FHIR-ed Up for Tobacco Cessation

Informed Consent Form

NCT06292130

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Consent/Authorization for participation in a research study

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Study Title
refresh: A new take on tobacco

Sponsor
Pro-Change Behavior Systems, Inc. via a grant from
National Heart, Lung, and Blood Institute

DESCRIPTION OF THE RESEARCH AND THE RIGHTS OF PARTICIPANTS

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center or Pro-Change will not change or be affected.

Purpose of Study: The purpose of this study is to get feedback on a new mobile app to help people get ready to quit using tobacco. Your feedback will help us make improvements to the app so people will find it helpful and want to use it. If you agree to participate in this study, your participation may last for about a month.

If you agree to be in this study, you will be asked to participate in the following activities:

- Complete a more in-depth online survey on your tobacco use that should take about 10 minutes.
- Download the *refresh* app from the Apple app store, and allow the app to access the iOS Health app from your phone. Information from the app will then be shared to your electronic health record (EHR) at Rush University Medical Center and be available to your health care provider.
- Receive daily text messages/app notifications and be asked to complete brief activities through the app over the next 30 days.

- Talk with your health care provider at your upcoming appointment about your answers to the questions in the survey and your use of the app.
- Complete a second and final survey in about 30 days. The survey will ask how you're doing and will ask for feedback on your experience with the app. It will take about 10 minutes. If you don't complete the survey, someone from our team will give you a call to complete it by phone.

Risks: In this study, there is a risk that you may find that some of the questions make you uneasy and that you don't want to answer them. That's OK. You are free to stop answering questions at any time. If you want to talk to someone about these issues or have questions or concerns later, please talk to your health care provider or another person you trust.

There may be other risks that may happen that we cannot predict.

Benefits: You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit other smokers in the future. The information gathered in this research will help us improve our mobile app to help people get ready to quit using tobacco. Some people may find that taking part in this project is interesting and helpful.

You have the option to not take part in this study.

Detailed Information: Please review the rest of this document for details about the study and additional information you should know before making a decision about whether or not you will take part in it.

Why are you being invited to participate in this study? You are being asked to participate in this study because your medical record says you are a smoker who has an upcoming appointment with your health care provider at Rush University Medical Center.

How many participants will take part in this study? Approximately 100 people are expected to take part in this study.

Can you leave or be removed from this study? You have the right to leave a study at any time without penalty. The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information? This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Drs. Johnson and Stein, their study team, and other Pro-Change Behavior Systems and Rush personnel involved with the

conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Drs. Johnson and Stein and their study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes your use or tobacco and that you have an upcoming appointment at Rush University Medical Center.

Drs. Johnson and Stein and their study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The Researchers, including those at Pro-Change Behavior Systems, Inc.
- The study Sponsor, including Pro-Change Behavior Systems, Inc. and its representatives (for example, the Data Safety and Monitoring Board);
- Monitoring agencies such as the National Institutes of Health, and the Pro-Change and Rush Institutional Review Boards (IRBs).

While you participate in the study you will have access to your medical record, but Dr. Stein is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Johnson at refresh@prochange.com. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All data provided will be stored on secure servers and transmitted via encrypted/secure channels. All identifying information will be removed from the study database at the conclusion of the study.

What are the costs to participate in this study? There are no costs to you for participating in this research. This project is funded by the National Heart, Lung, and Blood Institute. All costs for the required study will be paid for by a grant awarded to Pro-Change Behavior Systems, Inc.

Will you be paid for your participation in this study? You will receive a $25 Amazon.com gift card (restrictions apply, see amazon.com/gc-legal) for completing the first survey and downloading the app. You will receive another $25 Amazon.com gift card for completing the final survey. You will receive the gift card(s) within two weeks after completing each activity.

Your participation in this study may contribute to the development of commercial products from which Pro-Change Behavior Systems, Inc. may derive financial benefit. There are no plans to pay you for any of these developments.

What other information should you know about? If your doctor is also the person responsible for this study, please note that she is interested in both your clinical care and the conduct of this study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Who can you contact for more information about this study? Questions are encouraged. If you have further questions about this study, you may contact the study Pro-Change Project Manager, Deborah Van Marter, at refresh@prochange.com, or call (888) 958-5733. You may also contact Dr. Kelly Stein at Rush University Medical Center, (312) 942-6544 or kelly_stein@rush.edu, with any questions you may have.

Who can you contact if you have concerns about your rights as a study participant? Questions are encouraged. Questions about the rights of research participants may be addressed to the Pro-Change Institutional Review Board Chairperson, Dr. Ted Myatt, at (401) 489-8332 or to the Rush University Medical Center Office of Research Affairs at (800) 876-0772.

What are your rights as a study participant? Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Sara Johnson in writing at the address on the first page. Dr. Johnson may still use your information that was collected prior to your written notice.

Do you consent to participating in this research study?

Yes. I have read the information given or someone has read it to me. I am consenting to participate in this research study. I have had the opportunity to ask questions, which have been answered satisfactorily to me by the study staff. I do not waive any of my legal rights by signing this consent/authorization form. I may download a copy of this information.

No. I do not consent to participate in this research study.