

Because you shared with 2-1-1 that you smoke daily, we're inviting you to participate in a research study called Fresh Start led by Washington University in St. Louis.

The purpose is to see if telephone quitlines and smoke free homes help people stay healthy.

The National Institutes of Health (NIH) is funding this research study. Roughly 2,000 people will take part.

If you participate, you will complete 3 phone surveys over 6 months: one today, one in 3 months, and one in 6 months. The surveys ask about you, your smoking, your health, how you are feeling, and other needs. Each takes about 30 minutes.

You will get a \$25 grocery store gift card for each survey completed, so you can earn \$75 total.

You can use your state's tobacco quitline program and may also be offered the Smoke-Free Homes program. In the Smoke-Free Homes program we would mail you activities and information to create a smoke free home and a coach would call to talk and answer questions. A computer will randomly select which group you are in. If you choose to participate in either program, we will share your name and phone number with our partners, Optum and Emory University. Some participants may be asked to do an in-home urine test or nicotine air monitoring. If chosen you will receive another \$25 gift card for in-home testing.

There are minimal risks and discomforts that may be associated with the study. Some survey questions may seem sensitive, like income, race/ethnicity, smoking, physical and mental health, and life's daily challenges. If you are uncomfortable with any question, you can choose not to answer. It is possible that confidential information about you may be accidentally disclosed, though unlikely, and we have taken precautions to prevent it.

Even if you do not benefit from participating, others may benefit in the future from what we learn. There are no costs to you for participating in the study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research.

We will ask for your address and social security number (SSN) so we can pay you. Your social security number is not required for this study; you can refuse if asked. If provided, it will be used for payment purposes only.

Information you provide is confidential. We will make our best efforts to keep it secure. Identifiers may be removed from your private data and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

If you choose to use the quitline, delivered through Optum, Inc., or Smoke-Free Homes, calls between you and those programs will be audio recorded, and could be shared with researchers at Washington University or Emory University for quality improvement. Optum will also share participant data related to quitline usage with the researchers. Any audio files that are shared will be password protected.

As part of this study we will generate Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained in this letter. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect and copy records pertaining to the research. This could include university representatives, to complete university responsibilities, including the Institutional Review Board (a committee that oversees the conduct of research involving humans and has approved this study) and the Human Research Protection Office, government representatives (including the Office for Human Research Protections and the Food and Drug Administration), to complete federal or state responsibilities, the National Cancer Institute, and Optum which runs state tobacco quitlines.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this letter. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this letter. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. If you agree to take part, you authorize the use of your PHI for this research, and your authorization will not expire. You may later change your mind and not let the research team use or share your information.

In order to revoke your authorization, you will need to complete a withdrawal letter. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you revoke your authorization, the research team may only use and share information already collected for the study. Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons. You will not be allowed to continue to participate in the study.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify

you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Your participation is voluntary. You may stop at any time. If you decide not to take part or to stop taking part, you won't be penalized or lose any benefits for which you otherwise qualify.

We encourage you to ask questions. If you have any questions about the research study itself, any concerns or negative feelings from your involvement in the study, or if you feel you have been harmed from being in the study, please contact Taylor Butler (314-935-2721) or Matthew Kreuter (314-935-3701). If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-800-438-0445 or email [hrpo@wustl.edu](mailto:hrpo@wustl.edu). General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the same number.

Do you have any questions?

**Note verbal consent here:** Do you agree to participate? Agree to participate / Refuse to participate