

**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 showing interest in joining our research project aimed at learning how community members support one another and hoping to increase actions that increase wellness and prevent suicide. This research will also evaluate the PC CARES curriculum which aims to increase wellness and suicide prevention in Native Alaskan communities. We will ask you to complete a survey that will take approximately 25 minutes. There is a small risk that the survey questions will remind you of a difficult event or will point out something you are not currently doing for prevention, 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. I want to explain the whole project to you and let you ask any questions. At the end of our visit, you can decide if you want to join in the project by filling out a survey. Participating in this study is totally voluntary and up to you. Even after starting the survey, you can 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. We will stop and ask if you have any questions to make sure that you fully understand before we move on to the next part. It's okay to stop me and ask questions at any time. It will take us about 10 minutes to go over this information.

PURPOSE OF THIS STUDY

The survey asks questions about what you think and what you do for prevention and wellness. We are trying to understand what community members are doing for wellness and suicide prevention, and specifically what supports and protective factors are in place for young people who live here. We hope to learn specifically how community members are there for each other in different ways. This information will inform PC CARES: a community education model that was done in your community over the past 6 months or so. PC CARES brings local people together to learn about prevention and to build a community support network so that youth get the care and support they need before a suicide crisis.

Do you understand why this project is being done?

Affirmed by youth	<input type="checkbox"/>
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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	<input type="checkbox"/>
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INFORMATION ABOUT STUDY PARTICIPATION

What will happen to me in this study? We will be asking you and other people who live in the community if they have done certain things for prevention in the past 3 months, how often and with whom. There will also be questions about how much you know about increasing wellness in your community. Questions might include,

“In the last 3 months, did you openly share your thoughts and feelings?” or “In the last 3 months, did you help someone solve a problem?”

How much of my time will be needed to take part in this study? The survey will take about 25 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 you’ll feel sad about not doing some of the prevention actions described. Remember, you can choose not to answer a question(s), take a break, or stop doing the survey at any time: no problem. You do not have to answer any questions you do not want to answer. Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality.

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? You will not get any direct benefit from participating in this research study, but your answers combined with answers from others in your community will help demonstrate the actions people in your community take related to suicide prevention. It will also help evaluate the PC CARES program that took place in your community and help us to make it more effective in promoting wellness and preventing suicide.

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 quit this study at any time, and there will be no penalty?

Affirmed by youth

FINANCIAL INFORMATION

Will I be paid or given anything for taking part in this study? You will receive a gift of \$20.00 for your participation. You will also be given three recruitment bonuses worth \$5 each. You can make an additional \$15 if all 3 people who got a coupon from you come to take the survey.

Do you understand how much you will be paid?

Affirmed by youth	
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PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my information? Your answers will be private and will not be linked to your name. Your answers will only be attached to a numerical ID that we'll assign to you so we can see if things have changed when we come back in around 6 months. 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 survey data will be stored at the University of Massachusetts. Paper copies will be kept in a locked file cabinet in a locked office and electronic files will be kept on a secure encrypted server that is accessed only with a password. All linkfiles and any data that includes your name or other identifiers will be destroyed at the completion of the research project. The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

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.

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

Affirmed by youth	
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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 1169 Ann 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 ASSENT

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): _____