THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Strategies to Promote Cessation in Smokers Who Are Not Ready to Quit (PACE)

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1. INTRODUCTION:

You have the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. Please tell the study staff if you are taking part in another research study.

This research study is being conducted at the University of Tennessee Health Science Center (UTHSC) and is sponsored by the National Institutes of Health. The purpose of this study is to examine the benefits of telephone counseling sessions to help people prepare for a change in their smoking habits. Approximately 950 smokers who are not ready to quit will be enrolled. All study contact, no matter where you live, will be over the telephone.

Your participation in the study will last one year.

2. PROCEDURES TO BE FOLLOWED:

Once enrolled in the study, you will receive three 30-minute telephone counseling sessions and three booster sessions that are aimed towards moving you down the path to a quit attempt. Each session will be with a staff member who is trained in behavior change skills.

You will be randomly assigned to one of four intervention groups, which means that a computer picks which group you join. No one has control over which group you are assigned to. Here is a description of each of the groups you may be assigned to.

> **Group 1:** If you are assigned to the first group you will receive the standard of care. You would receive advice to quit smoking, be provided research on health consequences and the positive impact of smoking cessation on mortality and morbidity, as well information for national tobacco quitlines. In addition to the 3 intervention sessions across 6 weeks, there will be 3 Booster sessions and questionnaires at 2 months, 4 months, and 6 months. We would also call you at 12 months from enrollment to see how you are doing.

Group 2: If you are assigned to the second group you will receive counseling in a style called "motivational interviewing," where the counselor helps you to define your own goals regarding smoking and contemplating a quit attempt. In this group you would receive "the 5Rs," which is a set of skills to help individuals understand their smoking triggers. In addition to the 3 intervention sessions across 6 weeks, there will be 3 Booster sessions and questionnaires at 2 months, 4 months, and 6 months. We will also call you at 12 months from enrollment to see how you are doing.

Group 3: If you are assigned to the third group you will receive a rate reduction intervention to reduce your tobacco use, which includes reducing your intake so that a future quit attempt is easier. In addition to the 3 intervention sessions across 6 weeks, there will be 3 Booster sessions and questionnaires at 2 months, 4 months, and 6 months. You would receive 26 weeks worth of 4 mg nicotine gum and a handout on how to use the gum will be provided. We would also call you at 12 months from enrollment to see how you are doing.

Group 4: If you are assigned to the fourth group you will receive a combination of motivational interviewing, the 5Rs, and rate reduction interventions. In addition to the 3 intervention sessions across 6 weeks, there will be 3 booster intervention sessions and questionnaires at 2 month, 4 months, and 6 months. You would receive 26 weeks worth of 4 mg nicotine gum and a handout on how to use the gum. We would also call you at 12 months from enrollment to see how you are doing.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

At each phone session of the study, we will collect the following data: Information about your motivation and confidence to quit, smoking habits, withdrawal symptoms, use of other products, and potential side effects of nicotine replacement therapy (NRT). Please alert the study team if you have any illnesses or hospitalizations over the course of participation.

Questionnaires:
Completion of the questionnaires may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.

Audio recording:
Being audio recorded during the simulated session may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who listens to your audio recording might identify you.

Side effects:
Although it is expected that all study treatments will be beneficial, it is possible that any of the treatments may later turn out to be less effective or to have more risks or side effects than other therapies. All participants, however, get a highly effective stop smoking program initially.

Smoking cessation is associated with a variety of nicotine withdrawal symptoms including depressed mood, difficulty sleeping, irritability, anxiety, difficulty concentrating, restlessness, and increased appetite or weight gain. These symptoms typically are not severe and dissipate within a few weeks of cessation. Study staff will be available to discuss these symptoms with you and provide appropriate strategies to cope with them.

The side effects of nicotine gum are minor, but you should be aware of them. They may include headache, diarrhea, gas, heartburn, hiccups, and sick to your stomach. If you are assigned to a group that does not receive nicotine gum, you will not be exposed to these risks.

While you are taking part in this research study, you're at risk for these side effects. If you experience any of these side effects, it's important that you alert the study staff as well as your medical doctor. You can call the PACE study at any time during operating hours with questions or concerns. Although unlikely, if you should have a significant study related adverse experience after operating hours, and you feel it's a medical emergency, you are urged to contact your doctor, go to the nearest emergency room, or call 911.

4. BENEFITS ASSOCIATED WITH PARTICIPATION:

Counseling to help stop cigarette smoking and using nicotine gum can help some people quit smoking, although it's not guaranteed that your health will improve. It is possible that you will be able to stop smoking for some time with the help of this research study.

5. ALTERNATIVES TO PARTICIPATION:

You do not have to be in this study to receive treatment to stop smoking; there are alternative treatments. Other treatments for smokers include national quitlines; classes; other forms of NRT such as nicotine nasal spray, lozenge, or inhaler; or prescription medications to help you quit smoking. Nicotine gum may also be obtained without being in this study.

You will not have to undergo the following procedures if you do not take part in this study:

- Complete 14 questionnaires

- Participate in 3 sessions and 3 booster sessions about your smoking behaviors over the phone
- Using nicotine gum (if you are assigned to one of the two groups that receives gum)

6. CONFIDENTIALITY:

Research records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Medical Records
Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Authorization to Use and Disclose Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your personal health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are authorizing the researchers at the University of Tennessee to have access to the PHI collected in this study; we will not have access to your medical records. Your PHI may be shared with other persons involved in the conduct or oversight of this research. For example:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- The National Cancer Institute at the National Institutes of Health

However, some of these organizations or institutions above do not have the same obligations to protect your PHI. Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used for as long as the sponsor reports study information to the FDA.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

7. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, University of Tennessee does not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities. You and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc. No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

8. QUESTIONS:

Contact Sarah Hand at 901-448-3072 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury or a reaction to the study drug, contact Karen Derefinko at 1-844-680-7223.

You may contact Terrence F. Ackerman, PhD, UTHSC IRB Chairman, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

9. PAYMENT FOR PARTICIPATION:

You will receive a gift card for $20, emailed to you after each completed study visit, and $40 for completing the 12-month follow-up. If you complete all the study visits, you will receive up to $160. If you do not complete the study, you will be paid for the visits you have completed. If you refer a friend who enrolls in the PACE research study, then you will receive an additional $20 for the referral.

10. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. We will provide the nicotine gum free of charge if you are randomized to group 3 or 4 during this study.

11. VOLUNTARY PARTICIPATION AND WITHDRAWAL:

Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you are a student of UTHSC participating or not participating in this study will in no way influence your grade in any course. If you are an employee of UTHSC, participating or not participating in this study will not affect your employment status.

If you decide to stop being part of the study, you should tell your counselor, and any information that you have already provided will be kept in a confidential manner. You will be advised whether any additional procedures need to be done for your safety.

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

- If you experience a serious adverse event associated with Nicotine Gum
- If it is not in your best interest
- If you do not follow the study doctor's instructions
- If the study is stopped

12. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways. Please initial for each method we may use to contact you. If you do not wish for us to contact you via a particular method, you may leave the line blank.

_____ The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.

_____ An email will be sent to the email address you provided asking you to call us.

_____ A letter will be sent to the address you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

_____ A message on Facebook will be sent if you have provided us with your Facebook page information

_____ Public records search

Please note that if we lose contact with you and there is new information about your participation in the study that could affect your safety, we will attempt to find you or make contact with you in any way possible.

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on <u>one</u> of the lines below:

_____ We CAN keep your contact information and health information to ask you about participating in future studies.

_____ We MAY NOT keep your contact information and health information to ask you about participating in future studies.

13. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

Signature of Research Subject (18 years +)	**Date**	**Time**

Printed Name of Adult Research Subject

Signature of Person Obtaining Consent	**Date**	**Time**

Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Signature of Investigator	**Date**	**Time**