholders as they are implemented across different tribes.**

For Aim 3, we will combine qualitative and quantitative approaches to better understand the acceptability, feasibility and sustainability of the Southwest Hub's main intervention components. All in-depth interviews will use semi-structured theoretically driven interview guides and will be transcribed and thematically coded using emergent coding. From the quantitative data, item frequencies and summary scale scores will be examined to identify barriers and facilitators to program acceptability, feasibility and sustainability. Summaries and inferences about the data will be reviewed with participants through member checking and sustained engagement with key stakeholders.

*We will also review the last 5 years of surveillance system data, in combination with the results of the Aim 3 surveys, to inform a systems dynamic model of program sustainability that has been informed by stakeholder feedback and is aimed at supporting teams implementing the CL program in deciding which strategies are feasible to promote long-term sustainability and impact of the program.*

***For the Opioid Data Collection Sub-Study,*** *we will ask these same key stakeholders if they are willing to participate in roundtables specific to understand opioid use. These roundtables will follow similar procedures and analyses as the implementation focused roundtables (see Appendix for opioid related questions).*

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

**Aim 1:** We will randomize **304 participants**; 76 to CM alone, 76 to CM+NH, 76 to CM+ ER, and 76 to CM+NH+ER. Based on the previous work with the SIQ, we believe a 25% reduction among individuals with a score of 30 or greater would represent clinically significant change in suicide ideation.[5] Using pilot data of NH among the WMAT, an average baseline score of 45 could be expected on the SIQ.[5] A clinically significant reduction translates into a large Cohen's D effect size (>0.8). However, we want the power to observe the more moderate effect expected to result from comparing the sequencing of the interventions (NH+ER vs. NH+CM vs. CM+ER vs. CM alone). Using an adjusted alpha to account for multiple comparisons of 0.013, and a correlation of 0.2 among repeated measures, with four groups (NH+ER vs. NH+CM vs. CM+ER vs. CM alone), n=58 people per group (n=116 randomized at each randomization time-point) would provide 80% power to detect a small to moderate effect (Cohen's F=0.2). Adjusting these estimates for 30% attrition would result in n=76 per each of the four groups (n=152 per arm) for a total sample size of N=304.

Please note for our ***the Opioid Data Collection Sub-Study***: We will use a mixed methods approach to examine opioid use among our SMART trial participants through addition of a quantitative opioid related measure and qualitative interviews (N=30) with a subset of those who endorse recent or current use.

***For the economic evaluation supplement***: We will use the same sample of participants as Aim 1. We are not drawing statistical inferences about cost estimates so there is no sample size requirement. Instead, we are reporting on the health care services utilization and costs incurred by study participants before, during and after the intervention. To administer a time use survey and conduct in-person interviews we will use all HUB program case managers (five or more) and healthcare providers (three or more).

***For the diversity supplement****:* We will use a sub-sample of n-239 WMAT participants enrolled in the parent trial. This sample size is based on the estimated enrollment rates during the Diversity Supplement study period.

**Aim 3:** Study participants will be 25-50 key stakeholders including youth, caregivers, program providers, community members, tribal leaders, and other researchers across the Hub, including satellite partners. Sample size for Aim 3 is based on qualitative research theory on saturation, a point after which common themes and information from respondents tend to converge. Quantitative data collected is exploratory in nature and will be used to help inform future implementation and scale-up of the programs.

Please note for our ***the Opioid Data Collection Sub-Study***: Key stakeholders will only be asked about opioid use generally in relation to the community, not their personal use. However, we are aware that personal use may still be disclosed. We will use the same referral and follow-up procedures for these participants as those in our SMART trial. We estimate 25 participants based on the number of Hubs sites and advisory board members.

## IV. <u>Participants</u>:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care.

Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

**Aim 1:** Study participants will be self-identified Native Americans who are between the ages of 10 and 29 years old and reside on or near the Fort Apache Indian Reservation and are identified in the existing surveillance and case-management (CM) system as having recently had a validated suicide attempt, ideation, or binge substance use episode and recent ideation. The majority of these tribal populations lives below the federal poverty line. The economic evaluation supplement does not involve any contact with the study participants.

A. **Inclusion Criteria:**

- Native American youth ages 10 to 29 years old.
- Reside on or near the Fort Apache Indian Reservation.
- Parent/guardian consent for youth under 18 years old.
- Suicide ideation, binge substance use with recent (i.e. within the last 3 months) suicide ideation, or suicide attempt in the past 30 days as identified and verified by the surveillance system OR release from inpatient care related to suicide ideation or attempt within past 30 days
  **Terms and Definitions:** Definitions for reportable behaviors are modeled on the Columbia Classification Algorithm for Suicide Assessment (C- CASA).[11] **Suicide attempt**: intentional self-injury with intent to die. (Aborted and interrupted suicide attempts are included as part of this category). **Suicidal ideation**: thoughts to take one's own life with or without preparatory action. **Binge substance use with recent ideation**, defined by Apache stakeholders, as consuming substances with the intention of modifying consciousness and resulting in being found unresponsive or requiring ED treatment and answering positively to a 1-item screening question on the assessment indicating suicide ideation within the past three months.

B. **Exclusion Criteria:**

- Factors identified at baseline that preclude full participation, including: unstable and severe medical, psychiatric or drug use problem that necessitates inpatient treatment; acute suicidal or homicidal ideation requiring immediate intervention; recent, severe stressful life events such as physical or sexual abuse, or violent crime victimization that requires specific and high intensity interventions or out of home placement. Participants must speak English and not be severely visually impaired. Ambiguous cases will be reviewed by one of the co-PIs before being deemed eligible for recruitment.

**Aim 3:** Study participants will be 25-50 key stakeholders including youth, caregivers, program providers, community members, tribal leaders, and other researchers across the Hub, including satellite partners. Please note for our opioid supplement: key stakeholders will only be asked about opioid use generally in relation to the community, not their personal use. However, we are aware that personal use may still be disclosed. We will use the same referral and follow-up procedures for these participants as those in our SMART trial.

C. **Inclusion Criteria:**

- Youth over the age of 16 with parental consent and youth assent or adults over the age of 18 with their consent.
- A person with an interest or concern related to youth suicide among AI populations.

D. **Exclusion Criteria:**

Factors identified at baseline that preclude full participation including: being under the influence of a substance; active psychosis or mania; any other condition that makes an individual lack capacity to give consent. Children who are a ward of the court/no guardian will not be included.

- Participants must speak English and not be severely visually impaired. Ambiguous cases will be reviewed by one of the co-PIs before being deemed eligible for recruitment.

**NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.

## V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

### A. Recruitment Process:

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

1. **Aim 1:** Participants will be identified and recruited from the Apache Surveillance System. Please note that individuals that come through the Apache Surveillance System receive a referral for mental health care as part of standard procedures. Currently Surveillance System Staff attempt to meet face-to-face with all individuals for whom a self-injury report was made within 1 month of receiving a report. This visit is conducted in order to confirm the event and support referrals to services. All youth (10-29 years old) who are reported to the surveillance system for a suicide attempt, ideation, or binge substance use episode will be informed about the study by a staff member working for the surveillance system. When a youth is identified as meeting study eligibility criteria, Surveillance System Staff will briefly talk with the youth about the study. If the youth is interested, the Surveillance System Staff will give youth the contact information for a Research Program Assistant who can explain the study in detail and set up a time for consent/assent. Assent be obtained first because the it allows for better protection of the child's privacy. It is permissible to contact the parent to reach the child, but formal consent should follow assent.

   The Clinical Research Supervisor will train and manage Research Program Assistants, and coordinate participant recruitment and consent. The Apache study team consists of five JHSPH-employed Research Program Assistants who have deep experience in implementing the local Apache suicide surveillance and case management system. Potential participants will be identified using the existing surveillance system as having suicide ideation, a binge substance use episode and recent suicide ideation, or a suicide attempt in the past 30 days. A Research Program Assistant will explain the nature of the study, the reason the person is being asked to participate, and nature of data gathering during a routine case management visit, following a uniform recruitment script. If youth remain interested, Research Program Assistants will screen them for initial inclusion and exclusion criteria, and obtain informed consent/assent. Special attention will be given to verbally reviewing the risk protocol for current suicidal thoughts and behaviors, as well as the procedures related to identifying current opioid use, both of which will be described in the consent forms.

**Aim 3:** The Clinical Research Supervisor, Dr. O'Keefe, will recruit and consent key stakeholders from the Southwest Hub's Administrative Core Tribal sites. Potential participants will be identified by the Project Leads at each site, as well as staff and administrators that are knowledgeable about suicide prevention initiatives. Interviews regarding the acceptability, feasibility and capacity for sustainability of the Hub's key intervention components (Surveillance/Case Management, New Hope and Elders' Resilience) will be conducted by Dr. Haroz or Dr. O'Keefe either in person, or online via Qualtrics (PSAT). Potential participants will be asked to join the study, and assured that participation is not mandatory and will in no way effect their Southwest Hub partnership.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

**Aim 1:** Maintaining confidentiality is of the utmost concern. Recruitment will take place in the participants' home or another private location of their choosing, minimizing risk. Privacy for minors will be protected including reporting of high risk behaviors such as past or current opioid use as well as healthcare usage information. All forms that contain participants' confidential information (i.e., consent form, contact information, etc.) will be kept separate from survey data and secured in locked file cabinets on site. The consent form will describe in detail the methods used to protect participants' confidentiality and those individuals and entities (i.e., Johns Hopkins IRB, NIH) that have access to the data. We will obtain a Certificate of Confidentiality for this study. We will explain to the participants that we will have obtained this Certificate of Confidentiality as added protection for their privacy.

**Aim 3:** The only foreseeable privacy risk will be the potential that responses to the qualitative interview might be identifiable. Every effort will be made to ensure privacy and confidentiality is maintained including use individualized interview methods (i.e. not done in groups and conducted in private space) and efforts to refrain from using identifying information during the interview. Identifying information will be redacted from final transcripts and will not be published. No identifying information will be recorded on any study document. The quantitative version of Aim 3 (the online program sustainability assessment tool; PSAT) will not include identifying information.

B. **Consent Process**:

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

   a. Who will obtain informed consent, and their qualifications:

   **Aim 1:** As described above, Research Program Assistants are very experienced with both the surveillance system and assent/consent procedures, will obtain consent after recruitment.

   **Aim 3:** Drs. O'Keefe or Haroz, Baltimore-based investigators, will obtain informed consent during an in-person meeting with each stakeholder individually. Drs. O'Keefe and Haroz are trained in the ethical conduct of research and has lead trainings for data collectors on the consent process for other studies. Dr. O'Keefe will briefly describe the study, then provide the potential participant with the consent form, and be available for any questions she/he may have. For the PSAT, an online "consent form" will be administered as part of the Qualtrics survey.

b. How, where, and when the consent discussion(s) will occur:

**Aim 1:** Consent in this study will be obtained prior to any research-related participation. Research Program Assistants will ask prospective participants if they fully understand the consent process/forms. For written consent, copies of consent/assent forms will be provided. All participants will understand that participation is completely voluntary, acceptance or refusal will not influence their ability to participate in other Tribal or JHU services, and they can withdraw from study participation at any time. Recruitment will take place in the participants' home or another private location of their choosing. Consent discussions will at the end of routine case management visits and right after recruitment into the study. Special attention will be given to verbally reviewing the risk protocol for current suicidal thoughts and behaviors, as well as the procedures related to identifying current opioid use, both of which will be described in the consent forms.

**Aim 3:** Drs. O'Keefe or Haroz will conduct the consent process with each potential participant individually over the phone. Drs. O'Keefe or Haroz will read the study introduction script, and encourage the potential participant to ask questions. She will be available to offer any clarifications or answer any questions that arise. If the participant does not want to participate, Drs. O'Keefe or Haroz will thank them for their time and consideration. If the potential participant is interested in participating, the participant will print, sign, and date the consent form, and email the form back to Drs. O'Keefe or Haroz, who will also sign and date. The participant will be emailed a copy and the original will be kept in a locked cabinet. For the online survey related to sustainability (PSAT), the consent will be included as part of the Qualtrics survey. Dr. Cwik may additionally participate in opioid roundtable recruitment.

c. The process you will use to determine whether a potential participant meets eligibility criteria:

**Aim 1:** The surveillance system will be used to identify youth who have a validated suicide attempt, ideation, or binge substance use episode with recent suicide ideation in the past 30 days or who have a recent event that resulted in in-patient hospitalization/treatment. Those potential participants who have been sent to in-patient care will continue to be eligible to enroll in this study for 30 days after their return from treatment. Please note the opioid related questions added to the SMART trial battery will identify those who have endorsed current or recent opioid use, related to our Opioid Data Collection Sub-Study Aims. Surveillance System Staff will confirm the episode with the youth (i.e. that the reported event happened), then a Research Program Assistant conduct the recruitment process including screening for inclusion and exclusion criteria, using the uniform recruitment script.

**Aim 3:** Project Leads at each Southwest Hub site will identify stakeholders who may be eligible to participate.

d. Whether you will obtain a signature from the participant or will use an oral consent process:

**Aim 1 & 3:** We will obtain a signed consent form.

e. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:

**Aim 1 & 3:** We will not obtain a legally authorized representative's signature for adults lacking capacity. These individuals will be excluded from the study.

f. If children are included in the study, if and how you will obtain assent from them:

**Aim 1 & 3:** Assent will be obtained through a separate form, after parental consent is obtained. The study will be explained to the child in simple terms and Research Program Assistants will ask prospective youth participants if they fully understand the consent process/forms.

g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision):

**Aim 1 & 3:** Research Program Assistants will obtain permission from the youth's parent, legal guardian or other legal authority (if the child is in foster care) if the youth is under 18 years of age. The study will be explained to the parent by the Research Program Assistant, including the nature of the study, the reason the child is being asked to participate, and nature of data gathering. If the parent is interested in having their child participate in the study, a Research Program Assistant will ask the parent to complete the parental permission form and will ask if they may obtain assent from the youth.

h. If you are seeking a waiver of informed consent or assent, the justification for this request:

N/A

i. Whether you will include a witness to the consent process and why:

**Aim 1 & 3:** No witness is needed. Participants or their parents must speak English, be literate, and not visually impaired.

j. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:

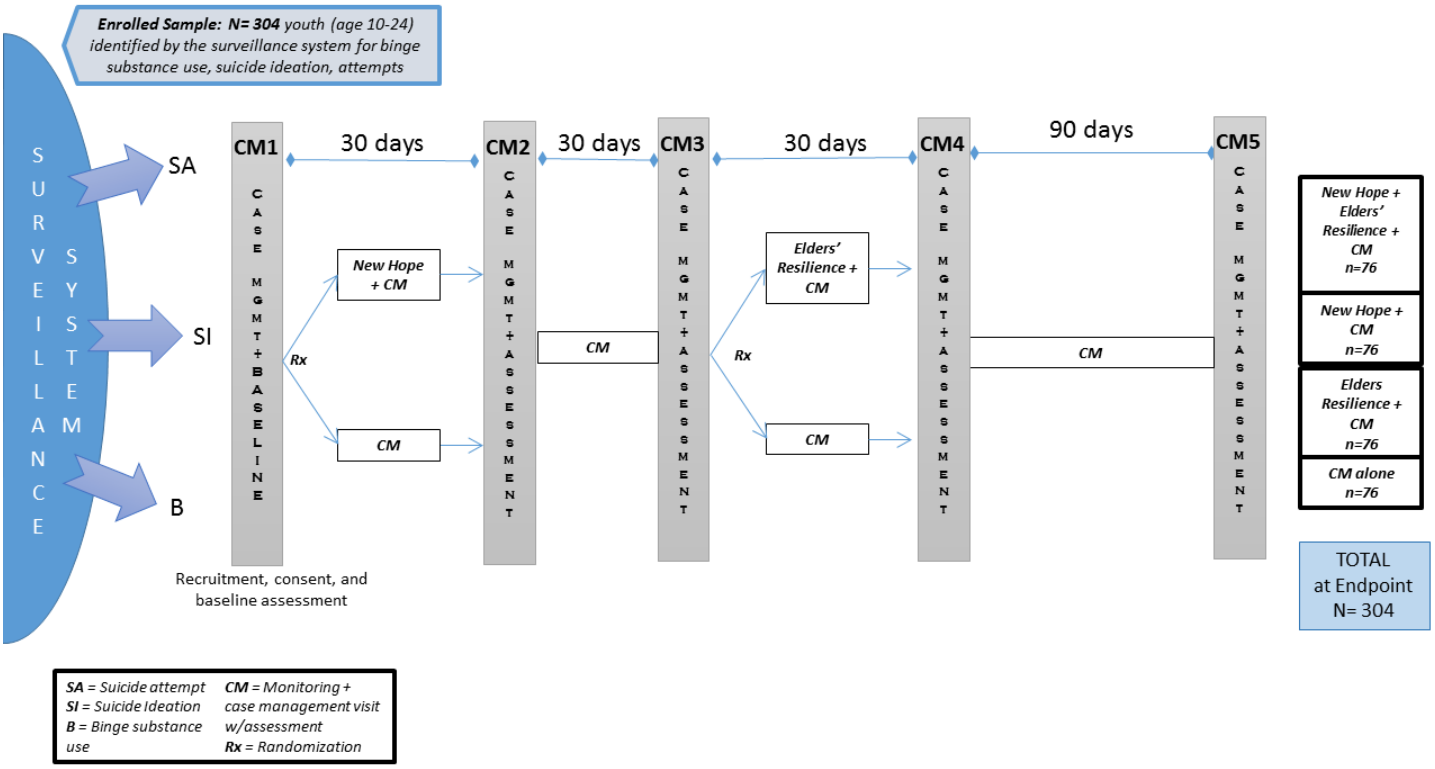
N/A

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

| **Country** | **Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)** | **Languages** |
|---|---|---|
| United States of America | Aim 1: Adult Consent | English |
| United States of America | Aim 1: Parental Permission | English |
| United States of America | Aim 1: Youth Assent | English |
| United States of America | Aim 3: Adult Consent | English |
| United States of America | Aim 3: Parental Permission | English |
| United States of America | Aim 3: Youth Assent | English |
| United States of America | Aim 3: Adult Consent (Roundtables) | English |

C. **<u>Study Implementation</u>**:

1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.




**Aim 1: STUDY PROCEDURE (Fig. 5 Study Design)**

Once participants are identified via the surveillance system and consent/assent is completed, Research Program Assistants will administer the **baseline assessment** (**CM1**). During the same visit (**CM1**), participants will be stratified by gender and event type, and then randomized to New Hope (NH) plus CM, or CM alone.

**Randomization Procedure 1.** Participants will be stratified by age groups (10-14, 15-19, and 20-29) and event type (ideation, attempt, binge + recent ideation), then randomized to the control or intervention condition using a 1:1 assignment ratio. Re-randomization of all participants will occur again at **CM3** (another 30 days or 60 days/2 months post-baseline assessment).

**Control Condition:** *Monitoring and **C**ase **M**anagement **(CM):*** Research Program Assistants, who are trained Surveillance System Staff, will conduct the monitoring and case management visits in participants' homes or other private settings at baseline, 1, 2, 3 and 6 months post-enrollment. This time-period was selected as the highest risk period for a subsequent suicide event following an initial episode.[12, 13] The CM visit includes rapport-building, use of the Suicide Ideation Questionnaire (SIQ) to assess imminent risk, and if youth report not yet having connected to services, referral to Apache Behavioral Health Services (ABHS), the local community mental health center. As we have added opioid related questions through an administrative supplement, the monitoring and case management visits will also allow us to track any safety concerns related to opioids and provide appropriate referrals to treatment. If minors seek treatment elsewhere or express disinterest, case managers will also facilitate connections to other care providers

(traditional healers, church, IHS social services/mental health, and private providers). At CM visits, the **Research Program Assistants will also monitor participants' completion of the study battery**, which will be self-administered using tablets. In addition, Research Program Assistants will score the SIQ before leaving the youth. If the SIQ reveals the participant is at imminent risk, Research Program Assistants will employ a protocol for rescue services (*described below*), which involves triaging youth immediately to the ED for further assessment and care.

***Intervention 1: New Hope*** is based on a brief empirically-validated Emergency Department (ED) intervention.[14-17] Our intervention, adapted with strong guidance from a Community Advisory Board (CAB), was designed to be implemented over 1 visit (2-4 hours) in a youth-preferred setting after ED discharge for a suicide attempt, and in the past few years has been updated to also target suicide ideation and binge behavior, including substance use more generally which could encompass opioids. Note: the intervention does not however focus directly on opioid use. NH emphasizes the seriousness of a suicide attempt; teaches coping skills to reduce risk, including emotion regulation, cognitive restructuring, social support, and safety planning; and helps participants overcome barriers to treatment motivation, initiation, and adherence. A center-piece of the intervention is a 20-minute video produced by WMAT-CAIH with Native actors, vignettes specific to this community, and Elders speaking in Apache (with sub-titles) about the seriousness of suicide, its impact on the community, their concern for the adolescent, and beliefs about the communal importance of each individual's life. ***Youth are encouraged to choose a support person from his/her family to take part in the intervention because surveillance data indicated family conflict was one of the major reasons reported for suicide events and family members can reinforce skills including the youth's safety plan***.[17-19] The oral consent script for family members participating in New Hope will be used to introduce the intervention to the family member. NH is psychoeducation to supplement and promote mental health services, while encouraging connections to traditional healers and caring adults.[5] NH will be provided by CMHWs (and not Research Program Assistants) to reduce potential bias in the assessments. Intervention sessions will be recorded for quality assurance purposes. Two trained raters will use a standardized form to rate various components of the intervention session including—if all components of the lesson were delivered, the quality of delivery and the relationship between faciliator and participant.

All youth will complete another study assessment after 30 days (**CM2**). The 30-day time frame will allow ample time to complete the NH intervention with participants and assess any changes in youth's mental health status for all study arms. Following another 30-day period (**CM3**), all participants will be re-assessed and re-randomized, using the same blocking and 1:1 ratio to either the Elders' Resilience (ER) intervention plus CM, or CM alone.

**Randomization Procedure 2.** Participants will be stratified by age groups (10-14, 15-19, and 20-29) and event type (ideation, attempt, binge + recent ideation), then randomized to intervention condition using a 1:1 assignment ratio.

***Intervention 2: Elders' Resiliency (ER) intervention.*** Our CAB, Elder's Council and other key stakeholders have taught us that Apache traditions confer behavioral repertoires and values taught through storytelling, observation, and parenting at the family and community level that have carried the Apache people through generations of adversity and historical trauma. Starting in 2015, CAIH and local suicide prevention staff helped Apache Elders to create and teach a monthly manualized curriculum intended to bolster Apache youths' resilience to suicide ideation, attempts and substance abuse by promoting Apache cultural identity and values, youth's self-worth and role in the community, and fostering connectedness to society and community, *with an emphasis on extended family as a nexus of strength*. Each lesson

introduces youth to cultural knowledge, stories, and songs with an emphasis on respect and the sacredness of each life. Specific themes include: respect, Apache culture, spirituality, self-worth, endurance, gender roles, Apache history, education/work, responsibilities, relationships (including the clan system), discipline and communication. The Elders, CAIH, and suicide prevention team are now adapting the monthly curriculum into a brief intervention for youth who come through the surveillance system. ER will be provided by a separate CMHW and an Elder to reduce potential bias in the assessments.

The current cadre of Elders teaching the school-based curriculum will be group from which we will select Elders for the study. For this study, our community-based Apache staff will select Elders who both express an interest in the current project and have demonstrated affinity and skill for teaching the current curriculum in the schools. After this group of Elders is recruited and agree to participate, they will be paired with our paraprofessional Apache study staff. This paring will be based on two primary factors: 1) previous experience working together, 2) not having a familial relationship. To avoid any conflicts that may arise, we will incorporate a process into our study policies and procedures manual and include it as part of the training for the Elders and Apache paraprofessionals. "If you have a concern or complaint with your co-teacher, please report them to our local PD, Novalene Goklish. She will gather information from both individuals, facilitate a meeting to resolve any conflict, make a change in partners if necessary, and document the resolution (which may include a re-pairing)." In addition, our Elders will be trained on the following components: 1) the overall study protocol and accompanying policies and procedures manual, 2) the content and delivery of the Elders brief curriculum, 3) human subjects research, 4) Good Clinical Practice, and 5) our safety protocol that the accompanying case managers will complete at each visit (Elders will not be expected to implement/carry out the safety protocol). Intervention sessions will be recorded for quality assurance purposes. Two trained raters will use a standardized form to rate various components of the intervention session including—if all components of the lesson were delivered, the quality of delivery and the relationship between faciliator, Elder and participant.

After 30 days from **CM3**, all youth will be visited by Research Program Assistants and complete a fourth assessment (**CM4**). The 30-day time frame between **CM3** and **CM4** will allow ample time to complete the ER intervention with participants and assess any changes in resilience across study groups. To track long-term outcomes, all youth will complete a final assessment 3 month later (**CM5**: 6 months post-enrollment). All youth will be followed to the end of the study period (up to 4.75 years from the first participant's enrollment) for any subsequent suicide events using the Apache surveillance system. If necessary, assessments may be conducted over the phone for participants who start in the study but are located elsewhere during an assessment timepoint.

As part of the economic evaluation supplement, our staff will be asked to fill out time logs listing how they spent time the preceding day. This will not affect the study participants in any way.

**Aim 3: STUDY PROCEDURE**

If stakeholders provide informed consent, they will be interviewed by Drs. O'Keefe or Haroz using a semi-structured guide to gather their views on the Southwest Hub's key intervention components (Surveillance/Case Management, New Hope and Elders' Resilience Interventions). They will also be asked to participate in a 2x annually administered online survey to better understand how capacity for sustainability changes over time. If they consent to the online survey, the Program Sustainability Assessment Tool (PSAT) will be administered via email to participants every six months.

2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

   **Aim 1:** Five study visits will take place over the course of 6 months. All study visits will take place in the participants' home or a private location.

   **CM1:** Recruitment, consent, randomization, baseline assessment: 2 hours
   **Intervention Group: NH**: 2-4 hours
   **CM2:** Assessment: 1 hour
   **CM3:** Assessment and randomization: 1 hour
   **Intervention Group: EC**: 2-4 hours
   **CM4:** Assessment: 1 hour
   **CM5:** Assessment: 1 hour

   *Opioid Data Collection Sub-Study (for a subset): Additional 60-90 minutes interview*

   ***For the economic evaluation supplement aim****:* Medical claims data will be requested electronically from the Indian Health Services electronic health records. We will request participants' consent (see consent and assent forms) to review their medical claims. No additional study visits are needed to collect the other information, as these have been added to our existing assessment battery.
   As part of the *economic evaluation supplement,* our staff will be asked to fill out time logs listing how they spent time the preceding day. This will not affect the study participants in any way. To ensure collection of high quality data a designated HUB team member will supervise the daily collection and accuracy of staff time-logs. Data collection will begin in July of 2019. Depending on the quality of data from the first couple of months the team may decide whether periodic or continuous data collation may both produce high quality data and least interrupt staff's work load and procedures. If periodic data collection is preferred, data will be collected at least three times every year, each time daily for at least two consecutive weeks, and each period will be planned in advance ensuring capturing important variation in data (e.g. seasonal changes, etc.). During collection of time-logs, we will also conduct in-person interviews with case managers and health providers to assess the number, type and change of resources used to provide services as well as to assess capacity needs and levels.

   **Aim 3:** There will be one to two study contacts: 1) informed consent (~ 20 minutes), and 2) the interview (~45 minutes). They may elect to do both the same day or at separate times.

3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

   **Aim 1:** The study duration from the perspective of the participant will be 6 months. All youth will be followed to the end of the study period (up to 4.75 years from the first participant's enrollment) for any subsequent suicide events using the Apache surveillance system.

   **Aim 3:** The qualitative interview should take no longer than 45 minutes and will be done at a convenient time. There will only be one-two study visits, although stakeholders will be encouraged to provide feedback at any time about their experiences with the Southwest Hub's key intervention components. For the online survey, the survey is expected to take 20 minutes and will be administered twice a year in years 2-5, for a total of 8 time points. *The opioid roundtables are estimated to take 60-90 minutes.*

4. Provide a brief data analysis plan and a description of variables to be derived.

**Primary and Secondary Outcomes**

**Aim 1:** Given the longitudinal nature of the data, we will use mixed-effects regression models (MRMs)[41] to estimate average treatment effects while accounting for shared variance of repeated measures within adolescent. MRMs are highly flexible, addressing: variability in number and spacing of measurements, a variety of outcome distributions, linear and non-linear patterns of change (e.g., quadratic), and are robust to missing data.

**Suicide ideation (primary outcome):** Measured by the Suicide Ideation Questionnaire (SIQ/SIQ-JR). The SIQ is a 15-item scale that analyzes frequency and severity of suicidal ideation over the past 6 months. Items are scored on a 7-point scale ranging from 0 "I never had this thought" to 6 "Almost every day." Scores of 30 for the SIQ and 23 for the SIQ-JR indicate severe suicidal ideation and need for clinical intervention. The scale has been used among AI adolescents with sound psychometric properties (Cronbach's alpha=0.97).[22]

**Resilience (secondary outcome):** Measured by The Resiliency Scales. These are self-report scales measuring the individual's Sense of Mastery (MAS; composed of 20 items), the Sense of Relatedness (REL; 24 items), and the Emotional Reactivity (REA; 20 items). Each item has five response choices ranging from 0 (Never) to 4 (Almost Always).

***For the economic evaluation supplement aim****:* To evaluate healthcare expenditures per participant and intervention we will employ standard two-part regression models used in the analysis of healthcare costs. Variables per claim will include non-identifiable individual study ID, utilization date, charge per claim, and CPT code. Service claims will include all inpatient services and respective length of stay, ED services, outpatient services, specialist care, pharmaceuticals, home health, health transportation, and mental health care utilization and any other health-care related costs. In addition, time use of our staff will be categorized according to the various protocols that they work on. We will estimate the weekly total hours spent in delivering services to youth. The cost of the time allocated to youth services will be estimated by multiplying wage rate for that worker times hours spend delivering services to youth. *We will analyze Celebrating Life Apache surveillance system (CL) data for related data points for study participants, including intake and follow-up case management visits. This data counts the number of times study staff visited or attempted to visit study participants, and is key in accounting for the time and financial costs of conducting study visits with participants.*

***For the diversity supplement:*** Data will be analyzed in several stages to assess the association of individual characteristics and the co-occurrence of suicide ideation or attempts and opioid use compared to individuals with suicide ideation or attempts alone. First, data will be explored to understand the univariate distributions for this population. Second, bivariate associations will be explored between those with co-occurrence compared to those with suicide risk alone. We will use chi-square tests to test the association of all dichotomous independent variables against the outcome variable (suicide behavior and opioid co-occurrence vs suicide behavior alone). For continuous independent variables, simple generalized linear models will be fitted with one independent variable while specifying a binomial family distribution with a logit link function. After a foundational understanding of the bivariate relationships is established, we will use generalized linear regression models to investigate the multivariate relationships between individual characteristics on the outcome of either co-morbid suicidal behaviors and opioid use (1) vs. suicidal behaviors alone (0). All models will control for gender and age. All analyses will be conducted in the current version of R using a variety of packages necessary.

**Aim 2:** Potential moderators such as gender or age will be evaluated by including them at the appropriate level of measurement in the models detailed above, and interactions terms will be specified between moderator and intervention terms of interest. Key mediators include connectedness, self- esteem and cultural identity. Hypothesized moderators for both interventions include: gender, age and event type. We will also examine adolescent depression, negative cognitive thinking, and family functioning.

***For the diversity supplement***: We will capture an ID (from registry) in the Celebrating Life Surveillance System to link them to Hub (parent grant) data and the location of the index event (from registry) that triggered their involvement with the Hub study. We will use GIS (ArcGIS Pro 2.4, ESRI, Redlands, CA) to map GPS locations of each event and all participants' home locations to determine places of opioid co-occurring and non-opioid cooccurring suicidal individuals. Following this, we will perform a global test for hotspots of all types of suicidal behavior and opioid use across the entire community through the use of a population-based spatial cluster analysis. United States Census data will be utilized to determine the underlying population of the community surrounding each suicidal event and reported opioid location. The expected incidence of co-occurrence of suicidal and opioid behavior will be calculated by assuming a uniform event per population distribution throughout the community. Next, spatial Statistics will identify a critical distance at which the clustering occurs in the dataset and then test for local clustering. Hotspot maps will be created to identify social patterns of suicide and opioid use that are informative for approachable visualization and interpretation by community members to generate insights and community-based participatory research (CBPR) approaches to future intervention. After visual maps are produced and clustering is determined, the information will be quantified and used for regression models. These regression models that account for geospatial data explicitly adjust for possible dependency structures that may be present.

**Additional Measures:**

**Aims 1 & 2:**

Centers for Epidemiologic Studies of Depression – Revised 10-item version (CESDR-10) is a self-report scale used to measure depressive symptoms (Cronbach's alpha ranged from 0.90 to 0.91 in a validation study) [35]. The full version has been widely used among adolescent and AI populations, including Apache youth.[5, 30, 31]

Children's Negative Cognitive Errors Scale is a 17-item self-report scale that assesses cognitions about social/peer rejection, group activity competence and academic competence, and demonstrated excellent internal consistency reliability (Cronbach's alpha=0.89). It has been previously used in a sample of Apache youth.[5, 32]

Problem-oriented screening instrument (POSIT) Family Functioning Items is an 11 item scale that measures poor family functioning around parenting, communication and monitoring. It has been used with Apache adolescents and demonstrated adequate internal consistency reliability (alpha=0.73).[10, 33]

UPPS Impulsive Behavior Scale is a 45-item inventory designed to measure four personality pathways to impulsive behavior: Urgency to Act, Lack of Perseverance, Lack of Premeditation, and Sensation Seeking. Each item is rated on a 4-point scale from *1= strongly disagree* to *4 = strongly agree*. Internal consistency has been established for each of the four pathways, with have high internal consistency reliability among Apache youth (Cronbach's alpha=0.92).[10, 26]

Multicultural Mastery Scale is an adapted version of the self- and communal mastery scales for adolescents. This measure explores a wide parameter of topics, including youth resilience, stress and coping, and protection from substance abuse and psychopathology. Each item is rated on a 3-point scale from *0 = not at all, 1 = somewhat, and 2 = a lot.*[45]

Voices of Indian Teens Cultural Issues and Interest are a sub-set of 5 items that assesses the importance following traditional AI practices and values. Questions are drawn from the Voices of Indian Teens Survey (NIAAA grant R01 AA 08474) and have been used widely with AI teens including the Apache.[10]
Rosenberg Self Esteem Scale is a widely used 10-item self-report scale measuring feelings of self-worth, acceptance and self-esteem. Respondents rate how much they agree/disagree on a 5-point scale ranging from *1= strongly disagree* to *5 = strongly agree*. The scale has been used with adolescent AIs with good reliability (alpha=0.84).[27]
The Children's Hope Scale (CHS) consists of 6 items and is based on a conceptualization of hope as consisting of two factors: agency and pathways.[43] Agency is defined as the perception by the child that he or she is able to initiate and sustain action toward a goal. The pathways factor involves the child's capability of producing the means to achieve these goals. [43]
The ASSIST The World Health Organization (WHO) Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) is a questionnaire that screens for all levels of problem or risky substance use in adults.[44] A risk score can be provided for each substance, and scores are grouped into 'low risk', 'moderate risk' or 'high risk'. It has been validated in youth and adolescents, as well as adults. [44]
For locally created items, During our initial research meetings we asked our team about changes they have observed in children as a result of the New Hope and Elders curriculum. We then generated a list of items to include on the research study to help in capturing locally relevant changes in youth's thoughts, feelings and behaviors that could occur as a result of the interventions under study.
*For opioid related items, we consulted with other researchers examining substance use in Native American populations to compile our list of questions (see Appendix). The questions we included have been used and validated in other studies with Native American populations (e.g., Monitoring the Future study), as well as come from national surveys (e.g., 2015 NSDUH Survey, CDC National HIV Behavioral Surveillance).*
Exit Interview Questions: Additional questions asked during the last case management visit about the participant's overall experience in the study and their experience with the interventions (if applicable)
Session Summary Form: Administered after each study visit to better understand what happened between sessions and during sessions.
Additional Case Managemnt Form: Administered during additional case management visits to better understand what happens during those interactions with participants
Work Absenteeism: For participants 16 and over who are not enrolled in school to better understand work performance for use in the costing analysis (Economic Evaluation Supplemental Aim).
PROMIS Pediatric Anxiety Short Form: For all participants, includes 8 items assessing symptoms of generalized anxiety disorder.
COVID-19 Questions: Historically, Native American populations have been extremely vulnerable to severe respiratory illnesses. They also experience large disparities in underlying conditions that increase their risk of COVID-19 related morbidity and mortality. The mitigation strategies for COVID-19 also may increase risk of suicide given the association between social isolation and suicidal behavior. We developed 47 multiple choice questions, with community input, to assess COVID-19 exposure, risk, resilience factors, and historical trauma. These questions take approximately 10-15 minutes to complete and will be asked at each study timepoint.

*Safety assessment only: The Opioid Risk Tool (ORT) is a brief, self-report screening tool designed by the NIDA.*

*Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior. This will be explanined to parents and youth in the consent forms. ORT can be administered and scored in less than 1 minute and has been validated in both male and female patients. The Risk Tool is embedded in the REDCap survey and participants are shown the tool if they endorse any opioid items. Although the ORT is in the assessment, it will not be used for research purposes; it will only be used to ensure the safety of participants.*

**Aim 3:**

*Acceptability and feasibility* will be measured using 13-item and 20-item scales, respectively. Both scales were developed by researchers at Johns Hopkins to measure implementation of mental health programs in low resource settings. Items included in these scales are based on leading implementation science frameworks (Consolidated Framework for Implementation; Reach, Effectiveness, Adoption, Implementation, and Maintenance; and a conceptual model of evidence based implementation in public services sectors)[36-38], as well as knowledge gathered from health systems, dissemination and implementation science experts. The scales have demonstrated good psychometric properties across a range of stakeholder groups in low income settings internationally (alpha=0.79 and alpha=0.77).[39, 40] Each scale is scored on a 4-point ordinal scale ranging from 0 "not at all" to 3 "a lot," with an additional category for "don't know/not applicable."

Capacity for *sustainability* will be measured using the Program Sustainability Assessment Tool (PSAT)[34] which has been adapted for use in low resource settings with providers and organizational staff. The original PSAT is a 40-item instrument used to assess a program's current capacity for sustainability across a range of organizational and contextual factors.[6] The goal of the PSAT is to identify barriers and facilitators to program sustainability, which can be used to guide development of a sustainability action plan.[7] The PSAT was developed based on a literature review of 85 studies focused on sustainability of public health programs. Data from these studies identified eight core domains that affect a program's capacity for sustainability. These domains include: environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, and strategic planning.[8] It has demonstrated internal consistency reliability, structural validity and usability.[6, 9] The PSAT is freely available online and also can be used in paper format. The PSAT will be administered twice each year to the administrative Hub affiliates.

| **Table 2: Assessment Table** | **CM1 (Baseline)** | **CM2 (+30 days)** | **CM3 (+60 days)** | **CM4 (+90 days)** | **CM5 (+180 days)** | **2x year for y2-y5** | **Implementation (y2-y3)** |
|---|---|---|---|---|---|---|---|
| Demographics | X | | X | | X | | |
| Suicide Ideation Questionnaire (SIQ/SIQ-JR) | X | X | X | X | X | | |
| Resilience Scales (MAS, REL, REA) | X | X | X | X | X | | |
| Centers for Epidemiologic Studies of Depression (CESDR-10) | X | X | X | X | X | | |
| Children's Negative Cognitive Errors Scale | X | X | X | X | X | | |
| Problem Oriented Screening Instrument (POSIT) Family Functioning items | X | X | X | X | X | | |
| The Children's Hope Scale | X | X | X | X | X | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| The WHO Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) plus opioid questions | X | X | X | X | X | | |
| UPPS Impulsive Behavior Scale | X | X | X | X | X | | |
| Multicultural Mastery Scale | X | X | X | X | X | | |
| Voices of Indian Teens Cultural Issues and Interest | X | X | X | X | X | | |
| Rosenberg Self Esteem Scale | X | X | X | X | X | | |
| Index of local indicators of well-being | X | X | X | X | X | | |
| COVID-19 Questions | X | X | X | X | X | | |
| Exit Interview Questions | | | | | X | | |
| Opioid Data Collection Sub-Study: Opioid Follow-Up Interview (offered at first assessment point they endorse use) | X | X | X | X | X | | |
| JHU Acceptability | | | | | | | X |
| JHU Feasibility | | | | | | | X |
| Program Sustainability Assessment Tool (PSAT) | | | | | | X | |
| Opioid Roundtables (when stakeholders are available) | X | X | X | X | X | | |
| Implementation Qualitative Interview | | | | | | | X |
| Session Summary Form | | X | X | X | X | | |
| Additional Case Management Form | As needed | | | | | | |
| Work Absenteeism | X | X | X | X | X | | |
| PROMIS Pediatric Anxiety Short Form | X | X | X | X | X | | |

**Qualitative:** In-depth interviews will use semi-structured theoretically driven interview guides and will be transcribed and thematically coded using emergent coding. From the quantitative data, item frequencies and summary scale scores will be examined to identify barriers and facilitators to program acceptability, feasibility and sustainability.

*For the opioid guide, we consulted with other researchers examining substance use in Native American populations to create our semi-structured guide (see Appendix).*

5. Answer the following **if they are relevant to your study design**:

A. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.

**Aim 1:** Participants will be stratified by age groups (10-14, 15-19, 20-24, 25-29) and event type (ideation, attempt, binge + recent ideation), then randomized to the control or intervention condition using a 1:1 assignment ratio. Re-randomization of all participants will occur again at CM3 (another 30 days or 60 days/2 months post-baseline assessment).

**Aim 3:** N/A

B. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.

N/A

C. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.

N/A

D. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.

N/A

E. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

N/A

F. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:

Answers for this section apply only to Aim 1. Aim 3 does not involve an intervention.

a. Will the study staff be blind to participant intervention status?

Yes.

b. Will participants receive standard care or have current therapy stopped?

All participants will receive standard of care, which is case management visits and referrals to care. Participants may still receive this care post study.

c. Will you use a placebo or non-treatment group, and is that justifiable?

We will use a control group who will receive case management and will be referred to mental health care—the standard protocol for the existing Apache system.

d. Explain when you may remove a participant from the study.

Participants will be removed from the study if they move off reservation or are relocated for treatment.

e. What happens to participants on study intervention when the study ends?

The interventions are intended to be brief (2-4 hours). During the intervention and case management visits youth will become acquainted with available local resources, including visits by CMHWs.

f. Describe the process for referring participants to care outside the study, if needed.

As is standard practice, CMHWs will refer all youth to care outside of the study, including referrals to mental health care providers, traditional healers, and spiritual leaders. In addition, we have an established protocol created as part of previous studies to ensure triage and access to emergency care for youth who are at immediate risk for suicide. This procedure was approved by Tribal, Hopkins and IHS IRBs, and will be employed by CMHW for this project. At the close of each visit, youth will complete the Suicide Ideation Questionnaire (SIQ/SIQ-JR) and Opioid Risk Tool. CMHWs immediately score SIQ and Opioid Risk Tool at the time of visit, and depending on score will respond in a graduated fashion. Youth may also be viewed as higher risk if a staff member working with them has concerns.

## VI. Data Security and Confidentiality Protections:

### A. Personally Identifiable Information (PII):

Please identify the Personally Identifiable Information (PII) that you may be collecting and using at any of the following stages of your study: ***Recruitment, Consent,*** *and* ***Study Implementation***.

| | |
|---|---|
| Name, signature, initials, or other identifiable code | ☒ |
| Geographic identifier: address, GPS location, etc. | ☒ |
| Dates: birth, death, clinical service, discharge, etc. | ☒ |
| Contact information: phone numbers, email address, etc. | ☒ |
| ID: Social Security Number, driver's license number, etc. | ☐ |
| Health record identifiers: medical record, insurance plan number, etc. | ☒ |
| Account numbers | ☐ |
| **Device identifiers: e.g., implants** | ☐ |
| Internet identifiers: IP address, social media accounts | ☐ |
| Biometric identifiers, including finger and voice prints | ☐ |
| **Audio recordings** | ☒ |
| Video or full face photographic images | ☐ |
| Genomic/genetic data | ☐ |
| Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data) | ☐ |
| Other: Click here to enter text. | ☐ |

### B. Recruitment:

Will you collect identifiers for the purpose of contacting potential participants? Yes ☒ Aim 1 only. No ☐

If **yes**, will you retain the identifiers after the recruitment contact has been made? Yes ☒ No ☐

## C. Data Collection:

In what form will you collect and store PII? When you respond, think of PII collected for recruitment, consent, and other study purposes.

1. **Hard Copy/Paper:** Yes ☒ No ☐

   If yes, please answer the following:

   a. How will the data be kept secure during transfer from study collection site to storage site?

      **Aim 1:** We will collect signed consent forms from each participant. Signed consent forms will be stored in a locked cabinet at local JHU offices on the Fort Apache reservation separately from study data.

      ***For the economic evaluation supplement aim****:* Once a link is made between a study participant (using name, date of birth and medical ID number), the corresponding study ID will be assigned to the electronic medical records. All data identifiers will then be removed from electronic medical records before transfer from the Indian Health Service's Medical Records to storage site. The link between study IDs and personal identifiers will be maintained in a password protected excel database on a password protected computer maintained by the study team.

      **Aim 3:** Signed consent forms will be stored in a locked cabinet at local JHU offices on the Fort Apache reservation separately from interview notes. Interview notes will be taken on a notepad using only a study ID. The link between study IDs and personal identifiers will be maintained in a password protected excel database on a password protected computer maintained by Dr. O'Keefe in the Baltimore office, and interview notes will be kept in a locked cabinet in CAIH's offices.

      Online consent will be obtained via an agreement to continue the survey on Qualtrics. The link between study IDs and personal identifiers will be maintained in a password protected excel database on a password protected computer maintained by Dr. Haroz.

   b. Will the data be secured in a locked cabinet or room? Yes ☒ No ☐

   c. Are the data collection forms and study data stored without personal identifiers and separate from the study IDs/code? Yes ☐ No ☒

   d. How long after study completion will you keep the hard copy/paper forms?

      Data will be retained until the end of study analysis or three years after the final participants exit the program, whichever comes first.

2. **Electronic:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will the data be collected/stored on a portable device (laptop, mobile phone, tablet, PDA) protected by encryption? Yes ☒ No ☐

b. Will the data be stored on a secure server or in the Cloud/Web?

Secure Server ☐ Cloud/ Web ☒

c. Will it be encrypted? Yes ☒ No ☐

d. Will you be backing up your data? Yes ☒ No ☐

3. **Audio Recording:** Yes ☒ . No ☐

If yes, please answer the following:

a. Will you store the audio recording securely in a locked cabinet/room until transcription is complete?
b. Yes ☒ No ☐
c. Will the audio recording be destroyed after transcription? Yes ☒ No ☐
For intervention session recordings, they will be destroyed after quality assurance ratings are completed.
If no, why not?

4. **Photograph/Video:** Yes ☐ No ☒

If yes, please answer the following:

a. Will the photographs/videos be stored securely in a locked cabinet or room? Yes ☐ No ☐

b. Will the photograph/video be destroyed? Yes ☐ No ☐

If yes, when?

## D. PII De-Identification of Data Used for this Study:

When will you destroy the PII and/or the code linking the PII with the study ID?

**Aim 1:** Normally collected surveillance data will be stored in the surveillance system indefinitely. PII associated only with the study and not surveillance will be destroyed when the study is complete.

**Aim 3:** When the study is complete, we will destroy the file linking the PII with the study ID.

*Economic Evaluation Supplement Aim: All identifiers from IHS medical claims data will be destoyed immediately after linking of data to study participants is completed.*

## E. Data Storage and Analysis:

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the system that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.

☐ **JH Virtual Desktop**: IT@JH provides (for a monthly fee) a virtual Windows desktop.

☐ **JHSPH SharePoint and File Shares**: These systems provide a managed and secure platform for your research project. They also provide a built-in encrypted backup solution.

☒ **JHSPH RedCAP or HPCC**: These are departmentally managed applications.

☒ **JHBox**: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing and file storage service.

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff.

☐ **Other**: Please provide details regarding any other systems being utilized.

## F. Other Data Security Measures:

In addition to the details regarding data collection, please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts and additional requirements.

1. Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan? Yes ☒ No ☐
   If yes, please provide a contact name: Dr. Mary Cwik

2. Does your sponsor have other specific data security requirements for the study data? Yes ☐ No ☒
   If possible, please explain:

3. Please add any other information that you believe is relevant to data security. N/A

## G. Certificate of Confidentiality:

Will the study data stored in the **United States** be protected by a Certificate of Confidentiality?

Yes. All study information will be protected by a Certificate of Confidentiality. This Certificate will allow us, in some cases, to refuse to give out participants information even if requested using legal means. It will not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing participant information if we learn of possible harm to them or others, or if they need medical help. Disclosures that participants consent to in the consent form are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that participants make are also not protected.

If yes, explain who will apply for and maintain the Certificate.
(http://grants.nih.gov/grants/policy/coc/appl_extramural.htm)

Dr. Mary Cwik will apply and maintain the Certificate.

**H.** Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?
Yes ☐ No ☒

If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.

**VII. Risks of the Study:**

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

**Aim 1:** All participants will be informed about any *potential risks*. The main potential risks to youth enrolled in the programs are: a) the possibility of discomfort in completing the assessments; b) worsening of symptoms; c) breach of confidentiality including sensitive data regarding opioid use; and d) the need to report to tribal/state authorities for dangerousness to self or others or if the participant is a victim of abuse. If youth or adults are identified as using or abusing opioids, the above risks apply for the qualitative interviews to which they will separately consent.

The main additional risk would be the requirement to undergo an additional opioid abuse assessment (described above) to continue in the parent study, which may include additional discomfort. In the case of minors, another risk is the possibility of having to disclose their opioid abuse to their parents. Specifically, when a youth participant is identified at high risk from their own opioid use, research staff would share with the youth's parent(s): the opioid use (of which the parent may or may not be aware); the determination of high risk; the referral information; and the importance of the parent(s) following through on the referral for their youth. Per the Opioid Risk Tool scoring guidelines, a score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse. We would consider a score of 8 or higher to necessitate parent notification. In the moderate risk level, we will encourage and support youth to talk with their parents about their opioid use, but would not require disclosure.

Other risks not known now may occur during study participation.

**Aim 3:** The goal is to gather information to improve interventions and workflow. Any suggestions or criticisms of will be viewed as an opportunity to better meet Southwest Hub partner communities' needs. The biggest risk is that stakeholders' views might become known to others, including their supervisors, employers, or partners. We will attempt to minimize this risk by ensuring that the interviewer is trained in confidentiality procedures. The interviewer will refrain from using an identifying information during interviews, and only two Baltimore-based research staff (Dr. Haroz and Dr. O'Keefe) will have access to the audio files and transcripts. For the online survey, only Dr. Haroz will have access to the link between the study ID to the identifiers. No data collected will have identifiers. All data will be reported in aggregate to avoid identifying individual participants.

**Risks of economic evaluation aim:** We do not anticipate added risks with the additional items on the assessments for participants. The only potential added risk is the risk to confidentiality of the medical claims data. We will only use identifying data to link participants with their medical claims data. After the link has been established, we will destroy all identifiers in either dataset.

B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an

"anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

**Aim 1:** We anticipate minimal frequency and low severity of the harms associated with the risks above based on previous Apache-JHU studies with this population.

**Aim 3:** As the topic is views about the Southwest Hub's key intervention components (Surveillance/Case Management, New Hope and Elders' Resilience), we anticipate minimal risk.

C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

**Aim 1:** We have attempted to minimize these risks by employing Native paraprofessionals who will be trained in active listening, problem-solving, maintaining confidentiality, assessing worsening of symptoms, providing support, and other relevant procedures to ensure each youth's comfort and well-being. The highest standards of confidentiality protection procedures will be followed. Although there are minimal risks directly associated with study participation, it is possible that study participants may experience adverse life events that will need to be addressed. Specific steps taken to minimize risk are described below:

*a. Discomfort with Assessment Procedures*

To prevent discomfort or embarrassment, Research Program Assistants will undergo intensive training in the administration of the assessment procedures, rapport building and strategies to identify and minimize distress. Data collection will be done using audio assisted interviews. Participants are informed prior to the assessment that they may choose to skip any questions they do not want to answer or that make them uncomfortable. If any individual becomes distressed during the assessment, a break will be provided or the assessment will be stopped, and the Research Program Assistants will work with the participant to reduce the participant's distress. If the participant's distress is not able to be addressed by these approaches, the Research Program Assistants will ask if the participant wishes to address the distress in another manner and will facilitate the participant's request when possible. In addition, Research Program Assistants can enlist one of the Principal Investigators (PI), Dr. Mary Cwik, a clinical child psychologist, to talk with the participant via phone and facilitate referrals if necessary. *All research staff have the PI's cell phone number to contact her for these types of events 24 hours a day and the Co-PI (Dr. Barlow) and Clinical Research Supervisor (Dr. O'Keefe) serve as back-up.*

*b. Worsening of Symptoms:*

An imminent risk procedure was developed by WMAT-CAIH as part of previous studies to ensure triage and access to emergency care for youth who are at immediate risk for suicide. This procedure was approved by Tribal, Hopkins and IHS IRBs, and will be employed by CMHWs for this project (*see Protection of Human Subjects*). At the close of each visit, youth will complete the Suicide Ideation Questionnaire (SIQ/SIQ-JR) (*see Appendix*). CMHWs immediately score SIQ at the time of visit, and depending on score will respond in a graduated fashion. The staff member also has the training and discretion to recognize high risk individuals and will act accordingly, even if SIQ does not indicate risk.

*c. Identified to be Using or Abusing Opioids:*

If current opioid use is identified through our supplement, a two-fold strategy will be used. First, once opioid related items are approved to be added to the surveillance system, substance specific referrals and case management will be covered by the surveillance system. Second, an additional opioid abuse assessment will be conducted to ensure the safety of participants in the SMART trial who endorse current or recent use. This assessment would be conducted *at the study visit*. This assessment will allow the study team to determine if

the participant can continue in the trial, in addition to get them into the most appropriate treatment. All participants who endorse opioid use will receive referrals.

*d. Risk of a Breach in Confidentiality*

There are two methods by which participants' confidentiality can be breached, including inadequate safeguards of the collected data and a direct breach of confidentiality by study personnel. The consent form will describe in detail the methods used to protect participants' confidentiality and those individuals and entities (i.e., Johns Hopkins IRB, NIH) that have access to the data. As mentioned above, we will obtain a Certificate of Confidentiality for this study. We will explain to the participants that we will have obtained this Certificate of Confidentiality as added protection for their privacy.

*Data Safeguards* – As described above under "Confidentiality," all participants will be assigned a confidential identification number, which will be the only link between identifying information and the data. The master list of participants' names and ID numbers will be kept on a password protected computer with restricted access. Only those directly involved in study coordination will have access to the database, under the close supervision of the PI. The information gathered will be used only for scientific, educational or instructional purposes. No information about the identities of participants will be published or presented at conferences. The computers are password protected and maintained in locked buildings that are only accessible to study team personnel.

*Direct Breach of Confidentiality* – All Research Program Staff will be trained and certified in the ethical conduct of human subject's research, including confidentiality safeguards, before beginning work on the study. This involves an on-line training and testing program that focuses on the principles from the Belmont Report. During the study, ongoing review of the needs for participant confidentiality and specific training will occur at regular intervals both formally (i.e., on site trainings by the PIs/Co-Is) and informally (i.e., weekly conference calls). All Research Program staff are aware that a breach of confidentiality is cause for termination of employment and subject to both criminal and civil penalties.

*e. Procedures for Implementing Mandatory Reporting*

Participants are informed in the consent form that Research Program staff must report to the authorities: i) if the participant is in imminent danger to him/herself or others; and ii) if there is confirmed or suspected abuse or neglect of the participant. Research Program staff will work to ensure the safety of the participant, and in acute situations will act immediately to involve parents and appropriate authorities (i.e., call the police), as well as the Local Project Director (PD) (Novalene Goklish) and one of the PIs (*as the PIs are in Baltimore and research in Arizona all consultations with them occur via phone*) in managing the acute crisis.

*Dangerousness to self*; s*uicide thoughts or attempts.* We recognize that this population is high risk and have developed a risk management protocol that has been approved by the community and our partner IRBs and successfully implemented in several previous studies (e.g., NARCH III 1S06 GM074004; SAMHSA 5 SM057835) with suicidal youth from this community. As part of the first assessment visit, participants will be questioned about medical, behavioral or psychological events since the last visit, and Research Program Assistants will administer the SIQ to monitor and assess risk. In addition, as the participant completes the assessments, Research Program Assistants will note participant responses that indicate concern. Research Program Assistants will be required to review disclosure information with the local PD; Novalene Goklish) and, if deemed necessary, conduct follow-up inquiry with the participant to further determine level of risk and call one of the PIs to review the information. Our response to each such event will be graded and proportionate. If the SIQ score is above the clinical cutoff as determined by the measurement developers, , the SIQ-Past Few Days (SIQ-PFD) is administered. For immediate risk for suicide (i.e., active ideation with a plan and unwillingness to cooperate with a mental health referral as assessed by the SIQ-PFD and follow-up inquiry), Research Program Assistants will be trained to secure the immediate safety of the participant, engage the

participant's parent, and call the police and then the PI and local PD. At the lowest level of suicidal ideation (i.e., passive ideation without plan, no interest in dying and willing to cooperate with a mental health referral as assessed by the SIQ-PFD and follow-up inquiry), Research Program Assistants will conduct safety planning, engage the parent/guardian and provide a mental health referral as soon as possible.. *Please note safety plans are developed with all participants (and reviewed with their parents) who score above the clinical cut-off for the SIQ, and/or whom the research staff have concerns about.*

*i. Threat of danger to others.* The threat of danger to others includes disclosure of potential physical harm by a participant to others, including members of the participant's family or other individuals in the community. At any time during the study, if this information is obtained by Research Program Assistants we will complete a procedure like our graded and proportionate response to suicidal ideation and abuse/neglect. For acute and imminent danger, the Research Program Assistants will do their best to secure the situation and notify the parents, police, and then the PI and PD. At the milder end of the spectrum, such as a cooperative participant with unresolved anger at another person, the Research Program Assistants will contact either the PI or PD to develop a plan. Current local and national legal standards regarding duty to warn will guide all contact with outside authorities and the intended victim. The PD and Research Program Assistants assigned to the participant will track the referral process and report directly to one of the PIs.

*ii. Participants are identified to be using/abusing opioid (adults and minors).* Substance abuse does not fall under mandated reporting requirements unless the minor participant is deemed to be in danger from opioid abuse/addiction or danger from involvement in related activities (i.e., selling opioids). Danger will be deemed from the assessment (Opioid Risk Tool) as described above. Study staff will work to ensure the safety of the participant, and in acute situations will act immediately to involve parents/guardians, local authorities, as well as the PD and the PI (*as the PIs are in Baltimore and field site in Arizona, all consultations with them occur via phone*) in managing the acute crisis. While clincians on our team are not legally required to report risky substance use, we are following this protocol for safety purposes.

*iii. Abuse/neglect.* Child abuse/neglect concerns may arise from any or all of the following sources: 1) the participant or a parent/guardian may indicate abuse/neglect has occurred or is occurring; 2) the participant answers one or more assessment questionnaire items suggesting abuse of him/herself; 3) the participant is observed being abused during program visits; and 4) the Research Program Assistant observes potential signs of child abuse (i.e., bruises, burns, black eyes) or neglect (i.e., weight loss or less than expected weight gain due to limited availability of food); absent or unsafe parenting due to opioid use that are not easily explained. The response to each such event will be graded and proportionate. For very recent and severe abuse with the potential for future abuse, Research Program Assistants will be trained to secure the immediate safety of the participant, engage the participant's parent if possible and appropriate, and then call the police and then the PI and PD. At the lowest level - questionable neglect (i.e., lack of parent/guardian's appreciation of child's nutritional needs and willingness to address such issues through the program and referrals) –Research Program Assistant will discuss the situation with the PI and PD within 24 work hours and develop a plan to address the participant's needs. In each case of suspected or actual abuse, we will inform the appropriate tribal and state authorities who will complete an investigation. The PD and Research Program Assistant assigned to the participant will track the referral process and report directly to one of the PIs.

*iv. Other crises that put participants or their children at risk.* Other crises may threaten the basic support for participants or their children during the study such as the development of a mental health problem in the minor participant's parent including opioid addiction, a minor participant's parent leaving the home to enroll in a residential substance abuse program, domestic violence (that does not involve the child), and natural disasters – fires, floods, etc. The protocol developed for the project will have guidelines for responding to such crises within the scope of the project objectives including

identification of such issues, securing the acute situation as much as possible, contacting the PI and senior study staff, making referrals and facilitating access to needed services for participants and their families. The Field Supervisor and project staff assigned to the participant will track the referral process and report directly to the PI.

*f. Possible Risks of Study Participation Not Known at the Current Time.*
It is possible that there are risks to study participants from participation that are not known at this time, including those related to our addition of opioids to data collection. The protocol has in place strategies to provide referrals for all participants who may encounter problems and provide follow-up to ensure those connections to care are made. These procedures and relationships with referring agencies have been refined over 10 years of doing mental health research with high-risk participants. Relationships with referral agencies include Apache Behavioral Health Services, Rainbow Treatment Center and Indian Health Services Social Services Department. In the event that participants experience any adverse or untoward effects, regardless of their relationship to the program, every step will be taken to provide the appropriate assistance to the participant. We will also continue to consult with our NIH colleagues, local partners, the DSMB and our opioid consultants to refine our safety procedures specific to opioids as needed.

D. Describe the research burden for participants, including time, inconvenience, out of pocket costs, etc.

**Aim 1:** The main burden for participants will be the time associated with the case management and interventions. The control group will spend 6 hours in case management over 6 months, while for the intervention group this will be a total of 10-14 hours. Any travel barriers or inconveniences and associated out of pocket costs will be addressed by conducting visits at their home or other private location of their choosing.

**Aim 3:** For the qualitative interviews, participants will have to devote approximately 65 minutes total over two study visits: 1) consent (~20 minutes); and 2) interview (~45 minutes). All consents and interviews will be done at a time and location of their choosing. The PSAT online survey will take approximately 20 minutes and will be administered 8 times over the course of the study for a total of 2.67 hours over the course of 4 years.

E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

**Aim 1:** Participant privacy will be protected by completing questionnaires on tablets in a private location of the participants' choosing. Data will be held in a secure, password protected database. Only CMHWs will have access to the data. Privacy for minors will be protected including reporting of high risk behaviors such as past or current opioid use. Study data will not be shared with participant's legally authorized representative unless there is evidence that the participant is a danger to him/herself including from opioid addiction, danger to others, or if there is confirmed or suspected abuse or neglect of the participant. Research staff will work to ensure the safety of the participant, and in acute situations, will act immediately to involve parents and appropriate authorities. In the case of opioid use that does not warrant breaking privacy protections but would benefit from treatment or prevention strategies, research staff will encourage both adult and youth participants to disclose their use to parents with research staff support in order to engage a familial support system for youth related to opioids. Communication between investigators and participants will be conducted in-person or by phone versus in writing (i.e., email) to further protect privacy by limiting additional paper or electronic documentation that could be more easily breached.

**Aim 3:** There are no sensitive questions included in the interviews.

**VIII. <u>Direct Personal and Social Benefits</u>:**

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

**Aim 1:** Participants may benefit from the interventions by experiencing a reduction in their suicidal thoughts or binge behaviors, and an increase in coping skills and resilience.

**Aim 3:** Participants will be able to voice challenges to implementation and scale-up of suicide prevention and resilience promotion programs.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

We hope that by doing the research study described in Aim 1, we will be able to identify interventions that sustainably reduce the burden of youth suicide and promote resilience in Native communities. Aim 3 will guide the implementation and scale-up of suicide prevention and resilience promotion programs. In addition, our aims through the Opioid Data Collection Sub-Study will help us better understand opioid use as a potential precipitant, facilitator and risk factor for subsequent suicidal behavior, as well as community perspectives about opioid use. Together, successful achievement of these aims will inform American Indian communities about which types of suicide prevention programs are effective, acceptable, feasible and potentially sustainable in certain settings. The scientific field will benefit from answers to questions about which suicide prevention strategies are effective, and for whom, as well as information about their acceptability, feasibility and capacity for sustainability in different tribal communities.

Policy makers will likely benefit from knowledge gained from these studies which may be used to inform evidenced-based and culturally congruent local policies and programs. Policy makers and stakeholders will be involved with the initial and ongoing review of study protocols. They will also be invited to share their opinions on the acceptability, feasibility and capacity for sustainability of the suicide prevention programs. Their involvement will be critical, thus allowing for real-time policy influence.

## IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

**Aim 1:** Compensation will be provided to 304 Aim 1 participants. Compensation will increase with each of the five study visits: $20, $25, $30, $35, $40.

**Aim 3:** For the qualitative interviews, key stakeholders will not be given compensation. For the PSAT online survey, participants will be provided with a $20 gift card for each completed survey. Participants in the Opioid Data Colletion Sub-Study will receive an additional $25.

B. Include the possible total remuneration and any consequences for not completing all phases of the research.

**Aim 1:** Participants who complete all study visits can receive a maximum of $150 over the course of 6 months. If they do not complete study assessments or drop out of the study they will receive compensation commensurate with their participation.

**Aim 3:** For the PSAT online survey, participants can receive a maximum of $160 over the course of the four years of the study.

## X. Study Management:

A. **Oversight Plan:**

1. Describe how the study will be managed.

   **Aim 1:** Drs. Barlow and Cwik will oversee all aspects of the study and will provide regular check-ins with on-site Local Project Director and Research Program Assistants throughout the course of the study. Dr. Cwik will serve as the clinical advisor on the team and will provide guidance to Dr. Haroz, including assisting in interpretation of the data. Dr. Haroz will oversee all data collection and secondary data analysis, and will provide supervision on analyses to Dr. O'Keefe. Dr. O'Keefe will coordinate the implementation of the study, perform some analysis, and train local evaluation coordinator and Research Program Staff in study procedures. Ms. Lake will develop the curriculum for the interventions and will train Research Program Assistants in implementation. Ms. Alfonso will conduct the economic evaluation analysis.

   **Aim 3:** Drs. Barlow and Cwik will oversee all aspects of the study and will provide regular check-ins with Dr. Haroz and Dr. O'Keefe throughout the course of the study. Dr. Cwik will serve as the clinical advisor on the team and will provide guidance to Dr. Haroz, including assisting in interpretation of the data. Dr. Haroz will oversee all data collection and secondary data analysis, and will provide supervision on analyses to Dr. O'Keefe. For the qualitative interview, Dr. O'Keefe will obtain consent, conduct interviews, and perform some analysis.

2. What are the qualifications of study personnel managing the project?

   Dr. Barlow is the director the CAIH and has worked with WMAT for over 25 years. Dr. Cwik is a clinical psychologist and has helped to establish the suicide prevention program over the past 10 years. Dr. Haroz is an epidemiologist and statistician with extensive experience working on mental health care programs and implementation science research in low resource settings. Dr. O'Keefe is a clinical psychologist and has extensive experience studying the social, historical, and cultural determinants that relate to health status, as well as strengths-based approaches to mental health. Ms. Lake is a certified health educator with specialized education and training in curriculum development. She has directed the development and/or adaptation of all behavioral health prevention and intervention curriculums at the Center for nearly 10 years. Ms. Alfonso is a health economist with has 8 years of experience conducting economic evaluations and evaluating health care claims data.

3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website: www.jhsph.edu/irb.)

   All personnel involved with data collection have been trained in human subjects research protections and have up to date CITI certifications. In addition, we will train our Elders on the following components: 1) the overall study protocol and accompanying policies and procedures manual, 2) the content and delivery of the Elders brief curriculum, 3) human subjects research, 4) Good Clinical Practice, and 5) our safety protocol that the accompanying case managers will complete at each visit (Elders will not be expected to implement/carry out the safety protocol). We will cover all these components in a 1-day in-person group training led by our local PD, Novalene Goklish. We use a combination of didactic and role-playing for components 1) and

2). We will utilize materials provided by Hopkins for components 3) and 4), specifically, the human subjects training for field workers (JHSPH Human Subjects Research Basic Course), and abbreviated Good Clinical Practice slide set (Good Clinical Practice, Social/Behavioral Interventions). Elders will review these individually, after which there will be a group review.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

   **Aim 1:** Throughout the duration of the study, the PI will have weekly conference calls with the local Research Program staff to monitor study progress and assure that the study is being implemented according to protocol. The PIs (located in Baltimore) will make at least 2 trip to the study sites each year during the study's duration. Additionally, the PI or one senior member of the investigator team will conduct at least 2 other visits to the study location to assess fidelity to study protocol, protection of human subjects, and assurance of data quality and safety. The Local Project Director and evaluation coordinator will provide in-person oversight and monitor consent and data collection to ensure the study is progressing according to protocol.

   **Aim 3:** Interviews will be conducted by phone and no site visits will be necessary.

B. **Recordkeeping:**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhu.edu.

**Aim 1:** The Local Project Director and evaluation coordinator will be trained in study procedures and will oversee data collection and storage to ensure fidelity to the study protocol. The Local Project Director and evaluation coordinator will discuss all concerns with the investigator team. As noted above, the PIs or other members of the investigator team will conduct in-depth quality assurance checks during at least 2 of their visits to the field during the study period. The PIs will be responsible for reporting to the IRB.

**Aim 3:** Drs. Barlow and Cwik will meet regularly with Dr. Haroz about the project, and Dr. Haroz will check in about appropriate data storage with Dr. O'Keefe.

C. **Safety Monitoring:**

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

   **Aim 1:** The PIs assume responsibility for the safety of study participants. Research Program staff will be trained to monitor for safety of study participants and report any concerns immediately to the Local Project Director, the Clinical Research Supervisor and the PIs. All Research Program staff will be trained in human subject's research and will be required to complete the CITI ethics module prior to any interaction with participants or study data. Certificates of human subject's completion will be kept on file at the Center for American Indian Health's office in Baltimore.

   To determine and quantify the participant's current risk for suicide at the close of all study visits, the Research Program Assistants will complete the Suicide Ideation Questionnaire (SIQ) (participants 15 and over) or the SIQ-JR (participants <15years) with participants. The screen will identify recent suicidal ideation

or behavior, worsening of psychopathology and recent acute stressors. Research Program Assistants will immediately score the SIQ. Depending on the SIQ score, the Research Program Assistants will administer the SIQ-Past Few Days, and then respond in a graduated fashion based on the following risk categories as determined by the SIQ /SIQ-Past Few Days: 1) Does not Appear at Risk; 2) At Some Risk; 3) At Medium to Very High Risk. The following actions, which are clearly outlined in the consent form and will be reviewed prior to each assessment, are taken depending on the SIQ/SIQ-Past Few Days Risk Score:

If the SIQ score is below 37 or SIQ-JR is below 16, the risk category is deemed to be **"Does Not Appear at Risk."** Research Program Assistant takes the following steps:

When the SIQ does not identify any acute risks and Research Program Assistant observations corroborate this impression, no additional immediate action is needed. If staff has any concerns about these participants, they should not hesitate to contact:
- Local Project Director, Novalene Goklish, Whiteriver, AZ
- Principal Investigators, Dr. Allison Barlow, PhD and Dr. Mary Cwik, PhD, Baltimore, MD
- Clinical Research Supervisor, Dr. Victoria O'Keefe, PhD, Baltimore, MD

If the SIQ score is 37 or above, the SIQ-Jr is 16 or above, and 0 items on the SIQ-Past Few Days scored a 4, 5, or 6 the risk category is deemed to be **"At some risk".**

Research Program Assistants take the following steps:
If at the time of the assessment some risk factors are identified, Research Program Assistants will call the senior staff person on site, the Local Project Director (Novalene Goklish), to review the case and develop a plan. Most often the plan will be to alert the Apache Surveillance System Team, which will implement its procedures for assessment and referral. The Local Project Director will notify the PI. If the local Project Director cannot be reached, staff are instructed to reach out directly to the PI, Mary Cwik, or Clinical Research Supervisor Victoria O'Keefe.

If the SIQ score is 37 or above, the SIQ-Jr is 16 or above, with any items on the SIQ-Past Few Days that were a 4, 5 or 6, the individual is deemed to be "**At Medium to Very High Risk**" Staff will call the senior staff person on site, the Local Project Director, Novalene Goklish, to review the case, including: the SIQ scores, family support available, reviewing any counseling appointments scheduled and develop a plan. The range of interventions could include setting up an appointment with the Surveillance Team, an urgent appointment with Apache Behavioral Health Services, or an Emergency Department visit.

The Local Project Director will notify the PI, Mary Cwik in Baltimore the same day to review the plan. If the PI is not available they will call the Clinical Research Supervisor, Victoria O'Keefe. The Local Project Director and the PI (or back-ups) will review the case, identified risk factors and the developed plan.

These procedures are clearly outlined in the consent form and will be reviewed prior to each visit.

Opioid Data Collection Sub-Study: If current opioid use is identified through our supplement assessments (*opioid related questions will be asked at each study assessment visit*), a participant could be discontinued if the use is determined to be abuse and they need immediate opioid specific treatment. This assessment would be conducted *at the study visit*. They will use the *Opioid Risk Tool*. There are strategies in place to provide referrals for all participants who endorse use and provide follow-up to ensure those connections to care are made. These procedures and relationships with referring agencies have been refined over 10 years

of doing mental health research with high-risk participants. Relationships with referral agencies include Apache Behavioral Health Services, Rainbow Treatment Center and Indian Health Services Social Services Department. Research staff will encourage both adult and youth participants to disclose their use to parents with research staff support in order to engage a familial support system for youth related to opioids. Our staff will remind the participant of the study protocol which would have been explained to them during consent. A participant may refuse the opioid abuse assessment at the time of the study visit. In this case, they would be required to have the opioid abuse assessment conducted before the next intervention or study visit to continue in the parent grant and supplement.

**Note**: Parent/guardian will be notified during the consent process that their child's responses to the items on the study instruments will not be shared with them. However, if immediate triage of study participants is required due to the identified worsening of symptoms or using or abusing opioids, the Research Program staff member will notify the parent/guardians of the <18 year old participants at the same time that the appropriate tribal authorities are notified. For study participants aged 18-19, it is not required that the Research Program staff notify the parent or guardian, but Research Program staff will attempt to do so with the study participant's verbal permission.

**Aim 3:** We expect minimal risk, however, Dr. Cwik, a clinical psychologist, and be available if unexpected issues arise.

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:

This section only applies to Aim 1. Aim 3 will not have a DSMB.

a. The DSMB membership, affiliation and expertise.

The Data and Safety Monitoring Board (DSMB) will be comprised of a group of independent experts that advises the Southwest Hub and will include at a minimum, one suicide expert, one tribal nations expert, and one biostatistician.

b. The charge or charter to the DSMB.

The DSMB will meet at least once yearly via phone conference calls for the duration of the project. They will assist the study in monitoring adverse events. At the initial meeting the DSMB will review and approve all study protocols before study initiation to ensure participant safety. Protocols will include formal procedures for reporting and tracking all adverse reactions to the NIH and IRBs; tracking progress in the study; and identifying any need for premature termination of the protocol. At subsequent meetings, the DSMB will be provided with summary study progress reports and adverse events. The DSMB will provide a summary report following each meeting. The DSMB will conduct interim analyses of data prior to end of study to closely monitor effectiveness and any possibility of harms associated with the programs.

c. Plans for providing DSMB reports to the IRB.

Annual reports will be prepared by the Clinical Research Supervisor and report any risks identified, what steps were taken to mitigate them and any new areas of risk that need attention.

All types of adverse events will be summarized for the DSMB and reviewed during their meetings. The DSMB will also review participant safety and confidentiality, and data safety. Specifically, the DSMB will be asked to evaluate:

1) all serious, unexpected and commonly experienced adverse events, including those related to opioids, or other unanticipated problems that involve risk to study participants, regardless of whether these events appear related to the study-based interventions or research assessment protocols;
2) whether participants' safety, privacy, and confidentiality has been consistently assured by the investigators;
3) whether data is being managed, stored, and maintained in accordance with scientific standards; and
4) the risk/benefit ratio to determine if it has changed to the extent that the study should be modified or discontinued.

4. Describe plans for interim analysis and stopping rules, if any.

Stopping rules will be established by the DSMB prior to study initiation.

In cases where participants score in the high-risk category on the Opioid Risk Tool, the local research staff will consult with the two Co-PIs to determine if the participant can continue in the parent study. The parent study is an effectiveness trial, where participants can receive other services as necessary. The main factor for deciding whether they can continue in the trial is whether participating in our study is interfering with them participating in needed opioid treatment (i.e., participation in our trial may be a barrier to the time commitment needed for substance use treatment) or vice versa— i.e., participation substance abuse treatment may be a barrier to the time commitment needed to participate in our trial.

D. **Reporting Unanticipated Problems/Adverse Events (AE's) to the IRB (*all studies must complete this section*)**:
**Aim 1 & 3:** Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

The Research Program staff will immediately alert the Local Project Director and PIs in the event of an adverse event or unanticipated problem. The PIs, Drs. Barlow and Cwik, and the Clinical Research Supervisor, Dr. O'Keefe, will report serious adverse events to the JHSPH IRB if it is unanticipated, poses risk of harm to participants or others, and is related to the study. If there is any suspected harm to self, others, or abuse reported during an interview (including those related to opioid use), the Research Program staff will immediately report this information to the PIs. The PIs and the Local Project Director will report this to appropriate Tribal or Law Enforcement Authorities. With experience from previous studies with the White Mountain Apache community, the study team is knowledgeable of how to report this type of event without revealing study participation.

NOTE: The IRB does not require submission for all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.

E. **Other IRBs/Ethics Review Boards:**

If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

This project was approved by the White Mountain Apache Tribal Health Board and the White Mountain Apache Tribal Council. (Note: White Mountain Apache Tribal Health Board and Tribal Council approval was granted simultaneously when the grant application was submitted to conduct the research).

F. **Collaborations with non-JHSPH Institutions:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

**Insert Name of Institutions in Partner column(s); add additional columns if necessary.**

| | JHSPH | Partner 1 | Partner 2 |
|---|---|---|---|
| Primary Grant Recipient | X | | |
| Collaborator | | | |

**For the following, indicate "P" for "Primary", "S" for "Secondary" (as appropriate to role and level of responsibility.) Add additional items if useful.**

| | | | | |
|---|---|---|---|---|
| 1. | Human subjects research ethics training for data collectors | P | | |
| 2. | Day to day management and supervision of data collection | P | | |
| 3. | Reporting unanticipated problems to the JHSPH IRB/Sponsor | P | | |
| 4. | Hiring/supervising people obtaining informed consent and/or collecting data | P | | |
| 5. | Execution of plan for data security/protection of participant data confidentiality, as described in the Data Security and Confidentiality Protections section above . | P | | |
| 6. | Biospecimen processing, storage, management, access, and/or making decisions about future use | P | | |

## XI. Secondary Data Analysis of Existing Data:

### A. Study Design:

1. Describe your study design and methods. The study design must relate to your stated aims/objectives.

   The study design and method is the same as for the Southwest Hub aim 1, see section III.A.

2. Provide an estimated sample size and an explanation for that number.

   The study sample size is the same sample population described in aim 1, see section III.B.

3. Provide a brief data analysis plan and a description of variables to be derived.

   See section V.4.

### B. Participants:

1. Describe the subjects who provided the original data and the population from which they were drawn.

   The Indian Health Service (IHS) is a public agency within the Department of Health and Human Services and is responsible for providing federal health services to American Indians and Alaska Natives. The Indian Health Service keeps record of all medical claims filed by members of federally-recognized tribes. We will request IHS medical claims only for Southwest hub study participants. Consent to access medical records will be requested in all informed consent documents.

2. If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

   YES

3. If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.

   N/A

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