Healing and Empowering Alaskan Lives Towards Healthy-Hearts Study

Informed Consent Form

NCT# 02137902

March 14, 2018

NORTON SOUND HEALTH CORPORATION

HEALTHH (Healing and Empowering Alaskan Lives Towards Healthy-Hearts) Research Study

Participant Consent Form – (this will be read to you)

This research study is being conducted in partnership with the Norton Sound Health Corporation (NSHC), led by Dr. Matt Schnellbaecher from the Alaska Native Medical Center (ANMC), Dr. Judith Prochaska from Stanford University, and Dr. Neal Benowitz from the University of California, San Francisco (USCF). The National Heart, Lung and Blood Institute is funding this study.

This form tells you about the research study so that you can choose if you would like to take part. You may ask as many questions as you like and as often as you wish. Take as much time as you need. You will need to sign this form if you choose to take part in this study. A copy of this form will be given to you to keep.

Question 1: What is the name of this research study?

Answer 1: The study name is Healing and Empowering Alaskan Lives Towards Healthy-Hearts Research Study, or HEALTHH for short.

Q 2: Why is this research study being done?

A 2: The following reasons are why the research study is being done:

- To learn more about how we can treat tobacco use and heart disease risks. For example, supporting Alaska Native People with taking their heart medications on a regular basis, eating heart healthy food, and staying active.
- To look at cost-effective interventions to healthcare systems for tobacco use and other heart health risk behaviors among Alaska Native People in rural villages.

Q 3: How many people will be in the research study?

A 3: This study will enroll up to 300 Alaska Native People. All participants will be recruited from the Norton Sound and Bering Strait region of Alaska.

Q 4: What will I need to do if I want to be in the research study?

A 4: We will ask you to do several things if you choose to be in the research study. It will take about 1 hour of your time today:

- You will need to go through this consent form with the study staff. Ask any questions you have. You will be asked to sign the last page of this form, if you agree to be in the study.

- You will be asked questions today and in 3, 6, 12 and 18 months' time about:
    - your contact information
    - your health
    - use of health care services
    - home and work
    - diet
    - alcohol use
    - drug use
    - physical activity habits
    - tobacco use
    - heart health
    - medications that you take for your heart
- You will have up to 5 teaspoons of blood drawn from your arm with a needle today. Then another blood draw in 6 months if you are placed in Group 2, and again in 18 months if you are in either group 1 or 2. If you are unable to complete your blood draw today at study baseline, we will ask to obtain a blood sample from you at a later date or at a follow-up interview. Your blood will be tested to find out the amount of cholesterol in your blood and to test for nicotine products.
- You also will have your height, weight, and blood pressure, measured today. These will be taken again in 3,6,12 and 18 months.
- After that research session you will be placed in Group 1 or Group 2 of the study. There is no choice of what group you will be put in. This is chosen by chance, like the roll of dice. All participants will have research sessions on the VTC (video telemedicine conferencing) with study staff at ANMC in Anchorage or at Stanford University in California within a week after you agree to take part.
- If your mailing address is the same as another participant's, then we will put you in the same group. In this case, you will not be placed in a group by chance, like the roll of a dice.
- All participants in both groups will be mailed education tools to help them learn more about how to make healthy choices.

Group 1 (150 people):

a) The VTC research sessions will focus on smoking and physical activity habits.

b) Group 1 participants will get a step counter (pedometer) in the mail. Participants will be given details from the study staff on how to use it.

c) The study will offer 12-weeks of nicotine patches, gum, and/or lozenges to help with quitting smoking.

Group 2 (150 people):

a) The VTC research sessions will focus on education about blood pressure and cholesterol management, medication use, and nutrition.

b) Group 2 members will get support on blood pressure and cholesterol management, medication use and a cookbook in the mail with heart healthy Alaska Native recipes.

- You will be contacted by mail and phone by the study staff to schedule follow-up research sessions. These will be your VTC (Video) research sessions. This will happen within a week

from today and at 3, 6, and 12 months. None of the information about the session will go into your medical record.

- You will be contacted by phone and be asked to answer research surveys at 3, 6, 12, and 18 months after today. Each survey will take about 1 hour to finish. You have the right to refuse to answer any of the questions. You will be asked to provide a urine sample if you tell us you quit smoking. The urine sample will be used to be certain that you have no nicotine from tobacco in your body.
- You will be asked to give permission for the study staff to access your medical record. This will be for heart health information to find out if this study saves money and time and to confirm that you are receiving and taking your heart medications. You will be asked to agree or disagree to what types of information we can look at in your medical record by signing the bottom of this consent form where it says "Permission to access medical record."

Q 5: How will my blood and urine specimens be used?

A 5: Your blood will be checked for nicotine and the parts of nicotine that are in your blood after the body breaks it down. These are called metabolites or trans-3 Hydroxycotinine (3HC). Another sample of your blood will be tested at NSHC for a Fasting Lipid Panel (FLP). A FLP is a test that looks at the amount of cholesterol in your blood. Your urine will be tested for a chemical that indicates you have been exposed to tobacco. Testing for anabasine is one way to tell if a person has used tobacco. The specimens will be stored temporarily at CDC Arctic Investigations bank to the UCSF laboratories. The samples will only be used for this study. Research using blood and urine is an important way to understand human disease. You have been given this information because the researchers want to use your blood and urine in a research study. There are several things you should know before allowing your blood and urine to be studied:

- Your blood and urine will be stored at the CDC Arctic Investigations Specimen Bank and at the UCSF laboratories temporarily. Your samples will be stored until the findings of the study have been published. Once the study's findings have been published the specimens will be destroyed by being burned.
- Samples will be labeled with your study ID number. The codebook linking your ID number and name will be stored in a secure, locked data file. The codebook will be destroyed after 10 years.
- You have the right to refuse to allow your blood and urine to be studied now or at any time. You may withdraw from this study at any time without penalty. It will not affect your regular healthcare or access to your provider.

Q 6: Will I be given the results of my blood, urine, and other tests?

A 6: Participants in Group 2 will get brief feedback from the study staff on the results of their blood pressure, the importance of managing blood pressure and cholesterol, taking their heart medications (if prescribed), and making healthy food choices. We will send the results of your blood pressure test and FLP (test for cholesterol) to a NSHC provider ONLY if they are high risk (BP DBP > 110, SBP > 190 and cholesterol TG > 500, LDL> 200, total cholesterol > 300).These test results will not go into your medical record. The NSHC provider may contact you for an

appointment if there is any reason for a follow up based on the information they learn - if it is high risk only. This would not be of any cost to you.

Q 7: How long will this research study last?

A 7: We will enroll people into the research study for up to 4 years. We will then assess data and report our findings for up to 10 years. Your personal data will be on file during this time. The research study codebook linking your name, address, and other contact details to your samples will be destroyed at the end of 10 years. The samples will be destroyed once the study findings are published.

Q 8: Will I be paid to be in the research study?

A 8: No. You will be given money for your time. You will be given $30 if you answer the first survey, give blood, and have your height, and weight measured at the clinic. This is not payment for you enrolling in the research study. If you are unable to obtain transportation to the research interview you will be offered a taxi cab voucher to and from the research interview.
You will get $40 at the 3 month, $40 at the 6 month, and $40 at the 12 month survey times. You will get $50 at the 18 month survey for your time. If you complete each survey in the study it is a total of $200. You will get payments from the study staff in the form of a debit card. The debit card will be given or mailed to you after each survey and VTC research session.

Q 9: If I am in the research study what are the possible risks to me?

A 9: The following are possible risks:

- Taking blood from your arm could cause pain, bruising, swelling, or, very rarely, infection.
- You may feel discomfort by answering questions about alcohol and other drug use. You can refuse any questions you want.
- You do not have to want to quit smoking to be in this study. You may have withdrawal symptoms if you do quit smoking. Most withdrawal symptoms are their worst in the first 48 to 72 hours. They get better in 2 to 4 weeks. You will be offered nicotine patch with gum or lozenge from the study staff if you are in Group 1 (smoking and physical activity). Group 2 participants (cholesterol and blood pressure management and nutrition) can request quit smoking treatment from NSHC.
    - Possible side effects of the nicotine patch are: redness of the skin, itching, headache, sleeplessness, diarrhea, upset stomach, and nervousness. Possible side effects of the nicotine gum and lozenge are: mouth sores, jaw muscle aches (gum only), increased saliva, hiccups, and headache. Side effects of nicotine replacement are rare and minimal. Even at high doses while smoking. You will be given written instructions about the correct use of nicotine replacement therapy and how to contact study staff if there are any problems. If there are any harmful effects reported by you, a NSHC health care provider will be notified by a member of the HEALTHH study staff.
- Pregnant and breastfeeding women are not eligible for the study. Women who join the research study and become pregnant during the study, should let study staff know as soon as

possible. Use of the nicotine patch, gum, and lozenge may be continued with doctor's care for women who become pregnant.

- We will do all we can to protect your privacy. There is a small risk that your data could be released by accident. To protect your privacy, we will:
    - Keep all data from the research study in locked files and on computers with passwords. Only Dr. Judith Prochaska, and other members of the research team will have access to research study files and research study computers.
    - Keep your name, address, and other contact details separate from blood and urine samples at all times. Only a study ID number will be used on your survey, blood and urine samples.
    - Never identify you in reports and publications resulting from this research study. All data will be reported as a group. All results published will first be approved by the NSHC and the ANTHC Board.

Q 10: What else will you do to keep my information private?

A 10: We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. This means the research team cannot be forced to give out information about you. With the following exceptions, the Certificate cannot be used to:

- Keep you or someone who knows you from giving out information about you or your involvement in the research study.
- Stop the researchers from giving information about you if you tell the study staff that <u>you are aware of child or elder abuse, or that you plan to hurt yourself or someone else.</u>
- Stop a federal employee from looking at the research study. Your consent form and other research documents may be looked at in this situation.

Q 11: What are the possible risks of this research study to my community?

A 11: The risks of a study to a community are not always known. It is possible the study results could be used by others to connect your community with health risks.

The research team has worked closely with the NSHC Board of Directors and its Research Ethics Review Board (RERB) to create a plan. This plan is to lessen the risk of harm to your community. This plan says that the name of your community will not be given out in any national presentations or publications. All presentations or publications must be approved by the NSHC Board of Directors and its RERB.

Q 12: If I am in this research study, what are the benefits to me?

A 12: We cannot guarantee or promise that you will get any benefits from this study. Possible benefits for Group 1 are better heart health by stopping smoking and doing more physical activity. Possible benefits for Group 2 are better heart health, blood pressure, cholesterol and better diet.

Q 13: What are the benefits of this research study to my community?

A 13: We may be able to use results of this research study to help people in your community who have heart risks quit using tobacco, have healthier diets, learn ways to help manage blood pressure and cholesterol, and be more physically active.

Q 14: What if I choose later that I do not want to be in the research study?

A 14: You can change your mind at any time, and decide you do not want to be in the research study. It will not change your health care at NSHC if you choose not to be in the study. You do not have to answer all the questions to be in the research study. You can also tell the research study staff that you want to stop at any time during the research sessions, surveys, urine sample collections, or blood draws. If you choose after today, that you do not want to be in the research study, you can ask to have your unused blood and urine samples destroyed. You are not giving up any of your legal rights to be in this research study.

Q 15: If I join the study what are my rights?

A 15: You will be told of any new information learned during this research study.

Your healthcare will not be affected if you choose not to be in this study. Anyone who requests quit smoking referrals from study staff will be given them. Nicotine patch, gum and/or lozenge are available to adults for purchase at a local grocery store.

Q16: What if I get injured?

A 16: There is a very low risk for participants in this study. All forms of medical care that you may need if injured in this study are part of your coverage as a beneficiary of the tribal healthcare system.

Q17: What are my rights as a research study participant?

A17: Your rights include but are not limited to being given:

- information on the purpose of the research study;
- a description of the procedures and drugs to be used in the research study;
- a description of any discomforts and risks that may be expected;
- a description of any benefits from being in the research study;
- information on how to get medical care if you need it during or after the study;
- a chance to ask questions about the research study or the treatment being used;
- the right to give or refuse consent to be in the research study, and you will not lose your rights to medical care;
- a copy of the signed and dated consent form.

Q 18: Who can I contact if I have more questions later?

A 18: If you have any questions or research-related injuries or complaints, you may contact the Principal Investigators:

Dr Matthew Schnellbaecher	Judith Prochaska, PhD, MPH	Neal Benowitz, M.D.
ANMC Cardiology	Stanford Medical School	UCSF Medical School
(907) 729-2076	(650) 725-5465	(415) 206-8324

You may contact the Alaska Area Institutional Review Board if you have any questions or concerns about your rights as a research participant:

Terry Powell	Alaska Area IRB, Administrator (907)729-3924(collect calls accepted)
	email: tjpowell@anmc.org
Shanda Lohse, M.D.	Chairperson of the Alaska Area IRB slohse@southcentralfoundation.com

If you are not happy with how this study is going, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

You agree to be in this study and that you were given a copy of this signed and dated consent form by signing your name.

_____

First MI Last

Print name of participant

_____/_____

Signature of participant Date

_____/_____

Signature of staff member Date

Permission to access medical record

This section allows the HEALTHH study staff to look for data in your medical record. The data is related to the heart medication that you may have been prescribed by a NSHC provider to determine if you are receiving and taking that medication and/or the cost effectiveness of the treatment we are creating in this research study. Please fill in name, date of birth, and then initial next to the types of information we can look at in your medical record. You are not required to give us access to any or all of these types of information. Lastly, please sign and date the bottom. This data will be kept confidential just as the rest of the data in the study as explained above.

I, _____ with a date of birth, _____, give my permission for
(Printed full name) (Participants DOB)

the HEALTHH study staff specific to the cost analysis and collection of data only to access my medical records. Initial at each line to allow the study staff to look at the types of data in your medical record:

_____ Heart related drugs prescribed to you

_____ Heart related emergency room visits

_____ Heart related inpatient and outpatient visits

_____ Heart related lab results

_____ Heart related billing statements

_____ _____
Participants Signature Date