A Native Path to Courage: Feasibility of a Culturally Adapted Emotional-Behavioral Prevention Program for American Indian Children

Study Protocol and Statistical Analysis Plan

NCT05371665

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Document Summary

This document contains the study protocol, including the data safety and monitoring plan, approved by the tribal IRB. Names of the tribe and tribal members have been redacted from this document for the purpose of confidentiality. The final approval of the study protocol and data safety and monitoring plan as presented in this document was obtained on June 10, 2025. All requested and approved modifications to the study protocol by the tribal IRB during the study period are included in the document. In addition, the statistical analysis plan for the study outcomes is included in the document.

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STUDY PROTOCOL

Background

American Indians (AI) have endured colonization, war, and genocide that has resulted in historical trauma loss and grief, continuing racial discrimination, and financial hardships.[1-3] These experiences may guide how Native children view and interact with the world around them and put them at greater risk for anxiety and depression early in life.[2,4-6] Moreover, research suggests that youth anxiety and depression are major risk factors for later negative health outcomes that are highly prevalent in Native people, such as substance use and suicide.[7-10] Data from recent studies suggests Native youth-reported clinical levels of anxiety and depression are highly prevalent. In two studies, 10% to 23.3% of Native youth (9-17 years of age) experienced clinical levels of depression[11,12], as well as greater anxiety and depression as compared to their non-Hispanic White and racial/ethnic minority peers. In a 2020 study, 39.15% (*n* = 92 of 236) of 8-18-year-old Native youth reported clinical levels of anxiety in US northwest and Canada.[13]

Our collaborative research with the [tribal name\ School revealed that 7.3% and 8.7% of 8-13-year-old [tribal name] youth (only one 13-year-old) reported clinical levels of anxiety and depressive symptoms, respectively, and 5.9% and 2.9% reported subclinical levels.[14] These findings suggest that anxiety and depressive disorder development may be in the early stages and that 8-12-years old may be an optimal age to prevent or mitigate anxiety and depressive symptoms. Moreover, and given the COVID-19 pandemic and restrictions, Native youth from [tribal name] may be a greater risk for anxiety and depression and findings from past pandemics suggest possible long-term effects on AI youths' physical and mental health.[15,16] Taken together, findings suggests that anxiety and depression are important health concerns that need to be addressed in Native youth and demonstrates a critical need for intervening early with Native youth from [tribal name] to prevent or mitigate anxiety and depressive disorder development.

Brief cognitive-behavioral PEIs have shown to be efficacious in reducing anxiety and depression in non-Native youth.[17-21] However, there is minimal, though promising, evidence of efficacy to address anxiety and depression in Native youth.[22-25] One of the potential barriers to developing an efficacious PEIs for Native youth is the need for culturally grounded adaptation using a community-based participatory research approach, as opposed to traditional cultural adaptation that involves simply minor add-ons of cultural practices and language substitutions (i.e., swapping out an English word with Native words) suggested by cultural experts.[26] Our cultural advisory board (CAB) agrees with Indigenous researchers who strongly recommend a culturally grounded adaptions of existing PEIs, including integration of tribal knowledge and ways of thinking, tribal language and associated cultural meaning/context (e.g., the tribal language word for anxiety may mean more than being scared or afraid), cultural beliefs, and healing practices, to enhance fidelity, community ownership, participant buy-in, and intervention effects.[4,27,28] For example, researchers have emphasized that cultural adaptions of the cognitive-behavioral interventions consider that providers learn to avoid misconstruing reasonable thoughts within the context of the tribal culture as distorted.[5,28]

To our knowledge, there are three culturally adapted interventions aimed at reducing anxiety and depression for AI youth. The *Cognitive Behavioral Intervention for Trauma in Schools (CBITS)* was culturally adapted for Northern Plains American Indian youth living on a

reservation with a history of trauma and post-traumatic stress disorder (PTSD) symptoms.[23,24,29] They found pre- to post-intervention changes in PTSD, anxiety, and depression in 43 Northern Plains American Indian youth. However, they had low recruitment and retention rates (25% dropped out or left treatment). *FRIENDS* was culturally enriched for Canadian Indigenous 4th-6th graders using two Indigenous school board consultants and universal "surface" level changes, but did not find significant reductions in anxiety symptoms in 192 Indigenous youth using a wait-list control design.[30] *Coping with Depression for Adolescents* was culturally modified for American Indian students with community health professionals and educators and intended for adolescents with high levels of depression.[22] Findings showed no differences from pre- to post-intervention for anxiety and depression between the treatment group and a treatment-as-usual control group.

One of the potential barriers is the need for cultural adaptations, which takes community support and trusting, equitable partnerships. We continued using a community-based participatory research (CBPR) approach for this study. CBPR is different from traditional research methodology as it is built on trust and true collaboration between the academic research team and the tribal community that involves a "commitment to build on community strengths and resources, foster co-learning and capacity building, and to balance research and action for mutual benefit of all partners.[31,32] That is, tribal members are not simply participants being researched on, but the researchers and tribal community work equitably with each other on all aspects of the research process, including research design, data collection and analysis, and dissemination of the study's findings to community stake-holders and academic outlets.[31,32] Over the past seven years we have engaged in CBPR to build an equitable, trusting, and mutually beneficial partnership with the [tribal name] Reservation. We have an established Cultural Advisory Board (4-6 members) who continue to take an active role in research decisions and ensure that our collaborative research efforts maintain cultural appropriateness and benefit the tribal community. Moreover, we have built positive and respectful relationships with the tribal council, schools (e.g., teachers, school counselors), mental health services, and social services department and have sought their input on research design, implementation, and interpretation of the findings.

The CAB reviewed potential evidence-based PEIs to adapt. They identified a brief, indicated PEI program for adaption, which is aimed at reducing youth anxiety and stress.[21,33] They indicated its brevity and potential for youth engagement (board games, playing cards) as appealing. Moreover, it was designed using a CBPR approach and successfully adapted for Latinx youth. There is evidence supporting its feasibility, fidelity, and acceptability with non-Native youth and shown promise in reducing anxiety.[21,33] It is grounded in cognitive-behavioral and emotional theories of anxiety and stress[34,35] and aims to improve emotion awareness and expression, reduce cognitive biases, and enhance self-efficacy to manage anxious or stressful situations. It uses streamlined cognitive, behavior, and social skills training using a 12-page manual, active learning (role-playing, games), and brief 30-minute sessions. Training is also minimal at 5 hours plus two 30-minute feedback sessions.

The PEI program[21,33] is delivered across six weeks with 20-30 min weekly sessions. Youth engage in games and role-play reducing anxiety and stress in mildly challenging situations to provide in-vivo exposure. Session 1 involves introductions, guided relaxation training by

listening to a audio-recording, and learning about different types of emotions using playing cards with characters who display facial emotional expressions. Session 2 teaches youth about worries and how to handle them using a group board game. Session 3 focuses on having conversations with others through guided practice using a role-playing format revolving around different scenarios with the youth. Session 4 teaches youth how to be assertive through guided practice using a role-playing format revolving around different scenarios with the youth. The CAB identified this as an area of adaptation in initial meetings due to the lesson focusing on looking a person in the eye. Session 5 teaches youth how to face their fears by roleplaying mildly fearful situations and learning how to make themselves less scared. Session 6 is a review session. Parents and teachers are sent notes of what youth learned in each session and asked to encourage youth to practice their learned skills.

Purpose of the Study

The purpose of this study was to build upon our community-based participatory research (CBPR) partnerships with the [tribal name] tribal community to culturally adapt an evidence-based, indicated PEI program for universal delivery with 8-12-year-olds living on the [tribal name] Reservation using a systemic, theory- and culturally-grounded qualitative approach. In addition, we will use a mixed methods approach to evaluate the feasibility of delivering the adapted PEI in two tribe-serving schools and estimated effect sizes of changes in anxiety and depression from pre- to post-intervention using single-group design (i.e., no control group). We also aimed to determine the extent to which the program was acceptable and enjoyable for [tribal name] youth.

Research Design

Our study involved two major phases:

1) a qualitative phase, which included collaboration between the CAB and research team that resulted in a conceptual framework for cultural adaption of the PEI program, gathering suggestions for cultural adaptations and to improve the PEI program from focus groups with key adult stakeholders in the [tribal name] community (Elders, parents, teachers, and mental health specialists) and youth stakeholders, and the CAB making cultural adaptions to the PEI program based on the focus group data.

2) a clinical trial phase, which included delivery of the adapted intervention in two tribal serving schools for the [tribal community name] Reservation using a pre-post, single group design (i.e., no control group). We evaluated feasibility and acceptability using youth and provider self-report data and estimated the effect sizes of changes in youth anxiety and depressive disorder symptoms using youth and teacher reports. In addition, we gathered survey data on youth resilience, anxiety control beliefs, and rumination.

Cultural Adaptation of the PEI Program (Phase 1)

Development of Conceptual Framework and Review of the PEI program (Step 1)

In Year 1, the 8-10 member CAB (Elders, parents, teachers, mental health professionals, cultural experts) and research team met once a month and engaged in several activities throughout Step 1 described in this section and Step 3 described in a later section. All CAB members completed a

4-6 hour modified CITI ethics training that has been approved for previous CABs in other studies with Native communities. In Step 1, the CAB used a combined theory- and culturally-grounded systematic approach,[39-42] to develop a conceptual framework of the PEI of anxiety and depression in Native youth from [tribal name]. The CAB worked with the PI, Project Manager, and the original PEI developers to review the current literature to identify behavioral determinants (risk and protective factors, mediators, moderators) of youth anxiety and depression (e.g., low anxiety control beliefs), as well as the expected behavioral outcomes (e.g., decreased anxiety and depressive symptoms) of PEIs addressing youth anxiety and depression in [tribal name] youth. The CAB used this information to develop an initial conceptual model.

To deeply integrate cultural and tribal aspects into the model and thus inform adaptation more from the bottom-up, the CAB altered the model as needed to include a clearer understanding and meaning of both anxiety and depression and the behavioral determinants and outcomes from a tribal perspective. This involved changing certain constructs or the underlying meaning of constructs within the model to better algin with the [tribal name]'s worldview of mental health and healing. Moreover, they identified cultural or tribal behavioral determinants (e.g., cultural identity) of youth anxiety and depression that may influence the behavioral outcomes not described in the literature and added them to our conceptual model. This conceptual framework was refined by the CAB following the analysis of focus group data from key-stakeholders within the community, school, and families.

Work (WG) and Focus Group (FG) Discussions: Adult Community Stakeholders and Native Youth from [tribal name] (Step 2)
In Years 1 and 2, we conducted 4 homogenous work groups (WGs) of adult community stakeholders, and 6 homogenous groups of AI youth (3 from each school) to review all modules of the non-adapted PEI program.

Adult Community Stakeholders: 3-8 adult community members with shared interest in preventing or reducing anxiety and depression among [tribal name] AI youth residing on the reservation (~45 adults):

1) Three groups of Elders in training or Elders with knowledge of the history, culture, social, and spiritual aspects of the [tribal name] Tribe and reservation life.

2) One group of parents or caregivers (one from each school) of 8-12-year-old youth residing on the [tribal reservation name].

3) One group of 3rd-6th grade teachers (one from each school) who work with AI youth daily in the schools.

4) One group of mental health specialists (e.g., school counselors or psychologists, substance use counselors, social workers).

Native Youth: 2-4 Native 8-12 years-old residing on the [tribal reservation name] and attending either [tribal school name] or [tribal school name] Schools participated in each group.

We obtained written informed consent from the adult community stakeholder for the work groups and the parent/legal guardian for youth before the focus group (see attached Parental Consent for Pre-Adaptation Focus Group) and obtained written assent from the youth (see attached Youth Assent for Pre-Adaptation Focus Group). The project manager reviewed each part of the informed parental consent and youth assent with them in person or on the phone. She answered all questions the adult community stakeholder and parent/legal guardian may have about the study and made attempts to ensure that the adult community stakeholder, the parent/legal guardian, and youth understood the purpose, the youth's right to withdraw without consequence, and the risk and benefits of participating.

We held all WGs and FGs at a convenient location on the [tribal reservation name] that was familiar and comfortable, but free of distractions, and provided refreshments. The project manager co-facilitated each WG and FG with Dr. Scott. The project manager, who is an enrolled tribal member, offered a prayer at all youth FGs. First, we offered a prayer, discussed group confidentiality guidelines, and obtained informed consent (assent for youth). Second, we described the general purpose of the WG and FG was to review the non-adapted PEI program modules (youth will only review three modules). We then explained the concepts of anxiety and depression in a cultural- and age-appropriate manner. Third, we emphasized the community value and positive implications of preventing and reducing anxiety and depression in AI youth and highlighted the need to draw from community strengths, values, and core beliefs. Fourth, we discussed the features of PEI program and its efficacy with non-Native youth and presented the aims of the study. All WGs and FGs were audio recorded.

Work and Focus Group Discussion. Each group engaged in an interactive discussion and review of each module (adults and youth). Native youth only reviewed 3 modules due to time constraints.

Elder group only: Dr. Scott and the project manager asked specific questions about explaining anxiety and depression in a cultural way, what does anxiety and depression mean coming from a cultural context, and what words would you use for anxiety and depression (this added about 60 minutes to their group discussion).

All groups: Dr. Scott and the project manager asked specific questions on how content, materials, learning strategies, and delivery methods of the non-adapted PEI program modules could more culturally appropriate or improved, what is not cultural appropriate, and what changes could be made.

At the end of the discussion the facilitators provided a summary of the group's suggestions, invite feedback from participants, and talk about next steps for the project. Adults received a $40 gift card and youth will receive a $25 gift card for their participation. Elders will received a $60 gift card for the additional hour of the work group session.

Youth also completed a usability survey after reviewing each module (3 per focus group) used in previous adaptation studies with Alaskan Native youth (see attached).[36] It assessed the likability, acceptability, enjoyable, ease of learning and using skills, credibility, motivational appeal, perceived impact, and cultural appropriateness. The CAB assisted in adapting the items and

rating scale of the useability survey to improve fit for use with 8-12-year-old Native youth from [tribal reservation name].

Cultural Adaption of the PEI Program (Step 3)
At the end of Year 2, the CAB and research team met to review all grouped suggestions gathered from the WGs and FGs. The CAB identified and integrated modifications or additions to our conceptual framework if needed based on the FG feedback. Next, the CAB reviewed the content, format, and learning objectives of each of the six PEI program modules and training protocol within the context of this finalized conceptual model. Specifically, the CAB identified the type of change needed (e.g., content, language, learning strategy), amount of change required (no change, small change, moderate change, large change), and barriers (timeline/budget). The CAB decided on the importance of the change (essential or non-essential), made final decisions on adaptations, and the physical adaptations of the PEI program materials were made by the developers of PEI as requested by the CAB.

Adapted PEI Program Intervention Evaluation (Phase 2; Clinical Trial)
In Year 3, The CAB worked with the research team to culturally adapt the intervention and identified two school counselors (i.e., an American Indian tribal member and a white non-tribal member) to provide it in the schools. Both providers completed the modified PEI program training based on CAB decisions for adaptation and the CITI Training (through Montana State University-Bozeman) before working with youth in the school. They also completed a background check for each school. Providers recorded youth attendance, dropout of the intervention, and completed the Brief Reactions Form for after each session.

In Year 3, we recruited 28 Native youth ages 8-12 years-old from the [two tribal serving school names] (15 youth per school) to participate in the adapted PEI program. The adapted PEI program was delivered to a group of 3-5 youths at one time with three groups participating in each school. Written informed consent was obtained from the parents or legal guardians before youth participated in the intervention or complete pre- and post-survey assessments. Youth participants also provided written assent before completing the pre-intervention and post-intervention surveys or participating in the adapted PEI program.

Youth participants completed the pre-intervention survey (~30 minutes to complete based on our pilot study) one week before session 1 and the post-intervention survey one week after session 6 of the adapted PEI program. The post-adaptation usability survey was administered at the end of each session. Youth completed the survey using paper and pencil. The research team explained the purpose of the study and intervention. They also read the assent form out loud to youth and answered any questions youth had about the study. Those youth who verbally agreed and checked “yes” on the assent form completed the youth survey and participated in the intervention. Youth who choose not to participate in the study returned to their classroom. All youth were notified of their right to withdraw the study and intervention at any time without consequence. The research team helped youth who may have difficulty comprehending items or response options.

Youth Assessments. The CAB reviewed and approved the following instruments as being culturally appropriate (minor changes were made to existing measures) for our previous study

with 71 Native 8-13-years-old at the [tribal school name]. Each measure showed acceptable to excellent reliability and both convergent and discriminant validity with other established measures in that study (Scott, Sunchild, Small, & McCullen, 2023).

Youth Demographics. We asked children to provide personal information including gender, age, ethnicity, tribal affiliation, grade level, and family structure.

Revised Child Anxiety and Depression Scales – Short Child Version (RCADS-SC).[37,38] The RCADS-SC is a 25-item self-report instrument used to assess DSM-IV criteria (APA, 1994) of symptoms for anxiety disorders (excluding Posttraumatic Stress Disorder and Specific Phobias) and depression. We asked the children to rate how often each anxiety and depression symptom is true of them on a rating scale consisting of: 1 (Never), 2 (Sometimes), 3 (Often), and 4 (Always). Higher scores represent the experience of more anxiety and depression symptoms as based upon the DSM-IV criteria.

The Child and Youth Resilience Measure (CYRM).[39,40] The CYRM is a 36-item measure (10 items constructed by the CAB and used in our previous pilot study; Scott, Sunchild, Small, & McCullen, under review) that assesses global and tribal specific resilience across a number of areas including: personal skills, peer support, social skills, physical and psychological caregiving, spiritual, educational, and cultural. We asked the children to indicate to what extent each statement described them (e.g., "Getting an education is important to me," "I try to finish activities that I start," and "I feel supported by my friends") on a three-point scale of "No," "Sometimes," and "Yes." Higher scores reflect greater resiliency for each of the sub-domains (e.g., peer support, spiritual).

Anxiety Control Questionnaire for Children- Short Form (ACQ-C Short Form).[41] The ACQ-C Short Form is a 10-item developmentally modified version of the ACQ and assesses children's control beliefs over anxiety-related "external" threats (e.g., fear-producing objects, events, and situations) and/or "internal" emotional or bodily reactions (e.g., flushed face). The items on the ACQ-C were changed to be developmentally appropriate and include such questions as "I can usually stop my anxiety from being seen by other people" and "I can usually stop thinking about things that make me nervous or afraid if I try." We asked children to rate how much they agreed with the item on a 6-point Likert-type scale consisting of: 0 (Strongly Disagree), 1 (Moderately Disagree), 2 (Slightly Disagree), 3 (Slightly Agree), 4 (Moderately Agree) or 5 (Strongly Agree).

Child Response Styles Questionnaire – Rumination Subscale (CRSQ).[42,43] The CRSQ – Rumination Subscale is 12 items that assess children's regulation of sadness using rumination. We asked children to rate how often they engage in rumination when feeling sad (e.g., "When I am sad, I think about how alone I feel." on a 4-point scale consisting of "Almost Never," "Sometimes," "Often," and "Almost Always. Higher scores represent greater use of rumination when feeling sad.

Teacher Assessments. The following two questionnaires were completed by each child's homeroom teacher. The CAB previously reviewed and approved the following instruments as being culturally appropriate (minor changes were made to existing measures) for our previous study with 71 Native 8-13-years-old at the [tribal school name] School. Each measure showed

acceptable to excellent reliability and convergent/discriminant validity (Scott, Sunchild, Small, & McCullen, 2023).

Teacher Demographics. We asked teachers to provide personal information including gender identity, age, race, and ethnicity.

Revised Child Anxiety and Depression Scales – Short Teacher Version (RCADS-TC).[37,38] The RCADS-TC is a 25-item teacher-report instrument used to assess DSM-IV criteria (APA, 1994) of symptoms for youth anxiety disorders (excluding Posttraumatic Stress Disorder and Specific Phobias) and depression. We asked the teacher to rate how often each anxiety and depression symptom is true of their student on a rating scale consisting of: 1 (Never), 2 (Sometimes), 3 (Often), and 4 (Always). Higher scores represent the experience of more anxiety and depression symptoms as based upon the DSM-IV criteria.

Provider Assessments. The following questionnaire will be completed by the two providers of the PEI program. In addition, both providers will record youth attendance for each session and which youth dropout of the program.

Brief Reaction Form. We asked the providers about the implementation of the program for each of the six modules. Specifically, they will be asked to indicate how well they covered each activity for each module on a scale from 0 (not covered) to 4 (covered well) and how useful each activity was for youth on a scale from 0 (not useful) to 4 (very useful). They also were asked to indicate how much (or to what extent) how clear the explanations of activities were, if they had enough time, used examples or stories, students understood the material, and student participation on a scale from 0 (none) to 5 (a lot). They also indicated whether any modifications had to be made to program implementation.

Post-Intervention Acceptability Focus Groups and Interviews
We will conduct 6 homogenous focus groups of youth intervention participants (5 per group; 30 youth) to discuss experiences with the adapted PEI program and suggest improvements. In addition, we will conduct individual interviews with 3-4 participating youth across each school to better understand their experiences with the provider and make suggestions on how the provider could improve their teaching of the lessons.

We also will conduct individual interviews with 4 parents, 4 3rd-6th grade homeroom teachers, and the two providers of youth intervention participants. Youth will participate in the focus group on the last day of the intervention and parent/teacher/youth interviews will happen within a month of the last day of the intervention. Focus groups and interviews will be audio recorded.

Post-Intervention Acceptability Focus Group and Interview Procedure. We followed the same aforementioned general procedures for the focus groups. Dr. Scott and the project manager asked youth to describe what they liked about the adapted PEI program, which they thought was most useful, and whether it was appropriate for AI youth. They also asked for suggested improvements to content, material, and learning strategies. AI youth received a $20 gift card for their participation.

Youth Post-Adaptation Usability Survey. Youth completed the identical usability survey[36] from the pre-adaptation phase at the end of each session. It assessed likability, acceptability, enjoyable, ease of learning and using skills, credibility, motivational appeal, perceived impact, and cultural appropriateness.

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42. Abela JR, Brozina K, Haigh EP. An examination of the response styles theory of depression in third-and seventh-grade children: A short-term longitudinal study. *Journal of Abnormal Child Psychology.* 2002;30(5):515-527.
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Data and Safety and Monitoring Plan (DSMP)

This DSMP describes the procedures for the proposed research activities, including the responsibilities of the Project Leader (PL), Project Manager, and Cultural Advisory Board (CAB), as well as the reporting of adverse events.

Dr. Scott (PI) and project manager will be responsible for knowing and adhering to the cultural protocols and official policies of the [tribal name] and the two participating tribe-serving schools; the tribal Institutional Review Board (IRB) policies and procedures; and the Montana State University (MSU) policies and procedures. The PI will be the primary person who is responsible for correspondence and reports to the tribal and MSU IRBs and maintain accurate documentation of these interactions in his encrypted and password-protected Knox folder maintained by MSU (only Dr. Scott has access to this folder).

Dr. Scott (PL) and the project manager are responsible for documentation and handling of possible adverse events that are related to the study. They both have experience in conducting research in the schools and the tribal community and experience in implementing and evaluating intervention in schools with ethnic minority youth. The project manager has received and oversaw Substance Abuse and Mental Health Services Administration (SAMSA) grants implementing suicide prevention and interventions with youth and conducted work/focus groups as part of that research. They will ensure that all data and safety monitoring systems are established before the study begins and implemented as planned.

1. Potential Adverse Events Due to Participation

A. Possible breach of confidentiality
B. Possible violation of cultural protocols and official policies
C. Possible discomfort due to participating in work/focus groups or completing surveys
D. Possible disclosure of information indicating intended a) harm to oneself and b) harm to others, including child or elder abuse requiring mandatory reporting to the appropriate welfare agency and possible investigation that could ensue
E. Potential Exposure to COVID19

2. Procedures to Safeguard Against Adverse Events

We will include a form for as part of the data collection procedures for research team members to record any problems with data collection, concerns about youth or adult participants, and unusual events that occur during the work/focus groups, intervention, or survey data collection. The forms will allow for the research team to quickly review and respond to any possible concern or adverse event. The form will include Dr. Scott's and the project manager's contact information and one of them will be available during data collection. We will discuss and process all problems and concerns during monthly or weekly meetings during the intervention and with other study personnel as needed. All study personnel will need to complete or be up-to-date on Collaborative Institutional Training Initiative (CITI) training, including the CITI Social and Behavioral Research Best Practices training for clinical trial. The Cultural Advisory Board (CAB) will complete an modified 4-6 hour community training on ethical research practices

(adapted from CITI Social and Behavioral Research training) that has been used in previous MSU IRB approved studies with Native American communities using a community-based participatory research approach.

A. Informed Consent. The project manager will thoroughly review the consent form with the adult community stakeholder or parent/legal guardian either over the phone or in person, if needed. We have found that parents/legal guardians are more informed about the nature and purpose of the study when explained to them by tribal community member. The consent form will include a description of the non-adapted or adapted [PEI name] components, the types of questions being asked in the survey or work/focus group, and the risk and benefits of their child participating in the study. Adult community stakeholders will need to sign the written informed consent before participation is allowed in the work/focus groups. Parents/legal guardians will need to sign the written informed consent before youth participation is allowed in focus groups or adapted intervention.

   The tribal research team member will thoroughly review the assent form with the youth at before the focus groups and pre-intervention survey assessment in a developmentally appropriate manner and ensure to the best of their ability that each youth understands the study's purpose, risks/benefits, and voluntary nature of the study (i.e., they can quit at any time or not answer questions without consequence). Tribal research team members will be required to successfully complete the CITI Social and Behavioral Research Best Practices training before working on the study. The assent form will provide a description of the adapted [PEI name] components, the types of questions being asked in the survey and focus group, and the risk and benefits of participating in the study using developmentally appropriate language for youth comprehension. They will make all attempts possible to help the students understand the nature of the study. Youth written assent (check the box "Yes" to participate and print their name) will be required before youth participation is allowed.

B. Confidentiality. We will ensure the steps necessary to ensure confidentiality of the work and focus group discussions and audio recording data. Ms. Sunchild (Project Manager) will inform participants that she cannot guarantee confidentiality of group discussions. However, she will explain to all work/focus groups members the importance of respecting others and maintaining confidentiality of the group discussions. All digitally recorded data gathered from the work and focus groups with tribal community stakeholders (Elders, parents/legal guardians, counselors) and youth will be kept on the Montana State University's Knox password-protected server as an encrypted electronic file. The server is maintained by the university. We will use unique ID code as the file name, which will include the school code, session number, and the recording date. The name of the participant or other identifying information will not be used in the file name. Only trained research staff will have permission to access the Knox folder and review the audio recordings for transcription and analysis.

   We also will take the necessary steps to ensure the confidentiality of the survey data. Specifically, we will assign a unique ID number for each youth prior to the administration

of the pre-intervention survey. This unique ID number will only be included with the youth's name on a Master List and will be used as the ID number in the complete deidentified aggregate data file used for study analyses. In addition, only the unique ID number will be present on the surveys. The Master List will contain the unique ID number and the associated youth's name. The Master List with identifying information (i.e., names) and associated unique ID numbers will be kept Dr. Scotts' encrypted and password-protected electronic file on the Montana State University's Knox password-protected server, which is maintained by MSU. Dr. Scott will be the only person to have access to the Master List (paper and electronic copy). Additional research staff will not have access to the Master List. The data will only include the unique ID code and no other identifying information.

American Indian PEI program providers from [tribal school] also will record youth attendance and dropout, which will contain the youth's names. However, the unique ID codes will not be included in this survey and the only information will be the youth's name, attendance (0 = absent, 1 = present) and dropped out of the study (0 = no, 1 = yes). Unlike survey data, Dr. Scott will be the only research staff to have access to the attendance and dropout data.

Dr. Scott will notify the school counselor and provide the names of youth who report anxiety or depression in the clinical range as compared to their peers at the post-intervention (i.e., T-score > 70 on the Revised Anxiety and Depression Scale). Dr. Scott will not provide the actual score and will instruct the school counselor to just talk with the youth about their experiences with anxiety and depression lately. Parents/legal guardians and youth will be informed of this during the informed consent and assent procedures.

C. Cultural Protocols and Tribal/School Policy. Dr. Scott and the project manager) will be responsible for working with the Cultural Advisory Board and consultants to ensure the intervention adheres to the cultural protocols and official policies and procedures of the [tribal name], tribal IRB, MSU IRB, and the two tribe-serving schools participating in the study. Tribal Elders (which three Elders serve on the CAB) will be consulted on traditional topics and protocols to follow during data collection and the intervention. We will discuss these cultural protocols, policies, and procedures during the cultural adaptation phase of the study in Year 1 and will revisit in our bi-monthly meetings during Year 2 and 3. We will discuss any problems that are brought to our attention with the CAB until a resolution is achieved.

D. Mandatory Reporting.

All informed consent and assent forms will state that the research team member must report to the proper authorities: (a) there are reports that someone is in immediate physical danger of harming themselves or others, (b) there are indications of child or elder abuse, such that there is physical injury caused by other than accidental means. The project manager will ensure parents/legal guardians, youth, and other adult participants understand this limitation of confidentiality.

E. Research Team Safeguards. All research team members and study personnel who are involved in data collection, data analysis, and intervention development or protocol will be required to complete and be up to date with the extensive Collaborative Institutional Training Initiative (CITI) training as noted before. In addition, the CAB will complete an adapted 4-6-hour community training on ethical research practices (adapted from CITI Social and Behavioral Research training) that has been used in previous MSU IRB approved studies with Native American communities using community-based participatory research. We will require weekly or monthly meetings with Dr. Scott, project manager, and the research team to provide ongoing training, monitor adherence to study protocols, and address potential barriers and other problems with the study. The project manager will oversee all research activities (data collection and intervention delivery) on the reservation and at the schools. She will report all activities, concerns, and questions to Dr. Scott on a continual basis. All research team members will be trained on how to identify adverse events and events that fall under the mandatory reporting parameters, which include physical injury to any child or elder caused by other than accidental means, or information that leads to research team members to believe that a youth or adult is in imminent physical danger to themselves or others.

F. Discomfort with Completing Intervention Surveys or Disclosure During Work/Focus Groups. While completing the intervention surveys and work/focus group discussions there is minimal risk that youth and adults will feel embarrassed or uncomfortable with the question or topic as they may be personal and/or sensitive in nature. The informed consent and youth assent form state that there may be questions or topics that are personal and sensitive in nature, and they may not want to answer or discuss them. The project manager and tribal research team members will ensure that the parent/legal guardian, youth, and other adult participants know that they do not have to answer questions that make them feel uncomfortable. They will be trained to respond to participants in a compassionate, caring, and professional manner and Dr. Scott will be available via phone, email, or in person if they have problems with the data collection process.

G. Possible Exposure to COVID19 Safeguards. There is a slight risk for exposure to COVID19 due to the group nature of the study. We will ensure that all groups are held in a location that allows for proper airflow, social distancing, and that all participants wear masks or a protective shield. This will be stated in the consent form and the project manager will inform all potential participants upon scheduling the work/focus group or planning the intervention in the schools. We will use a COVID19 screening tool that Dr. Scott has successfully used in his lab at MSU to collect physiological data from human participants in small spaces.

3. Response Procedures for Adverse Events

A. Discomfort with Disclosure. All study personnel will respond to participants in a compassionate, caring, and professional manner when feelings of uncomfortableness or embarrassment arise. Adult participants who experience these feelings will be referred to tribal health and youth will be referred to the school counselor, who will then make the

decision to control tribal health and the parents/legal guardians. All participants will be encouraged to reach out to the research team if a late adverse reaction occurs and will be given specific written and verbal instructions on how to do so during the informed consent and assent explanation.

B. Mandatory Reporting. Participant reports of physical abuse and neglect or the threat of imminent physical harm to oneself or others is required to be reported to the proper authorities. Each school has its own procedure for handling these types of reports and in anticipation of the possible risk of such disclosures, we have established our procedures to coincide with the schools. In addition, we have established our own procedures for the work/focus groups that are not held within the school system.

1) Suicidal Thoughts and Attempts: Youth and adults may report that they are experiencing thoughts of harming themselves (suicidal ideation) and/or a plan and means to hurt themselves (suicidal attempt). Although our assessments and work/focus group topics do not ask questions about suicide, it is possible that youth and adults may spontaneously talk about suicidal ideation or planned suicide attempts. If disclosure occurs in the school setting with youth or teachers, the research team member will notify the school counselor or principal (depending on school protocol) immediately and the school counselor or principal will assess the situation. We will ensure that the school counselor and/or principal is freely available and easily contactable during the intervention sessions and survey completion. If the disclosure occurs in a non-school setting for the work/focus groups, the project manager will follow through with an in-depth interview to fully assess the situation and clarify the presence of suicidal risk and develop a plan of action. She has training and experience as an Emergency Medical Technician for 13 years and has conducted suicide prevention and interventions with youth in the tribal community. We will train all facilitators and tribal research team members on how to identify suicidal risks in both ideations and planned actions and demonstrate this competency.

2) Child or Elder Abuse: Child and elder abuse may be reported or suspected in several ways: 1) youth or elder verbally reports that they have been physically harmed or abuse has occurred, 2) youth or elder is observed being physically harmed, and 3) youth or elder is observed with bodily injury (e.g., bruise, burns, black eyes) and their explanation appears to differ or seem unlikely given the observed injury. If any of these events occur during the work/focus groups, intervention, or survey data collection the research team members, a thorough assessment of the situation will occur. The research team members will document all steps taken to obtain additional information and contact Dr. Scott and the project manager) if any of this information leads them to suspicion of abuse or neglect. Dr. Scott will then contact the principal and/or school counselor (depending on the school's procedures) if the event occurs in the school setting to discuss the situation and formulate a safety plan. If not in the school setting, the research team will determine the appropriate further inquire and follow-up and develop a safety plan that may include referral to tribal health or the appropriate state welfare agency (e.g., Department of Public Health and Human Services).

3) Threat of Danger to Others: Youth and adults may disclose a threat of danger or of harm to others, including other participants, the participants family, or other individuals in the school or community. If this information is disclosed at any time during the work/focus groups, intervention, or survey data collection the research team will review the information and determine the next steps in accordance with the law, school policies, and the guidance of the CAB and other study personnel.

C. Exposure to Positive Case of COVID19. It is possible that adults and youth may be exposed to someone who is or tested positive for COVID19. If a person screens as having tested positive recently or is having COVID19 symptoms upon arrival to the work/focus group, intervention survey, or intervention they will not be allowed to participate. If we become aware that someone in the group tested positive after participation Ms. Sunchild (Project Manager) or a research team member will document all steps taken to obtain additional information and contact Dr. Scott. Dr. Scott and the project manager will notify via fax, phone, or email tribal health, the tribal IRB, MSU IRB, and our DSMB within hours of obtaining possible exposure information. We will work with the tribal health, tribal IRB and MSU IRBs, and DSMB to plan a course of action.

1) Reporting Procedures for Adverse Events. The potential risk for an adverse event to occur is minimal during the work/focus groups or the completion of the youth and teacher surveys. The tribal research team members will have completed CITI training through MSU and all have experience with working with youth and utilizing mandatory reporting procedures. Tribal research team members will report adverse events during the survey collection immediately to the project manager and Dr. Scott will report adverse events to the tribal IRB and MSU IRB Chairs, the Data and Safety Monitoring Board, and others as appropriate in the participating tribe-serving school.

In the case of a serious and unanticipated adverse event, Dr. Scott and the project manager will ensure the events are reported to MSU Center for American Indian and Rural Health Equity (CAIRHE) and National Institutes of Health (NIH) within hours by phone, fax, and/or email and will submit a written report no more than two days later. All study personnel will follow these procedures:

D. Reporting requirements after becoming aware of a serious adverse event must be implemented in a timely manner. Dr. Scott must complete an Adverse Event Report and submit it to tribal IRB and MSU IRB Chairs, the DSMB, and CAB. The CAB will help the research team identify cultural and socially appropriate ways to remedy the adverse event. The tribal IRB and MSU IRB will review the study protocol, with input from Dr. Scott and the DSMB, to determine whether further action is warranted and in the best interest of the participants and research.

5. Oversight

The MSU Office for Research Compliance is responsible for the general oversight of all grant activities and will inform Dr. Scott (PL) about changes and requirements for the DSMP. Moreover, we will appoint an independent three-member Data and Safety Monitoring Board

(DSMB) to provide ongoing oversight of the study. We will have an expert in behavioral intervention science, a statistician with expertise in evaluating behavioral interventions using mixed method designs, and a researcher with expertise behavioral interventions with Native American youth. Meetings will occur semi-annually by telephone or WebEx, and unless closed by the Chair, will be joined by Dr. Scott (PL), [project manager name] (Project Manager), and one of the CAB members.

The DSMB responsibilities will include monitoring and evaluation of the following:

A. the study protocols, materials (e.g., consent and assent forms; measures) and plans for data and safety monitoring
B. study progress with respect to participant recruitment, accrual and retention, follow-up and protocol adherence
C. participant safety in regard to adverse events and other safety issues, including recommendations to terminate the study due to safety concerns (if necessary)
D. maintaining the confidentiality and quality of the study data
E. ongoing risks and benefits to participants throughout the study

The research team will update the general Data and Safety Monitoring Plan procedures as needed. We will report adverse events to the [tribal name], participating tribe-serving schools, and the IRBs annually. In terms of serious adverse events, we will report them immediately to these entities, CAIRHE, NIH, and the DSMB. We will submit a written report within 3 days of the event serious adverse event occurring and the report will be in a format stipulated by the [tribal name], schools, and IRB. It will contain information pertaining to the date of the event, description of the event, assessment of the cause, whether the event indicates an increased risk for current or future participants in the study, and whether changes to the informed consent or study protocol is needed.

STATISTICAL ANALYSIS PLAN FOR PHASE 2 (CLINICAL TRIAL)

Study Aim 2: Evaluate the feasibility and acceptability of the culturally adapted PEI program. We calculated the frequency of youth attendance rates across sessions, dropout rates, and survey response rates. We also created tabular summaries of the Likert scale ratings from the usability survey and proportion of respondents who rated each module or all modules on average as 2 or 3. A module or the entire program was successfully adapted if at least 80% of youth rated it as a 2 or 3 on the Likert scale for acceptability and enjoyability.

Study Aim 3. Estimate effect size changes in anxiety and depressive symptoms in [tribal name] youth. Primary outcomes of interest for a future efficacy trial will be changes in the RCADS-S scales. For each scale, we computed the change in the scale score from baseline to post-intervention (post – pre) and computed unadjusted averages and standard deviations. A one-sample t-test of the changes in any response scale will have 80% power to detect a standardized effect size (Cohen's d) of at least 0.53, and 90% power to detect an effect size of at least 0.61. We will also obtain adjusted estimates using mixed effects linear regression models of post-test score on pre-test score with demographic factors and random effects for school and intervention group nested within school. This will allow us to estimate intra-class correlations for intervention group and schools, which will be required for sample size estimation in a full efficacy trial.

INSTITUTIONAL REVIEW BOARD AMENDMENTS

The following pages (not numbered, but in order of date) contain tribal college IRB amendments that were submitted and approved throughout the study period.

MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

February 9, 2021

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

1) We plan on using a professional online transcription service (Rev.com) to transcribe work and focus group data. The company uses state-of-the-art encryption procedures for audio files to be uploaded and all professional transcribers are required to sign nondisclosure and confidentiality agreements (https://www.rev.com/enterprise/security). In addition, we can request for all audio files to be removed from their servers after transcription is complete. We will remove names from the transcription documents upon receipt. Only first names are mentioned in the audio recordings.

2) We also plan on storing audio files and other research data on OneDrive. However, we will continue to store Master Lists on Knox Folder as added protection. We have consulted with UIT and the Office of Research Compliance on moving data files to OneDrive. They have provided approval for the level of data we are collecting.

3) We have modified the protocol to state the following:

All digitally recorded data gathered from the work and focus groups with tribal community stakeholders (Elders, parents/legal guardians, counselors) and youth will be kept on the Montana State University's Business OneDrive password-protected server as an encrypted electronic file. We will use unique ID code as the file name, which will include the school code, session number, and the recording date. The name of the participant or other identifying information will not be used in the file name. Only trained research staff will have permission to access the OneDrive folder and review the audio recordings for transcription and analysis. We will upload the audio files to an encrypted server on Rev.com to be professionally transcribed. We will request that the audio files and transcriptions be deleted after editing and validating the transcription documents as per the Rev.com policy.

Sincerely,

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MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

August 5, 2021

Dear [tribal college] IRB,

We are requesting a few minor modifications for the approved studied titled, "A Native Path to Courage" based on feedback from the Montana State University IRB. We have outlined each modification below. In addition, we have attached an update application with the modifications and the approval letter from the MSU IRB for this study.

1) We are adding [project manager name] and the following Cultural Advisory Board members as research personnel for this study, including [tribal member names]. Please see revised application for the listed individuals and their requested information. In addition, all [tribal name] Cultural Advisory Board (CAB) members will complete a 4-6 hour modified version of the CITI training used in previously MSU IRB-approved studies with Native communities. We have attached the PowerPoint slides for that training.

2) We have also attached a revised Data and Safety Monitoring Plan that includes these changes. We also removed a conjoined meeting between the [tribal college name], MSU, and Data and Safety Monitoring Board under section D (Reporting Procedures for Adverse Events) as requested by the MSU IRB. Instead, both IRBs will review the study protocol in the presence of a serious and unanticipated adverse event with input from Dr. Scott and the Data and Safety Monitoring Board to determine further action.

3) We have changed the language for the preadaptation focus groups. We call these groups "work groups" as they will be part of the adaptation process and is more in line with a community-based partnership. The youth groups are still considered focus groups as we are asking for their usability ratings on the modules. We have made this term change in the application and associated adult community stakeholder consent forms.

4) We have edited the consent and assent forms in following ways:

    a. We added the following statement on all adult and parent/legal guardian consent forms in the "What are the risks?" section to address COVID19 tribal and MSU guidelines: "All procedures for in-person research will comply with current [tribal name] and Montana State University COVID-19 IRB Guidance. https://www.montana.edu/orc/irb/Covid-19_irb_guidance.html"

    b. Adult Key Stakeholder Pre-Adaptation Consent

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i. We corrected the title to “Adult Key Stakeholder Informed Consent for Participation in Pre-Program Work Group”
ii. We changed “focus group” to “work group” in Consent Statement.

c. Adult Key Stakeholder Post-Intervention Focus Group

i. We added the sentence “Participation is completely voluntary” and bolded the text.

d. Caregiver Informed Consent for Child Participation in Focus Group

i. We added the sentence “Participation is completely voluntary” and bolded the text. In addition, we bolded the next sentence “Your child is free to not talk, not answer, or skip any question, or leave the study at any time without penalty.”
ii. We corrected the Consent Statement to refer to “the child” and not the caregiver (“I”) and now ask the caregiver to print the child’s name

e. Caregiver Informed Consent for Child Participation in a Culturally Adapted Program

i. We corrected the Consent Statement to refer to “the child” and not the caregiver (“I”) and now ask the caregiver to print the child’s name

f. All Child Assent Forms

i. We added the statement “When we are in the same room together, we will follow safety rules for COVID-19.”

Sincerely,

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MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

November 16, 2021

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

Discussion with [tribal name] community members and [project manager name] in designing the work/focus group guide led us to the decision to add an hour to the beginning of our Elder focus groups (not the other work/focus groups) to discuss anxiety and depression. It is not clear to our tribal research team or tribal members whether Westernized views of anxiety and depression apply to the [tribal name] people. Moreover, it was difficult for [project manager name] or our CAB to think of culturally appropriate ways of explaining anxiety and depression to Elders, parents, teachers, mental health professionals, and children in our work/focus groups.

We have attached a step-by-step guide for our work/focus groups, including the additional hour for the Elder work group discussing anxiety and depression. We anticipate this will increase the time for the Elder work group by an hour (2.5-3 hours). As such, we will incentivize Elders with a $40 gift cards per 2 hours (up to $60 gift card) and a lunch for each of the Elder work groups. In addition, we have made modifications to the approved IRB application (see attached with track changes) and modified our adult stakeholder consent form for the pre-program work groups for Elders (see attached). The analyses of the focus group data will follow similar procedures already described in the approved application using content analysis and will be discussed with the CAB. The CAB will provide [project manager name] with an agreed upon way of explaining a culturally appropriate manner of anxiety and depression in the work/focus groups based on these initial focus group findings.

Sincerely,

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MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

April 28, 2022

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

1) We have worked with the Cultural Advisory Board to develop the pre-adaptation usability survey for the youth to complete after each module/lesson is reviewed (1-5). Please find the survey attached.

2) In addition, we have a question for the [tribal college] IRB to consider before moving forward. As with the Elders and mental health professions, it will take two sessions to complete the work and focus groups for the youth, parents, and teachers. Should we revise our consent/assent forms to indicate it will take two sessions (we will compensate accordingly for two sessions) or have them sign the original consent/assent forms for each session?

Sincerely,

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MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

July 25, 2022

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

1) We have worked with the Cultural Advisory Board to develop the pre-adaptation usability survey for the youth to complete after each module/lesson is reviewed (1-5). Please find the survey attached.

2) In addition, we have a question for the [tribal college] IRB to consider before moving forward. As with the Elders and mental health professions, it will take two sessions to complete the work and focus groups for the youth, parents, and teachers. Should we revise our consent/assent forms to indicate it will take two sessions (we will compensate accordingly for two sessions) or have them sign the original consent/assent forms for each session?

Sincerely,

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MONTANA
STATE UNIVERSITY
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Department of
Psychology

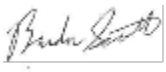
August 24, 2022

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

1) We request to ask participants (adult stakeholders and youth) to complete a brief demographic questionnaire. We have attached the demographic questionnaire for both adults and youth. Although we did not ask for permission to gather demographic information in the original consent/assent forms, we wanted to ask permission to forgo obtaining consent/assent for completing the brief demographic questionnaire. We are not asking questions that pose no risk to the adults or youth and there will be no identifying information attached to the brief demographic form other than the group number and date of the work/focus group.

Sincerely,



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MONTANA
STATE UNIVERSITY
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Department of
Psychology

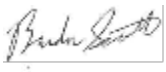
September 8, 2022

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modification below.

1) We request to ask participants (adult stakeholders and youth) to complete a brief demographic questionnaire. We have attached the demographic questionnaire for both adults and youth. Although we did not ask for permission to gather demographic information in the original consent/assent forms, we wanted to ask permission to forgo obtaining consent/assent for completing the brief demographic questionnaire. We are not asking questions that pose no risk to the adults or youth and there will be no identifying information attached to the brief demographic form other than the group number and date of the work/focus group.

Sincerely,



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MONTANA
STATE UNIVERSITY
College of
LETTERS & SCIENCE

Department of
Psychology

January 3, 2024

Dear [tribal college] IRB,

We are requesting a minor modification for the approved studied titled, "A Native Path to Courage." We have outlined the modifications below and attached a modified, track-changed protocol for review.

1) We have added co-investigators [personnel name] and [personnel name]. See attached modified IRB protocol for specific information.

2) We request to have providers complete the "Brief Reaction Form for [PEI name]" measure after each intervention session. Please see attached modified IRB protocol and the measure.

Sincerely,

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MONTANA
STATE UNIVERSITY
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Department of
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February 16, 2024

Dear [tribal college] IRB,

We are requesting a minor modifications for the approved studied titled, "A Native Path to Courage." We have outlined the modifications below and attached a modified, track-changed protocol for review.

1) We have revised the study protocol in the following ways (see attached application amendments):
    a. The intervention will be offered as part of an after-school program instead of during regular school hours.
    b. We will collect pre-intervention survey data 1 week before the intervention begins, instead of 2 weeks.
    c. We will conduct the child focus groups on the last day of the intervention, instead of 2 weeks after the intervention ends.
    d. The provider will lead the focus group and Laurie Sunchild will assist the provider.
    e. [Project manager name] will say a prayer before the focus group, as it may be difficult to have an Elder present for after-school activities.
2) We have revised the caregiver consent forms and child assent forms to reflect these changes to the protocol.

Sincerely,

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MONTANA
STATE UNIVERSITY
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Department of
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March 23, 2024

Dear [tribal college] IRB,

We are requesting a minor modifications for the approved studied titled, "A Native Path to Courage." We have outlined the modifications below and attached a modified, track-changed protocol for review.

1) The original application alluded to each homeroom teacher's assessment of youth anxiety and depression. However, the application did not explicitly state the specific measure to be administered or provided the IRB with the actual measure which is the Revised Child Anxiety and Depression Scale (RCADS). The RCADS-Teacher Version is identical to the approved youth version with minor wording changes (e.g., "I" to "My student." Please see attached RCADS-Teacher Version measure which was previously used and approved by the [tribal college] IRB for our initial study at the [tribal school name].

2) We request that each homeroom teacher complete a four-item demographic form asking for their age and gender identity, race, and ethnicity.

3) Due to time and resource constraints all youth and teacher consent, assent, and pre-post intervention surveys will be completed using paper and pencil. The data will be kept in a locked filing cabinet in the PIs office at MSU as indicated in the modified application. In addition, we tribal research team members will not read each item to the child, but will be available for helping each child comprehend the items on the survey.

Sincerely,

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MONTANA
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Department of
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May 21, 2024

Dear [tribal college name] IRB,

We are requesting a modifications for the approved studied titled, "A Native Path to Courage." We have outlined the modifications below. We also have attached a modified, track-changed protocol for review, as well as modified consent forms.

1) We request to conduct interviews with the two intervention providers to better understand their experiences in implementing the [name of PEI] program and make suggestions on improving the program for future use and research. See attached consent form.

2) We also request to change the parent/teacher focus groups to individual interviews. The project coordinator and the two intervention providers voiced their concern of getting 5-8 parents/teachers to participate in a focus group at the same time. We plan to get at least 4 parents and 4 teachers across both schools to participate in the interviews. See attached modified consent form for adult stakeholders and the list of questions for parents and teachers.

3) We also request we interview 3-4 participating youth across each school to better understand their experiences with the provider. See attached modified consent form for parents/caregivers. We also request only obtaining verbal assent from youth, which will be audio recorded before the interview begins.

Sincerely,

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