Washington University in St. Louis

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# INFORMED CONSENT DOCUMENT

**Project Title: Genetically Informed Smoking Cessation Trial**

**Principal Investigator:** Li-Shiun Chen

**Research Team Contact:** **Nina Smock**
**(314) 362-1854**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate because you are a smoker who would like to quit smoking. The purpose of this research study is to find out more about how genetic information can be used to help people receive the most effective treatment to quit smoking successfully. The results of this study could lead to more effective ways to help people stop smoking.

## WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, information about smoking and health will be collected from you today. You will then be randomly (like flipping a coin) assigned to one of three smoking treatments: either 1) smoking cessation counseling and nicotine patch plus nicotine lozenge, 2) smoking cessation counseling and varenicline (also known as Chantix), or 3) smoking cessation counseling and placebo (looks like a patch or lozenge or pill but without any active drug). You will be treated for 3 months, but participation in the study will last for 1 year.

The first visit takes about 90 minutes in the office and will include an interview about your smoking history, medical history, and mental health. You are free to skip any questions that you would prefer not to answer. You will also take a carbon monoxide breath test that will measure the level of carbon monoxide in your lungs. The test will take one minute to complete and involves exhaling into a carbon monoxide monitor. We will record the result of the test and use it for research purposes. You will also provide a blood sample of 15 ml (approximately 1 tablespoon), which will be used to look at genes related to nicotine metabolism and other genetic markers. You will be asked to set a date on which you will quit smoking. We will give you the medications you are to use for 12 weeks. We will instruct you

on how to use the medications and side effects to be aware of. These smoking cessation treatments will be provided at no cost to you. Finally, we will provide you with counseling to help you quit smoking.

You will receive phone calls from a member of our study team on the day before your quit date, the day you quit smoking, and 1, 2, and 4 weeks after you quit. These calls will take approximately 30 minutes each, and we will ask you questions about your smoking status, use of the medications you were given to help you quit smoking and physical and mental health. We will also provide smoking cessation counseling.

You will have two additional visits at 12 weeks and 6 months after you quit smoking. These visits will be in person or over the phone. During these visits, we will ask you questions about your smoking status, use of the medications to help you quit smoking and physical and mental health. You may take another carbon monoxide breath test that will measure the level of carbon monoxide in your lungs. We will also provide smoking cessation counseling at week 12.

You will receive a final phone call from a member of our study team 12 months after your quit date. This call will last approximately 20 minutes and we will ask you about your smoking status and physical and mental health.

You previously participated in the COGEND study (a family study of nicotine dependence) and donated your blood or saliva for genetic analysis at that time. You also recently participated in the GERS study (a follow up study of COGEND participants). Under this current study, we will use your genetic information from COGEND and your interview data from COGEND and GERS to examine associations between genetic factors, environmental factors, and smoking cessation outcomes. We hope that this study will help improve future smoking cessation treatments.

**Will you save my samples or research data to use in future research studies?**

As part of this study, we are obtaining blood and coded data from you. By agreeing to be part of this study you give up any property rights you may have in the blood and data. We would like to use your blood and data for other research projects in the future. These future studies may provide additional information that will be helpful in understanding smoking cessation, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood and data, you give up any property rights you may have in the blood and data.

We will share your blood and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These investigators may be at Washington University or at other research centers. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research

data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

To ensure other investigators receiving the blood and data will not have your name or any other kind of link that would identify you, we maintain and securely store your blood and data and the link to your identity through a random identification number which is different from your study identification number.

If you change your mind and do not want us to store and use your blood and data for future research you should contact the research team member identified at the top of this document. The blood and data will no longer be used for research purposes. However, if some research with your blood and data has already been completed, the information from that research may still be used. Also, if the blood and data has been shared with other researchers it might not be possible to withdraw the blood and data to the extent it has been shared.

**Audio Recording**

One aspect of this study involves making audio recordings of interviews for accuracy in editing by the interview staff and quality control of the study. Your name will not be recorded and the recordings will not be shared with anyone outside of the research staff. They will be stored on password-protected computers in locked offices, and kept separate from identifiable data (consent form, payment form). The audio files will be destroyed 1 year after the completion of the study.

This audio recording is optional, and you can still be in the study without being recorded.
I give you permission to make audio recordings of me for internal research quality control during this study.

**_____ Yes** **_____ No**
**Initials** **Initials**

**HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 720 people will take part in this study conducted by investigators at Washington University.

**HOW LONG WILL I BE IN THIS STUDY?**

If you agree to take part in this study, your involvement will last for one year and include one to three in-person visits (each lasting approximately one hour) and 6-8 phone calls from a study team member (each lasting approximately 30 minutes) and reminder calls and text/emails if you consent below. For the results of this study to be useful, it is important that you are committed to participating in all of the in-person visits and phone calls. If you do not think you can commit to this, you should not participate in this study.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

**Risks from smoking cessation:** You will be asked to quit smoking as part of this study. When people quit, they often experience smoking withdrawal, which is associated with a number of unpleasant experiences such as sleep disturbance, hunger, a strong desire to smoke again, and negative mood. Most smokers have tried to quit in the past and are familiar with these experiences.

**Likely /Common Withdrawal Experiences**

Mild

- sleep disturbance
- hunger
- craving—a strong desire to smoke again
- negative mood

**Less Likely /Less Common Withdrawal Experiences**

Mild

- headache
- inability to sleep

**Risks from the nicotine patch:** The nicotine patch has very few side effects, but you may have a local skin reaction where the patch is attached, and rarely, a more systematic allergic reaction. The most common side effects associated with the nicotine patch are diarrhea, indigestion, nausea and vomiting, dry mouth, muscle and joint pain, sleeplessness, and strange dreams. Side effects associated with wearing an adhesive patch include skin rash, redness, and itching or irritation of the skin. In most cases, these side effects have been mild to moderate in intensity and go away once the patch is removed. Although most smokers have tolerance to nicotine (meaning the body has grown accustomed to it, so you no longer respond the way you did when you first started using it), symptoms of acute nicotine poisoning (nausea and vomiting) are possible.

**Likely /Common Nicotine Patch Side Effects**

Mild

- local skin reaction
- diarrhea
- indigestion
- nausea and vomiting
- dry mouth
- muscle and joint pain
- sleeplessness
- strange dreams

**Less Likely /Less Common Nicotine Patch Side Effects**

Mild

- skin rash, redness, and itching or irritation of the skin

**Rare Nicotine Patch Side Effects**

Serious

- systematic allergic reaction
- increased heart rate
- increased blood pressure
- Central nervous system effects including: Impaired concentration, Depression, Anxiety, Insomnia, Nervousness

**Risks from the nicotine lozenge:** The nicotine lozenge is available over the counter and has very few side effects. The most common side effects associated with the nicotine lozenge are heart burn, hiccup, nausea, upper respiratory tract infection, coughing, and sore throat. In most cases, these side effects have been mild to moderate in intensity and go away once the lozenge is removed. Although most smokers have tolerance to nicotine (meaning the body has grown accustomed to it, so you no longer respond the way you did when you first started using it), symptoms of acute nicotine poisoning (nausea and vomiting) are possible.

**Likely /Common Nicotine Lozenge Side Effects**

Mild

- heart burn
- hiccup
- nausea
- upper respiratory tract infection
- coughing
- sore throat

**Less Likely /Less Common Nicotine Lozenge Side Effects**
Mild

- redness, and itching or irritation of the throat

**Rare Nicotine Lozenge Side Effects**
Serious

- systemic allergic reaction (an allergic reaction involving multiple parts of the body or the entire body)
- increased heart rate
- increased blood pressure
- Central nervous system effects including: Impaired concentration, Depression, Anxiety, Insomnia, Nervousness

**Risks from varenicline:** Varenicline is a medication approved by the Food and Drug Administration (FDA) for smoking cessation and is medically safe for most smokers except for individuals with severe (end stage) kidney failure or hypersensitivity to varenicline. The most commons side effects associated with varenicline are nausea, vomiting, and headache. Rare side effects are depression, suicidal ideation, and emotional lability. In 2009, the FDA issued a warning about these rare side effects. In 2011, the FDA updated this warning because new research did not find an increase in these rare side effects. The FDA continues to monitor the medication risk, and we will closely monitor any side effects you may experience in this study.

**Likely /Common Varenicline Side Effects**
Mild

- nausea
- vomiting
- indigestion
- headache
- fatigue
- drowsiness
- sleep problems (trouble sleeping of vivid, unusual or strange dreams)
- constipation
- gas

**Less Likely /Less Common Varenicline Side Effects**
Mild

- mild joint pain
- increased urination
- changes in appetite

**Rare Varenicline Side Effects**
Serious

- allergic reaction
- depression or suicidal ideation
- chest pain
- difficulty in urination

**Risks from the interview**: You might find some of the questions personal or uncomfortable to answer. You can refuse to answer any specific questions or stop the interview at any time.

**Less Likely /Less Common Risks of Completing the Interviews**
Mild

- emotional discomfort

**Risks from the breath test**: There are no foreseeable risks associated with the breath test.

**Risks from the 15 ml Blood Draw**: You may experience some discomfort, bruising, and/or minor bleeding at the site of the needle insertion. Occasionally, some people experience dizziness or feel faint. The research staff is prepared to handle such situations.

**Likely / Common Risks of blood draw**
Mild

- bruising
- discomfort
- bleeding at site of needle insertion

**Rare Risks of blood draw**
Serious

- infection at the site of needle stick
- fainting or dizziness

**Risks from DNA tests**: DNA, the material in cells that is passed from parents to children, will be obtained and tested from your blood sample. Participation in this genetic study may ultimately reveal that you are at risk for smoking-related disorders and other diseases. You will not receive any results

from any of these analyses.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

**WHAT ARE THE BENEFITS OF THIS STUDY?**

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because this research has the potential to provide improved treatment strategies for doctors trying to help patients quit smoking. This could result in more effective treatments for smokers in the future.

**WHAT OTHER TREATMENT OPTIONS ARE THERE?**

Before you decide whether or not to be in this study, you have other options that are available to you. Instead of being in this study, you could seek medications to help you quit smoking and smoking cessation counseling without being in a research study.

**WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

There is no cost to you for being in this research study. The smoking cessation treatments will be provided to you at no cost.

Message and Data rates may apply to the text messages. You will receive a maximum of 4 messages a month. You can text STOP or contact Nina Smock at 314-362-1854 to opt-out of receiving these messages. You may also decline to receive text messages from the study.

**WILL I BE PAID FOR PARTICIPATING?**

You will be paid $40 for the first visit. You will be paid $20 for completing phone calls at 12 weeks and 6 months and $10 for completing a brief phone call at one year. If you are asked to come in for an in person visit at 12 weeks or 6 months, we will pay you an additional $20 for your time. The total compensation is up to $130. You will be paid by cash for in person visits and by check for telephone assessments. You will need to provide your address so that the checks can be mailed to you. You may also need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. Your social security number is obtained for payment purposes only.

## WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study. Pfizer will provide active and placebo varenicline.

## WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Dr. Li-Shiun Chen, MD at (314) 362-3932 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

## WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in our research database. The database will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this database secure in password-protected computers in a locked office. You may request that your personal information be removed from this file at any time by contacting the research coordinator Nina Smock at 314-362-1854 or the principal investigator Dr. Li-Shiun Chen, Department of Psychiatry, Washington University, 314-362-3932.

I give you permission to put my name and personal information in a research database so that other researchers can contact me in the future about different research studies.

**_____ Yes** **_____ No**
**Initials** **Initials**

## HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The sponsor, National Institute of Health
- GlaxoSmithKline (GSK), as required by law, to report adverse events associated with GSK products to the FDA.

- Pfizer, to report any severe adverse events associated with Pfizer products.
- Hospital or University representatives, to complete Hospital or University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants.) The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, all research information is coded, using an individualized I.D. number. Paper forms are kept locked in file cabinets in our locked office. Electronic files are password protected and stored on a secured Washington University, Department of Psychiatry Server. Blood samples will be stored at Washington University. Only members of the research team have access to your study information. We encourage you to password protect your phone during the course of this study so that others cannot go through your phone and see text messages that have been sent from the study.

If we write a report or article about this study or share the study dataset with others, we will do so in such a way that you cannot be directly identified.

We will disclose, to the proper authority, information you share with us concerning child abuse, child sexual abuse, or harming yourself or others.

**Are there additional protections for my health information?**

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

**If you sign this form:**

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpo.wustl.edu/participants//withdrawing-from-a-study/) or you may request that the Investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

**Can we contact you by text?**

We would like to contact you by text message for the purposes listed below.

- **Appointment and phone call reminders**

Only the research team will have access to your texting communications. We will only communicate by text to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with allowing us to text you for the purposes of this study.

- There is always a risk that the text message could be intercepted or sent to the wrong telephone number. To avoid sending messages to the wrong number, the first text we send you will be a test message to ensure we have the correct telephone number.

Do you agree to allow us to send your appointment and phone call reminders via text?

**Yes_____** **No**
**Initials** **Initials**

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter.

### Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

### Can someone else end my participation in this study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because you have severe adverse effects from the medication and the study does not seem to be helping you. For safety, it may be in your best interest to allow follow-up outside the study. This decision would be made in consultation with the study physician.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact the research coordinator, Nina Smock, at (314) 362-1854. If you experience a research- related injury, please contact Dr. Li-Shiun Chen, at (314) 362-3932.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, or 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

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This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to

the best of your ability unless you choose to stop your participation in the research study.

- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

**Do not sign this form if today's date is after EXPIRATION DATE: 05/20/15.**

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

**Statement of Person Who Obtained Consent**

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)