

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

ID: 1R01MH112458-01A1

June 10, 2018

PROTOCOL APPLICATION FORM

SOCIAL, BEHAVIORAL, AND EDUCATIONAL EXPEDITED REVIEW
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL
RESEARCH

University of Massachusetts Amherst

Protocol ID: 2017-4429

Title: Promoting community conversations about research to end native youth suicide in rural Alaska (Bering Straits)

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Human Subjects Training Completed?			Y	

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http://www.umass.edu/research/compliance/human-subjects-irb/training-education-and-outreach/citi-trai > Human Subjects Training Completed?				

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Other Personnel				
Name of Other Personnel	Degree:	Title	Department Name	E-mail
http://www.umass.edu/research/compliance/human-subjects-irb/training-education-and-outreach/citi-trai > Human Subjects Training Completed?				

				Training Completed?
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Subject Population(s) Checklist

Yes/No

- Minors (under 18) Y
- Pregnant Women Y
- Cognitively Impaired or Decisionally Challenged N
- Older individuals (75 and over) Y
- Healthy Volunteers Y
- Students/Employees Y
- International Populations N
- Prisoners N
- Other (i.e., any population that is not specified above) N

Study Location(s) Checklist

Yes/No

- University of Massachusetts Amherst N
- Baystate Medical N
- University Health Services N
- Hartford Hospital N
- Other (Specify other Study Locations) Y

Villages in the Bering Straits region of Alaska, served by the collaborating tribal health organization, Norton Sound Health Corporation

General Checklist

Yes/No

- Training Grant? Y
- Funded Study (or proposal submitted to sponsor)? Y
- Cooperating Institution(s)? Y

University of Nebraska

- Federally Sponsored Project? Y
- Human blood, cells, tissues, or body fluids (tissues)? N
- Subjects will be paid for participation? Y

Funding Checklist

Funding - Grants/Contracts

Funding Administered By UNIVERSITY	OGCA #:
GAID #:	Funded By: National Institutes of Health (NIH)
Principal Investigator: Lisa Wexler	

Grant/Contract Title

- Y Are contents of this protocol the same as described in grant/contract proposal?
Y Is this a training grant?
Y Are any subcontracts issued under this grant?

Funding - Fellowships**NONE****Gift Funding****Dept. Funding****Other Funding (e.g., FRG, Healey)****Social, Behavioral & Education Research Expedited Review**

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. N **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 31,32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) an investigational device exemption application (21 CFR Part 812) is not required; or
 - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. N **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
 - i) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - ii) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. N **Prospective collection of biological specimens for research purposes by non invasive means.**
4. N **Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

Examples:

- i) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - ii) weighing or testing sensory acuity;
 - iii) magnetic resonance imaging;
 - iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. N **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**
6. Y **Collection of data from voice, video, digital, or image recordings made for research purposes.**
7. Y **Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

1. Purpose of the study

a) Provide a brief lay summary of the purpose of the study.

Rural Alaska Native youth have a suicide rate that is 18 times that of all American youth, and help is mobilized for youth only when someone is in imminent risk of suicide. To initiate activities to promote wellness, safety and support before a suicide crisis, our tribal working group developed and piloted PC CARES: Promoting Community Conversations About Research to End Suicide. This promising and feasible educational intervention is led by local facilitators, and offers village stakeholders a series of learning circles to study ?what we know? from prevention research and figure out how they can apply it to their jobs, families, and lives. The goal of the intervention is to enhance knowledge, skills and attitudes among service providers, family members and tribal residents so that they promote wellbeing, recognize risk, support vulnerable youth, and work with others in their community to take supportive and safety actions when they notice signs of vulnerability. Our community intervention utilizes indigenous pedagogy and prevention science to increase village members? and service providers? capacity to find ?up-stream?, self-determined and culturally-responsive ways to reduce suicide risk. Using a community-based, participatory research (CBPR) approach, our specific aims track change on both individual and community levels.

b) What does the Investigator(s) hope to learn from the study?

Specific Aim 1: Track the impact of PC CARES on participants' knowledge, attitudes and behavior, and identify key factors influencing these outcomes over time.

Specific Aim 2: Document how PC CARES affects the number and type of interactions aimed at preventing youth suicide and promoting wellness in participating communities, and describe changes in the supportive social networks of young people before and after the intervention.

IMPACT: Our scale-able model offers under-resourced Native communities a practical method for translating scientific research into culturally relevant efforts to reduce suicide risk factors, and increase safety, help-seeking and support to prevent suicide.

2. Study Procedures

a) Describe all study procedures.

Local Steering Committee Members

Before starting any dialogue, the Local Steering Committee (LSC) members will go through an ethics training along with an informed consent procedure given that their dialogue will be another form of data. 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. This group is co-facilitated by the PI Wexler, and participants are trained in ethical standards of research. Notes from the LSC meetings will be used to track the research process, to document changes and alternatives in the PC CARES curriculum and to identify key areas to consider in data collection and analysis. This on-going record will describe the key factors and mechanisms local people prioritize and believe contribute to strengthening village local safety nets in ways that reduce suicide risk. Each member will be asked for their permission to document conversations through minutes, and members will be sent minutes to review after each meeting. These minutes will be reviewed at the start of the next meeting and officially confirmed so the record reflects LSC members' views as to discussion foci and the decisions made. 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.

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 this Human Subjects document and in accompanying informed consent forms. Inupiaq and other community members with access to project data (de-identified) will be required to take a modified training that covers the key points and overall content of the Collaborative Institutional Training Initiative (CITI) curriculum and accompanying exams, but does so in a more culturally-responsive way. The content of the course will also include relevant IRB concerns from Alaska research (e.g. the Barrow alcohol study in addition to Tuskegee) to emphasize the importance of human subjects protections. This three-hour training will be given to all LSC members in the first session, and refreshers will be given before each data sharing session in subsequent years.

Aim 1: Training of Facilitators

PC CARES facilitators will be adults (over 18), living and/or working in the participating, predominantly Alaska Native village. These persons will be invited to participate based on the local service ecology and LSC members' and other stakeholders' community knowledge. More specifically, people who are in positions that allow them to facilitate the village learning circles, such as the village-based counselor, youth leader advisor, Wellness worker along with respected Elders, will be identified through our LSC members and other community partners. Once identified and they express interest, Kawerak Wellness Director Pungawiyi and Norton Sound Behavioral Health Director Johnson-- will seek permission from their respective supervisors to allow village-based workers (particularly village-based counselors, youth workers, community health aids and family workers) to be facilitators of PC CARES.

This permission is necessary since we assume that facilitators will be offering learning circles during their regular workdays, if they are employed. This permission will allow us to move ahead with planning to support future PC CARES facilitators in attending our facilitators' training, and for those who are interested, receiving 3 college credits in Human Services through the University of Alaska Fairbanks. We will make clear to facilitators that they can withdraw their participation at any time, and that their performance as facilitators will be private: meaning we will not share this information with their employers.

We aim to train 2-4 facilitators from each participating community who are interested and are already in positions that lend themselves to the effort (e.g. village-based counselors, youth leader advisors, wellness workers). The 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.

Participants in the training of facilitators (TOF) will be informed about the data collection procedures within the training, including a pre-post paper TOF survey measuring confidence, facilitator knowledge and readiness. They will be invited to do this pre-post survey, and will have the option of not filling it out without repercussions. Receiving college credit is not tied to whether or not facilitators fill out these surveys. They can opt out of answering surveys and still get college credit for their participation in implementing the Learning Circles.

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 8 areas of content in ?What we Know.? Assessment, done at the end of the week-long TOF, will involve 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.

Aim 1: Learning Circle Participants

The PC CARES learning circles, in keeping with tribal partners' preferences, will be open to every adult and older youth (age 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. Those who are actively suicidal or in distress will also be excluded from participation since the learning circles are not intended to be a therapeutic intervention but rather an educational one aimed at sharing information with those able to take prevention actions. People attending learning circles generally include the first responders to suicidal ideation in a community. Specifically, the itinerant licensed mental health provider and a local village-based counselor will either be facilitating each PC CARES session or they will be invited to attend. If someone who is in distress comes to a PC CARES learning circle, the first responder will ensure that their needs are addressed outside of the PC CARES intervention.

Trained facilitators will recruit for 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. Participation in PC CARES will be voluntary, but will seek to have a variety of youth and adults. We will target people who are in the most advantageous position to bridge the gap between service providers and community members, meaning those who have many ties in the community and who are a part of a variety of social networks. The people who participate in the learning circles are expected to be local

paraprofessional, religious and tribal leaders, itinerant professionals along with community members (parents, Elders, aunts and uncles), including youth 15 and older. We will also actively recruit young people who are Youth Leaders, a school-based youth peer mentoring program in all area schools and people in informal support roles including (but not limited to) parents, Anas and Tatas, Apas, mothers and fathers, teasing cousins, and aunts and uncles family members, pastors, teachers, principals, youth leaders, family service workers, school classroom aids, sports coaches, Temporary Assistance for Needy Families (TANF) workers, tribal leaders, city workers, Norton Sound family service workers and other interested people. People in these informal social roles, particularly those who are frequently relied upon, will be personally invited to participate in PC CARES. These social roles are essential for village wellness and safety.

Before the PC CARES intervention begins, we will collect baseline data from a wide swath of the people over age 15 in each participating community. This will be done in tandem with the Social Network surveys described in Aim 2 on the same computer interface, so the PC CARES baseline survey and the initial Social Network Survey will be combined into one survey. Some of these respondents will self-select to participate in the PC CARES intervention, and others will not. The data collected here will contain 53 items, including demographic data (gender, age, ethnicity, suicide training, and their primary reason for coming to the learning circle (parent, teacher, village-based counselor, mental health clinician etc.), baseline data on readiness to act, collaboration, prevention and health promoting behaviors done in the past 3 months, and will offer participants the option to consent (or not consent) to be contacted for a follow-up interview within three months after the last learning circle in that community. If a community member attends a PC CARES learning circle, but did not complete the demographic and baseline survey, they 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 55-item survey, which includes the same items from the baseline survey without the demographics, 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 envelope to the research team.

Each PC CARES participant will receive a \$20 incentive for purchases from the village store or from the AC grocery store in Nome (which will box and send purchases to villages) for completing a 15-20 minute survey.

Approximately 3 months after the final PC CARES learning Circle, we will again use the iPad-like tablets to collect data from all who responded to the initial (baseline) survey and all who participated in the PC CARES intervention. This survey will be identical to the baseline survey, and again will be done in combination with the Social Network surveys in Aim 2.

The PC CARES learning circles in the villages will be recorded if the participants give permission for this to be done. 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 anytime during the session, you

change you 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 envelop 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. The audiotaped sessions will be sent to the research team on a password-protected thumb drive after each session. These password-protected thumb drives will be stored in a locked cabinet for the duration of the study. After the research is completed, the recordings will be destroyed.

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

Aim 2: Social Network

Social Network data will be collected both before the PC CARES learning circles begin(Pre), and again approximately 3 months after the last Learning Circle ends (FollowUp) in each village. This data collection will be open to anyone in the village aged 15 or older. Within each village, we will specifically recruit people who we expect to attend PC CARES Learning Circles (Pre) People who attended PC CARES learning circles (Follow Up), and people who inhabit certain pertinent formal or informal roles in the village (Pre and Follow Up).

For data collection before the intervention we will recruit widely in each village, focusing on those who we expect will attend PC CARES such as 2-3 people from each village and regional-level network position (n=~20-30 from tribal, health, behavioral health, school, etc in each village; from Norton Sound doctors, CHAP supervisors, School District-level health counselors, etc in the region), whether or not they attend any PC CARES learning circles. Our pilot research produced a roster of 12 social ecological roles within the village (hereafter: 'network positions') that are relevant to suicide prevention. These network positions include 7 organizational affiliations: individuals interacting with young people on the basis of their position in schools, health care facilities, mental health services, social services, religious institutions, tribal governments, city governments (including law enforcement). The roster also includes 5 family roles: Elder; parent or anayakaak; a sibling or cousin who is close: aakaura#a; other adult family member who is also a mentor: ilatka, or friend. The final ?network position? will be 'Other', with an open-ended response. We will recruit all available people within the village institutions, youth (ages 15-24), and others in the village interested in participating.

For data collection after the intervention, we will recruit all those who attended PC CARES, and will target all of those in the 7 formal network positions, whether or not they participated in our intervention. We also aim to have youth (ages 15-24), and community members who fill the 5 identified informal support roles and others (e.g. Elders, ilatka, mentors) to participate in each village. Each person filling out our network survey will report on a range of ties across all 12 network positions.

Recruitment for service providers will seek to represent all entities within a village (tribal, city, health, behavioral health, school, religious). For general community member participation,

recruitment will be open to all village residents, meaning that anyone in the community 15 years old or older will be allowed to participate. Everyone filling out a 15-20 minute survey will receive \$20.

Our recruitment efforts will involve inviting people who attended PC CARES to participate first and doing respondent driven sampling (RDS). 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 coupons that are redeemed for \$5 if the person (or people-up to 3) they recruited completes an interview. This means that each respondent can receive a stipend of \$20 for completing a survey, and an additional \$15 for recruiting 3 other people to fill out a survey, for a total \$35 per respondent. By starting with those who attend PC CARES sessions, we hope to document diffusion effects: meaning to learn how PC CARES impacts those who attend the learning circles, people close to them and others in the community. 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 Inupiaq 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 and to understand what changes happen between during adolescence. Our recruitment for young people will start by collaborating with the schools. We will set up a table in the school lobby after school to let students know about the survey, and to recruit them to participate. 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.

Total, in each village, we expect to interview between 65 and 150 persons, including those holding network positions in the village organizations and additional members of the community holding network positions in the informal networks, especially youth (ages 15-24).

Social Network Interviews will involve a computer interface that documents demographics, including Basic Participant Characteristics: ethnicity, gender, age, organizational affiliation: School, Norton Sound: health care, Norton Sound: mental health services, Norton Sound: social services, Kawerak: social services, Church, Tribe, City (including law enforcement), Other: and Job: fill in the blank:

Our surveys will be done on tablet computers with touch screens, allowing respondents to skip questions that do not apply to them, and to get follow-up responses tailored to their selections. Each of these 'up-stream' prevention and supportive interactions will be listed 10-11 to a page--with the prompt: 'In the last 3 months did you?'. If they mark 'yes' they did the action in the last 3 months, a follow-up screen asks them with whom and how often (see example below).

Social Network Survey Measures [Example]

In the last 3 months did you?

Openly share your thoughts and feelings

YES NO (If no, skip to the next question)

With whom did you openly share your thoughts and feelings?

(Choose as many as you want out of 12 network positions?)

- Friend Sibling or cousin: aakaura#a
- Elder, including Ana and Taatas
- Parent or anayakaak: the person who raised you
- Other adult family member who is also a mentor: ilatka
- Someone at School (teacher, principal, janitor?)
- CHAP/Health Aid at the Clinic

- o Norton Sound Counselor
 - o School Counselor
 - o Family worker or other social worker from Kawerak
 - o Priest, pastor or other Church leader
 - o Someone working for the Tribe
 - o City worker (including the Village Public Safety Officer, VPSO)
 - o Other: _____
- *** When one of these positions is selected, respondents will be asked

HOW OFTEN?

Once

A couple times

Many times

The iPad interface will allow the respondent to privately and quickly with a touch screen--answer these questions to document the occurrence or absence of these specific interactions in the previous 3 months for each kind of person (social or professional role). Done on a computer interface to protect privacy, respondents will be able to touch their answers, and press ?enter? so their answers are secured. Social Network surveys will be conducted before the PC CARES intervention begins, and then again approximately 3 months after the final Learning Circle in each village.

- b) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.**

If all participants agree, Learning Circle sessions will be audio recorded and saved onto a thumb drive. Facilitators will send the thumb drive to Umass where the audio will be transcribed with any identifiers deleted. After the research is completed, the recordings will be destroyed.

- c) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).**

No deception will be used.

3. Background

- a) Describe past findings leading to the formulation of the study.**

Youth suicide continues to disproportionately affect Indigenous communities, and has been difficult to detect early, prevent and reduce. In rural Indigenous communities, 8-16 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.

4.(a-f) Subject Population

- a) **State how many subjects you propose to use and state the rationale for the proposed number.**

We expect to conduct this study in 9 different villages.

In each village, we expect to train 2-4 facilitators, have 15-20 Learning Circle participants, and have 65-150 participants in the social network surveys. This comes to a minimum of 82 participants per village to a maximum of 174 participants per village.

Across 9 villages, we expect to have no more than 1566 subjects.

- b) **Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).**

Participation in PC-CARES will be voluntary, but will seek to have a variety of community members who are 'natural helpers', including (but not limited to) parents, family members, pastors, teachers, principals, youth leaders, family service workers, school classroom aids, sports coaches, and other people interested in contributing to wellness and the prevention of suicide.

This study will include anyone aged 15 or older who lives or works in the Alaskan villages in the Bering Straits region where PC CARES will be implemented.

We have no inclusion/exclusion criteria related to gender, ethnic background, or (dis)ability. Exclusion criteria includes persons under the age of 15 because the curriculum requires some level of maturity to understand and make use of. Those who are actively suicidal or in distress will also be excluded from participation since the learning circles are not intended to be a therapeutic intervention but rather an educational one aimed at sharing information with those able to take prevention actions. Given that the villages are majority Alaska Natives, we expect that the majority of our participants will be Alaska Natives. We will recruit people who hold specific formal and informal roles to participate in PC CARES, but participation will be open to anyone in the village (aged 15+) who is interested.

- c) **State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.**

Because of the focus of this study-- testing a suicide prevention intervention aimed at encouraging and supporting community members and behavioral health practitioners to notice, reach out to and support youth, ages 15-17, we include young people as participants in our research as participants in the social network surveys and in the PC CARES learning circles.

For participation in the PC CARES learning circles, we will work with local facilitators, tribal leaders and Youth Leader Advisors at the school to recruit youth participation. If learning circle participants are under the age of 18, we will seek parental permission for their participation in data collection (PC CARES participant surveys).

Since suicide risk is highest for Inupiaq 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 and to

understand what changes happen between during adolescence. Our recruitment for young people will start by collaborating with the schools. We will set up a table in the school lobby after school to let students know about the survey, and to recruit them to participate. 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.

- d) **If women, minorities, or minors are not included, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.**

NA

- e) **State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.**

People who will be recruited to be facilitators may include Village-Based Counselors, Youth Leader advisor, Wellness workers, Community Health Aides, and Family workers. Permission from supervisors will be sought to allow facilitators attend the training and to offer the Learning Circles as part of their regular workday.

Since the training and facilitation of PC-CARES are currently within their job responsibilities, there will not be compensation for these tasks. However, additional research tasks such as completing surveys, sending in videotaped session will receive participant compensation. All facilitators will receive \$50 Amazon gift card when they return completed measures, videos and consent to contact documentation after facilitating a PC-CARES session.

- f) **State the number, if any, of subjects involved in research conducted abroad and describe any unique cultural, economic or political conditions.**

NA

4.(g-i) Subject Population

- g) **Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach all recruitment materials in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.**

Facilitators:PC CARES facilitators will be adults (over 18), living and/or working in the participating, predominantly Alaska Native village. These persons will be invited to participate based on the local service ecology and LSC members? and other stakeholders? community knowledge. More specifically, people who are in positions that allow them to facilitate the village learning circles, such as the village-based counselor, youth leader advisor, Wellness worker along with respected Elders, will be identified through our LSC members and other community partners. Once identified and they express interest, Kawerak Wellness Director Pungawiyi and Norton Sound Behavioral Health Director Johnson-- will seek permission from their respective supervisors to allow village-based workers?particularly village-based counselors, youth workers, community health aids and family workers?to be facilitators of PC CARES.

PC CARES Participants:The PC CARES learning circles, in keeping with tribal partners? preferences, will be open to every adult and older youth (age 15+), and will take place in public spaces in each village (e.g. tribal building, school, city building). There are no exclusion criteria for adults participating in the training, but do put an age limit on participation since the curriculum requires some level of maturity. Trained facilitators will recruit for 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. Participation in PC CARES will be voluntary, but will seek to have a variety of youth and adults. We will target people who are in the most advantageous position to bridge the gap between service providers and community members, meaning those who have many ties in the community

and who are a part of a variety of social networks. The people who participate in the learning circles are expected to be local paraprofessional, religious and tribal leaders, itinerant professionals along with community members (parents, Elders, aunts and uncles), including youth 15 and older. We will also actively recruit young people who are Youth Leaders, a school-based youth peer mentoring program in all area schools and people in informal support roles including (but not limited to) parents, Anas and Tatas, Apas, mothers and fathers, teasing cousins, and aunts and uncles family members, pastors, teachers, principals, youth leaders, family service workers, school classroom aids, sports coaches, Temporary Assistance for Needy Families (TANF) workers, tribal leaders, city workers, Norton Sound family service workers and other interested people. People in these informal social roles, particularly those who are frequently relied upon, will be personally invited to participate in PC CARES. These social roles are essential for village wellness and safety.

Social Network Survey:For data collection before the intervention we will recruit widely in each village, focusing on those who we expect will attend PC CARES such as 2-3 people from each village and regional-level network position (n=~20-30 from tribal, health, behavioral health, school, etc in each village; from Norton Sound doctors, CHAP supervisors, School District-level health counselors, etc in the region), whether or not they attend any PC CARES learning circles. Our pilot research produced a roster of 12 social ecological roles within the village (hereafter: ?network positions?) that are relevant to suicide prevention. These network positions include 7 organizational affiliations: individuals interacting with young people on the basis of their position in schools, health care facilities, mental health services, social services, religious institutions, tribal governments, city governments (including law enforcement). The roster also includes 5 family roles: Elder; parent or anayakaak; a sibling or cousin who is close: aakaura#a; other adult family member who is also a mentor: ilatka, or friend. The final ?network position? will be ?Other?, with an open-ended response. We will recruit all available people within the village institutions, youth (ages 15-24), and others in the village interested in participating.

For data collection after the intervention, we will recruit all those who attended PC CARES, and will target all of those in the 7 formal network positions, whether or not they participated in our intervention. We also aim to have youth (ages 15-24), and community members who fill the 5 identified informal support roles and others (e.g. Elders, ilatka, mentors) to participate in each village. Each person filling out our network survey will report on a range of ties across all 12 network positions.

Recruitment for service providers will seek to represent all entities within a village (tribal, city, health, behavioral health, school, religious). For general community member participation, recruitment will be open to all village residents, meaning that anyone in the community 15 years old or older will be allowed to participate.

- h) Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.**

Facilitators: Will receive \$50 Amazon gift card for each Learning Circle that they send paper surveys and thumbdrive with audio recording for a maximum of \$200.

PC CARES participants: Will receive \$20 giftcard/credit at the local grocery store for each survey they complete after each Learning Circle for a maximum of \$80

Social Network survey: Anyone who fills out a survey will receive \$20 cash when they complete the survey. In addition, they can earn up to \$15 cash more if they are able to recruit 3 friends to also complete the survey. (They will get \$5 for each new participant they recruit, with a maximum of \$15 for recruitment. Each person can earn a maximum of \$35 cash for the Social Network Survey (\$20 +\$15).

- i) Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be**

1-session for a total of 90 minutes).

TOF: 40 hours to take place over the course of 1 week. People who are trained to be facilitators will take a survey at the beginning and again at the end of the week-long training. These surveys should take approximately 15 minutes to complete.

Learning Circles: 4 sessions taking place over 4 months or less. Each session is expected to be 3 hours long. Participants will take a survey after each learning circle session. Each survey will take approximately 15 minutes.

Social Network Survey: This electronic survey will take approximately 20 minutes to complete and participants will be asked to fill it out before PC CARES begins and again approximately 3 months after it ends in their village.

We will implement PC CARES and data collection across 9 villages in 3 cohorts or 3 villages each. Each village will be involved in the study for no more than 1 year, but it will take 3 years to implement and collect data across all 9 villages.

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a) Describe the risks related to:

Physical well-being

None

Psychological well-being

Emotional risks are inherent merely because our research is interactive and focuses on the tragedy of suicide. Suicide is a heart-wrenching issue that has affected almost all of the people living in Bering Straits and Northwest Alaska, so discussions about it are sometimes painful. However, all such discussions that occur as part of this project are aimed at prevention. Participants will be self-selected, according to their desire to contribute to solving this devastating issue, and village learning circles offer community members and professionals a variety of perspectives to help them find tools to address the issue. This productive approach to a difficult issue has felt empowering to those who have participated thus far, rather than hurtful.

Aim 1: There are two basic groups of participants in Aim 1, and each has a distinct risk-reward configuration related to participation. These are the PC CARES Facilitators, and the PC CARES learning circle participants.

The facilitators of PC CARES will take pre-post surveys to assess their perceived readiness to facilitate PC CARES. The survey should not cause distress, but may call attention to some areas that the facilitator is less comfortable facilitating or some aspect of facilitation s/he is not sure about. Additionally, facilitators will participate in a group true and false exercise that affords privacy (everyone is facing to the front of the room), but could be stressful if one doesn't know the answer. In our pilot work, this exercise was more like a game than a test: people seemed to enjoy it. Lastly, pairs of facilitators will be asked to facilitate a learning circle while at the training and to debrief the session with trainers and peers. This experience may be slightly stressful for these future facilitators.

Importantly: facilitators will self-select into the position. We have support from key regional tribal organizations, who will allow their staff to participate as facilitators if they wish to as part of their job. If they are 'shy' or not interested in facilitating PC CARES for any reason, they will not become facilitators.

Although we feel that this careful tracking of the trainings offered by trainers is important, the audio recordings of PC CARES sessions signal a potential discomfort to facilitators (although, to date, we have not heard this after conducting 61 learning circles in NWA). If facilitators are not able to facilitate learning circles with fidelity and accuracy--meaning they do not meet minimum requirements--they will be targeted for additional training and support. This result will in no way effect their professional advancement, but could feel awkward. The PI has established a long history with the tribal organization, and has developed long-term relationships with practitioners working there over the last 9 years in Bering Straits and 22 years in NWA. The length of these relationships shows the PIs commitment to sustaining working relationships and flexibly negotiating next steps without hurting people's feelings. Beyond this, the on-going support sessions-biweekly meetings with facilitators--can allow for continued education and support with an emphasis on improving performance.

PC CARES learning circle participants will be asked to fill out a 15-20 minute survey after each Learning Circle they attend. These surveys are minimal risk, asking about the person's knowledge of prevention and health promotion, their attitudes about suicide prevention and their behaviors related to prevention and health promotion. They will also be asked about their satisfaction with the PC CARES learning circle they just attended. To even further reduce risk, participants will be told they can skip any question they do not want to answer.

PC CARES learning circle participants will also be asked if they will allow us to audio record the session. This request could cause them to feel uncomfortable, but the procedures we have put into place--with an indication of agreement or not with thumbs up or down instead of verbally--has allowed people to quietly and unobtrusively not give their permission. If given unanimous permission, PC CARES participants will be informed of this intention and assured that the audiotaped sessions are for quality assurance.

Aim 2: The community members and service providers who will participate in the social network interviews will be giving information in a way that protects confidentiality (private setting, interacting with a computer screen, identifying data with ID rather than name). Since much of this data focuses on interactions focused on support-giving, health promotion and suicide intervention, there can be emotional risk. It is also possible that the questions could highlight ways in which a person might have given more help in solving a problem or reacting to suicide vulnerability. There will be a screen at the end that highlights helping resources available locally, regionally and nationally (crisis lines). We have conducted similar surveys in Northwest Alaska, and even people who recently lost a loved one to suicide, remarkably found that filling out the survey was helpful and good for them to share their experiences. Thus, we believe the interactive database data collection methods are worded in ways that are supportive to respondents and pose minimal risk.

Economic well-being

None

Social well-being

None

Breach of confidentiality (including audio/video taping)

To assure the confidentiality of all data and to avoid public disclosure of sensitive, personal information, all data will be safeguarded by assigning identification numbers to participants and codes to data collected for the project. ID numbers and codes will be used for written, audio sources of data, transcripts, observational field notes, and all related project documents. Participants providing surveys containing identifiers will enclose their individual survey in a sealed envelope. It will travel in that sealed envelope back to the research team, where the survey will be

given and ID and de-identified before the data is entered. Identified documents will be kept in a secured filing cabinet in the site PI's office at the University of Massachusetts, Amherst. All personal identification data (Link File) will be stored on a password protected hard drive, physically separate from the data management and analysis sections of the main project site. Unique passwords will be assigned to data management and data analysis team members. Confidentiality of data will be a high priority of project staff, with unique participant identifiers rigorously protected by team members.

- b) **For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)**

NA

- c) **Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.**

PC CARES is a community education model that brings together community leaders, workers, family members, friends and practitioners in each community to learn "what we know" about suicide prevention and health promotion, and to discuss "what it means" and "what they want to do" in relation to prevention in their community, work and homes. Those attending these learning circles generally include the first responders to suicidal ideation in a community. Specifically, the itinerant licensed mental health provider and a local village-based counselor will either be facilitating each PC CARES session or they will be invited to attend. One or both of these mental health counselors attended the learning circles in our pilot research. These mental health providers are the region's primary response to suicidality. If a participating community member is at immediate risk for suicide, the mental health clinician and village-based counselor will intervene as appropriate. Indeed, they are the providers who would be called to intervene in any case. Important to note, PC CARES learning circles are aimed at natural helpers in the community, not those who are themselves at risk for suicide. Nonetheless, the participating mental health providers are capable and responsible for identifying if there is a person at immediate risk of suicide and responding appropriately (based on Norton Sound Behavioral Health Services procedures). Facilitator training for those hosting PC CARES learning circles includes crisis intervention for suicide, and each learning circle reminds participants about local, regional and state resources for prevention. Together, the design and implementation of PC CARES minimizes this concern.

6. Benefits

- a) **Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).**

While this intervention is intended to have benefits for participants and for the entire community, participation in the research (filling out surveys, allowing audio recording) may not have any direct benefit on participants. Participating in the research will help to move future suicide prevention efforts forward and to make them optimally effective.

The benefits of the study will be the introduction of an intervention "PC CARES" into 9 Alaska Native villages. This intervention is intended to increase community networking related to youth risk and suicidality, and provide a deeper cultural and community understanding of effective suicide intervention and care for those who provide services. People that participate in the intervention will increase their knowledge and skills related to suicide prevention and increase their understanding of additional and accessible resources for prevention. The facilitators who participate in the Training of Facilitators will potentially benefit from the additional training and on-going support. Lastly, the Local Steering Committee members will gain knowledge and understanding of the cultural, structural and service-based factors that are involved in suicide prevention. It is also expected that all participants in the project will experience increased

awareness of the value of research to improve health outcomes.

7. Procedures to Maintain Confidentiality

- a) **Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.**

Many of the villages in this study have limited access to the internet. Therefore, facilitators will send all data to the research team via USPS in self-addressed stamped envelopes provided by the research team.

To assure the confidentiality of all data and to avoid public disclosure of sensitive, personal information, all data will be safeguarded by assigning identification numbers to participants and codes to data collected for the project. ID numbers and codes will be used for written, audio sources of data, transcripts, observational field notes, and all related project documents. Participants providing surveys containing identifiers will enclose their individual survey in a sealed envelope. It will travel in that sealed envelope back to the research team, where the survey will be given and ID and de-identified before the data is entered. Identified documents will be kept in a secured filing cabinet in the site PI's office at the University of Massachusetts, Amherst. All personal identification data (Link File) will be stored on a password protected hard drive, physically separate from the data management and analysis sections of the main project site. Unique passwords will be assigned to data management and data analysis team members. Confidentiality of data will be a high priority of project staff, with unique participant identifiers rigorously protected by team members.

- b) **If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.**

NA

- c) **Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.**

When participants complete their consent form, they will place it in a blank envelope (provided by research team). The facilitator will collect all enveloped consent forms and put them in a self addressed stamped envelope that will go by USPS to the research team.

The same process will happen with any surveys. After completing a survey, each participant will place their survey in a blank envelope. The facilitator will collect the enveloped surveys and place them all in a self addressed stamped envelope to mail to the research team.

Consent forms and surveys will travel in separate envelopes.

Once the research team receives envelopes from the facilitators:

All paper surveys will be kept in a locked file cabinet in the project coordinator's locked office. All electronic data will have a Study ID rather than name or other identifying information. All Link Files will be kept on a password protected hard drive, physically separate from the data management and analysis sections of the main project site.

Only trained and relevant members of the research team will have access to link files or data with identifiers. LSC members will have access to aggregated and de-identified data.

Hard copies of consent to contact sheets with names and contact information will be stored separately from any data, and will be in locked cabinets at the University of Massachusetts Amherst office of the project coordinator.

8. Potential Conflict of Interest

- a) N Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- b) N Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?
- c) N Is any Investigator(s) a member of an advisory board with the Sponsoring company?
- d) N Do any investigators receive gift funds from the Sponsoring company?
- e) N Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1 Consent Form facilitators

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

9.2 Consent Form pc cares participant

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

9.3 Consent Form social network

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

9.4 Consent Form stamped 01/16/18 facilitators

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

9.5 Consent Form stamped 01/16/18 participant

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

9.6 Consent Form stamped 01/16/18 social network

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

10.1 Assent Form pc cares assent

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

How is assent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

10.2 Assent Form assent for social networks

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

How is assent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

10.3 Assent Form stamped 01/16/18 pc cares assent

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

How is assent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

10.4 Assent Form stamped 01/16/18 social network assent

Who is obtaining child assent and parent consent? The person obtaining consent must be knowledgeable about the study and appointed by the PI to perform this function of the research.

How is assent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Pre-post-follow-up survey (PC CARES)	12/08/2017
Questionnaires	Social Network Survey Questions	12/08/2017
Sponsor's Protocol Amendments	R01MH112458-HS-44-Wexler-PI	12/08/2017
Sponsor's Protocol Amendments	Wexler_PAR_humansubjects2012-06-20-revised-12-8-17	12/08/2017
Federal Grant/Sub-contract	PAR-PCCARES-Proposal-2388-7/08	12/08/2017
Advertisements	Recruitment Script-PC-CARES	01/10/2018
Other	PCCARES Facilitator Guide	01/10/2018
Other	Manual for Training Facilitators	01/10/2018

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the

IRB as soon as possible, but not later than ten (10) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days;

Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

Y The Principal Investigator has read and agrees to abide by the above obligations.

Comments

Comment Title	Comments / Responses	Response Necessary
NEW: 02/08/2018		
Cycle: 1		
1	<p>Thank you for your recent submission to the IRB. If you have any questions after reviewing these comments and suggestions, please contact Joanna an IRB Analyst in the Human Research Protections Office at jmboody@umass.edu or (413) 577-0691. Your protocol has undergone preliminary review and some additional information or clarification is needed as indicated below: Study Procedures: 1. In section 2a, please clarify if the PC CARES FACILITATOR will retain any credits if participation in the study ends. Please clarify if they can continue until the end to receive course credit if they are to withdraw from the study itself. 2. In section 2a, please clarify if there will there be internet access to transfer the audio via BOX (http://www.umass.edu/it/box) rather than mail a thumb drive or if there will be limited or no internet access. 3. In section 4b, please clarify the age range as 13 is mentioned as well as 15+. 4. In section 4h, please clarify the maximum amount a Social Network Survey Participant can receive in addition to their maximum of 3 referrals equaling an additional \$15 on top of their \$20 for the survey. 5. In section 5, please address how you will immediately review any materials that may suggest a participant is suicidal to get that individual aide as soon as possible. 6. In section 6a, please first acknowledge that there may be no direct benefits to participants before discussing intended benefits. 7. In section 7a, please clarify if the option of using mail return for data transfer is due to limited or no access to the internet. 8. In section 7c, please discuss the storage of the informed consent documents and handling prior to receipt by project coordinator at UMass.</p> <p>1. The course credit and their participation in the research are separate issues. They can receive credit for conducting the 4 Learning Circles whether or not they participate in the research, and can choose not to receive credit and participate in the research (complete surveys and audiorecord their LCs). We thought the option of college credit would be appealing to some, and offer another possible benefit of capacity building if participating facilitators are</p>	Y

Comment Title	Comments / Responses	Response Necessary
	<p>interested. Language has been added to section 2a to clarify that the college credit is not reliant on participation in the research. 2. Internet is not available in all the villages, and in the pilot, found it was user-friendly and easy enough to send the thumb drive with audio. This language has been added in section 2a. 3. We plan on inviting those 15+, but will be meeting with our local steering committee to get their input on extending the range to younger youth. If they decide to do so based on their local knowledge, we will modify this application. This has been corrected in section 4b and in 2a. 4. Participants can receive up to \$35 if they complete a survey (\$20) and if the 3 people they refer come in to do a survey (\$5 + \$5 + \$5). This has been clarified in section 4h. 5. Our surveys do not include any questions related to participants' suicide risk. So, nothing in our data collection would give any indication of someone's risk status. 6. The following paragraph has been added to section 6a: "While this intervention is intended to have benefits for participants and for the entire community, participation in the research (filling out surveys, allowing audio recording) may not have any direct benefit on participants. Participating in the research will help to move future suicide prevention efforts forward and to make them optimally effective. 7. The following sentence has been added to section 7a: "Many of the villages in this study have limited access to the internet. Therefore, facilitators will send all data to the research team via USPS in self-addressed stamped envelopes provided by the research team. 8. The following language has been added to section 7c: "When participants complete their consent form, they will place it in a blank envelope (provided by research team). The facilitator will collect all enveloped consent forms and put them in a self addressed stamped envelope that will go by USPS to the research team." The same process will happen with any surveys. After completing a survey, each participant will place their survey in a blank envelope. The facilitator will collect the enveloped surveys and place them all in a self addressed stamped envelope to mail to the research team.</p>	
2	<p>Informed Consent: Facilitators Consent: Please clarify the 3-credits that can be earned in the informed consent. **Please note to remove all older versions of the informed consent when attaching updates for review. Pc cares participant consent & assent: Please review this video/audio recording template: http://www.umass.edu/research/form/informed-consent-template-video-use and consider the language and checkboxes used at the end of the template's consent. Please include information regarding recordings that will occur in the learning circles and that participants will be asked to be recorded. Please explain how this will work as it is voluntary in the informed consent document. **Please note to remove all older versions of the informed consent when attaching updates for review.</p> <p>Facilitators Consent form has been edited to include language about the 3 credits and the newest version has been added to this application The following paragraph has been added to the PC CARES participant consent and assent forms: "We would also like to audio record this and future learning circles. Before the audio recorder is turned on for each Learning Circle, you will all be asked if you agree to being recorded. If any one person does not want to be recorded, the audio recorder will not be used. You will have the option at each Learning Circle you attend to agree or not agree to being recorded." Updated versions of the consent form and assent form have been added to this application</p>	Y
3	Attachments: 1. Please include scripts for word-of-mouth recruitment in the schools, churches, tribal offices, public safety offices, and city	Y

Comment Title	Comments / Responses	Response Necessary
	<p>buildings and CB radio announcements as mentioned in section 2a of the protocol. 2. Please include training packets or examples of lessons for facilitators.</p> <p>Script has been attached. The Facilitator Guide which has been used in the past (when we did 9 LCs instead of 4) is attached. Also attached is the training curriculum previously used at the Training of Facilitators.</p>	
Cycle: 2		
4	<p>At this time a final review has been done by the UMass-IRB. From that review, some comments have arisen to address below: Informed Consent/ Assent: Please either clarify why an exact birth date is needed on both forms in section 2a of the protocol or adjust the form to only ask age and not exact birth date. A birthdate is much more identifying than age. Additionally, the participant's code should not be on the informed consent. This code would go on another sheet entirely that was then used to identify all other study data. Please update the forms and any remove any older versions before attaching any updates.</p> <p>DOB and Research ID# have been removed from all Consent and Assent forms. Updated versions are attached to this application.</p>	Y