

**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

Your child is invited to take part in a research study. This form contains information that will help you decide whether your child should 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 your child to complete a survey that will take approximately 25 minutes. There is a small risk that the survey questions will remind your child of a difficult event or will point out something your child is not currently doing for prevention, and the benefit of participating is that your child 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 your child to join in the project by filling out a survey. Participating in this study is totally voluntary and up to you and your child. Even after starting the survey, your child can quit at any time and that will be okay.

This consent form is set up to describe the project and your child's 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 is 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 your child thinks and what your child does 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 will start in a month or so in your community. 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.

WHO CAN PARTICIPATE IN THE 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 over the next 3 years.

INFORMATION ABOUT STUDY PARTICIPATION

What will happen to my child in this study? We will be asking your child 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 your child knows about

increasing wellness in your community. Questions might include, “In the last month, did you openly share your thoughts and feelings?” or “In the last month, 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. We will return in about 6 months, after PC CARES is offered in your community, to see if you are willing to fill out another one of these surveys. We will be back in touch to see if you are interested whether or not you participated in the PC CARES learning circles.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

What risks will my child face by taking part in the study? It is possible that your child may feel sad about not doing some of the prevention actions described. Remember, your child can choose not to answer a question(s), take a break, or stop doing the survey at any time: no problem. Your child does not have to answer any questions they do not want to answer. Because this study collects information about your child, one of the risks of participating is a loss of confidentiality. We are very careful to make sure your answers are private.

How could my child benefit if my child takes part in this study? How could others benefit? Your child will not get any direct benefit from participating in this research study, but your child’s 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 will take place in your community and help us to make it more effective in promoting wellness and preventing suicide.

STOPPING MY CHILD’S PARTICIPATION IN THE STUDY

If my child wants to stop participating in the study, what should I do? Your child is free to leave the study at any time. If your child leaves the study before it is finished, there will be no penalty to you or your child. If your child decides to leave the study before it is finished, please tell one of the persons listed in the “Contact Information” section below. If you or your child chooses to tell the researchers why your child is leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about your for the research unless you or your child ask us to delete it from our records. If the researchers have already used your child’s information in a research analysis it will not be possible to remove your child’s information.

FINANCIAL INFORMATION

Will my child be paid or given anything for taking part in this study? Your child will receive a gift of \$20.00 for their participation.

PROTECTING AND SHARING RESEARCH INFORMATION

How will the researchers protect my child’s information? Your child’s answers will be private and will not be linked to your child’s name. Your child’s answers will only be attached to a numerical ID that we will assign to your child 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 child’s 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 child’s 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 child's 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 the information my child gives be used for future research or shared with others?

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

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

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

CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

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

Principal Investigator: Dr. Lisa Wexler

Email: lwexler@umich.edu

Phone: (413) 824-1190

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

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 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 CONSENT

Parent or Legally Authorized Representative Permission

By signing this document, you are agreeing to your child’s participation 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. 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 for my child to take part in this study.

Print Participant Name

Print Parent/Legally Authorized Representative Name
Relationship to participant: Parent Spouse Child Sibling Legal guardian Other

Signature Date

OPTIONAL CONSENT

CAN WE CONTACT YOU WITHIN THE YEAR TO SEE IF YOU’D BE WILLING TO DO THIS AGAIN?

___ YES ___ NO

If yes:
Name: _____
Email: _____
Text: _____
Phone: _____

Someone else’s contact number (phone/text) who is likely to be able to reach you:

Name: _____
Contact number: _____