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 learning circle. 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 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 this training, and your feedback will help us improve PC CARES learning circles.

Do you understand why this project is being done?

Affirmed by youth

WHO CAN PARTICIPATE IN THE STUDY

Who can take part in this study? Anyone aged 15 or older who lives or works in this community.

How many people are expected to take part in this study? We expect to have up to 975 people across the Bering Strait region to participate in this research.

Do you understand who will be in this study?

Affirmed by youth

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 learning circle you attend for a total of 5, if you attend all of the learning circles in your community. We also ask if you will let us contact you for a short follow-up survey in three to six months

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.

Do you understand how the process will work, and what kinds of questions you'll be asked?

Affirmed by youth

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.

Do you understand that you probably won't have any problems participating in this research project, but that if you did feel uncomfortable you are always in control to take a break, skip answering a question or even stop participating all together?

Affirmed by youth

How could I benefit if I take part in this study? How could others benefit? The Learning Circle Surveys 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.

Do you understand that you will not receive any direct benefit from participating, but that your answers will contribute to improved wellness and prevention work in your community?

Affirmed by youth

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.

Do you understand that you can guit this study at any time, and there will be no penalty?

Affirmed by youth

FINANCIAL CONSIDERATIONS

Will I be paid? You will receive a \$20 credit at the local grocery store (or AC in Nome) in your name for each survey that you complete. If you attend all 5 learning circles and fill out a survey after each one, you will receive a total of \$100 in store credit.

Do you understand how much you will be paid?

Affirmed by youth

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? When you've completed your survey, you may seal it in the blank envelope you received. This will protect anyone from seeing your answers. 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. IRB-HSBS General 6.4.2019

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.

Special Requirements A description of this clinical trial will be available on <u>www.ClinicalTrials.gov</u>, 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.

Do you understand that your answers will not be connected with your name and how your data will be stored?

Affirmed by youth

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) <u>akaalaskaareaIRB@anthc.org</u> Norton Sound RERB: (907) 443-3304 / <u>research@nshcorp.org</u> IRB-HSBS General 6.4.2019

YOUR ASSENT

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):