My Pathway to Healing
NCT04585906
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JHSPH IRB Research Plan for New Data Collection

PI Name: Emily Haroz, PhD
Study Title: My Pathway to Healing: Adaptation and Testing of a Common Elements Treatment Approach to Address Trauma, Suicide Ideation, and Substance Abuse
IRB No.: 00009500
PI Version No. / Date: v12/ 01/27/2025

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

Primary Aims:

1) To characterize the meaning and impact of adverse childhood experiences (ACEs) and identify key resilience factors for Apache adults, 18 or older
2) To adapt a common elements intervention, My Pathway to Healing, based on Aim 1 findings and community advisory board (CAB) input for piloting by Apache Community Mental Health Specialists (CMHS) with Apaches ages 25-65 with recent suicide ideation and/or binge substance use, a high burden of ACEs, and elevated symptoms of post-traumatic stress.
3) To test the effectiveness of My Pathway to Healing using a randomized control trial with adults ages 18-65 with recent suicide ideation, suicide attempt, self-injury and/or binge substance use, a high burden of ACEs, and elevated symptoms of post-traumatic stress.

As a note, since the initial award, and based on challenges navigating the COVID-19 pandemic to recruit participants and complete study visits, we received approval from the sponsor to transition the randomized control trial (Aim 3) to a feasibility study with a smaller sample size. In the feasibility study for Aim 3, we aimed to recruit n=30 participants and understand the feasibility of scaling this study at a larger size and understand the challenges of implementing this intervention with this population of adults experiencing suicide, self-injury, and substance use. The rest of the study design, aside from the sample size in Aim 3, remained the same throughout the project.

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

In the past decade, personal and historical trauma has come to the forefront as a root cause of health disparities experienced by Native American (NA) communities. In a study of 1,660 individuals from seven tribes, 74%-100% of men and 83%-93% of women reported ≥1 types ACE. NA studies focused on ACEs have found associations with alcohol and drug abuse and suicidal behavior. Data from a remote plains reservation (N=288) found that each additional ACE significantly increased ($p < .001$) the odds of suicide attempt (37%), poly-drug use (51%), PTSD symptoms (55%), and depression NA studies targeting alcohol and drug use and suicide, including ours have also identified ACEs as risk factors.

Deeper understanding of the relationship between ACEs, trauma, alcohol and drug use, and suicide is critical to help prevent and treat the root causes of these intersecting public health problems for Indian Country. The types, meanings, and mental health impacts of ACEs, however, vary by context. The gold standard ACEs measure used in the Kaiser Permanente study was not designed for minority or low resource settings. Studies have found similar patterns in health outcomes with historical loss, discrimination, single-parent homes, exposure to community violence, criminal behavior, personal victimization, bullying, and economic hardship.

Moreover, the mechanism through which ACEs impact individuals is not well understood. Current research suggests that ACEs and associated problems are related through complex pathways of social, cognitive,

and emotional factors that beget high-risk behaviors, manifesting in long-term problems. There is a lack of effective interventions for individuals who have experienced ACEs and even fewer specific to NA populations despite openness from the community. The co-occurrence of ACEs, compounded by community and intergenerational traumas, will require: 1) a culturally-specific and customizable intervention as evidenced by the above studies, including our own, and 2) a strengths-based framework, as resilience has been shown to modify the effect of ACEs.

There is a lack of effective intervention programs for youth who have experienced ACEs and even fewer specific to American Indian/Alaska Native (AI/AN) populations. In the Apache community, suicide surveillance and prevention programming have been ongoing for over 20 years. Programs have targeted many of the identified causes of poor mental health, including but not limited to, bullying, school engagement, cultural connection, career opportunities, and teen parenting. “Common elements” interventions target cognitive, emotional, interpersonal and behavioral skills vs. specific disorder symptoms, consistent with a strengths-based approach that also fits with many traditional NA values. Furthermore, they are flexible enough to address the broad range of problems that may arise as a result of these experiences. Common elements interventions have medium-large effects on anxiety and depression.

III. Study Design:

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 Secondary Data Analysis of Existing Data/Specimens).

This is a mixed-methods study with qualitative data informing adaptation and evaluation of a common elements intervention delivered by community mental health specialists, named “My Pathway to Healing.”

International studies have demonstrated the feasibility and effectiveness of using paraprofessionals, such as community mental health specialists to implement these interventions. NIMH and other US organizations are increasingly recognizing the importance of this strategy in communities with shortages of professionals and where stigma or cultural preferences might not align with Western models —which Native communities have known for a long time. Apache-JHU studies, and other NA research, have supported the power of trained Native community mental health specialists to deliver psychoeducation interventions targeting varied public health disparities, including: teenager mothers’ parenting skills and early childhood development; connections to care for youth with alcohol, drug, and suicide risks; and psychoeducation to reduce STIs.

Given that the proposed research requires contextual understanding, multiple perspectives and exploration of cultural influences, Apache-JHU partners will use a *multiphase, sequential* mixed-methods design, with each aim corresponding to a phase in the overall project.

Aim 1**:** Apache-JHU partners will accomplish this aim by using Free Listing (FL) and In-Depth Interviews (IDI). These brief, informative, qualitative methods have been used to explore mental health problems, resiliency factors, and inform mental health interventions in low resource, culturally diverse settings.

Aim 2**:** Apache-JHU partners will use Rounsaville's treatment development guidelines[34] as they are one of the current gold standards (came out of workshops sponsored by NIDA), and Apache-JHU partners have had success utilizing them in previous studies (see Cwik et al. for details on adaptation steps).

Aim 3**:** Apache-JHU partners selected a RCT, as it is a rigorous study design for understanding whether an intervention works and was endorsed by the community, to evaluate the effectiveness of the My Pathway to Healing intervention delivered by community mental health specialists (CMHS). This intervention consists of an initial assessment to determine treatment priorities and safety. Common elements psychological interventions necessarily integrate psychoeducation and addresses safety (when identified as a problem area). They can also include teaching relaxation, cognitive coping, exposure-trauma memories, exposure-live, cognitive restructuring, behavioral activation, and problem solving. The intervention used in the tested arm of our study will be adapted to the specific context and culture of White Mountain Apache. We anticipate that these adaptions will mostly be minor in nature, but they will be guided by findings from the Aim 1 qualitative work. We will provide more information before the start of the RCT phase. Update, December 2021: we have integrated the findings from the Aim 1 qualitative work with feedback collected during the provider training of the intervention, and incorporated into the common elements intervention bundle a series of curricula targeting the symptoms of post-traumatic stress that have already proved to be acceptable to the providers and the community.

Update, January 2025: Since the initial award, and based on challenges navigating the COVID-19 pandemic to recruit participants and complete study visits, we received approval from the sponsor to transition the randomized control trial (Aim 3) to a feasibility study with a smaller sample size. In the feasibility study for Aim 3, we aimed to recruit n=30 participants and understand the feasibility of scaling this study at a larger size and understand the challenges of implementing this intervention with this population of adults experiencing suicide, self-injury, and substance use. The rest of the study design, aside from the sample size in Aim 3, remained the same throughout the project.

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 anticipate conducting free-listing, key informant interviews with approximately 30 respondents. This sample size is based on considerations in qualitative research theory regarding saturation, a point after which common themes and information from local respondents tend to converge.

Aim 2: We estimate having 8 team members (plus the PI) trained in the intervention and piloting the intervention with 8 non-research participants.

Aim 3: For the RCT, **estimated Sample Size is N=100 across the two groups**
Sample size for this aim is based on powering our sample to detect clinically meaningful and statistically significant difference in posttraumatic stress symptoms (primary outcome) between the two groups at 6-month (24wks) post baseline (12wks intervention period; 12wk assessment period). With power set to 80% and the type-I error rate set to alpha = 0.05, with a minimum of three time points and assuming a correlation of 0.3 between timepoints, we would expect to need a total sample size of *N*=70 to detect a medium effect of (*f*=0.25). We further adjusted our sample sizes to account for a conservative estimate of 30% attrition based on previous common elements RCTs, which yielded a total sample size of **N=100 across the two groups**.

In the updated feasibility study for Aim 3, we aimed to recruit a sample size of N=30 participants, which was an achievable goal for the study timeline based on recruitment patterns post-COVID. It

also allowed an estimated 15 participants to be randomized to receive the intervention to observe the feasibility of implementing and scaling the intervention. The sample size allowed for the follow-up time and effort required of study staff to pursue 5 lessons with each participant randomized to the intervention, plus the additional assessment visits after the final intervention lesson.

IV. Participants:

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: Participants will include adults knowledgeable about problems community members face (community members and leaders, behavioral health providers, and Elders). Our Community Advisory Board (CAB) will assist us to purposively sample for a range of genders and stakeholders.

Aim 2: Aim 2 will only be focused on the intervention development and training, and piloting. We will not collect any research data during the piloting.

Aim 3: Participants for the RCT will be 100 adults ages 18-65 with any one or more of the following behaviors: recent suicide ideation, suicide attempt, self-injurious behavior, and/or binge substance within the past 90 days as identified through the Apache suicide surveillance system (see below). Additionally, eligible participants must have a high burden of ACEs, elevated symptoms of post-traumatic stress, identify as Native American, and live on or near the Fort Apache Indian Reservation.
While the eligibility criteria and recruitment process remained the same, we adapted the plan to recruit n=30 participants in the feasibility study.

The Apache suicide surveillance system has been in place since 2002. In 2001, a spike in youth suicide led to tribally-enforced mandated reporting of all suicidal behavior (i.e., ideation, attempts and deaths), non-suicidal self-injury and binge drinking to a central surveillance system. This system has allowed the Apache to track their suicide rates over time (1) and identify patterns in co-occurring risks (2). Surveillance system case managers are all from the local community and all have worked responding to suicide risk for more than 2 years. For each report to the system, case managers attempt to meet face-to-face after receiving a report. This visit is conducted in order to confirm the event and support case management services, including referrals.

A. Inclusion Criteria:

Aim 1: Participants must be over the age of 18, be Native American, reside on or near the Fort Apache Indian Reservation, have experienced at least 1 Adverse Childhood Experience (ACE) or be knowledgeable about the impacts of ACEs.

Aim 2: There are no research participants for Aim 2.

Aim 3: Participants will be:

- Aged 18-65
- With any of the following behaviors in the past 90 days: suicide ideation, suicide attempt, self-injurious behavior and/or binge substance use;
- Have experienced 2 or more ACEs, as measured by the “ACE module” (See data collection instruments)
- Have elevated symptoms of posttraumatic stress, as measured by an average score of 1 or above on the “HTQ screening questions” measure (see data collection instruments)
- Self-identify as Native American

- Live on or near the Fort Apache Reservation

B. **Exclusion Criteria:**
For all aims, participants will be excluded from the study if they are unable to provide informed consent or participate in study activities, have a serious developmental disorder, or active psychosis.

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.

For **Aim 1**, participants will be identified in partnership with our existing Apache research staff and members of our community advisory board (CAB). Both our Apache research staff and the CAB are members of the community, familiar with Apache culture and customs, and knowledgeable about people in the community who will provide useful information to the study. CAB members will approach potential participants, asking if they are interested and if it would be ok for Apache research staff to contact them. They will also use recruitment fliers to recruit participants. This may include posting or sharing recruitment fliers in locations they deem appropriate. The recruitment flier can be found in the supplemental documents. If agreed, Apache research staff will reach out to participants to provide additional information about the study and set up a time to meet with the participant. We will ask also ask participants if they have suggestions for other community members who may be important to talk with (chain sampling). Participants identified in this manner will also be contacted and informed of the study as described. A recruitment script for CAB, and other community members who may recruit participants (chain sampling) can be found in the supplemental documents.

For **Aim 2**, we will not collect any research data during the piloting of the intervention materials.

Participants for **Aim 3** will be identified through the Apache surveillance system. During the routine follow-up visits that are part of the Apache surveillance system, Community Mental Health Specialists (CMHSs) who complete these follow-ups may approach participants they know to be potentially eligible (based on age and behavior, two pieces of information they gather as routine part of this follow-up) to see if they are interested in hearing about this study and participating. If the potential participant is interested in hearing about the study but is unsure about participation, the CHMS will note their contact info and make a plan with the person to follow-up to continue the recruitment process. If the potential participant is interested in participating in the study, the CMHS will either schedule a time to complete the eligibility screening or continue by having the potential participant complete the eligibility screening questions. Once screened, if the participant is eligible based on their responses, they will complete the informed consent process. For eligible participants who consented, the CMHS will then administer the remaining baseline assessment or schedule a separate time to complete the baseline. If the person is not eligible, the CMHS will convey that information to the person and inform them that they are not

eligible for the study but can continue to receive regular services through the Apache surveillance system.

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: A potential privacy issue associated with recruitment is that respondents may be identified as having participated in the study. We believe this will have little to no effect as people are being asked to speak about problems in general and not specific to themselves or any other individuals. Data collection will take place in private. For all participants, every effort, including password protected storage of identifying information and destruction of study files post study, will be taken to ensure that confidentiality is maintained. All data for analysis will be de-identified data. Participants will be asked to name additional *potential* participants using chained sampling methods, however, the recommending participant will initiate contact with this new individual, rather than Apache research staff, to respect their privacy.

Aim 2: N/A, there are no research participants for Aim 2.

Aim 3: Maintaining confidentiality is of the utmost concern. Adults for the RCT will be recruited through the Apache surveillance system. As current practice, individuals in the system are followed-up by case managers. Case management visits take place in a private location where the individual feels comfortable such as at a home or at an office. Case managers will ask about their interest in participating with this research at the end of the initial case management visit. Case managers 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 the aim 3 recruitment script (see recruitment materials). The Apache research team for this study consists of JHSPH-employed CMHSs who have deep experience in implementing the local Apache suicide surveillance and case management system.

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:

   Consent in this study will be obtained prior to any research-related participation. Apache Research Program Assistants (RPAs; above referred to as CHMSs in context of the Apache surveillance system, but who are known by both titles) who have been trained by JHU will obtain informed consent from participants. They will be trained in responsible conduct of human subjects research as a part of field training procedures. This will include training in the principle of respect for persons, protecting confidentiality, and the process of informed consent. All RPAs involved with data collection have been trained in human subjects research protections and have up to date CITI certifications, 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).

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

   Informed consent will be obtained in a private location agreed on by the participant. Consent discussions will take place prior to the collection of any data. In the case of individuals recruited

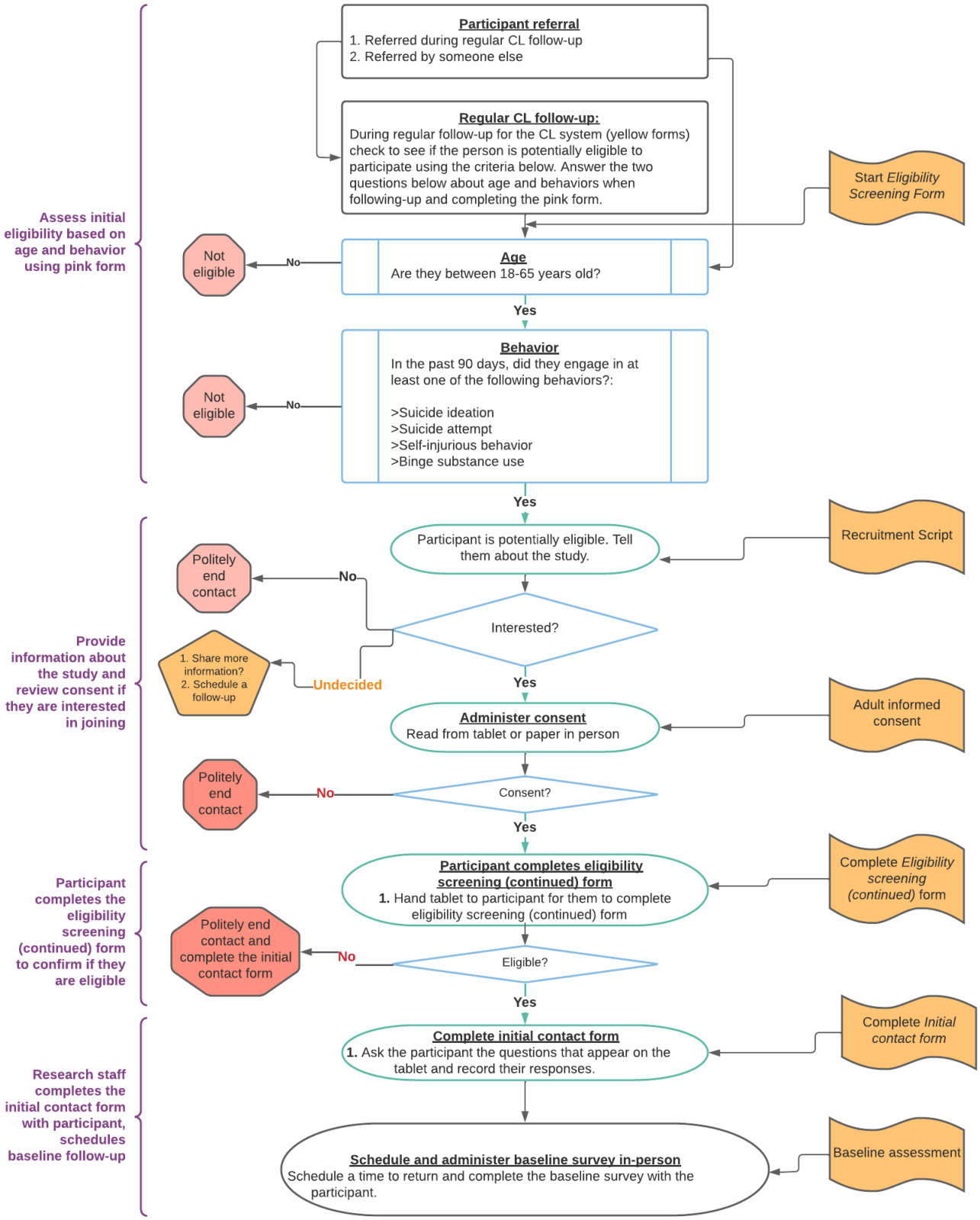
at places of residence, individuals will be asked to identify a private location within their home. Written informed consent will be obtained for all participants.

During the consent process, the Research Program Assistant will ask prospective participants if they fully understand the consent process/forms. 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. For **Aim 1** consent processes will happen at the time of the first visit if the potential participant is interested in the study. For **Aim 3**, the consent process will happen during the recruitment/eligibility screening process as described above and below in the "recruitment process" and "process you will use to determine whether a potential participant meets eligibility criteria" sections (i.e., private location, during the initial case management visit, unless otherwise requested by the potential participant).

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

For **Aim 1,** participant eligibility will be determined during discussions with the CAB, Research Program Assistants and/or Baltimore based study staff. For **Aim 3,** participants will initially be identified by the Apache surveillance system. During the routine follow-up visits that are part of the Apache surveillance system, Community Mental Health Specialists (CMHSs) who complete these follow-ups may approach participants they know to be potentially eligible (based on age and behavior, two pieces of information they gather as routine part of this follow-up) to see if they are interested in hearing about this study and participating. If the potential participant is interested in hearing about the study but is unsure about participation, the CHMS will note their contact info and make a plan with the person to follow-up and continue recruitment. If the potential participant is interested in participating in the study, the CMHS will either schedule a time to complete the eligibility screening or continue by having the potential participant complete the eligibility screening questions (the eligibility screening consists of two brief screening measures, one the ACEs measure, the other a subset of questions from the Harvard Trauma Questionnaire; see data collection instruments). Once screened, if the participant is eligible based on their responses, they will complete the informed consent process. For eligible participants who consented, the CMHS will complete the initial contact form as part of the enrollment process, and either administer the rest of the baseline survey or schedule another visit to complete the baseline. See Figure 1 for a flowchart illustrating the eligibility screening process.

Figure 1: My Pathway to Healing - RCT- Eligibility flowchart



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

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

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

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):
N/A

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:
No, we will not include a witness to the consent process.

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**
USA	Adult Consent Form-Aim 1	English
USA	Adult Participant Consent Form-Aim 3	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.

<u>Aim 1:</u> Participants will undergo the informed consent process as described above. Each participant will first complete a free listing activity during which they will be asked to list: 1) types of ACEs people experience, 2) the mental health impacts of these experiences, 3) common coping strategies and factors that contribute to resiliency, and 4) how community members care for themselves and others

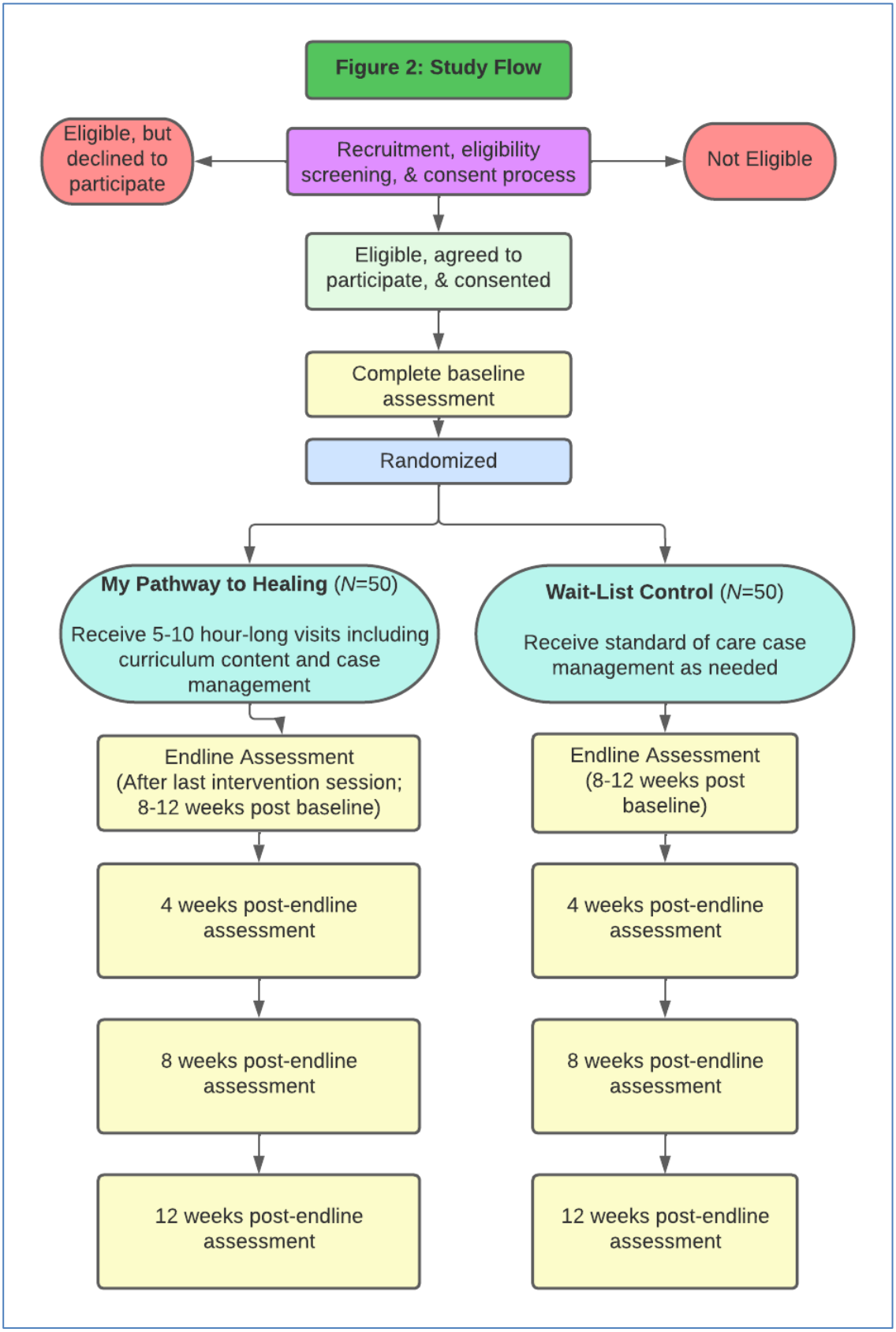
(See free listing guide). Second, we will conduct in-depth interviews with recommended community members. Some free listing participants may also be asked to participate in an in-depth interview. Free list participants who provide particularly rich data, express a strong desire to continue participation, or are otherwise deemed exceptionally knowledgeable about this topic will be asked to participate in an in-depth interview. Participants will be interviewed using a theoretically grounded, semi-structured, interview guide. They will be asked about the impact of the most frequently mentioned ACEs during free listing, as well as strategies to address trauma related problems and to promote well-being and resilience. IDIs will be audio recorded and transcribed.

Aim 2: N/A. There will be no research participants for Aim 2.

Aim 3: During the routine follow-up visits that are part of the Apache surveillance system, Community Mental Health Specialists (CMHSs) who complete these follow-ups may approach participants they know to be potentially eligible (based on age and behavior, two pieces of information they gather as routine part of this follow-up) to see if they are interested in hearing about this study and participating. If the potential participant is interested in hearing about the study but is unsure about participation, the CHMS will note their contact info and make a plan with the person to follow-up and continue recruitment. If the potential participant is interested in participating in the study, the CMHS will either schedule a time to complete the eligibility screening or continue by having the potential participant complete the eligibility screening questions (the eligibility screening consists of two brief screening measures, one the ACEs measure, the other a subset of questions from the Harvard Trauma Questionnaire; see data collection instruments). Once screened, if the participant is eligible based on their responses, they will complete the informed consent process. For eligible participants who consented, the CMHS will complete the initial contact form as part of the enrollment process, and either administer the rest of the baseline survey or schedule another visit to complete the baseline. After completing the baseline survey, participants will receive one snack box of approximately $30 value. After the baseline assessment the person will be randomized to either receive My Pathway to Healing intervention immediately, in addition to case management, or to receive case management alone (standard of care) while being asked to wait for the intervention. To ensure equal distribution of certain characteristics, participants will be block randomized by index event (ideation, attempt, self-injury, or binge substance use) and gender (male or female) using a 1:1 allocation ratio within blocks. The Research Program Assistants who collect study assessments will not be blinded to the intervention allocation. Previous work with the WMAT community has taught JHCIH that it is helpful for establishing trust and promoting participation when the Research Program Assistants who collect the study assessments can work with the Research Program Assistants who deliver the interventions to communicate with the participant, instead of the participant developing two separate relationships with each an evaluator and interventionist. Additionally, the Research Program Assistants who collect the study assessments do so by preparing a mobile tablet with the survey questions and handing it to the participant to complete, as such we believe that unblinding them will not influence the assessments that are collected. Regardless of assignment, the surveillance system provides regular case management as the existing standard of care. See Figure 2 for details on participant flow.

Those randomized into the My Pathway to Healing (intervention) group will receive 4-8 one hour-long sessions with a community mental health specialist, taking place over 8-12 weeks. The exact number of sessions will depend on presentation and symptom level using a stepped care approach where participants receive only what they need, but the provider can provide additional sessions if needed (i.e., increased lesson dosage; additional optional lessons for specific issues). The number of sessions and the content covered will be determined using 1) the participant monitoring form (see data collection instruments) and 2) provider knowledge and evaluation of specific participant needs. The My Pathway to Healing intervention is based on modifications made to the standardized common elements intervention during Aim 2 and informed by results of Aim 1. Participants assigned to receive the MP2H intervention who are deaf or hard of hearing will be supported by sign language interpreting services provided by HIS Sign Language Interpreting, an on-demand sign language interpreting

service whose interpreters must treat all information learned during interpretation as confidential. Those randomized into the control will continue to receive the standard case management via the Apache surveillance system. These control participants will be offered the intervention after they have finished their final study assessment (approximately 6 months post-baseline) on a rolling basis based on availability of providers. After completing either the endline assessment once their intervention or control is finished, participants will receive another snack box. Finally, participants who complete the entire study (i.e., complete all 5 assessments and the intervention or control sessions) will receive a third snack box.



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: After initial contact, each study participant will be asked to engage in a maximum of two study activities—a free listing interview and an in-depth interview. The duration of study participation will last no longer than 4 hours (maximum 2hrs per study activity). All research activities will be conducted in a setting that is convenient, comfortable and private.

Aim 2: N/A

Aim 3: Participants in the My Pathway to Healing group will receive 4-8 hour-long visits over the course of 8-12 weeks from community mental health specialists, depending on presentation and symptom level, and will receive a small journal or activity book as a token of appreciation and encouragement from their program educator after completing the My Pathway to Healing program (less than $10 value). All visits will be completed between 8 to 12-weeks post baseline. When possible, participants homes will be used for the intervention and data collection. Additionally, all participants, regardless of group, will be asked to partake in 5 study assessments. For intervention participants these assessments will take place at: baseline, after their last session (endline; 8-12 weeks post-baseline) and 4, 8, and 12 weeks post-endline. For control participants, these assessments will take place at: baseline, 8-12 weeks post-baseline (the time the intervention would last; will be referred to as an endline) and 4, 8 and 12 weeks post-endline. These assessment visits will be conducted by separate Research Program Assistants who will serve as the independent evaluators. Assessments will take approximately 45-90 minutes to complete. See figure 2 above for an outline of study flow and visits.

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

Aim 1: Participants will be involved in up to two interviews for a maximum duration of 4 hours (2 hours per interview). Interviews will take places within days or weeks of each other (i.e. participants will be involved in the study for a month or less).

Aim 2: NA

Aim 3: Participants will be involved in this part of the study for 6 months—up to 12 weeks of the My Pathway to Healing intervention sessions and regularly spaced assessments until 12 weeks post-end line.

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

Aim 1: Free listing data will be collected using a standard form. Analysis of free listing data will be done by Apache Research Program Assistants and Baltimore based study staff after completion of all interviews during a 1-2 day analysis workshop. Analysis will be led by Apache Research Program Assistants with oversight from JHU team. Participants will be given a unique ID number. The process begins with the study staff listing out all the different responses from all forms with the participant ID number listed next to each response. When multiple participants report the same problem, then all the relevant ID numbers are listed next to that response. Interview transcripts will be reviewed by Apache Research Program Assistants and Baltimore based study staff and coded using thematic coding. Similar themes are grouped across interviews and their corresponding unique ID number listed next to each theme. The end result will be one list for each question asked and the ID numbers of different participants who mentioned each problem. Where two or more participants clearly refer to the same concept but the wording is different, the study team selects and records the wording they feel is the most accurate and likely to be understood by the community. Finally, lists are re-organized in order of decreasing frequency of participants who mentioned each item as an indicator of relative importance or prioritization.

Aim 2: N/A

Aim 3 (RCT): Our main analysis will be done on the "intent-to-treat" sample. This study utilizes repeated measures which leads to a nested data structure: 5 repeated assessments (level-1), nested within individuals (level-2), and nested within providers (level-3). We will use mixed-effects regression models (MRMs), which accommodate variability in assessment number and spacing within and across participants, continuous and discrete outcomes, and varied patterns of change over time (e.g., quadratic).[41] *Model Building & Estimation.* Outcomes will be graphically and descriptively evaluated to determine the best distribution for modeling using "spaghetti plots" and boxplots of outcome scores at each time-point. We will compare the within subjects covariance structure using model comparison techniques, selecting the appropriate covariance structure based on model fit (AIC, BIC). Then, we will build our models using the approach described in Singer and Willett:[42] 1) Model 1 will estimate the proportion of outcome variance at each level specified above; 2) Model 2 will add growth terms (linear, quadratic) to examine how scores on outcomes change over time; 3) Model 3 will add fixed-effect indicators to test for differences in outcomes by baseline characteristic (gender, age). 4) Model 4 will add intervention (0=Control; 1=My Pathway to Healing) and condition by time interaction terms. Intervention effects will be the difference in outcome scores over time between the two groups.
In the feasibility study for Aim 3, we adapted the analysis plan to better understand the context, study population, and goals of the intervention for scaling and implementation. The feasibility analysis plan involves reviewing the notes from weekly study progress calls regarding challenges and successes in implementing the intervention in this sample of participants in this setting, and case manager responses to similar prompts in the intervention and assessment data collection in REDCap. Case managers have provided additional insights into the feasibility of implementing and scaling when giving feedback on the study progress and preliminary findings.

Study Participants:

A schedule of assessments for study participants is included in Table 2. In addition, the CMHSs will complete session summary forms at the completion of each intervention or case management visit. All data for Aim 3 will be collected using an electronic data collection platform (REDCap). Outcomes for Aim 3 are presented in Table 2 and described below.

Table 2: Schedule of Assessments for Participants (Aim 3)

Outcomes	**Measures**	**Frequency**					
		Screening	Baseline	Endline	Post-Endline		
					4wks	8wks	12wks
Demographics	• Demographic questionnaire		X				
Posttraumatic Stress	• Harvard Trauma Questionnaire	X	X	X	X	X	X
Suicide Ideation	• SIQ		X	X	X	X	X
Depression	• IDSS		X	X	X	X	X
Alcohol and Substance Use	• ASSIST		X	X	X	X	X
Grief Experiences	• Brief Grief Questionnaire		X	X	X	X	X

Hopefulness	• Trait hope scale		X	X	X	X	X
Communal Mastery	• Communal Mastery Scale		X	X	X	X	X
Functioning	• WHO DAS • Local Functioning Scale		X	X	X	X	X
Historical Trauma	• Historical Loss Scale		X	X	X	X	X
Adverse Childhood Experiences	• ACE module	X					
Coping skills	• Brief cope		X	X	X	X	X
Self-esteem	• Rosenberg self-esteem scale		X	X	X	X	X
Tribal identity	• Modified leech scale to measure tribal identity		X	X	X	X	X
Anxiety	• Hopkins symptom checklist		X	X	X	X	X
Session summary	• Session Summary Form (Control) • Session summary form (intervention)	To be completed with participant after each curriculum (intervention) or case management (control) visit with a CMHS.					
Participant monitoring form	• Questions based on items measured in baseline and curriculum content	To be completed with participant at the start of each My Pathway to Healing Visit (Only in participants assigned to this arm)					

****Endline for Control Participants:*** 12-weeks after baseline; also the maximum length of the intervention period for Intervention
****Endline for Intervention Participants:*** When they complete their final session, as determined by their provider Participants

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Primary Outcome:
The Harvard Trauma Questionnaire is an evidence-based instrument developed to measure symptoms of trauma. Part 1 asks participants about symptoms of PTSD (a brief version of this measure is included as well in the study screening process, see data collection instruments). Part 2 asks participants about symptoms of anxiety.

Secondary Outcomes:

*The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) a*dapted from the WHO ASSIST questionnaire covering 10 main substance groups, this 15-item questionnaire screens for all levels of problem or risky substance use (alcohol, illegal drugs, and prescription drugs). A risk score is provided for each substance, and scores are grouped into low, moderate, or high risk, providing a comprehensive view of substance use.

Suicide Ideation Questionnaire (SIQ) The SIQ is a 27-item, 7-point scale that assesses the frequency and severity of suicidal ideation in the past month, with scores from 0-90. Positive screens on the SIQ are defined as scoring at or above the suggested clinical cutoff of 37. The SIQ has previously been used with Native American groups, with a sensitivity and specificity of .80 and .86, and strong internal consistency for the total score (α = 0.96). As described above, the SIQ is administered during the initial follow-up visit as part of our current case management practice. The study team has devised a comprehensive safety protocol, approved by the JHU IRB, the Phoenix Area IHS IRB and the WMAT Tribal Council and Health Board to triage depending on risk.

The International Depression Symptom Scale (IDSS) is comprised of 27 items that measure the experience of depression from populations around the world. A total score is generated and then averaged to represent severity of depression symptoms.

The Trait Hope Scale[51] consists of 8 items, with 4 assessing an individual's sense of agency, and the other 4 assessing sense of pathways. Higher scores indicate higher levels of hope. The THS has been widely validated and used in NA populations to study suicide and hope with demonstrated excellent psychometric properties (*a*=0.92).

Communal Mastery Scale is a 10-item scale developed from two commonly employed measures of mastery and self-efficacy and adapted to add more collectivist statements for use specifically in NA populations.

Functioning: We will develop a locally relevant functioning scale from Aim 1 data, in which participants are asked about tasks and activities that are important for people to do for themselves, their families and the community. The most frequently mentioned responses are combined to create the scale. This approach has been used widely in culturally diverse contexts internationally. This scale was developed and is now included in the assessment battery.

Brief Grief Questionnaire is a 5-item scale for screening for complicated grief. We have adapted the scale to refer to one or more deaths of loved ones, rather than to the death of a single index loved one.

The Historical Loss Scale is a 12-item self-report measure assessing the frequency with which Indigenous individuals think about loss of land, peoples, culture, ways of life as a result of colonization (i.e., historical trauma). Responses are scored on a 6-point Likert-type scale from never (1) to several times a day (6); scores are recoded so that higher scores indicate higher frequency of thinking about historical trauma.

ACE module is a collection of 24 questions sourced from the Behavioral Risk Factor Surveillance System's (BRFSS) module on adverse childhood experiences (ACEs), the original ACEs questionnaire used by the CDC and Kaiser Permanente in 1998, and the qualitative data from Aim 1 which informed the development of a few local questions.

Brief cope comprised 28 questions that ask about how a person manages and copes with stress. Responses are recorded on a scale from 1 (I haven't been doing this at all) to 4 (I've been doing this a lot). Subscales for different types of coping are calculated based on responses to specific items.

Rosenberg self-esteem scale is a 10-item scale that measures self-worth by asking about positive and negative feelings related to oneself. Responses are recorded on a 4-point Likert scale.

Tribal identification scale comprises 7 questions that ask about identity and connection to ones tribal community. This scale was adapted and modified from Leach and colleagues' group identification scale.

The Hopkins Symptom Checklist includes 10 questions that ask about symptoms of anxiety. Each question is scored on a scale from 1 (not at all) to 4 (extremely) for how often the respondent felt each symptom in the past week. Questions for this measure are included in the approved measure titled "Harvard Trauma Questionnaire_v2.0_2021.12.03"

Session summary forms: One for intervention participants and one for control participants, these forms are used to track the mental health and well-being of study participants on a week-to-week basis. The forms ask questions about details of the control/intervention visits, including when they took place, what (if any) referrals were made, potential adverse events reported, interruptions during the visit, etc. The intervention form also asks about which parts of the MP2H curriculum were delivered.

Participant monitoring form is a brief form administered at each session of the My Pathway to Healing intervention that assesses for symptoms of depression, anxiety, trauma substance misuse, and safety. This form informs adaptations and tailoring of the intervention content and can help those delivering the intervention in identifying risk.

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.

      The study has different arms only for Aim 3. There will be an intervention (My Pathways to Healing) group and a control group. Eligible, participants will be block randomized by index event (suicide attempt, suicide ideation, self-injurious behavior, or binge substance use) and gender using a 1:1 allocation ratio within blocks to either receive My Pathway to Healing immediately or be asked to wait. Randomization will occur after informed consent to participate in the study and the baseline assessment has been completed. At that point, the Research Program Assistant will tell the participant that a person from the team will be in touch about either starting My Pathway to Healing or scheduling a next assessment visit. The study coordinator will then check the data and if assigned to My Pathway to Healing, facilitate the referral to one of the community mental health specialists, based on who has availability in their schedule and is in close proximity to where the participant lives. If assigned to the wait-control group, the Research Program Assistant will schedule the next assessment visit with the participant through a follow-up call or visit.

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:

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

The Research Program Assistants who collect study assessments will not be blinded to participant status as this will allow them to help introduce the participant to the Research Program Assistants who deliver the intervention/case management sessions and establish more trust and reduce attrition.

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

Yes, participants will continue to have access to current standard of care. This consists of regular case management by case managers for the Apache surveillance system.

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

No placebos will be used. There will be a control group, who will be offered the My Pathway to Healing intervention after their final study assessment. They will be reassessed before beginning the intervention. The reason for this design is that we do not have evidence of the effectiveness of this intervention for this study populations.

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

To determine and quantify the participant's current risk for suicide at the close of all assessment visits, the Research Program Assistants will complete the Suicide Ideation Questionnaire (SIQ) 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 graded risk categories as determined by the SIQ /SIQ-Past Few Days. If risk is indicated on the participant monitoring form, the Community Mental Health Specialist will use the SIQ-Past Few Days as well to understand recency and severity. For a detailed outline of how Research Program Assistants will respond, please see Appendix 1. This safety protocol has been previously approved by Johns Hopkins, Phoenix area and tribal IRBs. Research Program Assistants are trained and aware of these procedures from previous studies (e.g., NARCH III 1S06 GM074004; SAMHSA 5 SM057835; NIMH 5U19MH113136-02) with suicidal individuals from this community.

After these safety protocols have been followed, if the participants risk is not acute, they will remain in the study.

Participants would not remain in the study if they: have acute suicidal ideation requiring immediate intervention (This will be defined by demonstrating current suicidal/homicidal/self-harm thoughts, a plan, and means to the plan with the intention of completing it), enter inpatient treatment for suicide ideation or other medical issue, or make a suicide attempt. At that point, the community mental health specialists will work with their supervisors to seek more specific psychiatric assistance with the individual. When the participant stabilizes, study staff, study supervisors and the co-PIs would discuss individual cases to determine if the participant could re-enter the study.

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

At the end of the study, if the My Pathway to Healing intervention is found to be effective, community mental health specialists will continue to provide the program in the study communities and it will be available to those who received the intervention but still have elevated symptoms, wait-control participants, and new clients. If participation ends prematurely because they were identified as being in danger of suicide/homicide/self-harm (see above), then they will continue to work with the more specific psychiatric assistance or other care services as needed.

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

Study participants will be allowed to access any outside care. As part of the existing Apache surveillance and case management program, all adults receive referrals to services in the community including mental health services, 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 people who are at immediate risk for suicide. This procedure was approved by Tribal, Hopkins and IHS IRBs, and will be employed by community mental health specialists for this project. For details on this procedure, please see Appendix 1.

VI. Data Custody, Management, 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 ☒ No ☐

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

C. Data Collection:

Collection of data for a research study can take on many forms. It can be as simple as gathering the data with pen and paper or developing an on-line adaptive survey that changes based on the participant's answers. Regardless of the method, PII collection for the purposes of identifying the participants will most likely be collected. Once collected, the raw data should go through a de-identification process to further protect PII.

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.

      Aim 2: NA

      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. The link between study IDs and personal identifiers will be maintained in a password protected excel database on a password protected computer maintained by Ms. Grubin.

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

   c. If study IDs/Codes are used, will they be stored separately from the study data? Yes ☒ No ☐

   d. Will the hard copy/paper be destroyed after data abstraction and cleaning are complete? Yes ☒ No ☐

      If No, when do you plan to destroy the hard copies?

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) Yes ☒ No ☐

      If Yes, will the device be protected by encryption? Yes ☒ No ☐

   b. Will the device(s) be study-owned or privately-owned (e.g., personally owned by data collectors or study participants?) Personally owned ☐ Study provided ☒

   c. Is the application/website used for data collection being developed in-house (Hopkins) or by a 3rd party vendor? In-house ☐ 3rd party ☒

      If 3rd party, provide the name of vendor and URL:
      RedCAP: https://www.project-redcap.org/

      Identify Mobile Ecosystem (check all that apply): Apple ☐ Google ☐ Website ☐

d. Will the data be stored on a secure server (@JHSPH/on-site)? Yes ☒ No ☐

e. Will the data be stored in the Cloud/Web? Yes ☒ No ☐

f. Will it be encrypted? Yes ☒ No ☐

g. 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? Yes ☒ No ☐

   b. Will you use a transcription service? Yes ☒ No ☐

      If yes, if the PII comes from JHH/JHHS, you must use an approved vendor; otherwise, be aware of the data security protections that the transcription service provides.

   c. Will the audio recording be destroyed after transcription? Yes ☒ No ☐

      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:

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

   PII associated only with the study and not surveillance will be destroyed when the study is complete.

2. What is the method you will use to de-identify the data?

   Each study participant will be assigned a unique study ID. The master list linking study IDs to PII will be maintained by the study staff in a password protected file. This file will be destroyed at the completion of the study.

3. Is your research data governed by HIPAA (U.S. clinical data remaining within the covered entity)?

a. Yes ☐ No ☒

b. If yes, who is doing the de-identification?

c. If yes, what level of de-identification will you achieve (Limited data set? De-identified?)

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**: The Hopkins Institute for Clinical and Translational Research (ICTR) provides a virtual Windows desktop (SAFE Desktop). It includes productivity software such as Microsoft Word and Excel, as well as statistical software, including SAS, Stata, R, R Studio, and Python. 100 GB of storage space is provided.

☐ **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**: These are departmentally managed applications. RedCAP is an application designed for collaborative research projects.

☐ **JHSPH HPCC:** High Performance Computing Cluster (HPCC: https://jhpce.jhu.edu/) can provide the high capacity computing required for very large data sets.

☐ **JHBox**: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing service which enables people to collaborate and share information and may be accessed through any device: desktop, laptop, phone, or tablet with appropriate permissions. JHSPH IT recommends that investigators not use JHBox as a primary storage location, but use it instead for initial data collection, sharing results, and other collaborative information with the research team.

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff. Because these servers are not centrally managed by JHSPH IT, all documentation regarding data security protections will need to be provided by the owner/administrator of the server. This responsibility may fall to the data owners (PI).

☒ **Other**: Please provide details regarding any other systems being utilized. Examples may include servers and applications located at another university participating in your study or a 3rd party web-based application.

JHU OneDrive will be used to store files and data related to this project. JH Box is no longer available at the institution.

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. During the analysis phase, do you plan to use computer systems that are not managed by JHSPH or JH? Yes ☐ No ☒

   If yes, please explain:

2. 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:

3. Does your sponsor have other specific data security requirements for the study data? Yes ☐ No ☒

   If possible, please explain:

4. Please add any other information that you believe is relevant to data security.

G. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://humansubjects.nih.gov/coc/index)

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

H. JHM Clinical Records:

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.

I. Data Sharing:

Please describe your data sharing plan, including whether you plan to share your data with other investigators, make your data publicly available, deposit it into a repository for broader use, etc. Include information about how identifiable the data will be if shared.

The study leadership for this research project will ensure that all resources and data generated by this project will be made available in the most accessible, secure and ethical format to all study partners and users in the tribe and region. We will take all necessary steps to ensure we adhere to NIH data sharing guidelines in collaboration with our tribal partners, including seeking the appropriate tribal approvals to respect sovereignty.

We will only share de-identified data. Data related to the qualitative component, intervention adaptation and pilot, and effectiveness study will only be shared after seeking the appropriate approvals as described above. In the consent form, participants will be made aware of the potential for sharing de-identified data.

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: There are no physical risks to participants. The main risk of the study is an emotional risk; it is possible that some participants may experience discomfort in discussing problems faced by others in their community, including discussing problems of a mental health nature. However, questions will be asked about problems experienced by the community in general, and not about problems faced by participants themselves or their families. If participants begin to narrate personal experiences, they will be guided by interviewers to discuss issues that are also relevant for others.

Aim 2: N/A

Aim 3: With respect to the My Pathway to Healing intervention, the program includes discussion and recollection of potentially traumatic experiences with management of the emotional reactions with the interventionist. Research and experience suggest that exposure-based therapies are effective when treating individuals with post-trauma symptoms. With such an intervention there is a risk that such exposure could be harmful if the reactions are not properly managed. However, the emphasis of the training is on correct management so that the result should be symptomatic relief.

Respondents who are distressed may reveal suicidal intent during the course of the screening, baseline/follow up questionnaires or intervention. Although this is not a direct risk of participation in this study it is important to have a plan in place. A detailed suicide response plan (Safety protocol) is included in Appendix 1.

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: Based on our experience in other settings, we expect that any emotional risks would be minor and short lived if they occur at all.

Aim 2: N/A

Aim 3: In general, we expect to see mostly mild to moderate distress as a result of the intervention activities.

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.

While risks cannot be fully eliminated, we will take the following specific steps to minimize risk:

1. *Institutional Review Board at Johns Hopkins and Health Board review with White Mountain Apache:* The study research plan, study instruments and consent forms will be reviewed by an IRB at Johns Hopkins School of Public Health and have been reviewed by appropriate tribal health board.
2. *Training of Apache Research Program Assistants and Community Mental Health Specialists* will be provided with several days of intensive training prior to the start of data collection. Training

topics will include responsible conduct of human subjects research; procedures for recruitment, informed consent, and confidentiality; qualitative data collection methods including interviewing techniques; and qualitative data management. Where possible, interviewers with previous training in psychology or social work, experience working on research projects related to mental health, or practical experience in the community will be hired.

3. *Informed consent*. We will provide potential respondents a clear opportunity to understand the study objectives and procedures, to assess study risks and benefits, and, verbally, to give or decline consent freely and without pressure or penalty.
4. *Interviews in a safe, private location*. The study will rely on the local expertise and judgment of local partner organization staff-members to identify where interviews might best be carried out.
5. *Data Storage and Protection*. No unique identifiers will be collected in data collection forms or handwritten notes and the location of interviews will not be recorded.
6. *Adverse Event Monitoring.* Community mental health specialists will assist participants in obtaining additional services for adverse events. The PI will recommend premature study termination based on defined safety procedures.
7. *Rescue Plan.* An imminent risk procedure was developed by Apache-JHU for previous studies to ensure triage and access to emergency care for suicidal youth. This procedure was approved by Tribal and Hopkins IRBs, and will be employed for this project. Risk will be gaged by immediate scoring the Suicide Ideation Questionnaire at each visit. See the Appendix 1 for the details of this plan.

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

Aim 1: Interviews will be carried out at a safe and private location deemed appropriate by the interviewers and respondent to maximize convenience. There are no out-of-pocket costs to participation in the study. There may be some opportunity costs in time lost but on average we expect that research activities will last a maximum of 4 hours.

Aim 2: N/A

Aim 3: Burden to participants in My Pathway to Healing will be between 5-10 hour long sessions with community mental health specialists, and 4 follow up visits (approx. 60-90 minutes each). When possible My Pathway to Healing sessions will be provided in participants homes, eliminating the time and costs for travel.

E. Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.

Every effort will be made to ensure privacy and confidentiality to the participant. For **Aim 1**, all interviews will be conducted in a private location where the discussion cannot be overheard. For **Aim 3**, intervention visits and assessments will be done individually by the potential participants via self-administration on tablets. Apache Research Program Assistants will be available to answer questions or assist with technological problems with the tablets, but participants will complete questions on their own.

VIII. Direct Personal and Social Benefits:

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

Aim 1: There are no direct benefits to participants for participation in the qualitative study. This research will lead to the adaptation and implementation of an evidence-based trauma treatment program for Apache adults. It is possible that some respondents could later be included in the intervention study.

Aim 3: Our collaborative plan with existing community resources will result in participants with significant symptoms receiving the My Pathway to Healing intervention, an evidence-based mental health treatment that has been adapted and tailored to fit the local context and community.

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

Our intention is that this intervention will improve social, emotional, and physical functioning and enable people at risk of suicide and substance abuse to be more active and contributing members of their community. This would reduce the burden on families and community while improving their status within the community. In addition, we expect to learn about the effectiveness of My Pathway to Healing – allowing policy makers to make more informed decisions about what type of program to offer given existing resources.

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: Participants will receive compensation of $10 for free listing; and $25 for key-informant interviews. All compensation will be provided in the form of gift cards.

Aim 2: N/A

Aim 3: Participants in the RCT will receive compensation for each assessment they complete. The payment structure is included here:

Participants in RCT	
Baseline	$15
Endline	$15
4 weeks post-endline	$15
8 weeks post-endline	$20
12 weeks post-endline	$25

Participants in the RCT will also receive up to three snack boxes containing food and small snacks valued at approximately $30 per box. These snacks boxes will be given to all participants at three time points:

1) When they complete the baseline assessment
2) When they complete the endline assessment
3) When they complete the entire study (i.e., complete all 5 assessments and control or intervention visits)

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

Aim 1: If a person participates in both the FL and Key-Informant Interviews they can receive up to $35 total dollars.

Aim 2: Not applicable

Aim 3: RCT participants can earn up to $90. If they do not complete study assessments or drop out of the study they will receive compensation commensurate with their participation.

X. Study Management:

A. **Oversight Plan:**

1. Describe how the study will be managed.
   Drs. Haroz and **Cwik** will oversee all aspects of the study and will provide regular chick-ins with onsite Study Staff Manager, Research Program Assistants and Community Mental Health Specialists. **Dr. Emily Haroz**, will serve as the lead data analyst and Co-PI. **Novalene Goklish, BS, MS, PhD candidate (WMAT),** will serve as the Field Supervisor, overseeing Apache research staff. **Kristin Masten**, MPH, will work with the study team and the CAB to adapt the trauma intervention curriculum and manuals. **Dr. Victoria O'Keefe**, will serve as a clinical back-up to Dr. Cwik and provide oversite on Aim 1 activities and guidance and supervision for Aim 3. **Allison Barlow** will provide guidance on methods and analysis on an ongoing basis. **Fiona Grubin, MSPH and Meredith Stifter, MPH** will coordinate study activities and ensure data quality. Additional support will be provided by **Monica Desjardins, BA, Laura Murray, PhD Paul Bolton, MBBS, Chris Kemp, PhD, and Kristina Metz, PhD.**

2. What are the qualifications of study personnel managing the project?
   Dr. Mary Cwik, **PhD** Associate Scientist at JHU, has served as a PI or Co-I on several of our prior grants. She has adapted several EBIs, trained Apache staff, and serves as a national expert in research ethics and AI suicide prevention.

   Dr. Emily Haroz PhD, MA, MHS Assistant Scientist, who has over 5 years' experience conducting analyses for mental health research in low resource settings, and expertise in implementation science

   Dr. Allison Barlow PhD, MPH, Director of CIH, has led more than 20 years of behavioral health interventions in AI communities and dissemination of related findings to tribal and national settings.

   Dr. Victoria O'Keefe PhD Assistant Professor is a licensed psychologist and has been conducting research for 8 years on AI/AN suicide prevention. She has experience providing direct clinical service to AI adolescents and adults.

   Dr. Christopher Kemp PhD Assistant Scientist is a trained Implementation Scientist with over 8 years of experience working on mental and behavioral health interventions. Chris will serve as a consultant and data analyst.

   Kristin Masten, **MPH**, Curriculum Director, is a certified health educator with specialized training and has directed all curriculum development at the Center for ~10 years. She will work with the study team and the CAB to adapt the trauma intervention curriculum and manuals.

   Novalene Goklish MS, PhD Candidate (WMAT), Field Coordinator, has a 10+ year history co-designing suicide prevention public health and capacity building interventions with CIH**.** She is the Center's primary liaison to the Tribal Council and Health Board and fluent in Apache.

   Fiona Grubin, MSPH, Study Manager/Research Associate has 4 years of experience in qualitative data analysis and public health research. She has coordinated a variety of mental health research projects.

   Meredith Stifter, MPH, Study Manager/Research Associate has 4 years of experience in public health research and coordination. She has worked across a variety of social determinants and mental health projects, with a focus on multicultural health.

Monica Desjardins, **BA**, Research Assistant, has 2 years of experience in qualitative data analysis and developmental and social psychology research. She has assisted in the implementation of social psychology and global mental health research projects.

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 Apache Research Program Assistants hired as part of the project will be trained in human subjects research protection as a part of training for participation in the project. All study team members hold up to date CITI certifications, 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).

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.

   Throughout the duration of the study, the PI will have weekly conference calls with the local Research staff to monitor study progress and assure that the study is being implemented according to protocol. The PIs (who are off-site) will make at least 2 trips 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 Field supervisor will provide in-person oversight and monitor consent and data collection to ensure the study is progressing according to protocol.

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

Apache Research Program Assistants will be managed and supervised by Novalene Goklish. This will involve regular debriefings with staff to review field activities and identify any issues or challenges. In addition, consent and data collection forms and notes will be reviewed by Ms. Goklish and study staff, to ensure that the study protocol is being properly adhered to. Consent forms, data collection forms, and handwritten notes will be stored in a locked filing cabinet on site that will only be accessible by Ms. Goklish. No data or forms will be accessed or allowed to be taken out of the room directly by anyone other than them. Ms. Goklish takes responsibility for collecting data records (forms and notes) from interviewers and ensuring that files are destroyed once the study is complete. Ms. Goklish will be in close communication with Drs. Cwik and Haroz to ensure these processes are adhered to

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: Participant safety is not considered to be at risk due to participation in this qualitative study. There will not be a medical monitor on site for this research.

Aim 3: The PIs, Drs. Cwik and Haroz, assume responsibility for the safety of study participants. Apache Research Program Assistants will be trained to monitor for safety of study participants and report any concerns immediately to the Field Coordinator the Study Manager and the PIs. All study team members hold up to date CITI certifications, 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).

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) 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. For a detailed outline of how Research Program Assistants will respond, please see Appendix 1.

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

   a. The DSMB membership, affiliation and expertise.

      The data safety monitoring board (DSMB) will be comprised of a group of independent experts that advises this project and will include at a minimum one trauma 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 Aim 3. 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 NARCH and the IRB; 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 Study Manager 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.

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

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

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

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 Field Supervisor and PIs in the event of an adverse event or unanticipated problem. The PIs, Drs. Haroz and Cwik, and the Study Manager, Fiona Grubin, 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 the Research Program staff will immediately report this information to the PIs. The PIs and the Field Supervisor 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 PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**. Anticipated AEs may be reported with the Progress Report.

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.

N/A

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	N/A		

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

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.

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

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

B. **Participants:**

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

Note: 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.

2. 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.

3. Explain whether (and how) you plan to return results to the participants either individually or as a group.

XII. Oversight Plan for Student-Initiated Studies:

A. For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.

B. What is the data custody plan for student-initiated research? *(Note: Students may not take identifiable information with them when they leave the institution.)*

XIII. Creation of a Biospecimen Repository:

Explain the source of the biospecimens, if not described above, what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

C. Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens.

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

F. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form.

G. Explain whether the repository will have Certificate of Confidentiality protections.

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

I. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

XIV. Data Coordinating Center:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

B. How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?

C. Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.

D. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?

E. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?

F. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.

G. Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?

H. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. List the name(s) of the study product(s), and the manufacturer/source of each product.

Name of Study Product	Manufacturer/Source

B. List each study product by name and indicate its approved/not approved status.

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name)	Cleared for Use at Local Study Site

C. If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.

D. If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.

E. If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.

F. Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.

G. What drug monitoring and/or regulatory oversight will be provided as part of the study?

XVI. Medical Devices:

Complete this section if your study will involve an approved or investigational medical device (diagnostic, non-significant risk, significant risk).

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.

Name of Study Product	Manufacturer/Source	Powered?

B. List each study product by name and indicate its status as approved by a government authority or not

approved.

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved

C. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a diagnostic device, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

E. If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.