Informed Consent Form

Fred Hutch

Consent to take part in a research study:

Pilot Trial of a Web-Based Smoking Intervention for LGBTQ+ Young Adults (EQQUAL Study)

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To help you decide if you want to take part in the Empowered, Queer, Quitting, and Living (EQQUAL) Study, this form tells you about the study and its activities. You can also email us to ask any questions you have about the study to help you decide whether or not you want to take part.

What is the purpose of the study?
We are doing this research study to learn if a new mobile-friendly web-based program helps LGBTQ+ young adult smokers quit smoking and/or feel more ready to quit smoking.

If you agree to join the study, you will receive access to the new program at no cost to you.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty if you say no or if you change your mind later.

We plan to enroll 25 people in this study. Although the study may or may not benefit participants directly, the information we learn will help us design better smoking cessation programs in the future.

Following is a more complete description of this study. Please read this description carefully. If you join this study, we will email you a copy of this form for your reference.

What are you asking me to do?
The EQQUAL study includes using a mobile-friendly web-based program and filling out 2 surveys. Specifically, if you join this study, you will be asked to:

- Fill out a survey, called the *Baseline Survey*. It is a web-based survey that takes 15-25 minutes to complete and includes questions about:
  - Your current smoking habits and your smoking history
  - Demographics (for example, education, employment, sexual orientation)
  - Your personality and mood

- Utilize a mobile-friendly web-based program called EQQUAL, which stands for Empowered, Queer, Quitting, and Living. We will electronically record information on your use of the program (for example: if you logged into the program and if you completed a session or not).
- Fill out a follow-up survey after 2 months of being in the study. This survey can be filled out either online or by mail and will help us learn about your overall experieces with the program. The follow-up survey should take about 20-30 minutes to complete.
- After completing the follow-up survey, you may be asked to verify your smoking status by completing a saliva kit and uploading a photo of your results.

These details are described further below.

EQQUAL program

The EQQUAL program is a mobile-friendly, web-based program that helps you explore your personal values, teaches you about smoking triggers, and teaches skills to help you accept your thoughts and feelings related to smoking. The program contains 6 sessions spaced out over a minimum of 3 days between sessions. Each session takes approximately 25 minutes to complete. You will also receive daily text messages from the program letting you know when new sessions are available and providing helpful and encouraging information.

Research Surveys

You will be asked to complete surveys at the beginning (Baseline Survey) and end (Follow-up Survey) of the study. Surveys may take 15-30 minutes to complete. You will be asked about your smoking history, current smoking status, mood, alcohol use, and interest in quitting. At the follow-up survey, you will also be asked to give us your honest feedback about the EQQUAL program.

Saliva Sample

At the end of the study, you may be asked to confirm your smoking status by completing a saliva kit. If selected, we will mail you a saliva kit via overnight mail with detailed instructions on how to complete it. We will ask that you upload a photo of your test results to our secure survey system.

How long will I be in this study?

Your study participation will last about 2 months. This includes your time using the intervention program and the 2-month survey.

If you leave the study, your survey results and information cannot be removed from the study records.

Will you pay me to be in the study?

Yes. You will be sent $25 electronically through your choice of either Venmo or PayPal after you complete the 2-month follow-up survey. If you complete the survey online within 24 hours of the survey invitation arriving in your email inbox, we will give you an additional $10.

If you are asked to complete a saliva kit at the end of the study, we will give you an additional $25 after you upload a photo of your test results.

Therefore, you can receive up to $60 through Venmo or PayPal for participating in this study.

The study will not be responsible for re-sending compensation to any Venmo or PayPal account for any reason.

If you agree to join the study, you can do so at no cost to you. There are no extra costs for being in this study.

What are the benefits of being in this study?

- Participating could help us learn how to better help LGBTQ+ young adult smokers quit smoking, which could improve care options in the future.
- Participation in this study may help participants quit or cut back on how much they smoke.
- Some people feel good when they help with research like this.

What are the possible risks or discomforts of being in this study?

- If you quit smoking, you may experience some short-term discomfort associated with nicotine withdrawal including irritability, restlessness, difficulty sleeping, headaches, difficulty concentrating, and cravings to smoke. These symptoms typically last a few weeks and then go away.
- You may feel discomfort from some sensitive survey questions (e.g., questions asking about your mood).
- People not working on this study could learn your identity or learn information about you from your surveys. We will do everything we can to keep this risk small and have protected against this risk in the following ways: (1) Your personal information will be labeled with a number only and will not be linked to your name, (2) All of your identifying information will be kept in locked files or in a secure database for 5 years after the study is over and will then be destroyed, (3) your connection to the EQQUAL website as well as where you fill out the surveys will be password restricted and protected by secure-socket-layer (SSL) encryption; and (4) the website's server will be behind a hardware firewall.

Do I have other options besides this study?

You do not have to join this study. You are free to say yes or no. If you decide not to take part in this study, you can still receive treatment to help you quit smoking. Your other choices may include:

- Talking to your doctor
- National Cancer Institute's smoking cessation website: www.smokefree.gov
- National Cancer Institute's smoking cessation smartphone app: QuitGuide
- Your state quitline (available in all 50 states) by calling 800-QUIT-NOW

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers and research staff involved with this study.
- Datatope Inc., the company that handles the programming and maintenance of the EQQUAL web program
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- The study sponsor, National Institutes of Health (NIH), The Office of Human Research Protections (OHRP), and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others. For example, if you tell us you have plans to harm yourself or others, we may have to share this information.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if I get sick or hurt during this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact us when the medical emergency is over or as soon as you can.

For all other problems related to the study, please contact the project coordinator at 206-667-2428. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

Your rights
You do not have to join this study. You are free to say yes or no.

If you join this study, you do not have to stay in it. You may stop at any time (even before you start).

There is no penalty for stopping.

If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

For more information
Be aware that by agreeing to participate in this study, your information could be used for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

If you have any questions or concerns about this study you would like answered before deciding to participate, please email us at EQQUAL@fredhutch.org. We are committed to answering your questions within 2 business days. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-7314 (Dr. Jaimee Heffner, Principal Investigator)
If you get sick or hurt in this study	206-667-2428 (Project Coordinator)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

First Name:_____
Last Name: _____
Signature: _____
Date: _____

(Note: After signing the document, individuals will be required to select a box indicating, "I certify that all the information in the document above is correct, and I understand that

signing this form electronically is the equivalent of signing a physical document." If needed, participants will be able to go to the previous page to update information before submitting the consent).