

Consent

IRB Approval Period:
10/21/2025 - 10/20/2026



University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824 Adult Consent to Participate in a Research Study

University of Pennsylvania Institutional Review Board (Penn IRB)
3800 Spruce Street, 1st Floor, Suite 151 | Philadelphia, PA 19104-6006
UPenn Federalwide Assurance ID#: FWA00004028 Adult Consent to Participate in a Research Study

Title of research study: Remote vs. In-Person Study Evaluation (RISE) Trials: RISE Above Smoking (STUDY00008797: RISE Above Smoking)
Version Date: 03/27/2025
Investigators: Larry W. Hawk, Jr., PhD, and Martin Mahoney, MD, PhD

Co-Investigators: Caitlin Allen, PhD, Matthew Carpenter, PhD, Karen Cropsey, PsyD, Jennifer Dahne, PhD, Robert Schnoll, PhD, Van Nghien, PhD, Greg Wilding, PhD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you smoke cigarettes and you have expressed an interest in quitting smoking using nicotine replacement therapy (NRT).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide. Why is this research being done?

When the COVID-19 pandemic hit in 2020, many clinical research studies and treatment programs were forced to change to a remote or "virtual" format. Although in-person (in our clinic) and remote (in your own home or other private space with video-conferencing on your phone, tablet, or computer) formats may each have some advantages, there is no research that directly compares the two formats. The main purpose of the RISE Above Smoking clinical trial is to test how well each format performs in the context of a project helping people to quit smoking with a combination of nicotine replacement patches and lozenges.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 4 months. You will attend an Intake Visit that will last about 1 hour, followed by 5 Treatment and Assessment visits that will last 30-60 minutes each.

During the Intake Visit, you will learn about the details of the study, provide informed consent, and complete questionnaires that tell us more about you, your tobacco and drug use history, and your medical history and experiences. Some of your answers will determine whether you are eligible. You will then work with us to plan your quit smoking date and schedule your Treatment and Assessment Visits. To help you quit smoking, you will receive 8 weeks of combination nicotine replacement therapy (patch and lozenge), detailed instructions on how to use these products, and additional quit smoking resources. During each Treatment and Assessment visit, you will be asked to provide a breath sample, complete surveys about your experiences, and review your smoking behavior and medication usage with a research assistant.

Whether your visits are remote or in-person will be determined randomly by a computer program.

In addition, about 1 in 6 people will be asked to participate in an interview about their experiences in the study. If selected for this interview, you would be contacted to schedule it within 30 days of the date of the final Treatment and Assessment Visit.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way being in this study could be bad for me?

There are few risks associated with participating in this study. First, going without smoking may affect how you feel and/or behave; that is, you may experience "withdrawal" and/or "cravings". However, these symptoms generally lessen within 1-4 weeks. Some people can experience anxiety and other types of distress when they complete questionnaires about smoking and when they attempt to quit smoking. This is generally related to your feelings about quitting as well as learning about some of the health risks associated with continued smoking. These reactions are usually mild and typically fade away with time. Lastly, participating in research always raises issues of privacy and confidentiality. Every effort will be made on the part of the researchers to protect your personal information.

More detailed information about the risks of this study can be found under "Is there any way being in this study could be bad for me? (Detailed Risks)"

Please check to confirm you have read and understand the above section of consent.

Yes, I have read and understood this section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include learning more about your smoking habit and quitting smoking. All participants receive free smoking cessation medication and will be provided with additional quit smoking resources.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Instead of being in this research study, your choices may include talking to your doctor, or the New York State Smokers' Quitline (1-866-697-8487) about approved approaches to quitting smoking, including varenicline (Chantix®), bupropion (Zyban®), various forms of nicotine replacement therapy, and counseling. The important risks and possible benefits of these treatments are examined in detail at <https://smokefree.gov/tools-tips/explore-quit-methods>.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at the Behavioral Health Lab Study Line: 716-829-2323. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research. How many people will be studied?

This research project will include 200 people. We expect to enroll about 100 people from the Western New York area.

What happens if I say yes, I want to be in this research?

Your participation in this research program will involve completing an Intake visit (which will last about 60 minutes) where you will receive a more complete description of the study. If you are interested in participating after hearing the description and having your questions answered, you will be asked to sign this consent form and to complete the Intake portion of the visit. The Intake is necessary to make sure you meet the eligibility criteria and that it is safe for you to participate, as well as to provide us with basic information about you. If you are eligible to continue in the study after the Intake visit, you will be scheduled for your first Treatment and Assessment visit to take place 1 week before your planned quit smoking date. There are 5 Treatment and Assessment visits spread out over about 3 months. More detail is provided below.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include learning more about your smoking habit and quitting smoking. All participants receive free smoking cessation medication and will be provided with additional quit smoking resources.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Instead of being in this research study, your choices may include talking to your doctor, or the Pennsylvania Smokers' Quitline (1-800-784-8669) about approved approaches to quitting smoking, including varenicline (Chantix®), bupropion (Zyban®), various forms of nicotine replacement therapy, and counseling. The important risks and possible benefits of these treatments are examined in detail at <https://smokefree.gov/tools-tips/explore-quit-methods>.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Penn (215)746-7147. You may also contact the research participant advocate at the University at Buffalo (UB) at (716)888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at Penn (215) 898-2614 or at UB (716)-888-4888 or ubirb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research. How many people will be studied?

This research project will include 200 people. We expect to enroll about 100 people from the Greater Philadelphia area and the other 100 people will be enrolled from the Western New York area at a site hosted by the University at Buffalo.

What happens if I say yes, I want to be in this research?

Your participation in this research program will involve completing an Intake visit (which will last about 60 minutes) where you will receive a more complete description of the study. If you are interested in participating after hearing the description and having your questions answered, you will be asked to sign this consent form and to complete the Intake portion of the visit. The Intake is necessary to make sure you meet the eligibility criteria and that it is safe for you to participate, as well as to provide us with basic information about you. If you are eligible to continue in the study after the Intake visit, you will be scheduled for your first Treatment and Assessment visit to take place 1 week before your planned quit smoking date. There are 5 Treatment and Assessment visits spread out over about 3 months. More detail is provided below.

Experimental part of the study

Everyone who participates in the study will receive nicotine replacement therapy patches and lozenges at no cost and information on how to access additional support for quitting smoking.

The "experimental" part of the study compares the impact of completing visits in-person at the University at Buffalo South Campus (near Main St and Bailey Ave) to visits completed remotely/virtually in your own home or other private space using video-conferencing (with Zoom) on your smart phone, computer, or tablet.

As mentioned above, the format of each type of visit is determined randomly by a computer program, like flipping a coin. Neither you nor the study team will select what kind of visit you will complete. There is a 50% chance that your Intake Visit (this visit) is remote, and a 50% chance that your Treatment and Assessment Visits will be remote. Other than the location of visits (in-person at UB or remote with Zoom), everything will be the same between the groups.

Intake Visit

During this visit you will:

Receive a detailed overview of the study; Complete informed consent (if interested in continuing); Complete several surveys about your smoking and quitting history, current medications, mental and physical health, and information on your age, education and other similar items. Complete an interview about your recent use of cigarettes and other products; If your intake visit is in person, provide a breath sample for a carbon monoxide (CO) assessment Review your study payment card (details below in section "Will I get paid for my participation in this research?" within the section "What else do I need to know?") Payments to your study card will happen within 1-2 business days after each of your visits. If eligible:

You will find out whether your remaining visits are remote or in person; We will choose a date within the next month that you want to stop smoking and schedule the 5 Treatment and Assessment visits around that date; Treatment and Assessment Visits

At each of the 5 Treatment and Assessment Visits, you will also:

- Provide an exhaled breath sample for a carbon monoxide (CO) assessment (if your visits are remote, you will use a device we mail to you and an app you install on your smartphone);
- Complete electronic surveys, including possible side effects, smoking urges, and withdrawal symptoms (if your visits are remote, we will send you a link so you can complete these on your smartphone, computer, or tablet). Study staff will review any significant increases in side effects or other problems and consult with the study doctors as needed. At Treatment and Assessment Visit 1 (~1 week before your quit date), you will also:

- Receive your first 4 weeks of combination nicotine replacement therapy (patches and lozenges), with instructions to start the medication on your quit date (if your visits are remote, we will mail you the materials before this visit);
- Receive a booklet with detailed instructions for using the study medication, as well other materials and resources to help you develop your quit smoking plan, which we will briefly review with you (if your visits are remote, we will mail you the materials before this visit). At Treatment and Assessment Visit 2 (your quit date), you will also:

- Have any questions about the study medication and resources answered;
- Receive encouragement to continue using the treatment. At Treatment and Assessment Visit 3 (~2 weeks after your quit date), you will also:

- Review how many nicotine replacement patches and lozenges you have used and, if inperson, return any unused medication.
- Receive your next 4 weeks of nicotine patches and lozenges;
- Receive encouragement to continue using the treatment. At Treatment and Assessment Visit 4 (~9 weeks after your quit date), you will also:

- Review how many nicotine replacement patches and lozenges you have used and, if inperson, return any unused medication. Treatment and Assessment Visit 5 will take place ~12 weeks after your quit date.

Within 30 days of Treatment and Assessment Visit 5's scheduled date, you may be contacted by our colleagues to complete an hour-long interview about your experiences in this study. You have about a 1 in 6 chance of being asked

to complete the interview.

Experimental part of the study

Everyone who participates in the study will receive nicotine replacement therapy patches and lozenges at no cost and information on how to access additional support for quitting smoking.

The "experimental" part of the study compares the impact of completing visits in-person at 3535 Market St, Suite 4100 (on the corner of 36th and Market St) to visits completed remotely/virtually in your own home or other private space using video-conferencing (with Zoom) on your smart phone, computer, or tablet.

As mentioned above, the format of each type of visit is determined randomly by a computer program, like flipping a coin. Neither you nor the study team will select what kind of visit you will complete. There is a 50% chance that your Intake Visit (this visit) is remote, and a 50% chance that your Treatment and Assessment Visits will be remote. Other than the location of visits (in-person at Penn or remote with Zoom), everything will be the same between the groups.

Intake Visit

During this visit you will:

Receive a detailed overview of the study; Complete informed consent (if interested in continuing); Complete several surveys about your smoking and quitting history, current medications, mental and physical health, and information on your age, education and other similar items. Complete an interview about your recent use of cigarettes and other products; If your intake visit is in person, provided a breath sample for a carbon monoxide (CO) assessment Review your study payment card (details below in section "Will I get paid for my participation in this research?" within the section "What else do I need to know?") Payments to your study card will happen within 1-2 business days after each of your visits. If you are eligible:

You will find out whether your remaining visits are remote or in person; We will choose a date within the next month that you want to stop smoking and schedule the 5 Treatment and Assessment visits around that date; Treatment and Assessment Visits

At each of the 5 Treatment and Assessment Visits, you will also:

- Provide an exhaled breath sample for a carbon monoxide (CO) assessment (if your visits are remote, you will use a device we mail to you and an app you install on your smartphone);

- Complete electronic surveys, including possible side effects, smoking urges, and withdrawal symptoms (if your visits are remote, we will send you a link so you can complete these on your smartphone, computer, or tablet). Study staff will review any significant increases in side effects or other problems and consult with the study doctors as needed. At Treatment and Assessment Visit 1 (~1 week before your quit date), you will also:

- Receive your first 4 weeks of combination nicotine replacement therapy (patches and lozenges), with instructions to start the medication on your quit date (if your visits are remote, we will mail you the materials before this visit);

- Receive a booklet with detailed instructions for using the study medication, as well other materials and resources to help you develop your quit smoking plan, which we will briefly review with you (if your visits are remote, we will mail you the materials before this visit). At Treatment and Assessment Visit 2 (your quit date), you will also:

- Have any questions about the study medication and resources answered;

- Receive encouragement to continue using the treatment. At Treatment and Assessment Visit 3 (~2 weeks after your quit date), you will also:

- Review how many nicotine replacement patches and lozenges you have used and, if in- person, return any unused medication.

- Receive your next 4 weeks of combination nicotine replacement therapy (patches and lozenges);

- Receive encouragement to continue using the treatment. At Treatment and Assessment Visit 4 (~9 weeks after your quit date), you will also:

- Review how many nicotine replacement patches and lozenges you have used and, if in- person, return any unused medication. Treatment and Assessment Visit 5 will take place ~12 weeks after your quit date.

Within 30 days of Treatment and Assessment Visit 5's scheduled date, you may be contacted by our colleagues to complete an hour-long interview about your experiences in this study. You have about a 1 in 6 chance of being asked to complete the interview.

Please check to confirm you have read and understand the above section of consent.

Yes, I have read and understood this section.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- complete study visits and let us know if you need to reschedule,
- follow the instructions from the research team,
- complete study surveys in a timely fashion, accurately and honestly, and
- let us know if you are uncertain, confused, or upset about any aspect of the study. What happens if I say yes, but I change my mind later?

You can leave the research study at any time, and it will not be held against you. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You do not have to answer every question and may refuse to complete study activities (though doing so may make you ineligible for further participation). You may withdraw from the study at any time by contacting the research team. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

The likelihood and severity of the potential risks to you are described below. Overall, there is minimal risk for serious negative effects from participating in this research program.

While enrolled in this research study, you will be asked not to use any smoking cessation therapy other than that which we will provide. If you have used e-cigarettes or vaping devices in the past, we DO NOT want you to use these during this study.

Withdrawal: Most individuals who quit smoking experience some symptoms of withdrawal. These symptoms can occur almost immediately and can last for 1-4 weeks for most people, including:

- Sadness / depressed mood Irritability, frustration, or anger Anxiety Restlessness
 - Insomnia
 - Increased appetite
 - Craving for cigarettes
 - Difficulty concentrating
- The medication we provide will help you deal with any withdrawal symptoms that you may experience, as will the information/resources booklet.

Side effects of nicotine replacement therapy. The most common side effects of the nicotine patch are skin redness, itching, or burning; headache; and sleep disturbance such as difficulty sleeping and vivid dreams. The most common side effects of the nicotine lozenge are nausea, hiccups, or heartburn; trouble sleeping; headache; and cough. Side effects tend to be mild and decrease over time. The material we provide contains tips for minimizing these side effects. If side effects are severe, the study doctor may suggest other strategies for addressing them, including stopping the study medication.

Assessments: Some people can experience anxiety/distress when they complete questionnaires about smoking and when thinking about attempts to quit smoking. This is generally related to your feelings about quitting as well as learning about some of the health risks associated with smoking. These reactions are usually mild and typically diminish with time.

Threats to Privacy/Confidentiality: There is a small chance that someone who is not authorized could see your private study information. We are taking steps so that does not happen. More information can be found in "What happens to the information collected for the research?" Every attempt will be made by the investigators to keep all information collected in this program strictly confidential. Because we want to protect your confidentiality, we will identify most of your electronic data with an identification number only (not your name). Only authorized program personnel will be able to link your identification number with your name. We will store your information in a secure computer system with access limited to the study team, and any paper records will be stored in locked cabinets in locked rooms with access limited to the study team. When results of the program are published, no names or identifying information will be used.

Neither you nor your health insurance provider will be charged for costs of any of the procedures performed for the purpose of this research study (e.g., screening procedures, experimental procedures, medication, counseling, monitoring/follow-up procedures described above).

There may be risks that we do not know about at this time. We will notify you of any new information that may affect your willingness to continue participation in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to only people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and the sponsor of this study: The National Institutes of Health (NIH).

There are some limitations on confidentiality. Specifically, we may be required by law to report to appropriate authorities any evidence of ongoing child or elder abuse or neglect or evidence that you are intending to seriously harm or kill yourself or someone else. Confidentiality may need to be broken to ensure your safety if you report that you are considering suicide or selfharm.

If information that identifies you is removed from your study information, study data could be used for future research studies or shared with other researchers without your additional consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 brief summary of the results. You can search this Web site at any time.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- The Principal Investigators feel it is necessary for your health or safety. Such an action would not require your consent, but you would be informed if such a decision was made and the reason for this decision.
- You have not followed program requirements (e.g., you repeatedly fail to attend scheduled visits; you threaten or harass a staff member), and/or
- The Sponsor, University, or Investigators have decided to stop the program. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know? Who is paying for this research?

This research is being funded by National Institutes of Health (NIH).

Will I get paid for my participation in this research?

In addition to the nicotine replacement patches and lozenges provided, if you agree to take part in this research study, we will pay you up to \$180 for your time and effort. You will receive \$30 for completing the Intake visit. For the Treatment and Assessment visits, you will receive \$10 for providing an exhaled breath sample for a carbon monoxide (CO) assessment and \$20 for completing the rest of the visit (5 visits x \$30 each visit = \$150).

If you are selected to participate in an interview about your experiences in the study, you will receive an additional \$50 following completion of the interview.

The Study Card Program Group, under The University at Buffalo's Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a Reloadable Focus Blue Card, which is a prepaid debit card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your U.S. Bank Focus Blue Card balance. If you receive your bank card at the study visit, your payment will be available within the next 1-2 business days. The Study staff will provide you with additional information about how the bank debit card works. In order for U.S. Bank to be able to reimburse you using the Focus Blue Card, only your first and last name (required), physical address (required), and birth date (required) will be shared with U.S. Bank. The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to Study Card Program Group, under The University at Buffalo Office of Financial Management. No protected health information will be shared with the U.S. Bank or the Study Card Program Group.

Please note that an inactivity fee of \$2 per month will be deducted from your card balance after 365 days of card inactivity. This is in addition to a \$2 per month maintenance fee that will be deducted from any remaining balance beginning 12 months from the date of your card's activation. Your card will be considered activated as of today's date.

Please also note that U.S. Bank may use your personal contact information to market the bank's other products and services to you. You may limit U.S. Bank's direct marketing to you by visiting U.S. Bank online at <http://www.usbank.com/privacy>.

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds \$600.00 in a calendar year, you will be issued a form 1099.

What will happen to my information and samples?

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

What else do I need to know? Who is paying for this research?

This research is being funded by National Institutes of Health (NIH).

Will I get paid for my participation in this research?

In addition to the nicotine replacement patches and lozenges provided, if you agree to take part in this research study, we will pay you up to \$180 for your time and effort. You will receive \$30 for completing the Intake visit. For the Treatment and Assessment visits, you will receive \$10 for providing an exhaled breath sample for a carbon monoxide (CO) assessment and \$20 for completing the rest of the visit (5 visits x \$30 each visit = \$150).

Compensation will be provided through a Greenphire ClinCard, which is a reloadable, pre-paid debit card. Compensation in the amount outlined in the Informed Consent Form will be loaded onto the ClinCard at the end of successfully completed visits. Once you receive the ClinCard either by mail after the remote intake or at the in-person intake visit, your payment will be available within the next 24 hours. The Study staff will provide you with additional information about how the pre-paid debit card works. In order for Greenphire ClinCard to be able to reimburse you, it is required that your first and last name, physical address, and birth date be shared with Greenphire ClinCard. No other personal information will be shared with them.

Please note that an inactivity fee of \$4.50 per month will be deducted from your card balance after six months of card inactivity. New payments reset this six-month period. Cardholders can reach out to Greenphire customer support at 866-952-3795 or <https://support.greenphire.com> for any assistance that the Study team is unable to provide.

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds \$600.00 in a calendar year, you will be issued a form 1099.

What will happen to my information and samples?

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

PLEASE WAIT FOR THE RESEARCH ASSISTANT BEFORE CONTINUING WITH THE FORM Research Assistant, check box when all questions have been answered.

All questions have been answered.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Do you still want to participate in this study?

Yes, I would like to participate in this study. No, I would not like to participate in this study.

Please explain why:

Do you want a copy of your signed consent form emailed to you?

- Yes
- No

Please provide an email address to send copy of consent:

First Name:

Last Name:

Signature of Subject:

Today's Date:
