

APPENDIX H

Informed Consent

You have agreed to join the Oral Health 4 Life (OH4L) research study. This document summarizes key study details you agreed to when you joined. Please keep this for your records.

Principal Investigators:

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Project Manager:

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Research Funder:

This study is paid for by the National Institutes of Health.

Research Study Purpose:

This study will compare standard services offered through state tobacco quitlines to standard services plus additional counseling and resources designed to promote better oral health. We will examine how well each program helps people change their knowledge, attitudes, and health behaviors. Everyone in this study has been randomly assigned (as if by the flip of a coin) to one of these two programs.

What you have agreed to:

You have agreed to receive up to 5 calls from a tobacco quit coach and to receive other materials from your state tobacco quitline to help you stop smoking. You have completed at least one of these calls already. You have also agreed to receive one text message every 1-2 weeks over the 6 month study period. You may or may not also receive additional counseling and resources to help you reduce your risk of oral disease. The letter enclosed with this form provides more information about the services you have been randomly selected to receive.

You also agreed to answer 3 surveys. You have completed the first of these. Someone from the Group Health Research Institute will contact you by phone in about 2 months and in about 6 months to complete the remaining surveys. Each one will take about 15-20 minutes. After you complete each of these surveys, we will mail you \$30 as a thank you.

Your tobacco quitline is managed by a company called Alere Wellbeing. You agreed that information collected by this company as part of their standard services to help you quit smoking or as part of this study may be shared with researchers at the Group Health Research Institute. We will only look at information collected during 2015-2018. This includes information you provided about yourself and your use of the quitline services. When you enrolled in the quitline program, you gave Alere Wellbeing permission to audio record your contacts with the quitline. This is standard for all of the quitline counseling calls. Researchers at the Group Health Research Institute will randomly listen to a selection of calls from all study participants, to ensure study participants are receiving the correct advice and materials from the study. Your calls may be included in this group. This information will only be used for this research and it will be kept confidential as provided by law. Any identifiable information you provide to us or

we receive from Alere Wellbeing for the purposes of this research will be destroyed within 5 years after the end of this study (2023).

Benefits to You:

As a result of being in this study you may quit smoking and reduce your risk for cancer, heart disease, lung disease, and oral disease. You may also feel good knowing that you have contributed to science.

Risks to You & Protections:

If you stop smoking you may experience nicotine withdrawal. Symptoms include headaches, irritability, sleep disturbance, constipation, and cravings to smoke. These will go away in a few days or weeks. You can reduce these symptoms if you use a nicotine replacement therapy, which may have been provided to you by your quitline. If so, this medication can also have side-effects such as headaches, nausea, trouble sleeping, and rash or skin irritation. These symptoms are also temporary. If you change your oral care habits, such as brushing or flossing more often, you may experience some gum bleeding or oral discomfort. This usually goes away if you continue to brush or floss daily. It is also possible that someone not in this study could learn your identity. To reduce this risk, we will never intentionally share your name with anyone outside of the study. We have an agreement in place with the text message vendor and website hosting vendor to keep your phone number private, and we will never use your name or reveal your identity in any research papers or reports.

HIPAA:

Your health information is protected by a federal privacy law called HIPAA. Group Health and Alere Wellbeing must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By participating in this study, you are allowing us to share your health information with the study researchers (named above) and their staff. This health information includes your answers to the study surveys, details about your participation in the standard services offered through state tobacco quitlines, and, if assigned to the oral health program, any information about your participation in the additional counseling and resources designed to promote better oral health and your use of the study website. The study website is hosted by Isomedia, Inc. We will ask you to use your cell phone number as your user name to log into the study website. After the first time you log in you will have the option to change your user name, if you choose.

In some cases we are required to give information to government agencies or review boards who watch over the honesty and safety of research. If we are asked to do this, we have no plans to share information that could identify you personally.

Researchers working on this study have signed a confidentiality pledge to protect your privacy. No publications or reports from this study will identify you. Any information we share with others outside of Group Health and Alere Wellbeing may not be protected under federal law. However, other laws, regulations and agreements may protect the information from improper use.

The HIPAA Privacy Law does not always apply to those who are given protected information. Once Group Health and Alere Wellbeing have given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

In order to be in the study, you must agree to use of your health information. This permission for the researchers to obtain your health information ends when the study ends.

Who to Contact:

If you have any questions about this study or experience any of the symptoms listed above, please call the study manager listed on the other side of this page.

If you have questions about your rights as a research participant, you can call the Human Subjects Office at 206-287-2919.

Other:

Your participation in this study is voluntary. You can choose to withdraw at any time. If you withdraw, you will continue to receive services from your state tobacco quitline. You will not lose your rights to any treatment or benefits you are otherwise entitled to.

If you change your mind, you may take back by calling the Oral Health 4 Life Project Manager, Ella Thompson, at (206) 442 - 5211 or by writing to:

Dr. Jennifer McClure
Group Health Research Institute
1730 Minor Ave, Suite 1600
Seattle, WA 98101

If you drop out, we will keep any information already collected but will not contact you in the future or collect new information after your drop out date.

Representatives from the National Institutes of Health or their proxies may inspect data collected for this study.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. When the study is completed, summary results will be posted at this site. This site is available to the public.

There are no plans for study participants to receive any money or other benefits from products or procedures that may be developed as a result of this study.