INFORMED CONSENT

FOR CLINICAL TRIAL BY _____

Official Study Title:
Evaluation of a Smoking Cessation Program for Long-Term Abstinence

ClinicalTrials.gov Identifier:
NCT06746025

Document Date:
June 3, 2026

This Informed Consent for Clinical Trial is for adults over the age of 18 who are currently smokers (or vapers) and who we are inviting to participate in research on the newly developed Quit Center program.

This Informed Consent for Clinical Trial has two parts. The first is an information sheet containing information about the clinical trial and the research we are undertaking as part of it. The second is the certificate of consent where you will sign if you agree to take part in this clinical trial. You will be given a copy of the fully signed Informed Consent for Clinical Trial should you agree to take part.

Part 1: Information Sheet

A. Introduction

Business name of sponsor:	Quit Center
Legal name:	Quit Center LLC
Program Name:	Quit Center Trial to Determine the Efficacy of the Newly Developed Program to Quit Smoking
Program Date:	28, October, 2024

We are conducting research on a newly developed way to end the addiction to smoking and in this document we will give you information about the research and invite you to participate in the research. You do not have to decide today if you want to participate. It is important that you take the time you need to decide and to speak with anyone to help you make this decision. Quit Center reserves the right to close its acceptance of new participants at any time, without prior notice to any perspective participants.

In reviewing this document, there may be some unfamiliar words or concepts that are confusing or that you do not fully understand. Please ask any questions to clarify, and we will take the time to explain them to you. If you have questions later, please ask any member of the clinical trial team.

B. Purpose of the Research

The purpose of this clinical trial is as follows:

To determine if the new program is successful in aiding participants with their effort to quit smoking, and also to reduce or eliminate the cravings and triggers that so often derail the attempt to break out of the addiction.

C. Type of Research Intervention

This clinical trial involves the following intervention:

You will be participating in a series of 8 online sessions (one-hour each, and once each week for 8 consecutive weeks) in a group that will all learn the techniques developed by the Quit Center at the same time. There are NO drugs offered, no medical opinions, no alternative addictions, nor any medical advice of any kind. This is not a Nicotine Replacement Therapy program. We will not be providing patches, gums, gummies, or pharmacological products of any kind. The program consists solely of instructing you on how beat your addiction using our methodologies and your body's own built-in functionality.

D. Participant Selection

We are inviting all adults who are addicted to smoking to participate in the research on the new program. You need not live in any particular geographic area. The three selection criteria are that you are currently a smoker, that you are 18 years old or older – with no upper age limit, and that you have access to the internet that will allow you to participate in a two-way meeting via a zoom meeting platform.

E. Voluntary Participation

Your participation in this research is entirely voluntary. It is your decision whether to participate or not. You may change your mind at any time and stop participating in the clinical trial even if you agreed earlier.

F. Information on the Trial Drug

No drugs will be offered.

G. Procedures and Protocol

The program to help smokers and vapers quit smoking consists of 8 weekly, one-hour long online meetings with a live moderator. During these meetings you will be introduced to methods to end your addiction without the use of drugs or medical interventions. You will progress through the program in a group environment with approximately 20 to 30 people that are also trying to end their addiction. Each group will have its own dedicated "Slack" channel to allow communication between the other members of the group at times when you are not in the meetings. We will be teaching a method designed to make incremental lifestyle changes that can reduce or eliminate the "triggers" for smoking. Essentially re-training your brain back to a state that it was in BEFORE you ever smoked.

There will be no drugs of any nature involved, nor will there be any replacement addictions offered (ie; patches, gummies, etc.) The study will also assist us to learn about the demographic profile of inbound participants, and which is the best path for long-term success.

The complete Protocol can be found at http://www.clinicaltrial.gov and by searching for protocol id 052024CESS

H. Duration

8 weeks

I. Side Effects

There are no known side effects. Although some people (not in the Quit Center program) do report that their attempts to quit have made them anxious or irritable. Our program will strive to prevent those effects.

J. Risks

There are no known risks involved with the program.

K. Benefits

Quitting smoking will have immediate AND long-term benefits to you. You will immediately save substantially more money by no longer purchasing cigarettes or vapes. Your clothing will smell better. You should have more energy, and better lung capacity. Long term health benefits are enormous. For every year that you have stopped smoking your risks for serious and/or fatal disease are reduced.

L. Reimbursements

Participants in the program who attend all 8 of the online meetings will be given a $50 prepaid gift card. They will receive the card **whether they are successful in quitting or not.**

There are no costs associated with participating in the trial, although each participant will need to provide their own access to the internet, which allows them to join the meetings via Zoom.

M. Confidentiality

You will be required to give us your name, telephone number, mailing address, and email address. Additionally, we will be requiring you to fill out an intake questionnaire, an mid-term questionnaire, and an exit questionnaire, and also agree to us reaching out to you via email at two points in the near future to see how you are doing with your quitting journey. By its very nature our trial will need to accumulate this information from all of the participants in order to determine the success rate of the program, along with drawing other conclusions regarding the effectiveness of the program. Quit Center will not be releasing ANY of your questionnaire responses linked to your personal information. No outside parties will ever be given any of your personally identifiable information. The intake questionnaire will save demographic information about you that will NOT be tied to your individual information. The purpose of acquiring this information is to help us better understand which demographic groups are the most successful, and why. There will never be any instance of Quit Center releasing any of the demographic information that you provide as an individual. It will only be used in the aggregate to help future smokers in their efforts to quit, and to help Quit Center improve its program.

N. Sharing the Results

The aggregated information (compiled from all participants, and not individually) and knowledge we obtain from conducting this research will also be shared with you through your email before it is made available to the general public. Confidential information will not be shared. Within 2 weeks after the close of the trial we will publish the results to allow others to learn from our research.

O. Right to Refuse or Withdraw

You have the right to refuse to participate in the trial. In which case you need do nothing with this consent form. If you decide to participate, you will always have the right to withdraw from the trial **at any time** prior to the end of the 8 week program. There will be no negative effects to you if you decide to withdraw. There will, of course, be a negative to us if you begin the program and later withdraw. Because at that time we will have to count you as unsuccessful in our results. If you ***are*** successful in quitting or feeling positive about your prospects for quitting, we ask that you continue the program for the full 8 weeks, both for your own benefit and because our success (or failure) will be assessed at the end of the trial. If you elect to withdraw from the program before the end, we may need to count you as a negative for our purposes, even if you've been able to quit.

Only those participants that remain in the trial for the full 8 weeks will receive the $50 reimbursal. The reimbursal will be provided even if you are unsuccessful in quitting!

P. Who to Contact

This clinical trial and the associated protocol has been developed by The Quit Center LLC. If you would like additional information about this study or Quit Center please contact admin@quitcenter.org

Part 2: Certificate of Consent

Statement of Subject

I have read the foregoing information or it has been read to me. I have had the opportunity to ask questions about the research and this informed consent, and any questions I have asked have been answered to my satisfaction. I voluntarily consent to take part in this research. I confirm that I meet the following criteria:

1. I am over the age of 18
2. I am currently a smoker
3. I have access to the internet via a smartphone or a computer
4. I am not involved in any other program ie; weight loss or anti-depressant
5. I am committed to trying to quit smoking or vaping
6. You agree to filling out Quit Center questionnaires during the program, to help us improve our program

Print name of subject: _____

Signature of subject: _____

Date: _____

Link to the “Pre Program” questionnaire, with required demographic information. The information will never be shared as individual responses, but only as aggregated responses from all participants.

Follow this link to fill the required questionnaire:

https://docs.google.com/forms/d/e/1FAIpQLSfRWZpt5PXDkFoT13op4BjJjLCahE1qTUDJJVOjBYtaa2IrFQ/viewform?usp=sf_link