**UW HS-IRB #2015-1376**

**UNIVERSITY OF WISCONSIN-MADISON**

**Subject CONSENT to Participate in Research**
**And**
**AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research**

**Title of the Study:** UW Smoking Cessation Research Project

**Principal Investigator:** Michael C. Fiore, MD, MPH, MBA
Phone: 608-262-8673; email: mcf@ctri.wisc.edu;
1930 Monroe St., Suite 200, Madison, WI 53711

**Study Funding:** National Cancer Institute

## INVITATION

You are invited to participate in this research study that is studying the use of a combination of three FDA-approved medicines for quitting smoking. You are invited to take part because you are interested in quitting smoking. This is a 3 month research study. You will get 12 weeks of nicotine patch, nicotine lozenge and varenicline (Chantix). You will also receive quit-smoking coaching. The U.S. Public Health Service guideline on treatment for quitting smoking recommends both medication and coaching. Approximately 40 people will participate in this study.

Your participation in this research study is completely voluntary. If you decide not to participate, the health care provided to you by your primary care provider will not be affected in any way.

## A. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to discover whether a combination of three FDA-approved stop smoking medicines is well-tolerated and a useful way to help people who want to quit smoking.

## B. WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this study, you will be provided with study medicines and coaching and will receive medical monitoring throughout treatment. You will be asked to complete an initial in-person clinic visit which will last about 1 hour. This is the only in-person visit in the study. You will also complete 9 follow-up assessment phone calls on your quit day and 1, 2, 3, 4, 6, 8, 10 and 12 weeks after you quit (described below). In total, your participation could take up to 3 hours over 4 months.

**The in-person clinic visit will include the following:**

- We will ask you to fill out a questionnaire that will include information about your smoking (when and how often you smoke), how dependent you are on nicotine, your mood states, basic demographic information (age, gender) and social support.
- You will take a breath test that measures carbon monoxide in your lungs, which helps measure how much you smoke. After inhaling deeply and holding your breath for 15 seconds, you will breathe out into a disposable tube that will be placed over a sensor.
- We will collect information about your height and weight.
- We will also help you set a target quit date.

**Study treatments:**

- In this study, we are testing the use of 3 medications all designed to help smokers quit smoking, plus smoking cessation coaching. The use of the 3 medicines together is experimental. The treatments would be provided to you at no cost.
- The treatment includes 12 weeks of the nicotine patch, nicotine lozenge and varenicline (Chantix) and an in-person coaching session that would happen today.

**Study assessments:**

- We will ask you to complete 9, 5-10 minute follow-up assessment phone calls on your quit day and at Weeks 1, 2, 3, 4, 6, 8, 10 and 12 after the quit day. At each of these calls you will be asked to answer on smoking status, use of alcohol or other tobacco products, nicotine withdrawal symptoms, mood, stress, social support, and medication use and safety.

**We will also collect the following information about you:**

Name, address, phone number and information about your smoking and other tobacco use, height, weight, carbon monoxide level, and study medication use.

## C. ARE THERE ANY BENEFITS TO ME?

All participants will receive evidence-based treatment that includes FDA-approved medicines and quit-smoking coaching. Both quit-smoking coaching and the medicines have been shown to help smokers quit. We don't know if being in this study will make it easier for you to quit smoking, but it may. In addition, the information you provide during the study will help us learn how to help other people quit smoking.

## D. WILL I BE PAID FOR MY PARTICIPATION?

You will receive up to $140 for participating in this study. You will receive $50 for completing the initial clinic visit, and $10 for completing each of the 9 assessment calls.



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## E. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

1. The most common side effects to the nicotine patch are a skin rash, insomnia, and vivid dreams. In rare cases, a more severe allergic reaction may occur involving hives (raised, itchy areas of skin), difficulty breathing, and swelling of the face, lips, tongue, or throat. If you have symptoms of a severe allergic reaction, get emergency care right away.
2. The most common side effects of the nicotine mini-lozenge include heartburn, nausea, hiccups, and sore throat. It is also possible that you may get too much nicotine (nicotine overdose) and feel symptoms of nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat.
3. While using the mini-lozenge and patch together, mild or moderate nicotine overdose symptoms can occur. These usually resolve by lowering the patch and mini-lozenge doses. In cases of severe symptoms of nicotine overdose, the patch and mini-lozenge should be discontinued and you should contact your doctor and notify study staff.
4. The most likely side effects associated with varenicline are nausea and sleep disruption. It is also important to note that some individuals may experience worsening of psychiatric conditions or symptoms such as anger, agitation, depression, or suicidal thoughts. Varenicline may be associated with a small, increased risk of certain heart problems in people with heart and blood vessel disease or, in rare cases, a serious skin rash. Study staff will be checking your symptoms at every call. You should contact your doctor and notify study staff immediately if you experience any significant emotional, skin rash or heart-related symptoms.
5. Tolerability of the use of varenicline with nicotine patch and/or lozenge is not certain.

Another risk to taking part in the study is that your study information could be known to someone who is not involved in performing or monitoring this study.

## F. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

Your information will be entered directly into a password-protected computer and encrypted. Information will then be stored on a secure server in a locked room. Paper documents will be stored in locked filing cabinets in locked rooms and shredded when no longer needed.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison.

**Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:**

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison

**Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:**



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• The National Cancer Institute (the study sponsor)

• Serious adverse events associated with use of the study drug will be reported to the FDA and the drug manufacturer

• 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.

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

In addition, we are required by law to take appropriate action if we learn that you are in danger of hurting yourself or others. This action may involve sharing information about you with appropriate authorities (e.g., a police department) in order to protect your safety or the safety of others.

## G. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering. In addition, the Principal Investigator can end your study participation if there are serious violations of the study protocol or procedures by you that put you at risk. During your participation in the study, you will be informed of any new information that may affect your willingness to continue in the study.

**IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, ANY HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.**

## H. ARE THERE ANY ALTERNATIVES?

You do not have to participate in this study to receive help with quitting smoking. If you decide not to participate in this study, you can receive help from your primary care provider at your health clinic. Also, you can receive help from the Wisconsin Tobacco Quit Line by calling the toll-free number 1-800-QUIT-NOW (1-800-784-8669).

## I. WILL THERE BE ANY COMPENSATION FOR INJURY RESULTING FROM THIS RESEARCH?



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In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, (Michael C. Fiore, MD, MPH, MBA) at (608-262-8673) if you are injured or for further information.

## J. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

Michael C. Fiore, MD, MPH, MBA
UW Center for Tobacco Research and Intervention
1930 Monroe St. Suite 200. Madison, WI 53711

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

## K. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Michael C. Fiore, MD, MPH, MBA at 608-262-8673.

If you have any questions about your rights as a research participant or complaints about the research study that you could not resolve with the study team, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.



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**AGREEMENT TO PARTICIPATE IN THIS STUDY**
**AND**
**PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION**

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above. **YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.**

_____ _____
Printed Name of Participant Date

_____ _____
Signature of Participant Date

_____ _____
Printed Name of Person Obtaining Consent and Authorization Date

_____ _____
Signature of Person Obtaining Consent and Authorization Date



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## VOLUNTARY STATEMENT OF INTENT TO AVOID PREGNANCY

According to the FDA and the manufacturer of the nicotine patch and nicotine mini-lozenge, these medications should not be used by pregnant women. The risks of these medications to an unborn child are not fully known. We ask female study participants who are able to get pregnant or who believe that it is possible to get pregnant to agree to the statement below about avoiding pregnancy while taking study medication. Women who have had tubal ligation ("tubes tied") to prevent pregnancy do not have to sign below if the tubal ligation occurred more than a year ago and no pregnancy has occurred. Woman who are menopausal and have not had a menstrual period in more than one year are not required to sign. Male participants are not required to sign this statement.

I, _____ (print name) agree to attempt to avoid pregnancy while I am taking study medication. I will continue to employ medically acceptable means of contraception that have been approved by study staff. These methods include IUD, oral contraceptive, implantable or injectable contraceptives, barrier methods, or abstinence. I will immediately contact study staff if pregnancy is suspected. I am aware that I may decline to sign this statement and my refusal to sign will have no effect on my further treatment from my primary care provider; however, I cannot participate in this research study.

_____ _____

Signature of Participant Date



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