Promoting Community Conversations About Research to End Native Youth Suicide in Rural Alaska

NCT03661255

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Scientific Protocol and Data Management Plan

PC CARES (Promoting Community Conversations About Research to End Suicide) is a community-level educational intervention aimed at increasing key community stakeholders' understanding of current research in the field of suicide prevention and providing a structured time for them to discuss how they can use the research evidence in their own lives at work and at home. PC CARES was piloted in 2015-2017 in Northwest Alaska with promising results. Both the NWA pilot and this proposed implementation in Bering Straits are funded by the National Institute of Mental Health.
We will implement PC CARES in at least 9 of the 16 communities in the Bering Straits region. PC CARES implementation and data collection will take approximately 1 year in each village. We will select 6 villages to participate in the first year and 5 villages for each of the following 2 years. Some villages may choose not to participate, and others may decide to participate in a later cohort. Both options are acceptable.

Specific Aims:

1. Specific Aim 1: Track the impact of PC CARES on participants' knowledge, attitudes and behavior, and identify key factors influencing these outcomes over time.
2. Specific Aim 2: Document the community-level impact of PC CARES by tracking the number and type of interactions aimed at preventing youth suicide and promoting wellness in participating villages, and describe changes in the supportive social networks of young people before and after the intervention.

Background:

Youth suicide continues to disproportionately affect Indigenous communities, and has been difficult to detect early, prevent and reduce. In rural Indigenous communities, youth suicide is an extreme health disparity with Alaska Native (AN) suicide rates in remote villages up to 18 times higher than the rates of all American youth, ages 15-24 (124 vs 6.9 per 100,000). AN youth who are showing signs of vulnerability but are not yet suicidal, are likely to interact with a variety of community workers such as village public safety officers, health aids, and school personnel. In 62% of all suicidal behavior in Northwest Alaska (NWA), AN youth display distress to their family and friends. A local survey (n=355) also revealed AN youth sought help from peers (54%), parents (40%), grandparents/Elders (21%), uncles/aunts and teachers (20%). These supporters, however, are not prepared to recognize suicide risk or reduce it before an acute event, when there are more options for culturally-responsive, social care (i.e. Elder mentoring, cultural activities) and risk reduction (i.e. removing guns from the home). Now, 75% of all suicide interventions in NWA are 'imminent risk' requiring safety protocols that forcibly remove distressed youth from their community (50+ air miles away) for hospital risk assessment, and return them 48 hours later even less likely to seek help the next time. There is a clear need for 'upstream' suicide prevention before a crisis, which activates a youth's social network, reduces suicide risk and increases resources for wellness in rural AN communities. Representing a culmination of 20 years of community-based participatory suicide prevention research, Promoting Community Conversations About Research to End Suicide (PC CARES), does just that. It is built on the notion that community members are cultural and community experts, who are in the best position to create working solutions to their health problems, and recognizes that scientific knowledge can guide these efforts to strategic benefit. With strong tribal support and evidence of feasibility from the pilot study from 2014- 2017, the model has local facilitators host four 3-hour learning circles, where family members, youth, and village providers learn about prevention science, and adapt and apply it to their local and cultural realities. Demonstrating potential for changing participants' knowledge and attitudes in rural Alaska, this trial will assess the transferability and preliminary effectiveness of PC CARES on individual and community levels.

Organizational network positions
Village-level:
- Tribe staff
- Health workers (CHAPs)
- Behavioral health workers
- School personnel
- Social Services workers
- Religious leaders
- City Government/Law Enforcement

Region-level:
- Norton Sound Doctors
- CHAP supervisors
- School District health counselors

Baseline Steps toward Prevention (STP) Survey:

The Steps toward Prevention (STP) Survey will be administered at baseline (1-2 months before PC CARES implementation) and three months post-intervention. The questionnaire will be self-administered via a touch screen computer interface and will include 1) basic demographic questions, 2) questions about skills, knowledge, and attitudes toward taking preventive actions in their family and community, 3) questions about prevention actions they have done in the past 3 months, as well as permission to contact them again within a year to do a follow-up survey. The computer interface will allow the respondent to answer questions privately and quickly with a touch screen, and press 'enter' so their answers are secured. The Steps toward Prevention Baseline Survey will be open to any village resident aged 15 or older. Everyone filling out a 15-20 minute survey will receive $20. We will obtain informed consent from all participants on the touch screen computer interface before they proceed to the survey questions. In each village, we expect to administer the Baseline STP Survey to 65-150 people.

Network Positions:

Informal/Community Supporters
- Elders (Ana and Taata)
- Parents
- Sibling (includes youth 15+)
- Close cousins and peer family (includes youth 15+)
- Adult family (includes close family friends)
- Other adults
- Friends (includes youth 15+)

Formal/Organizational Supporters
- Youth Leaders (includes youth 15+)
- Tribal/Community leader
- CHAPs
- Behavioral Health Aid/TANF/Social Services
- Clinic staff
- Counselor/Regional Health Provider
- Teacher/school staff
- Pastor/Religious leader
- VPO/VPSO
- Kawerak staff

Recruitment for Steps Toward Prevention Survey: Our pilot research produced a roster of social ecological roles within the village (hereafter: 'network positions') that are relevant to suicide prevention. These positions are listed in boxes to the left. We will recruit all available people within the village institutions (targeted recruitment of individuals holding formal positions), youth (ages 15-24) (set up a table at the school to talk to students about our research), and others in the village interested in participating. We expect that some of those who participate in the Baseline Survey will also participate in the PC CARES intervention and some will not.

Beyond our initial baseline survey recruitment, we will use Respondent Driven Sampling (RDS) to recruit more widely throughout the community. This means that to recruit community members, we will use a peer-referral system that tracks recruitment patterns via referral coupons. RDS involves giving participants 3 coupons that are redeemed for $5 if the person they recruited completes a survey (up to 3 people). This means that each respondent can receive a stipend of $20 for completing the STP Baseline Survey, and an additional $15 for recruiting 3 other people to fill out a survey, for a total $35 per respondent. The recruitment payment is intentionally set low enough to avoid encouraging coercion on the part of recruiters, yet its presence provides the recruiter with an incentive to choose among his/her associates those individuals with whom he/she has enough influence such that the receiver will participate in the study, and the recruiter can be assured of getting the recruitment fee.

Since suicide risk is highest for Alaska Native young people, starting from age 15, it is important to understand the social dynamics, help-seeking and help-giving that occur for this age group. Our recruitment for young people to participate in the STP Baseline Survey will start by collaborating with the schools to determine the most effective, least intrusive means for recruiting students to participate. This could include setting up a table in the school lobby after school or during an event such as a basketball tournament to inform students about the STP Baseline Survey and to recruit them to

participate (see recruitment scripts). If interested, we will ask to speak with their parent (if under 18) and will go through an assent and consent process with both the young person and his or her parent.

Training of Facilitators (ToF):

Recruitment of Facilitators: We will recruit 2-4 people per village to be trained as PC CARES facilitators. They will be adults (over 18), living and/or working in the participating, predominantly Alaska Native village. Our Local Steering Committee and other community partners will help identify respected Elders as well as people who are in positions that related to community wellness (village-based counselors, youth leader sponsor, wellness worker, community health aides, and family workers) to be recruited as facilitators. (see recruitment scripts). Once identified and they express interest, potential facilitators (particularly village-based counselors, youth workers, community health aids and family workers) will seek permission from their respective supervisors to be facilitators of PC CARES. This permission is necessary since we assume that facilitators will be offering or preparing for Learning Circles during their regular workdays, if they are employed. This permission will allow us to move ahead with planning to support soon-to-be PC CARES facilitators in attending our weeklong Training of Facilitators (ToF), and for those who are interested, receiving 3 college credits in Human Services through the University of Alaska Fairbanks.

We will obtain informed consent from ToF participants before any ToF-related data collection begins. ToF participants have the option to participate in the ToF surveys and interviews or not, without repercussion. Receiving college credit is not tied to whether facilitators fill out these surveys or participate in interviews. They can opt out of answering and still participate in the training and get college credit for their participation in implementing the Learning Circles. We expect that most TOF participants will have already completed the Baseline PC CARES survey described above. Any who consent, but have not already completed the baseline survey, will be given the option to complete the baseline survey at the beginning of the ToF. All consenting participants will complete the Facilitator Post-Training Survey at the end of the ToF week. Additionally, consenting facilitators will be asked to participate in two 45 minute one-on-one interviews with a PC CARES research team member. These will be administered immediately after the training of facilitators and again after all learning circles have been facilitated. Interviews will cover topics related to quality of their training, adequacy of facilitator support, and confidence in facilitating.

Facilitators will need to reach a minimum level of proficiency before facilitating learning circles in their home communities. They will be told that they can opt out of having their data in the study, but that they need to reach a minimum level of proficiency before facilitating PC CARES. To ensure facilitators understand the content, a test of knowledge gains will focus on the content areas in 'What We Know.' Assessment, done at the end of the week-long ToF, will involve a content-focused group quiz. In our pilot study, this method was fun and acceptable to participants, and allowed trainers to clear up any remaining areas of confusion. When piloting this method at the end of our ToF in November 2015, 100% of our 36 participants answered 11 questions correctly, and the remaining 5 questions with mixed results (only about 70% or 25 people answering correctly), have been modified to be clearer to facilitators. Lastly, all ToF participants will demonstrate proficiency by facilitating one learning circle with a ToF trainer present. ToF trainers will assess facilitator fidelity using the tracking assessment.

After training, continuing virtual support will be offered to cohorts of facilitators monthly in teleconferences where they can check in with each other, hear about the progress each team is making and offer suggestions for addressing problems or issues as they come up.

RHS Cohort facilitators

A cohort of students in the Rural Human Services Certificate Program at University of Alaska-Fairbanks, Kuskokwim campus will fulfill their practicum requirement by facilitating PC CARES Learning Circles in their home communities. Students who consent to participate in the study will complete 3 surveys (Pre-Training, Post-Training, and 6 month Follow Up) with questions that have already been approved by IRB. In addition, we will ask for consent to take field notes during the Facilitator Training and during the monthly Facilitator support calls. These field notes will focus on what kinds of

questions are raised by trainees, what challenges and success they have as facilitators, and other information related to the experience of being a facilitator.

Surveys for Learning Circle Participants:

The PC CARES Learning Circles, in keeping with tribal partners' preferences, will be open to all residents aged 15+, and will take place in public spaces in each village (e.g. tribal building, school, city building). Exclusion criteria includes persons under the age of 15 because the curriculum requires some level of maturity to understand and make use of the information discussed.

Recruitment of Learning Circle Participants: Trained facilitators will recruit PC CARES participants in the villages they live in or serve. This will likely include word-of-mouth recruitment in the schools, churches, tribal offices, public safety offices, and city buildings and CB radio announcements, flyers, and Facebook events. At schools, tribal offices, health clinics, facilitators will do targeted recruitment of key employees in those organizations (teachers, principals, tribal leaders, health aids). They may also ask for permission to hang a flyer in that organization's building. Participation in PC CARES will be voluntary but will seek to have a variety of youth and adults. We will target people in the formal and informal network positions mentioned above.

If a community member attends a PC CARES Learning Circle, but did not complete the demographic and baseline survey, they will be given the opportunity give informed consent, and if they consent, will be given a paper copy of the survey and asked to complete it.

After each Learning Circle, all participants will be asked to complete (on paper) a survey that includes questions about their skills, knowledge and attitudes toward taking preventive action (from baseline survey), plus questions about satisfaction and about intention to use what was learned in the session. Each time they are asked to complete a survey, participants will be given the option of not filling them out without recourse. Whenever participants are asked to fill out a paper survey, they will be given a blank envelope. In order to maintain privacy and confidentiality, when they complete their survey, they can seal it in the envelope before returning their survey to the facilitator. The facilitator will send all surveys in their sealed envelopes to the research team. Each PC CARES participant will receive a $20 incentive for purchases from the village store or the grocery store in Nome (which will box and send purchases to villages) for completing the 15-20 minute survey.

Audio Recording:

The PC CARES Learning Circles in the villages will be recorded if all the participants give permission for this to be done. The recordings will be transcribed into written scripts and all identifying information for participants will be removed from the word processing files. The session transcripts will be reviewed to analyze the themes that arise from discussion among LC participants, for curriculum fidelity, and to continuously improve the curriculum as each village cohort implements PC CARES.

In order to obtain assent to be recorded, local facilitators will read a script:

"We will be audio-recording this session in order to track how PC CARES works and to make it better and better. We will not be connecting the recording to anyone's name. Instead, we will listen to see how useful and understandable the curriculum is. We want to hear how PC CARES works in villages and to see if there are any changes that need to be made in the format and content. Your name will not be connected to the voice recordings. At the end of the research study, all voice recordings will be destroyed. Can you give a 'thumbs up' if it is okay with you if we record. Give a 'thumbs down' if that is not OK with you. We will only record if everyone agrees."

If thumbs up and participants agree to audio recording: *"If at any time during the session, you change your mind, please just ask us and we will stop recording or will destroy the recording if you are uncomfortable with what you said."*

If participants agree, an audio recorder is set up and the session is recorded and saved on a thumb drive. The thumb drive is sent to UMass in a self-addressed, stamped envelope along with the paper surveys after the learning circle is finished. If there is 1 'thumbs down' indicating that a participant does not wish to be recorded, we will not record the

session. The transcripts for these sessions do not have names associated with recorded narratives nor do transcripts have a list of attendees. Attendance records for each learning circle are kept separately.

Because there is limited internet access in the village where Learning Circles will occur, transferring data electronically is not a viable option. All data will be sent to the research team via USPS in Self Addressed Stamped envelopes that we provide.

Each participating facilitator will receive a $50 incentive for collecting this data (attendance, surveys, audio recordings of Learning Circles) and sending it to UMass. Once the packet of data is received, the project coordinator will send an electronic Amazon gift card to participating facilitators in appreciation of their time.

Steps toward Prevention 3-Month Follow-Up Survey:

Approximately 3 months after the final PC CARES Learning Circle, we will again use the touch screen computer interfaces to collect follow-up data. This survey will be identical to the baseline survey. Again, the Steps toward Prevention 3-Month Follow-Up Survey will be open to all community members aged 15 +, and we will target recruitment to 1) those who completed the Steps toward Prevention Baseline Survey, 2) those who attended at least 1 PC CARES Learning Circle, and 3) those who inhabit specified formal and informal prevention related roles in the community whether or not they participated in PC CARES. Again, we will use Respondent Driven Sampling to recruit throughout the community with each participant receiving $20 for completing the Steps toward Prevention 3-Month Follow-Up Survey, and up to $15 for recruiting others to participate. Again, we expect 65-150 participants per village.

PC CARES at School: For the 2021-2022 school year, we will expand our research to include Nome Public Schools, in addition to the Bering Straits school District, and Northwest Arctic Borough School District.

During COVID, in addition to holding Learning Circles, we will offer inservice trainings for Bering Strait School District staff on what they can do (and the school as a whole can do) to prevent suicide among their students. Trainings include an all staff 'one time' training, and afterward, interested staff and community members will be invited to participate in on-going learning circles hosted by PC CARES curriculum trainers aimed at developing a suicide prevention and postvention plan for their school and/or district. School staff who are at least 18 years old, and who participate in any level of training will have the option to participate in 3 online surveys to assess their changes in attitudes, behavior, knowledge related to suicide prevention: 1) before any trainings are offered, 2) soon after the inservice, and 3) at the end of the school year. The link to participate in the survey will be provided to school staff, volunteers, and key service system personnel via email at the timepoints described below. Participants will receive a $20 Amazon.com gift card for the Baseline and $40 for the FollowUp survey, for a possible total of $60.

Baseline survey: Participants in the PC CARES at School training will fill out a registration form for the training. The registration form will include a brief description of the research (using recruitment script attached) and participants can opt in (or opt out) to participate in the research. They can choose to attend the training, but not be research participants/subjects. The school and district will not be informed as to which staff choose to participate in the research. If they opt in, they will click on a link that gives them the consent form. If they click their consent, they will be brought to the PC CARES at School Baseline Survey. This survey largely mirrors the Steps Toward Prevention survey, with a few added questions that pertain the to school context. If participants answer 'yes' to some questions, they get a follow up questions of 'with whom?'. For PC CARES at School, we will add some answer choices to the previously approved list that include Teacher, Administrator, Coach, Administrative Assistant/Front Desk, Classroom Aide, Other school staff (including janitor/cafeteria worker), Student, Parent of student.

After the training, all staff who opted into the research will be sent a link to a PC CARES at School Satisfaction survey. This survey consists only of previously approved questions from the previously approved Learning Circle survey, with very

slight changes to indicate that the questions pertain to the in-service training. The Follow Up survey will include a question in which we will ask survey participants to identify which people who attended PC CARES Learning Circles they are close to. We will list the names of all PC CARES Learning Circle attendees in their region (40-50 names), and ask survey participants to identify if they are close to any of the people listed. (Learning Circle Attendees attend the Learning Circles publicly and there is no expectation that their attendance be kept private. People can be Learning Circle Attendees without being research participants. We will not list the names of the research participants (confidential), but the names of the Learning Circle attendees (public).

Follow up survey: Approximately 6 months after the training, all staff who opted in to the research by participating in the Baseline survey will be sent a follow up survey. This survey will be identical to the Baseline survey, but with a few added questions.

We will continue to hold Learning Circles with school staff (and other local professionals) and as in our original PC CARES project, we will ask participants to complete a Learning circle survey after each Learning Circle they attend. We have added a Learning Circle to the curriculum, so there are now 6 learning Circles. Participants will receive a $10 giftcard for each Learning Circle survey they submit.

Recording for PC CARES at School: During each Learning Circle via Zoom, we start with approximately 45 minutes of researchers presenting information. This portion will be recorded, and shared back with participants who may want to re-review the material or who missed a session.

Notes during LC discussions for PC CARES at School: Participants will contribute their thoughts during 45 minute 'breakout sessions.' These breakout sessions will not be recorded. However, we will take notes (with no identifiers) on what is being discussed and shared in the 'breakout sessions.' At the first Learning Circle, we will conduct an anonymous poll (through Zoom) asking participants whether we can use the notes from their breakout sessions in our research. By default Zoom hides the results from participants. If we have 1 person who responds to the poll stating that they do not want to be included in notes used for research, then we will exclude the notes from their breakout session from analysis. We will use the following script to ask permission from attendees:

We will be taking notes and responding to prompts in google documents and the chat during this session to facilitate our learning. Our team may want save these notes and comments for later use to track how PC CARES works and to make it better. We will not be connecting the notes to anyone's name or school. Instead, we will listen to see how useful the curriculum is, to see if there are any changes that need to be made to the format, and to describe what people talk about and learn in each class. At the end of the research study, all notes will be destroyed. We'll use a zoom poll to ask you if you agree to have these notes saved for our use. We will only use them if everyone in your breakout group agrees. If at any time during the session you change your mind, please just ask and we will destroy any notes if you are uncomfortable with what you said.

Anonymous Zoom poll will then ask:

Do you feel comfortable with the notes from your breakout group being used as part of our research?

PC CARES at School Focus Groups: At the end of each cohort of PC CARES at School Learning Circles, we will invite research participants from the Learning Circles to participate in a Focus Group. Each focus group will be audio recorded, will take about 1 hour and will have approximately 8 participants. Audio recordings will be transcribed (redacting any personal or community identifiers). After transcription is complete, the audio recording with be destroyed. Each participant will earn a $50 Amazon.com gift card. Focus group questions will center around the experiences of participants in PC CARES at School. There will be a total of 6 focus groups:

1. In Bering Straits in Spring 2021
2. In Northwest Alaska in Spring 2021
3. In Bering Straits in Spring 2022
4. In Northwest Alaska in Spring 2022

PC CARES at Home:
Also due to COVID-related restrictions, we will send PC CARES Care packages to approximately 100 community members who 'opt in' to receive them. Care packages will contain brief information about what research shows community members can do to prevent suicide and promote wellness in their community. It will also contain small gifts that community members can use in their wellness promotion/suicide prevention, such as Uno cards they can use to spend time with young people, an emotion wheel they can use with young people to understand their emotions, and YouMatter cards that have affirming messages that they can share with others in their community. Approximately 8 Care packages will be sent over the course of a year and each will have different items and different information. Each care package will contain a survey with a self-addressed stamped envelope. Participants who return the survey to researchers will be entered into a raffle to win a prize worth approximately $50. After each care package is sent, we will also randomly select 5 Care package recipients to be invited to participate in a brief interview to collect additional data about how they are using the Care package information and items and to help us make the Care packages more useful to them over time. Interview participants will receive a $20 gift card as an incentive to participate.

Data Management:
Once data is received by University of Massachusetts personnel, all paper copies of surveys and all thumb drives containing audio recordings of LCs and facilitator interviews will be stored in a locked file cabinet in a locked office after data is entered. All electronic data will be stored on a secure, encrypted, password-protected, University-run server. The PI and key personnel will have access to all project data. LSC members will have access to de-identified and summarized project data. Names and proper nouns, like place names, on any transcripts made available to LSC members will be coded to protect the confidentiality of participants.

All academic partners will have an up-to-date Collaborative Institutional Training Initiative (CITI) certification to ensure that all researchers adhere to ethical standards and follow all informed consent and confidentiality protocols as spelled out in our AAIRB application and in accompanying informed consent forms.

The social network data collected (data about prevention actions survey participants have taken) will be maintained by Co-PI Dombrowski and stored in encrypted, password protected, electronic form at his offices at UNL. Because these data contain information from a small population, and thus the identity of project participants may be discernible from the data despite de-identification, the network data will not be made publicly available at any time. Requests to the PI/co-PI for relevant analysis from participating tribal partners will be honored in perpetuity, to ensure the highest level of access and collaboration without risk of public disclosure of participant identity or the data he/she supplied.

We are strongly committed to ensuring the safety of participants and the integrity of the study and will therefore convene a Research Advisory Board (RAB). The RAB will have four members (one who is an Alaska Native academic) who have combined expertise that includes clinical trials, research with Alaska Natives in Alaska and community-based research. The RAB oversees the scientific and ethical integrity of the research study. Members review protocols, ensure safety and aid in

dissemination activities. Quarterly meetings enable RAB members to guide all aspects of the research from the development of protocols, organization of data and data collection, analysis and dissemination. RAB member participation in the pilot work for this research was invaluable.

PC CARES at School:

All surveys for PC CARES at School will be completed on line in REDCap which is a secure, encrypted online survey tool. Data will be kept separately from identifying information. Data will be collected electronically. Participants will be asked to assign themselves an ID. Only the ID will be tied to the survey data. Spreadsheet that links the names to IDs will be stored separately and only available the research coordinator and the PI.

Data Analysis:

Using a multi-level growth model for participant outcomes, we will generate reliable estimates of changes in participants' knowledge, attitudes and behaviors before, over our 4-6-month intervention and follow-up: 7 occasions of measurement (Baseline STP survey, 5 Learning Circle surveys completed after each learning circle and a Follow-Up STP survey). We will model variability in these changes over time, and identify key factors affecting these outcomes within the three domains identified through our pilot study: a) cross-sector participation on a community level; b) individual dosage, and c) participant social role: informal or formal. In addition, we will record the effectiveness of our intervention at the network and community level by performing pre- and post-intervention Steps Toward Prevention surveys documenting the level and type of institutional/role interactions that take place across those institutions and the social positions best able to meet the needs of young people at risk for suicide. Pre-post intervention STP surveys and variation in initial rollout timing will create a natural stepped wedge design. To assess intervention outcomes we will collect bipartite (individual and institution/social role) interaction data in each participating community. This method builds on research previously undertaken by the research team in NWA in 2015-17 and Inuit communities in Arctic Canada in 2010-11, and will focus on levels of cross-sector collaboration (including informal supports) and youth support networks within each community. Rigorous network statistical analyses will focus on variation across participating communities, and before/after the community-level intervention. Structural clustering of 12 family and community level network roles and key organizations will be derived via the 1) transformation of bipartite graphs of individuals and organizations/roles in single-mode, sector-level social networks with interaction weighted links, 2) use of Generalized Ward's criterion to discover meaningful clusters of structured interaction, and 3) block modeling of these clusters (using standard density criterion) to create models of organizational structure. Analysis of the pre- and post-PC CARES structures will allow us to capture changes in suicide prevention and supportive practices within and between these network roles/organizations before and after each cohort wave of 3 villages, and across all the intervention villages.

Facilitator Interviews and Surveys. We will perform exploratory and descriptive qualitative analysis designed to yield information about specific contexts, characteristics, and processes of the PC CARES project from the facilitators' perspectives. For example, while the quantitative measures of this study track the number and type of interactions among different community sectors, this analysis will use facilitator interviews and surveys to explore in more depth *why* some sectors participated and/or reached across community sectors (e.g. history of organizational collaboration and the context of village relationships) while others did not. Before and after timing of both interview and survey data collection is designed to capture changes in facilitator perspectives as they gain experience with implementation of the PC CARES Learning Circle curriculum.

'PC CARES at School': Baseline and Follow up surveys will be analyzed for change over time using Wilcoxon or t-test. Outcomes measured over time will be compared for change using hierarchical linear modelling. Satisfaction surveys will be analyzed by mean scores for individual items and for constructs, as well as frequencies for individual items.

Local Steering Committee Members (LSC):

The LSC members will be local tribal administrators, leaders and young people interested in strengthening local communities' safety net to increase health and prevent suicide. Most of the members of this group have been involved in research for many years through the pilot research and through their participation in the Northwest Alaska Wellness Initiative. LSC members will not have access to project data, except in collated, region-level summaries. Names and proper nouns, like place names, on any de-identified and summarized project data made available to LSC members will be coded to protect the confidentiality of participants.

Informed Consent Forms to follow:

1. Baseline, Post- and Follow-Up *Steps Toward Prevention Survey* Consent Form
2. Post Learning Circle Survey Consent Form
3. Participant Focus Group Consent Form
4. Care Package survey consent form
5. Care package interview consent form
6. Facilitator survey consent form
7. Field notes consent form

1. Baseline, Post- and Follow-Up *Steps Toward Prevention Survey* Consent Form

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide (PC CARES at School)
Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Kawerak and Norton Sound Health Corporation
Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Introduction: Thank you for showing interest in joining our research project aimed at implementing, assessing and improving the PC CARES at School curriculum which aims to increase wellness and suicide prevention in Native Alaskan communities. We will ask you to complete a survey before the training begins, at the end of the training, and again approximately 6 months after the training. Your participation in our 3 surveys will take approximately 20 minutes each. There is a small risk that the survey questions may remind you of a difficult event or will point out something you are not currently doing for prevention. The benefit of participating is that you will help us understand where PC CARES at School is successful in improving wellness and prevention behaviors. Please ask any questions you have about the project or your participation in it. Participating in this research project is totally voluntary an up to you. Even after starting, you can choose to quit at any time and that will be okay.
This consent form is set up to describe the project and your part in it a little at a time. Take as much time as you need to read through this form.

PURPOSE OF THIS STUDY

We want to learn how we can make PC CARES at School better. Just to remind you, PC CARES stands for Promoting Community Conversations About Research to End Suicide. This study will help us evaluate how well PC CARES at School works, and to make the model better. Ultimately, we hope that successful implementation of PC CARES at School will increase wellness and prevention in your community.

WHO CAN PARTICIPATE IN THE STUDY

Who can take part in this study? Anyone aged 18 + who attends the PC CARES at School training can participate in this study.

How many people are expected to take part in this study? We expect to have between 100 and 200 people participate in this research.

INFORMATION ABOUT STUDY PARTICIPATION

What will happen to me in this study? If you participate in the training, we will give you the knowledge and skills you need to support students in a way that reduces suicide risk. By attending the training, you can also earn CEUs.
You can choose to just attend the training, or you can choose to attend the training AND also be a participant in our research about PC CARES at School. If you choose to participate in the study, we will ask you to do 3 surveys: 1) before this training begins, 2) at the end of this training, and 3) a final survey about 6 months after the training.
How much of my time will be needed to take part in this study? Each survey will take about 20 minutes to fill out. The entire study will be completed in 2021.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? It is possible that answering the questions may remind you of a difficult event or may point out something that you are not doing for prevention. If this happens, you can skip any questions or stop filling out the survey, no problem.

How could I benefit if I take part in this study? How could others benefit? By attending the training, you will gain skills in how to increase wellness and reduce suicide risk in your community. You can also earn CEUs for attending. If you also participate in the study, you will help us make PC CARES at School better by tracking what you and other school community members learn and do before and after participating in PC CARES at School training.

ENDING THE STUDY

If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in the "Contact Information" section below. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? Surveys will all be conducted using a secure, encrypted online survey platform. We will ask you to assign yourself an ID. All of your answers will be tied to that ID and no longer be tied to your name. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with Tribal leadership and may appear in scientific literature. Whether or not you choose to participate will not be shared with your employer or anyone else.

Who will have access to my research records? Only Dr. Wexler and her direct research staff will have access to you records.

What will happen to the information collected in this study? Your answers will be private and will not be connected with your name, just an ID number so we can see what people learn over time. We will not share your answers with your supervisor, employer, or anyone else. All results that are made public will be summary results, they will not report anything that would identify any particular person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Will my information be used for future research or shared with others? We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

Special Requirements A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To protect your privacy, this research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lisa Wexler

Email:lwexler@umich.edu
Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

Or

Alaska Area IRB: 907-729-3924 (collect calls accepted) akaalaskaarealRB@anthc.org
Norton Sound RERB: (907) 443-3304 / research@nshcorp.org

YOUR CONSENT

Consent/Assent **to Participate in the Research Study**
By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Email address:_____

Date of Signature (mm/dd/yy): _____

2. Post-Learning Circle Survey

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide
Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Kawerak and Norton Sound Health Corporation
Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Introduction: Thank you for coming today and participating in this PC CARES session. As part of our research and to help us know what you learn in the session and to evaluate PC CARES, we invite you to fill out a short survey (approximately 20 minutes) that asks you about your knowledge, beliefs, skills, relationships and suicide prevention actions. Participating in this research study is totally voluntary and up to you. Even after starting the survey, you can quit at any time and that will be okay. There is a small risk that the survey questions may ask about something you don't feel confident about, and the benefit of participating is that you will help us understand where PC CARES is successful in improving wellness and prevention behaviors in your school and community.

PURPOSE OF THIS STUDY

We are trying to learn what works about our approach, and how to make PC CARES better. We hope you will learn information and useful skills to help you reach out to young people in your lives, to share ideas about prevention, and to get help and support if are worried about someone. By filling out these surveys, you will help us track what you learned through these sessions, and your feedback will help us improve PC CARES.

WHO CAN PARTICIPATE IN THE STUDY

Who can take part in this study? Anyone aged 18 or older who attended this PC CARES session.

How many people are expected to take part in this study? We expect to have up to 100 people across the Bering Strait region and Northwest Alaska to participate in this research.

INFORMATION ABOUT STUDY PARTICIPATION

What will happen to me in this study? You will be asked to complete a short survey now, and at the end of each future PC CARES session you attend for a total of 5, if you attend all of the sessions. We also ask if you will let us contact you for a short follow-up survey in the spring.
How much of my time will be needed to take part in this study? Each survey will take about 20 minutes to fill out. The entire study will be completed in 2022.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? It is possible that completing the survey may point out something you may not be confident about or something that you have not yet done, which may not feel good. We only ask you questions about what you know and do for prevention. We do not ask about risk.

How could I benefit if I take part in this study? How could others benefit? The PC CARES sessions will help us track what you learned and how (or if) it was helpful and whether you used what you learned. This information will help us improve PC CARES for your community and others like it.

ENDING THE STUDY

If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before

it is finished, please tell one of the persons listed the "Contact Information" section below. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

FINANCIAL CONSIDERATIONS

Will I be paid? You will receive a $10 Amazon.com gift card for each survey that you complete. If you attend all 6 PC CARES sessions and fill out a survey after each one, you will receive $60.

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? At the beginning of this survey, you will be asked to enter a participant ID. All of your answers will be tied to that ID, not to your name. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Who will have access to my research records? Only Dr. Wexler and her direct research staff will have access to you records.

What will happen to the information collected in this study? Your answers will be private and will not be associated with your name, just a research identification number. We will use this number to look at what you learned over time. Your name will not be linked to your survey and will not be shared with anyone.

Will my information be used for future research or shared with others? We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

To protect your privacy, this research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lisa Wexler
Email:lwexler@umich.edu
Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road

Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

Or

Alaska Area IRB: 907-729-3924 (collect calls accepted) akaalaskaarealRB@anthc.org
Norton Sound RERB: (907) 443-3304 / research@nshcorp.org

YOUR CONSENT

BY FILLING OUT THE ATTACHED SURVEY, YOU AGREE TO PARTICIPATE IN THE EVALUATION OF PC CARES.

3. Participant Focus Group

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY
PC CARES at School Focus Groups

KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide (PC CARES)
Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Kawerak and Norton Sound Health Corp., Maniilaq, Bering Straits School District, and Northwest Arctic Borough School District
Study Sponsor: National Institutes of Health

This form can be read to you if you ask.
You are invited to take part in a research study. This is a consent form for a focus group about your experience with PC CARES at School. It will give you information about the focus groups so you can make an informed decision about whether you want to participate. If you have questions please ask us. Take as much time as you need to decide. If you choose to be in the study, you will need to sign this form.

Key Information

1. We are inviting you to take part in a focus group for this research study, and are asking for your consent to join. It is completely up to you to decide if you want to take part in a focus group.
2. The purpose of the PC CARES at School Focus Groups is to learn more about specific contexts, characteristics, and processes of the PC CARES project that encourage community changes to reduce suicide risk. Each focus group will take about 1 hour and will be conducted through Zoom or via phone. A facilitator will ask questions about your experience with PC CARES at School and how you have used the information you learned.
3. Risks for taking part are minimal. Focus Group discussion may remind you of a difficult experience, or you may feel uncomfortable if we discuss suicide prevention actions that you haven't yet taken.
4. The benefit of joining is that you will help us understand how to make the PC CARES program better overall in promoting community changes to reduce suicide risk.

PURPOSE OF THIS STUDY

Why are we doing this? We want to learn more about specific contexts, characteristics, and processes of the PC CARES project that encourage community changes to reduce suicide risk. Part of this is understanding what helps you take actions related to wellness and suicide prevention.

WHO CAN PARTICIPATE IN THE STUDY

Who can be in this study? Anyone who attended the PC CARES at School sessions can participate in these focus groups.
How many people are expected to take part in this study? We expect to conduct a total of 4 focus groups, each with about 8 people, for a total of about 32 focus group participants.

INFORMATION ABOUT STUDY PARTICIPATION

What will happen to me in this study?
If you choose to participate in the focus groups, we will set up a Zoom call in which you can join by videoconferencing or by phone. We will audio record the focus group for transcription later on, so we can remember what was said. Examples of questions we might ask are:

What was it like to participate in the PC CARES course?
What information from our course do you expect will be easy for you to do?
What do you hope to see happen in your community as a result of this class?
What has already happened in your community as a result of taking this class?

Incentives: Each focus group participant will receive a $50 Amazon.com gift card in appreciation for your time.
How much of my time will be needed to take part in this study? The focus group is expected to last about 1 hour. The entire study will be completed in 2022.

Who is funding this study? This research project is funded by the National Institute of Mental Health.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? We believe there are no known risks to participating, but it is possible that answering the questions may remind you of a difficult event or may point out something that you are not doing for prevention. If this happens, you can take a break or leave the focus group and it will be okay.

How could I benefit if I take part in this study? How could others benefit? The benefit of participating is that you will help us understand how to make the PC CARES program better at promoting community-wide increase in actions that promote wellness and decrease suicide risk.

ENDING THE STUDY

If I want to stop participating in the study, what should I do? You are free to leave the focus group at any time without any penalty to you. Whatever you share in the focus group before you decide to leave will remain as part of the researcher's data. Because the researchers will not keep track of who makes each comment in the focus group, it will not be possible for researchers to take out your comments after the focus group.

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? Researchers will not keep track of who in the focus group makes which comments; therefore, no identifying information will be kept in the audio recording or transcript of the focus group. We will not share any information from your focus groups with your supervisor, or anyone else. Transcripts and notes from focus groups will be recorded with all identifying information (for example: names of people, tribes, or villages), redacted. Once transcripts are completed, all audio recordings will be destroyed. We will ask all focus group members to protect the privacy of other focus group members by not sharing with others what they hear in the focus group. Researchers cannot guarantee that your fellow focus group members will keep your comments private.

All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Who will have access to my research records? Only Dr. Wexler and her direct research staff will have access to you records.

Will my information be used for future research or shared with others? We may use or share your research information for future research studies. If we share your information with other researchers it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

Special Requirements A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To protect your privacy, this research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

Data Storage: Your focus group data will be stored at the University of Michigan. Electronic files will be kept on a secure encrypted server that is accessed only with a password. We plan to keep your answers for as long as they are useful to the study, then the information will be destroyed.

You have a choice. Remember it's up to you if you want to participate in PC CARES focus groups, and even after we start you can choose to stop at any time and that will be okay.

CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lisa Wexler
Email:lwexler@umich.edu
Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

Or

Alaska Area IRB: 907-729-3924 (collect calls accepted) akaalaskaarealIRB@anthc.org
Norton Sound RERB: (907) 443-3304 / research@nshcorp.org

YOUR CONSENT

Consent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

5. Care Package survey consent form

If you wish to complete this survey, you can **either** fill it out and mail it back to us in the envelope provided **OR** take the survey online by following this link: [LINK] Or, use your smartphone camera to scan this code →

QR CODE

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY
KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide (PC CARES at Home) Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Kawerak Inc., Norton SoundHealth Corporation & Maniilaq Association

Study Sponsor: National Institutes of Health

Thank you for your interest in joining our research project aimed at improving PC CARES Packages which aim to increasewellness and prevent suicide. We'd love to find out what you think about this Care Package. If you complete this survey and send it back to us with your name, ***you will be entered into a raffle to win a $50 Amazon.com gift card.***

Study Purpose: This study will help us evaluate how well PC CARES Packages work, so we can make it better in an effort to support wellness and prevention in your community.

Who Can Participate? Anyone aged 18+ who receives PC CARES at Home Care Packages can participate in this study.We expect to have approximately 100 people participate in this research over the course of the next few years.

Study Participation: The survey will ask about the PC CARES Package you received and will take less than 10 minutes.The entire study will be completed in 2023.

Information about Study Risks and Benefits: There is very few (if any) risks in participating in this survey. There is asmall risk that the interview will bring up hard feelings about things you may not have done to increase wellness.
The benefit of participating is that you will help us understand how PC CARES Packages are helpful to you.

Ending the study: You are free to stop the survey at any time: no problem. Just don't send in this survey.

Protecting and Sharing Research information: Your information will be private. All paper surveys will be storedin a locked file cabinet and all electronic records will be stored on secure password-protected servers. Only Dr.
Wexler and her direct research staff will have access to your records. Your data will not be shared with other researchers or used for any future research studies. All results that are made public will be summary results. Allinformation will be de-identified, which means that it will not contain your name or other information that can directly identify you. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Special Requirements: To protect your privacy, this research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identifyyou, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

Contact Information: To (1) get more information about the study, (2) ask about the study procedures, (3) report an illness, injury, or other problem, (4) Leave the study before it is finished or (5) express a concern about the study, pleasecontact Principal Investigator, **Lisa Wexler at lwexler@umich.edu or (413) 824-1190**

If you have questions about your rights as a research participant, or wish to obtain information, or discuss anyconcerns about this study with someone other than the researcher(s), please contact the following:
University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board
(IRB-HSBS)2800 Plymouth Road
Building 520, Room 1169 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free
(866) 936-0933Fax: 734-936-1852 E-
mail: irbhsbs@umich.edu

Or

Alaska Area IRB: 907-729-3924 (collect calls accepted)
akaalaskaarealRB@anthc.orgNorton Sound RERB: (907) 443-3304 /
research@nshcorp.org
Dr. Klejka at YKHC Human Subjects Committee (907) 543-6028

6. Care package interview consent form

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide (PC CARES at Home)

Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Kawerak and Norton Sound Health Corporation, Maniilaq

Study Sponsor: National Institutes of Health

Recruitment Script: My name is [name] and I'm calling to ask you a few questions about the PC CARES Care Package you received. We'd like to know what you thought about the Care Package and how you used it. You will receive a $20 Amazon.com gift card for participating. Do you have a few minutes to review our consent form and to answer a few questions? Or can we schedule a different time that is more convenient for you?

[If Yes, the proceed to the consent form]

Introduction: Thank you for your interest in joining our research project aimed at improving PC CARES Packages which aim to increase wellness and prevent suicide. You recently received a care package with items including [name items included in care package]. We are calling a few people who received these to find out what they think about them. If you agree to talk with me today, the interview will take less than 15 minutes, and your answers will help us understand how people use the care packages and how we can make them better. We will send also you a $20 Amazon.com gift card.

Where should we send the Amazon.com Gift Card? (email address, text, mailing address):

_____

I am going to go over a few things about the study before we begin.

PURPOSE OF THIS STUDY

This study will help us evaluate how well PC CARES Packages work, so we can make it better in an effort to support wellness and prevention in your community.

WHO CAN PARTICIPATE IN THE STUDY

Anyone aged 18 + who receives PC CARES at Home Care Packages can participate in this study. We expect to have approximately 100 people participate in this research over the course of the next few years.

INFORMATION ABOUT STUDY PARTICIPATION

The interview will ask about the PC CARES Package you received, and will take less than 15 minutes.

The entire study will be completed in 2023.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

There is very few (if any) risks in participating in this interview. There is a small risk that the interview will bring up hard feelings about things you may not have done to increase wellness.

The benefit of participating is that you will help us understand how PC CARES Packages are helpful to you.

ENDING THE STUDY

You are free to stop the interview at any time: no problem. We will keep the information you gave up until then unless you ask us not to. If you prefer, just ask us to delete it from our records. If you decide a month after the interview, it is unlikely we will be able to remove your information from the research because it will be put with others' information and analyzed.

PROTECTING AND SHARING RESEARCH INFORMATION

Your information will be private. Instead of using your name, the information you give is assigned an ID. Your answers will saved on a secure, encrypted, password protected server.

Only Dr. Wexler and her direct research staff will have access to your records.

All results that are made public will be summary results, they will not report anything that would identify any particular person. All information will be de-identified, which means that it will not contain your name or other information that can directly identify you. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Because the research is supported by the National Institute of Mental Health, a description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To protect your privacy, this research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

Again: You don't have to participate if you don't want to. Even after we start, you can choose to quit at any time and that will be okay. Your answers are confidential: we hope you will be honest and tell us what you think so we can make the PC CARES Packages better. After we finish, we plan to keep your answers for as long as they are useful to the study, and then we will destroy them.

Contacts: Along with your gift card, we will send you a copy of all of the information I've just shared with you. It will also include the names, phone numbers and email addresses of several people that you can call if you have any questions or concerns. If you'd like, I can read those names and their phone numbers and email addresses to you now, or you can just wait and receive them in a few days with your Gift Card.

Would you like me to read them to you now or would you like them to receive them in a few days with your Gift Card?

[*If participant would like you to read them the contact info, please see the bottom of this document for appropriate information to read to them]*

Do you have any questions are is there anything you'd like me to explain more clearly?

YOUR CONSENT

AGREEMENT TO PARTICIPATE:

Do you agree to participate in this research study?

___ YES ___ NO

Interviewer signature _____ Date_____

To be read if the participant does not want this information sent with gift card

CONTACT INFORMATION

Please contact the researchers listed below to:

- Obtain more information about the study or ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished or express a concern about the study

Principal Investigator: Dr. Lisa Wexler

Email: lwexler@umich.edu Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

Or

Alaska Area IRB: 907-729-3924 (collect calls accepted) akaalaskaarealIRB@anthc.org

Norton Sound RERB: (907) 443-3304 / research@nshcorp.org

7. Facilitator survey consent form

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide

Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Yukon Kuskokwim Health Corporation

Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Things you should know:

- The purpose of the study is to better understand the experiences of PC CARES facilitators in implementing PC CARES
- If you choose to participate, you will be asked to complete 3 surveys. 1) Before the Facilitator training, 2) At the end of the Facilitator training, 3) during Spring 2023. Each survey will take 25 minutes or less.
- Risks or discomforts from this research include the possibility that answering the questions may remind you of a difficult event or may point out something that you are not doing for prevention. If this happens, you can skip any questions or stop filling out the survey, no problem.
- There are no direct benefits to you for participating, but your participation will help us build increased supports for future PC CARES facilitators.

  Participating in this research project is totally voluntary an up to you. Even after starting, you can choose to quit at any time and that will be okay. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

PURPOSE OF THIS STUDY

We want to learn how we can make PC CARES better by understanding more about the experiences of PC CARES facilitators. Just to remind you, PC CARES stands for Promoting Community Conversations About Research to End Suicide. As a PC CARES facilitator, you will work with your community members to prepare and support them to reach out to young people in their lives *before* a crisis. This study will help us understand what parts of PC CARES are challenging for facilitators and how we can build additional supports for future PC CARES facilitators. Ultimately, we hope that successful implementation of PC CARES will increase wellness and prevention in your community.

WHO CAN PARTICIPATE IN THE STUDY

Who can take part in this study? Anyone who attends the PC CARES Training of Facilitators can participate in this study.

How many people are expected to take part in this study? We expect to have approximately 20 people participate in this aspect of the research. The full research projects includes about 1600 people.

INFORMATION ABOUT STUDY PARTICIPATION

What will happen to me in this study? If you become a facilitator, we will give you the knowledge and skills you need during this week-long training to host PC CARES learning circles in your home community. After the week-long training, we also ask you to attend monthly teleconferences with the other facilitators here, and to hold 5 learning circles in your home community.

You can choose to just be a facilitator and complete the tasks mentioned above, or you can choose to be a facilitator AND also be a participant in our research about PC CARES. If you choose to participate in the study, we will ask you to do a number of surveys: 1) before this training begins, 2) at the end of this training, and 3) a final survey about 3 months after you've finished the 5 PC CARES learning circles in your village.

How much of my time will be needed to take part in this study? Each survey will take about 25 minutes to fill out. The entire study will be completed in 2023.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? It is possible that answering the questions may remind you of a difficult event or may point out something that you are not doing for prevention. If this happens, you can skip any questions or stop filling out the survey, no problem. Because this study collects information about you,the primary risk of this research is a loss of confidentiality. See the section on 'Protecting and Sharing Research Information' below in this document for more information on how the study team will protect your confidentiality and privacy.

How could I benefit if I take part in this study? How could others benefit? You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. By becoming a facilitator, you will gain skills in how to increase wellness in your community. If you also participate in the study, you will help us make PC CARES better by understanding more about the experiences of facilitating PC CARES Learning Circles.

ENDING THE STUDY

If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in the "Contact Information" section below. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive a $20 Amazon.com giftcard for completing the first survey, a $10 Amazon.com giftcard for completing the second survey, and a $40 Amazon.com gift card for completing the 3rd survey.

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? Once we enter your data into a computer database, we'll assign you a Participant ID. All of your answers will be tied to that ID and no longer be tied to your name. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Who will have access to my research records? Only Dr. Wexler and her direct research staff will have access to you records.

What will happen to the information collected in this study? Your answers will be private and will not be connected with your name, just an ID number so we can see what people learn over time. We will not share your answers with your supervisor, UAF instructor, or anyone else. All results that are made public will be summary results, they will not report anything that would identify any particular person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

Will my information be used for future research or shared with others? We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

Special Requirements A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To protect your privacy, this research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For additional information about the CoC please contact the Principal Investigator.

CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lisa Wexler

Email:lwexler@umich.edu

Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

You can also contact Dr. Joseph Klejka from the Yukon-Kuskokwim Health Corporation at 907-543-6024 email him at joe_klejka@ykhc.org if you have questions regarding your rights as a research participant.

The UAF Institutional Review Board (IRB) is a group that looks at research projects involving people. This review is done to protect people like you who are part of research. If you have questions or concerns about your rights as a research participant, you can contact the UAF Office of Research Integrity at 474-7800 (Fairbanks area) or 1-866-876-7800 (toll-free outside the Fairbanks area) or uaf-irb@alaska.edu.

YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

8. Field notes consent form

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Promoting Community Conversations About Research to End Suicide
Principal Investigator: Lisa Wexler, PhD, University of Michigan in collaboration with Yukon Kuskokwim Health Corporation
Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Things you should know:

- The purpose of the study is to better understand the experiences of PC CARES facilitators in implementing PC CARES
- If you choose to participate, you will be asked to sign this consent form to allow us to take notes during the Training of Facilitators and the monthly support calls. Then you can participate in conversations normally.
- Risks or discomforts from this research include the possibility that you may say something that you later regret. If this happens, you can contact the researchers to ask them to remove the remark from the notes.
- There are no direct benefits to you for participating, but your participation will help us build increased supports for future PC CARES facilitators.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

We want to learn how we can make PC CARES better by understanding more about the experiences of PC CARES facilitators. Just to remind you, PC CARES stands for Promoting Community Conversations About Research to End Suicide. As a PC CARES facilitator, you will work with your community members to prepare and support them to reach out to young people in their lives *before* a crisis. This study will help us understand what parts of PC CARES are challenging for facilitators and how we can build additional supports for future PC CARES facilitators. Ultimately, we hope that successful implementation of PC CARES will increase wellness and prevention in your community.

3. WHO CAN PARTICIPATE IN THE STUDY

Who can take part in this study? Anyone who attends the PC CARES Training of Facilitators can participate in this study.

How many people are expected to take part in this study? We expect to have approximately 20 people participate in this aspect of the research. The full research projects includes about 1600 people.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
If you choose to participate in this study, you will participate in conversations during the Training of Facilitators and during the monthly support calls normally. You don't need to do anything special. We will take notes about your experiences, concerns, challenges, successes, questions, but will not write your name.

4.3 If I decide not to take part in this study, what other options do I have?
If you choose not to participate in this portion of the study, that is fine. We will still take notes on what others in the class say, but we will not take notes on any of your comments.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? It is possible that you will say something during the Facilitator Training or during the monthly support calls that you later reconsider or regret. If that happens, you can contact the researchers to ask us to remove that comment from our notes.

Breach of confidentiality is a potential risk in all research. We avoid this risk by not writing down anyone's name or identifying information in our notes.

5.2 How could I benefit if I take part in this study? How could others benefit? You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. By becoming a facilitator, you will gain skills in how to increase wellness in your community. If you also participate in the study, you will help us make PC CARES better by understanding more about the experiences of facilitating PC CARES Learning Circles.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in the "Contact Information" section below. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? There is no compensation for this portion of the research study.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information Once we enter your data into a computer database, we'll assign you a Participant ID. All of your answers will be tied to that ID and no longer be tied to your name. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

8.2 Who will have access to my research records?
Only Dr. Wexler and her direct research staff will have access to you records.

8.3 What will happen to the information collected in this study?
Your answers will be private and will not be connected with your name, just an ID number so we can see what people learn over time. We will not share your answers with your supervisor, UAF instructor, or anyone else. All results that are made public will be summary results, they will not report anything that would identify any particular person. Summary results will be shared with Tribal leadership and may appear in scientific literature.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

This trial will be registered and may report results on www.clinicaltrials.gov. This site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Lisa Wexler
Email:lwexler@umich.edu
Phone: (413) 824-1190

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933 For International Studies, include the appropriate calling codes.
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

You can also contact Dr. Joseph Klejka from the Yukon-Kuskokwim Health Corporation at 907-543-6024 email him at joe_klejka@ykhc.org if you have questions regarding your rights as a research participant.

The UAF Institutional Review Board (IRB) is a group that looks at research projects involving people. This review is done to protect people like you who are part of research. If you have questions or concerns about your rights as a research participant, you can contact the UAF Office of Research Integrity at 474-7800 (Fairbanks area) or 1-866-876-7800 (toll-free outside the Fairbanks area) or uaf-irb@alaska.edu.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study
By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy

with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____