The Elders' Resilience Curriculum: Toward Building Empirical Evidence Around a Culturally-Grounded, Strengths-Based Intervention

clinicaltrials.gov ID:	NCT06045273
Protocol ID:	IRB00018615
U.S. NIH Grant/Contract Award Number:	K01MH122702
Principal Investigator:	Dr. Victoria O'Keefe
Document Date:	September 28, 2023
Included:	Study Protocol Statistical Analysis Plan (SAP) Informed Consent Form (ICF)

JHSPH IRB Research Protocol for Aim 3 New Data Collection

Use this template for new data collection and if you also will analyze secondary data. Answer the questions below and for numbered sections that do not pertain to your study, retain the section numbers and bolded questions, and write "N/A." **DO NOT DELETE ANY QUESTIONS.** Please start typing in the gray boxes provided. You may delete this instruction box.

PI Name: Victoria O'Keefe, PhD
Study Title: The Elders' Resilience Curriculum: Toward Building Empirical Evidence Around a Culturally-Grounded, Strengths-Based Intervention
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PI Version No. / Date: 12 / 09/28/2023

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

The overall goal of this research is to better understand if and how the Elders' Resilience Curriculum (ERC), a culturally grounded, school-based program taught by White Mountain Apache Tribe (WMAT) Elders to youth, prevents suicide ideation and behaviors for American Indian youth. To achieve this goal, the study will utilize a mixed methods design. In **Aim 3**, we will work with White Mountain Apache tribal community partners to collaboratively design and pilot a rigorous evaluation, collecting quantitative data to test the ERC theoretical model and culturally adapted assessment battery.

Aim 3: To pilot ERC's theoretical model, culturally informed measures, and the feasibility and acceptability of a rigorous evaluation design to inform the development of a fully powered effectiveness study in a subsequent R01.

As of July 2023, we have collaborated with our White Mountain Apache tribal research partners to prepare and discuss an evaluation plan for Aim 3 which is outlined in the updates to this research plan version 6.

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.

Suicide disproportionately affects American Indian/Alaska Native (AI/AN) communities, with the greatest burden experienced by AI/AN youth [1]. A paucity of mental health care resources in AI/AN settings points to a critical need to deliver suicide prevention interventions outside conventional mental health clinical settings [2].

Past research has shown cultural protective factor approaches will be more effective than risk focused interventions to reduce AI/AN youth suicide [2-5]. Culturally grounded (or "ground up") prevention interventions—which place local culture and values at the forefront of intervention design, implementation, and evaluation—hold strong promise to prevent AI/AN youth suicide [6,7]. However, we know little about core components, mechanisms, and constructs through which culturally grounded interventions can prevent suicide.

The Elders' Resilience Curriculum (ERC) is a school-based, culturally grounded, suicide prevention intervention currently delivered by White Mountain Apache Tribe (WMAT) Elders through monthly lessons

about tribal cultural values, beliefs, ways of life, and Apache language to youth ages 9-14, a nascent stage prior to the highest risk period for suicide (15-24 years old) in this community [8]. The proposed research builds upon the Johns Hopkins Center for Indigenous Health and WMAT's 35+ year research and public health partnership that continues to innovate and scale prevention interventions through community-based participatory research.

This Mixed Methods study is innovative in its quest to determine core components of a culturally grounded AI youth suicide prevention intervention through community-engaged research and developing an Indigenous youth resilience model against suicide. If successful, new understanding of the mechanisms and constructs through which ERC operates to prevent AI/AN youth suicide through this study will support a future larger effectiveness study followed by replication and scaling of this intervention to other AI/AN communities suffering youth suicide disparities.

III. Study Design:

A. Provide a BRIEF 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)*

Aim 3

Aim 3 of the project includes a pre-/post-test design evaluation of the Elders' Resilience Curriculum using culturally adapted measures. The ERC is a monthly curriculum delivered by Elders to youth in classrooms. Delivery of ERC curriculum content will be monitored by WMAT CMHSs using session summary sheets. The PI and a research assistant will check session summary sheets to check if core components were delivered with fidelity and to compare against core components determined in Aim 1.

A survey comprised of these culturally adapted measures will be administered to youth in schools where the ERC is delivered at three timepoints – once at the beginning of the school year, once during the middle of the school year, and finally at the end of the school year. Change in outcomes over time as students receive the ERC lessons will be assessed.

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 3

For the pre-/post-test survey in Aim 3 we will aim to recruit and enroll up to *N=200* youth ages 9-14 from 5-10 classrooms where the ERC is delivered. This sample size is based on feasibility and convenience (e.g., based on the classroom sizes in schools where the ERC is delivered) and leaves flexibility in case classroom sizes are larger than anticipated.

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.

A. **Inclusion Criteria:**

Aim 3:

Inclusion criteria for participants in the pre/post study:

1) Be between 9-14 years of age
2) Enrolled in a school where the Elders' Resilience Curriculum is delivered
3) Participating in the Elders' Resilience Curriculum program

B. **Exclusion Criteria:**

Aim 3:

Exclusion criteria for participants in the pre/post study:

1) Parent or legal guardian objects to child's participation.

***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.

   Aim 3:

   Students for the pre/post study will be recruited from classrooms at schools where the ERC is delivered (exact schools to be identified in collaboration with community partners who are implementing the ERC lessons in schools). Caregivers (i.e., parents, legal guardians) of students enrolled in classrooms where the ERC is delivered will be informed with an informational letter about the evaluation study (see recruitment materials) The letter will be sent home with each student and a copy will be mailed to the students' home as well. The survey procedures will be explained in detail in the materials shared with caregivers who will be encouraged to contact the CIH Whiteriver office to ask any questions about the study. Caregivers will be informed that youth's responses to the surveys will not be shared with caregivers. Caregivers who would prefer their children do not participate in the study will sign and return the form.

   After information has been shared with parents, CMHSs working on this study will introduce the study by reading a prepared script to the youth in classrooms during the scheduled ERC monthly lesson time (see recruitment materials) and youth will be asked to assent to participate in the study (see youth assent form – Aim 3). Youth will be informed that they will still be able to participate in the Elders' Resilience Curriculum lessons even if they choose not to take part in this evaluation study. Caregivers who want their children to participate do not need to submit any documentation.

These recruitment efforts will be carried out and supported by Dr. Goklish and the team of WMAT CMHSs that she supervises (see above description of this team in recruitment for Aim 1).

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 3:
   Maintaining privacy and confidentiality is a priority. Given that the survey in Aim 3 does not contain any sensitive topics or questions, we do not anticipate any privacy issues associated with recruitment for the survey.

B. **Consent Process**:

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

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

   Aim 3:
   Survey:
   As described above, a letter will be sent home to parents of students enrolled in the classrooms where the ERC is delivered (see recruitment materials). The letter will be sent home with each student and a copy will be mailed to the students' home as well. The survey procedures will be explained in detail in the materials shared with caregivers who will be encouraged to contact the CIH Whiteriver office to ask any questions about the study. Caregivers who would prefer their children do not participate in the study will sign and return the form.

   Youth participants will be asked to assent to participate in the study unless their caregiver (i.e., parent/legal guardian) has dissented to their participation. Study staff obtaining assent will make it clear that the decision to participate will in no way affect their ability to participate in the ERC program or any other WMAT or CIH program, and that they can withdraw from participating at any time with no consequences. Study staff will use the youth assent script to facilitate obtaining a signed assent form (see recruitment materials).

   For all Aim 3 activities, consent may be obtained by trained, CITI certified JHU team members (including Dr. Victoria O'Keefe, Novalene Goklish, Fiona Grubin, WMAT CMHSs who are JHU employees working as part of the local Celebrating Life team, and other JHU research staff in Whiteriver, AZ). All of the members of the research team who will obtain informed consent have prior experience working on research studies and obtaining informed consent, have completed relevant and appropriate CITI trainings, and will have been trained in study orientation before any data collection begins to ensure they are prepared to collect informed consent

   b. How, where, and when the consent discussion(s) will occur:
   Aim 3:
   Survey:
   Parents will be informed through a letter that is sent home with each student and copy of the letter will also be mailed to each student's home. The process of obtaining youth assent will occur in-person in the classrooms/ schools that are participating in the ERC and this study. CMHSs and study staff will review the assent form and assent script with each student in a private space at the students' school. Conversations will be held in a space that will allow for privacy so that other students are not able to overhear each student's answers. For obtaining

youth assent, study staff will utilize a script to review the information in the assent form with each student (see recruitment materials).

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

Aim 3:

Surveys: We will collaborate with 2-3 schools to identify classrooms that have students who are eligible to participate based on their age, being enrolled in school, and the ERC being delivered to the classroom. We will also collaborate with schools to identify any students who are in the foster care system or a ward of the state so as to exclude them from participating because a caregiver cannot agree or dissent to their participation.

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

Aim 3:
Survey: Written assent will be obtained from student participants. Parent permission will be passive and written dissent will only be obtained if a parent submits a signed form indicating that they do not want their child to participate in the study.

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

Aim 3: N/A. We will not include participants who lack capacity.

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

Aim 3:
Survey: Assent will be obtained from youth using the assent script to review the assent form with youth. Youth who agree to participate will sign the consent form after study staff have checked that they understand and are agreeing to participate.

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

Aim 3:
Survey: As described above, a letter will be sent home to parents of students enrolled in the classrooms where the ERC is delivered (see recruitment materials). The letter will be sent home with each student and a copy will be mailed to the students' home as well. The survey procedures will be explained in detail in the materials shared with caregivers who will be encouraged to contact the CIH Whiteriver office to ask any questions about the study. Caregivers who would prefer their children do not participate in the study will sign and return the form.

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:

N/A.

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:

Aim 3: N/a

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

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
United States	Adult Consent	English
United States	Parental Permission	English
United States	Youth Assent	English
United States	Youth Assent – Aim 3 Survey	English
United States	Parent Passive Permission – Aim 3 Survey	English
United States	Youth Assent – Aim 3 Cognitive Interview	English
United States	Caregiver Permission – Aim 3 Cognitive Interview	English

C. **Study Implementation**:

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

Aim 3:

Survey: Students will be asked to complete a paper survey containing the measures outlined below in the table below. The paper survey will be a hard copy document. Study staff will be available to answer questions and support students in completing the survey (e.g., if they do not understand what a question is asking, staff will help explain further). Students will be asked to complete this survey at three timepoints (see answer to #2 below and table) and will complete the surveys in their classrooms. The study team will work with classrooms and schools to schedule an appropriate time to go into the classroom during school and administer the survey.

Measure	Outcome(s) measure will assess	Frequency		
		Baseline (August 2023)	Midline (January 2024)	Endline (May 2024)
Demographics	Demographics	X		
Index of local indicators of well-being	Physical Health, Emotional Health, Social Health, Community Connectedness	X	X	X
Apache language questions	Apache language skills	X	X	X

Awareness of Connectedness scale	Community Connectedness, Family Connectedness	X	X	X
Cultural Connectedness Scale – Short form	Spiritual Health, Identity, Cultural continuity	X	X	X
Cultural Efficacy scale	Identity, Cultural continuity	X	X	X
Group level self-identification and self-investment	Identity, Belonging	X	X	X
Intergenerational Connectedness scale	Intergenerational Connectedness: youth and Elders being able to connect Intergenerational Connectedness: youth feeling connected to past, present, and future	X	X	X
Multicultural mastery scale	Emotional Health, Mental Health, Social Health, Community Connectedness, Family Connectedness	X	X	X
Reasons for life scale	Mental Health, Spiritual Health	X	X	X
Rosenberg self-esteem scale	Mental Health	X	X	X
Self-reported academic outcomes	Academic outcomes	X	X	X
Self-reported health ratings	Physical Health, Mental Health, Spiritual Health	X	X	X

Measure	Description
Index of local indicators of well-being	18 self-report items developed by our White Mountain Apache Tribe (WMAT) collaborators for a previous research study [9] and for this study. These items capture positive impacts among WMAT youth related to suicide prevention interventions, including the Elders' Resilience Curriculum.
Apache language questions	5 questions developed by our WMAT collaborators assess Apache language skills.
Awareness of Connectedness scale	The Awareness of Connectedness Scale [10] is a 12-item self-report measure that evaluates awareness of connection with self, family, community, and the natural environment. This scale has been used in previous research with WMAT youth [11, 12].
Cultural Connectedness Scale – Short form	The Cultural Connectedness Scale-short version [13] is a 9-item self-report measure that assesses connection to cultural identity, traditions, and spirituality among First Nations youth. This measure has been used in previous research with AIs [14].
Cultural Efficacy scale	5 self-report items measure cultural efficacy and are sourced from a research study with AI participants [15].
Group level self-identification and self-investment	6 self-report items that capture solidarity, satisfaction, centrality, individual self-stereotyping, and in-group

	homogeneity [16]. Items from this scale have been used in previous research with AI adolescents to assess cultural identification [17].
Intergenerational Connectedness scale	7 items developed through another ongoing study assess intergenerational connectedness.
Multicultural mastery scale	The Multicultural Mastery Scale for youth [18] includes 13 self-report items that were retained and adapted for use in the local WMAT context by [9] in another research study. Items in this measure assess mastery in relation to self and community. The original measure has been used with American Indian youth in previous research [18].
Reasons for life scale	11 self-report items from the Reasons for Life scale [19] measure beliefs and experiences that make youth feel like life is enjoyable, worthwhile, and meaningful. It was adapted from an adolescent measure of brief reasons for living [20] for use in research with Alaska Native youth and has been used in other research with AIs [18].
Rosenberg self-esteem scale	The Rosenberg self-esteem scale [21] is comprised of 10 self-report items that measure global self-worth through asking about positive and negative self-feelings. The scale has been used with adolescent AIs with good reliability (alpha=0.84; [22]).
Self-reported academic outcomes	Four self-report items to assess grades, academic performance, attitude toward school, and educational goals will be used to measure academic outcomes. These items come from a research study with AI adolescents [22].
Self-reported health ratings	Three questions asking participants to self-report their overall physical, mental, and spiritual health assess overall health. These questions were used in previous research with Indigenous young adults [17].
Demographics	Six questions asking about basic demographic information were created in collaboration with WMAT community partners and included here.

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 3:

Survey: Students who participate in the aim 3 survey will spend approximately 15 minutes interacting with study staff to obtain youth assent. Student participants will be asked to complete the survey at three timepoints, once in the beginning of the school year (baseline), once approximately halfway through the school year (midline), and once at the end of the school year (endline). It is estimated that each of these surveys will take students between 20-60 minutes to complete, meaning study participation in the survey would take a total of 1-3 hours of time across all data collection timepoints. At each timepoint the survey will be administered to students in schools. We will collaborate with the schools to schedule an appropriate time to come in and administer the survey with students in their classrooms. CMHSs supporting this study will help administer the survey in classrooms by providing instructions and distributing paper survey packets. CMHSs will be available to answer any questions a student might have to help them complete the survey and

will observe and monitor the classroom to ensure students are filling out the surveys independently and that all survey data remains anonymous and confidential.

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

   Aim 3:
   Surveys: Each survey will take between 20 minutes and 60 minutes to complete x 3 surveys = up to 3 hours total participation time.

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

   Aim 3: The overall goal of the analysis will be to assess for change in outcomes across time from all three survey timepoints (baseline, midline, and endline) using a pre/post analysis. All responses will be analyzed with SPSS software to examine internal consistency of each scale, item and scale level response distributions, inconsistencies in responses, and missing data patterns. Change over time in key outcomes (see table above listing outcomes) will be assessed. Session summary forms will be reviewed to assess intervention delivery fidelity and consistency across lessons. Cognitive interview responses will be compiled and analyzed to assess item fit and comprehension and to make potential improvements or changes to future surveys.

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.
   N/A

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

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

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

   E. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA

certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.
N/A

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

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

N/A

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

N/A

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

N/A

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

N/A

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

N/A

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

N/A

VI. Data Custody, Management, Security, and Confidentiality Protections:

Note: Principal Investigators are responsible for Data Protection and Use throughout the life of the study. You will need all of the following:

- *a data security plan that addresses each stage: data collection, transfer/analysis, storage, and sharing;*
- *a data management plan overseeing data access, storage, etc.;*
- *a data sharing plan that is consistent with obligations under the funding agreements associated with the study, and with the language in the consent documents.*

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 (Data Collection)***.

	Recruitment /Consent	Data Collection
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.	☐	☐

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 ☐

B. 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(s) will you collect and store PII? When you respond, refer back to the table above; think of PII collected during recruitment, consent, data collection, 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?

      All paper forms that contain participants' confidential information (i.e., consent form, contact information, brief demographics survey, handwritten notes from Aim 3 surveys) will be kept separate from survey data and secured in locked file cabinets on site in the CIH office (Whiteriver, AZ). In the event that any of these paper forms are collected at a location other than the CIH Whiteriver office, they will be transported securely by WMAT CMHSs who are employees of JHU. These CMHSs regularly travel throughout the community with paper forms that contain sensitive and private information related to the local surveillance system they work in as well as other research studies and have well-established procedures for safeguarding this information during transportation including limiting the amount of information they carry at one

time and checking in and out with supervisors at the office. CMHSs transport these paper forms in project vehicles leased and maintained by JHU to support research activities.

For Aim 3, the surveys will be collected on hard copy paper surveys in classrooms at schools. As soon as participants have finished filling out their surveys, they will be collected by WMAT CMHSs who will compile them in folders and transport them directly to the CIH office in a CIH project vehicle. These CMHSs regularly travel throughout the community with paper forms that contain sensitive and private information related to the local surveillance system they work in as well as other research studies and have well-established procedures for safeguarding this information during transportation including limiting the amount of information they carry at one time and checking in and out with supervisors at the office. When WMAT CMHSs return to the CIH office with these completed hard copy paper surveys, they will immediately store them in a locked filing cabinet setup for this study. The keys to this cabinet are stored in a locked safe that only the onsite supervisor and program coordinator have access to. They will be present to help CMHSs lock these forms securely in a filing cabinet. As time allows, paper surveys will be entered into REDCap by study staff. Staff will work with their supervisor to remove only a subset of forms for data entry at a time, ensuring that forms are locked up again after data entry and that a staff member is always in control of the documents while they are out of the locked filing cabinet.

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?
Data will be retained until the end of the study.

2. **<u>Electronic</u>:** Yes ☒ No ☐

If yes, please answer the following:

a. Will the data be collected or 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 ☒
Note: If personally owned, please address the privacy and data security risks under VII. Risks below.

c. Is the app (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:

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. Mobile Apps Yes ☐ No ☒

FOR STUDIES USING MOBILE APPS: When the use of a mobile app is approved solely for a research use, the IRB either requires that it be restricted to people who consented to the research, or when a screen/script is used, for participants to understand that this is not a medical tool or a public app but is for use only in a research study only. Please check the appropriate box(es) below that describe your study:

☐ Use of the app is restricted to people in the research, with access limited to those who have consented to the study.

☐ The consent information for participants clarifies that the app is not for clinical or public use but is restricted to this research study

4. **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 immediately after transcription? Yes ☒ No ☐

If no, why not? How long will it be retained?

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?

C. 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?

   When the study is complete, we will destroy the file linking PII with participants' study ID.

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

   Upon enrollment in the study, participants will be assigned a confidential identification number, which will be used as the only identifier on all data records. Study ID numbers will be linked with participants' PII in one master list that will be stored securely in a password protected file in JHU OneDrive.

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?)

D. 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 systems that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.
Check all systems used for data collection, storage and analysis.

☐ **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.

☐ **OneDrive-JHSPH**: Managed by JHSPH IT and available only to people with a JHSPH ID, a file storage and file sharing solution in the Microsoft cloud for faculty, staff, and students. With OneDrive, you can store files and access them anywhere with internet access. (https://my.jhsph.edu/Offices/InformationTechnology/ComputerSupport/SharedFolders/OneDrive-JHSPH/Pages/default.aspx)

☒ **JHU OneDrive**: Managed by IT@JH, personal cloud storage component of the Office 365 produce suite that allows users to store and share documents and files from any device with an internet connection. Share documents with colleagues, inside and outside of JHU (no JHED ID required). (https://it.johnshopkins.edu/services/collaboration_tools/OneDrive/)

☒ **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.

☐ **JHSPH Sharepoint:** For user-controlled private web sites, secure document storage, navigable directories, contacts and people searches, increased collaboration and sharing opportunities.

(https://my.jhsph.edu/Offices/InformationTechnology/CommunicationServices/MyJHSPH/Pages/default.aspx)

☐ **JHSPH-Shares** is a managed folder system for the secure storage and sharing of data. Folder owners have ability to granularly manage access permissions.

☐ **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, for example Qualtrics, ODK, etc. Examples may include servers and applications located at another university participating in your study or a 3rd party web-based application.

E. 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.

   N/A

F. 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 ☐

G. Data Sharing and Disclosure:

a. Please describe your data sharing plan, including whether you plan to share your data with your sponsors or with other investigators. Explain whether the shared or disclosed data will be individually identifiable. **Your data sharing plan should be consistent with Sponsor requirements, and the consent document should include a description of your data sharing plan.**

Data from Aim 3 surveys will only be shared and available to study research personnel while it is collected and analyzed. After data has been analyzed and de-identified, it will be available and reported and shared with the CAB as described above in the data analysis plan.

Dissemination activities throughout the K01 research will include conference presentations and peer-reviewed publications. The Johns Hopkins Center for Indigenous Health has a standard proposal, development and approval process, including approval by the White Mountain Apache Tribe (WMAT) review boards. This process will be overseen by Dr. O'Keefe with support from the WMAT community collaborator, Dr. Novalene Goklish. Dissemination of study results will also be presented to the relevant advisory boards comprised of WMAT community stakeholders convened at the beginning of the study. The purpose of sharing study results with these groups is to maintain tribal stakeholders as equal research partners in line with community-engaged research, allowing them to provide feedback about interpreting study results, and to collaboratively plan future research projects.

b. Are there laws limiting data sharing in the country where the research site(s) is located? If yes, please address those limitations and how you will comply with them.
No.

c. Will you make your data publicly available? If yes, what is your plan for de-identification?
No.

d. Will you deposit it into a repository for broader use? If yes, identify the repository and provide information about the data protections.
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*.

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 3: For the surveys in Aim 3, the primary risk to participants is the time it takes to complete the surveys. There is a small potential for participants to feel distressed by the questions, for example, if they have recently lost a relative some of the questions asking about connections to relatives may create some discomfort. Because all of the questions are strengths-based and focus on positive outcomes, we anticipate that the potential risk of emotional or psychological discomfort will be very low.

B. Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.

Aim 3: Participants will be informed that they may skip any questions in the survey that they do not wish to answer and that they can stop at any time if the questions make them uncomfortable. If any participant does become distressed during the completion of a survey, a break will be provided or the procedure will be stopped, and the research staff will work with the participant to reduce the participant's distress. If these approaches do not reduce the participant's distress, the research study staff person will ask if the participant wishes to address the distress in another manner and will facilitate the participant's request when possible. Local research staff who are CMHSs working as part of the local Celebrating Life team regularly encounter individuals in distress and are trained and have extensive experience supporting these individuals and can be called in to help support participants if needed, including providing referrals to local services if necessary.

In addition, field staff can enlist the Principal Investigator (PI), Dr. Victoria O'Keefe, a Licensed Clinical Psychologist, to talk with the participant in person (if Dr. O'Keefe is on site) or via phone and facilitate appropriate referrals for the participant if necessary. All research staff have the PI's cell phone number to contact her for these types of events 24 hours a day. All research staff also have Dr. O'Keefe's mentors' and colleagues at Johns Hopkins Center for Indigenous Health (Dr. Allison Barlow; Dr. Mary Cwik) cell phone numbers to serve as back-up should they be unable to reach the PI.

C. 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 3: We anticipate minimal frequency and low severity of the harms associated with the risks above based on previous Apache-JHU studies with this population.

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

Aim 3:
The main burden for participants in the survey will be time.

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.

Aim 3: The survey does not include sensitive questions and study visits will not occur in the home.

F. Levels of COVID-19 community transmission will vary considerably by geography and over time, and therefore, the responses to the pandemic may also vary. The risk of COVID-19 to study staff and participants from in-person research activities can be mitigated by appropriate study procedures. If you are conducting in-person research activities, please indicate the protections you plan to implement at your research site(s):

☐ Not applicable
☐ COVID testing of staff
☐ COVID testing of study participants
☐ Indoor masking/wearing PPE
☐ Social distancing for indoor activities
☐ Symptom screening of staff
☐ Symptom screening of study participants
☒ Vaccination of research team members
☒ Other procedures/comments: Masks and hand sanitizer are offered to all participants during in-person study activities.

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 3: Participants may benefit by understanding and feeling like they are contributing to supporting youth in their community by engaging in this research. They may enjoy some of the survey questions which ask about many positive topics (e.g., self-esteem, feeling connected).

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

American Indian/Alaska Native youth are the age and racial/ethnic group at highest risk for suicide nationally. The Elders' Resilience Curriculum, the focus of this study, is an innovative, culturally grounded suicide prevention intervention that targets modifiable cultural protective factors. Identifying and understanding its core components, producing an empirically-driven Indigenous youth resilience theoretical model and matched culturally informed assessment battery, and conducting a pilot evaluation (Aim 3) will lead to a critically needed fully- powered R01 effectiveness study. Collectively, this research is necessary for scaling this promising community-driven prevention intervention to other American Indian/Alaska Native communities to reduce youth suicide.

Capacity building: This study focuses on a community-driven suicide prevention intervention that is delivered by local Elders to youth in schools. Given numerous challenges in mental health care access and delivery of culturally-informed care, this approach has enormous benefit for participants on tribal lands. In addition, tribal capacity building is evidenced by White Mountain Apache community mental health specialists, including Dr. Goklish, who will serve as research study staff.

Scientific field: This study will provide answers to questions about identifying core components of culturally grounded mental health prevention interventions, how core components impact mechanisms of change within these interventions, and important contributions to expand the measurement development/adaptation field to evaluate American Indian/Alaska Native youth interventions. There is a dearth of research in this area, as well as generally about protective factors against suicide for American Indian/Alaska Native youth.

Policy: Knowledge gained from this study can be used to inform evidenced-based and culturally congruent local policies and programs. Community stakeholders will be involved with the initial and ongoing review of study protocols. Their collective involvement will be critical, thus allowing for real-time policy influence.

The proposed study will make significant contributions to the field of Prevention Science by understanding how an innovative, culturally grounded suicide prevention intervention, promotes mental health and reduces suicide for American Indian youth. This research includes an understudied population in a low resource setting targeting an age and racial/ethnic group at highest risk for suicide in the U.S. Thus, this study will yield valuable knowledge about how community-driven, culturally-based, upstream solutions to suicide outside conventional mental health care settings can be valuable in this context and how it can be generalized to other similar contexts.

IX. Payment or Token of Appreciation:

A. Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If yes, please describe below.

Aim 3: Participants will not receive any non-monetary tokens of appreciation.

B. If you plan to provide a monetary payment, 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 3: Students who complete the survey in Aim 3 will receive a $25 gift card for each survey they complete (up to three $25 gift cards if they complete all three surveys – baseline, midline, and endline). Students who complete all three surveys may receive up to $75 in gift cards.

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

There are no consequences for not completing all phases of the research, participants may choose to end their participation at any time without penalty and will receive payment for any completed study activities.

For **Aim 3**, total remuneration for each participant is up to $75 ($25 gift card per survey, three surveys).

X. Study Management:

A. Oversight Plan:

1. Describe how the study will be managed.

Dr. O'Keefe will oversee all aspects of the study and will engage in regular check-ins with on-site study staff and researchers throughout the course of the study. Dr. O'Keefe will be supported by her mentors, including **Dr. Allison Barlow** and **Dr. Mary Cwik**. Dr. O'Keefe will oversee all data collection and analysis and will coordinate implementation of the study, perform some analysis, and engage in training local research staff on study procedures. **Dr. Novalene Goklish**, BS, MS, PhD, the community collaborator who is a WMAT member and CIH Senior Research Associate located at one of two satellite offices on the lands of the WMAT, will support the study as a local Site Manager to oversee any activities that take place when Dr. O'Keefe is not on site. Dr. Goklish will also receive support from Celebrating Life team members (previously described as WMAT community mental health specialists) to coordinate and participate in study activities. **Ms. Fiona Grubin, MSPH,** will serve as the Study Manager.

This work will take place in collaboration with the Community Advisory Board (CAB) comprised of approximately 10-15 WMAT community stakeholders representing core tribal agencies (e.g., hospital, mental health clinics, schools, traditional healers, church leaders). The role of the CAB

members is to inform the research process and methods, serve as representatives of their community, assist with local logistics, and work with the CIH study team accomplish the goals of the study in a mutually respectful manner.

2. What are the qualifications of study personnel managing the project?
   Dr. O'Keefe, Mathuram Santosham Endowed Chair in Native American Health (JHU), Assistant Professor (JHBSPH, Department of International Health, Social and Behavioral Interventions Program), and Associate Director at CIH, is a licensed psychologist and has been conducting research for more than 10 years on AI/AN mental health and suicide prevention. She also has experience providing direct clinical mental health services to AI adolescents and adults and Veterans at high risk for suicide.

   Dr. Barlow is a Senior Scientist at Johns Hopkins Bloomberg School of Public Health, Executive Director of the CIH, and has worked with WMAT for over 25 years. Dr. Barlow has worked with tribal communities since 1991 to develop and evaluate ecologically sound, evidence-based and culturally informed interventions to address behavioral and mental health disparities, including suicide, among American Indian populations that have applicability in other indigenous and low resource populations.

   Dr. Cwik is a Senior Scientist and Associate Director at the CIH. Dr. Cwik also has a joint appointment in the Psychiatry Department at the Johns Hopkins School of Medicine. She is a child clinical psychologist and has helped to establish the suicide prevention program with the WMAT. Dr. Cwik has conducted suicide prevention research with AI/AN communities for over 14 years. She has managed four initiatives addressing suicide and substance abuse prevention through community-based participatory research with the White Mountain Apache Tribe, and currently serve as Co-PI (with Dr. Barlow) on a NIMH grant conducting a Sequential Multiple Assignment Randomized Trial testing a sequence of culturally adapted and culturally grounded suicide prevention interventions with the WMAT.

   Dr. Goklish is a Senior Research Associate at the CIH (Whiteriver, AZ satellite office). Dr. Goklish holds a Doctorate in Professional Counseling and is currently a doctoral candidate. Dr. Goklish has worked as a Mental Health Interventionist for 20+ years and is a certified suicide prevention community trainer. Dr. Goklish manages WMAT community mental health specialists, facilitates Elders' Council meetings, and has led community advisory board meetings for other studies.

   Ms. Grubin is a Research Associate at the CIH and has 3 years of experience in quantitative and qualitative data collection, including direct qualitative research experience with the WMAT community. She has experience managing, coordinating, and implementing study protocols.

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

   All personnel involved with data collection have been trained in human subjects research protections and have up to date CITI certifications, 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.

   Dr. O'Keefe aims to be on site throughout the data collection process of the FGDs and IDIs. When possible, Dr. O'Keefe will travel to be present for Aim 3 data collection of surveys. However, in the

event that this is not possible, Dr. O'Keefe will have regular conference calls with the local Research Program staff to monitor study progress and assure that the study is being implemented according to protocol. Dr. Goklish 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

Dr. O'Keefe and Dr. Goklish will be trained in study procedures and will oversee data collection and storage to ensure fidelity to the study protocol. Dr. O'Keefe and/or Dr. Goklish will discuss all concerns with the investigator team. Dr. O'Keefe will be responsible for reporting to the IRB.

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?

   The PI assumes responsibility for the safety of study participants. Research Program staff will be trained to monitor for safety of study participants and report any concerns immediately to Dr. Goklish and the PI. All Research Program staff will be trained in human subjects research and will be required to complete the CITI ethics module prior to any interaction with participants or study data. Certificates of human subjects completion will be kept on file at the Center for Indigenous Health's office in Baltimore.

   We expect minimal risk. However, Dr. O'Keefe, a clinical psychologist, will be available if if unexpected issues arise. Additionally, or if Dr. O'Keefe is unavailable, local WMAT CHMWs who work on the WMAT Celebrating Life program (a program which provides support and referrals to people experiencing suicidal ideations or behaviors) will be available to provide support and referrals if needed.

   In addition, field staff can enlist the Principal Investigator (PI), Dr. Victoria O'Keefe, a Licensed Clinical Psychologist, to talk with the participant in person (if Dr. O'Keefe is on site) or via phone and facilitate appropriate referrals for the participant if necessary. All research staff have the PI's cell phone number to contact her for these types of events 24 hours a day. All research staff also have Dr. O'Keefe's mentors, Dr. Allison Barlow and Dr. Mary Cwik, cell phone numbers to serve as back-up should they be unable to reach the PI.

   More specifically for Aim 3, The PI will meet with primary mentor, Dr. Allison Barlow (an expert in American Indian/Alaska Native mental/behavioral health research), co- mentor, Dr. Mary Cwik (an expert in American Indian/Alaska Native mental health and youth suicide prevention research and Licensed Psychologist), and Johns Hopkins Center for Indigenous Health Research Core Co-Leader and biostatistician, Dr. Emily Haroz, on a monthly basis to review study progress and any issues related to study protocol, participant safety and confidentiality, and data safety. The PI will consult with Dr. Barlow, co-mentor, Dr. Cwik, and Dr. Novalene Goklish, community collaborator, on any serious adverse events within 48 hours of the event being reported. They along with Dr. Haroz will also review any and all other unexpected adverse events at monthly executive meetings to ensure there are no concerning patterns.

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

a. The DSMB membership, affiliation and expertise.

N/A

b. The charge or charter to the DSMB.

N/A

c. Plans for providing DSMB reports to the IRB.

N/A

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

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 PI, with support from mentors Dr. Barlow and Dr. Cwik, will assume responsibility of monitoring participants' safety, including reporting any serious and unexpected adverse events. Any adverse event that occurs will be categorized by Johns Hopkins staff as ranging from mild to serious. All adverse event reporting procedures, as designated by the Johns Hopkins IRB, will be followed by key study personnel with strict adherence.

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 Local Study Staff Manager 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.

For Aim 3, Any adverse event that occurs will be categorized by Johns Hopkins staff as ranging from mild to serious. All adverse event reporting procedures, as designated by the Bloomberg School of Public Health IRB (BSPH IRB), will be followed by key study personnel with strict adherence. Serious Adverse Events (SAEs) include:

- Any death of a study participant
- A disability or incapacity which, in the opinion of the PI, causes substantial disruption of a study participant's ability to conduct normal life functions
- Hospitalization or extension of an existing hospitalization (excluding elective hospitalization for conditions unrelated to the study)
- Any intervention required to prevent one of the above outcomes

Serious and unexpected adverse events will be reported within three business days to BSPH IRB, tribal review entities, and the assigned NIH program officer. The PI, with guidance from mentors, will immediately report actions taken by any of these groups in response to adverse event reports to each of the other groups.

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). **For federally funded studies, subrecipient AND subrecipient's IRB MUST have a Federal Wide Assurance (FWA) number.**

Non-JHSPH IRB/REC	FWA Number

F. **"Engaged" in Human Subjects Research:**

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

Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:

	JHSPH		
For federally funded studies, collaborators' FWA	00000287		
Primary Grant/Contract Recipient	BSPH Center for Indigenous Health (CIH)		
Grant/Contract Subrecipient	n/a		
Hiring Data Collectors	BSPH Center for Indigenous Health (CIH)		
Training Data Collectors	BSPH Center for Indigenous Health (CIH)		
Obtaining Informed Consent and/or Identifiable Data	BSPH Center for Indigenous Health (CIH)		
Accessing/Analyzing Identifiable Data	BSPH Center for Indigenous Health (CIH)		
Overseeing storage, access and use of biospecimens	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.

   N/A

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

   N/A

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

   N/A

B. **Participants:**

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

   N/A

   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.

   N/A

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

   N/A

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.

   N/A

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.)*

N/A

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.

N/A

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

N/A

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

N/A

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.

N/A

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.

N/A

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.

N/A

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.

N/A

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

N/A

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.

N/A

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.

N/A

XIV. Data Coordinating Center:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

N/A

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?

N/A

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.

N/A

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?

N/A

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

N/A

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.

N/A

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?
N/A

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?

N/A

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
N/A	N/A

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
N/A	N/A	N/A

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.

N/A

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.

N/A

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.

N/A

G. 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.

N/A

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

N/A

XVI. Medical Devices:

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

N/A

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?
N/A	N/A	N/A

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
N/A	N/A	N/A

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".

N/A

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.

N/A

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.

N/A

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The Elders' Resilience Curriculum Statistical Analysis Plan

Aim 3:

The overall goal of the analysis will be to assess for change in outcomes across time from all three survey timepoints (baseline, midline, and endline) using a pre/post analysis. All responses will be analyzed with SPSS software to examine internal consistency of each scale, item and scale level response distributions, inconsistencies in responses, and missing data patterns. Change over time in key outcomes (see table above listing outcomes) will be assessed. Session summary forms will be reviewed to assess intervention delivery fidelity and consistency across lessons. Cognitive interview responses will be compiled and analyzed to assess item fit and comprehension and to make potential improvements or changes to future surveys.

The original plan was to run an Observed Change Score Model where we created difference scores from baseline to midline and midline to endline and examined which predictors explained changes during those two periods.

After running these models using SEM, the models were unstable and therefore the results were biased and untrustworthy. Thus, I pivoted to conducting a Linear Mixed Model or Mixed Effects Model that could account for the repeated measures structure with only one group and allows participants to vary at baseline. Due to the number of participants in the data set, I wasn't confident that this model would run when first deciding on a model, but it ended up running without issue. I checked the assumptions for running the model with our data and all of the assumptions were met. The assumptions are:

Linearity: Check with residuals vs predictors.

Independence: Accounted for by random effects but plotted residuals over time to check.

Homoscedasticity: Plot residuals vs fitted values.

Normality of Residuals: Histogram and Q-Q plot of residuals.

Normality of Random Effects: Plot random intercept distribution.

The equation for the model is as follows

$$RFL = \beta_0 + \beta_1 Midline + \beta_2 Endline + \beta_3 AWOC + \beta_4 CCS + \beta_5 CCS\ ID + \beta_6 CES + \beta_7 LWI + \beta_8 IC + \beta_9 MMS + \beta_{10} RES + \beta_{11} SDI + u_i + e_{ij}$$