The Patch/Zyban Consent Form for Partnership for Health Participants

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Introduction

You are currently part of the "Partnership for Health" research study. This study is being conducted by the Dana-Farber Cancer Institute (DFCI). Other hospitals participating in the study are Memorial Sloan-Kettering Cancer Center, St. Jude Children's Research Hospital, and Princess Margaret Hospital. This study is funded by the National Cancer Institute. About 750 people will be in this study.

Study subjects who are interested in quitting smoking can receive free nicotine replacement therapy (NRT), an over-the-counter quit-smoking drug, or Zyban, a prescription quit-smoking drug, through the study. The NRT will be in the form of the patch.

You are receiving this consent form because you have requested free NRT or Zyban as part of your participation in Partnership for Health. This consent form will review the information that you have already been given about why this study is being done. This form will also tell you why you are being offered quit-smoking drugs and describe what you need to do to receive the quit-smoking medications. It will cover any possible risks, inconveniences, or discomforts that you may have while participating. We also encourage you to ask questions now and at any time. If you decide to receive the free medication, you will need to sign and mail this entire form back to us.

It is up to you to decide if you want to try to stop smoking and to receive the drugs. You have the right to say no. Your decision will not affect your relationship with the Dana-Farber Cancer Institute.

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Why Is This Study Being Done?

This study is being done to learn about the best ways to bring health information to people who have had childhood cancer, leukemia, tumors, or similar illnesses. Some study subjects will receive current informational materials in the mail about health, survivorship and smoking. Other subjects will be invited to use a Web site. The goal of the study is to see which of these methods is a better way to provide information about smoking, health issues, and survivorship.

Study subjects will be invited to try to quit smoking, but they are not required to try to quit. To help them quit, we are offering free NRT and Zyban, as these drugs may make quitting easier for them.

Anyone who uses our free NRT or Zyban must get clearance from his or her regular doctor. The doctor will sign a form saying that it is medically OK for you to use these drugs and he or she will approve the right dosage. We will mail the drugs to your regular doctor, and you will need to go to his or her office to get them. If you have any side effects from the drugs, you should go to your regular doctor for care. The form that your doctor signs will also confirm his or her willingness to monitor the side effects of these drugs.

What Other Options Are There?

You may choose not to receive the free quit-smoking drugs. Or, you may also choose to purchase these drugs yourself. NRT is available at most pharmacies without a prescription. Zyban requires a prescription.

What Is Involved in the Study?

If you choose to receive free NRT or Zyban, you will need to give us your regular doctor's contact information. We will send or FAX a form to your doctor asking him or her to determine whether or not you can use either of these drugs. The form reminds the doctor of the risks and side effects of these drugs. It also tells your regular doctor that he or she will be responsible for monitoring your care while you are on the drugs. In order for your doctor to approve the medication for you, he or she may need to release medical information to us only as it relates to your ability to take the medication. If your regular doctor signs the forms, we will mail him or her the supply of the drugs that he or she approves for you. You will need to go to the doctor's office to pick them up.

These drugs may or may not help you to quit smoking or to stay quit. If you and your doctor agree that you need to continue using the quit-smoking drugs beyond the supply provided by Partnership For Health, you will need to buy them yourself.

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When you take your follow-up survey for the Partnership for Health study (which will be 18 months from the time you are enrolled in the study), you will be asked if you used the drugs and whether or not they were successful.

How Long Will I Be in the Study?

You will be in the study for about 18 months. You will receive an appropriate supply of quit-smoking drugs, which will range from 8 to 12 weeks.

What Are the Risks or Discomforts of the Study?

It is up to you whether or not you want to try to quit smoking. If you decide to try and quit, you may experience side effects from quitting. These may include withdrawal symptoms such as mood changes, anxiety, irritability, decreased concentration, restlessness, unusual hunger, trouble sleeping, and constipation. However, both the print materials and Web site provide information about how to relieve these symptoms.

If you decide to use the drugs, side effects could include headaches, dizziness, upset stomach, weakness, blurred vision, vivid dreams, mild itching and burning on the skin, diarrhea, insomnia, dry mouth, nausea, and sweating. These side effects are usually temporary. If you have some of these issues, your doctor may be able to advise you on how to relieve these syptoms. More serious side effects have been noted with Zyban. Individuals with a history of a seizure disorder, or with medical issues that make them more likely to have seizures, should not use Zyban.

What Are The Benefits of the Study?

Using the drugs may increase your motivation to quit smoking, may make it easier for you to try to quit, and may make it easier for you to stay quit. Quitting smoking can benefit you in many ways, including improved health status and decreased risk for disease. There are also financial benefits to quitting smoking, since the cost of cigarettes is considerable for some people.

Can I stop being in the study and what are my rights?

Yes. Receiving these drugs through this study is your choice. You can choose not to get them or not to use them. You may also stop using them at any time.

What are the Costs?

There is no cost to you for the supply of the drugs (8 to 12 weeks' worth) that your doctor approves while you are enrolled in the study. If you have any visits with your doctor related to side effects of the medication or other related issues, you would be responsible for any costs incurred. If you and your doctor decide that you should continue to take the quit-smoking medication(s) beyond the supply provided by Partnership for Health, you would need to buy it yourself.

What about Confidentiality?

In order for you to receive the drugs, we will need to collect information about you, including your name and the name of your regular doctor. However, no records with your name on them will be kept that indicate your choice to receive these drugs. Study staff will take several steps to protect your privacy. You will be given a code that will be used instead of your name or other identifying information on all of your study materials. The cross-list that matches names and codes will be kept in a password-protected computer file at Dana-Farber Cancer Institute. All data will be kept in a locked file drawer. Only study staff will be able to see your information. All project file cabinets and computer databases are secured within offices that are locked when not in use. The coded information, without your name attached, may be shared with others outside the research. We will destroy identifying information once this study is complete.

Whom do I contact if I have questions about the study?

We encourage you to ask questions about the study or your role as a participant at any time. If you have questions, please email the project at pfh@hcc-web.org or call Kim Sprunck, the Project Director, at 617-582-8294 or 1 (800) 950-8649.

For questions about your rights as a research participant, please contact a representative of the Office for the Protection of Research Subjects at Dana-Farber Cancer Institute at (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research-related injury, or if you feel/felt under any pressure to enroll in this study or to continue to participate in this study.

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How will my privacy be protected?

1. What information will be collected used and shared as part of this study?
In order for you to receive the drugs, we will need to collect information, including your name and the name of your regular doctor. All information will be kept confidential (private) and in coded form. We will store the code in a secure area and allow only the study staff to have access to it. We will keep this code in order to maintain a link between you and the information about you collected during this study. The coded information, without your name attached, may be shared with others outside the research.

2. Why will my information be used and shared?
The main reasons we will use and share your information are:
• to conduct and oversee the research study
• to make sure that this study meets legal, institutional, and accreditation requirements
• to conduct public health activities

3. Who will use or share the information about me that is collected by the research team?
We will share the study information with people at the Dana-Farber Cancer Institute, Memorial Sloan-Kettering Cancer Center, St. Jude Children's Research Hospital, and Princess Margaret Hospital. We may share the study information with other researchers outside of these institutions. We may also share the study information (without identifiers) with people outside of these institutions who are in charge of the research, pay for, or work with us on the research study.

The Study information may also be shared with members of the Institutional Review Board (IRB). These are the people who review and oversee research studies and study data to assure that the studies are safe and being well managed.

4. With whom may my information be shared?
We will protect the information about you that we have access to, and will take care to maintain your privacy as much as possible. We may, however, need to share this information with the following people or groups so that they can carry out their duties related to this study:

• Federal agencies, such as the Department of Health and Human Services (DHHS), the National Cancer Institute/National Institutes of Health (NCI/NIH) and the Office for Human Research Protections (OHRP)

• Individuals outside the hospital who provide services; for example, a transcriptionist.

Those who receive your information may share it if they are required to do so by law.

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These other groups may not be required to obey the federal privacy rules that the hospital and researchers must follow.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, neither your name nor other identifiers will be used in any publication or teaching material without your specific permission.

5. How long will my information be used or shared?
Your information will be kept for at least seven years after the study has ended. It will be destroyed by shredding the paper copies and deleting the computer files.

However, for those who request pharmacotherapy (NRT or Zyban), there is no scheduled date at which some of your protected health information that is being used or shared for this research will be destroyed. Your name, DOB, gender, race, ethnicity, and request for pharmacotherapy will be kept on file for future potential research. Because research is an ongoing process, this information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight or other purposes

6. What are my privacy rights?
You have the right to not participate in this study. If you change your mind about participating, please contact us about your decision. We may still need to use the information we have already collected. Once you tell us that you do not want to participate, we will not ask you for any other information.

7. Your signature
You have the right not to sign this form. If you do not sign and mail in this form, you cannot receive the free drugs to help you quit smoking. Whether or not you choose to request quit-smoking drugs, you are highly encouraged to continue using the Partnership for Health materials, information, and resources.

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Documentation of Consent

My signature below indicates my willingness to receive a free, doctor-approved supply of the quit-smoking drugs circled below through Partnership for Health. I also understand that my doctor may need to release medical information about me to the study team and that this information will only pertain to issues related to taking Zyban or using the patch. My understanding is that I can refuse them or stop using them at any time. It also indicates my understanding that it is my responsibility to work with my regular doctor to deal with any side effects or other problems I encounter with the drugs.

Circle the one you would like to receive: **the patch** **Zyban**

How many cigarettes do you currently smoke each day? _____

Signature _____DOB_____ Date _____

Print Name _____

Name of Doctor _____

Addresss _____

_____

_____

Phone _____

Certification from person obtaining consent:

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered any questions regarding the study to the best of my ability.

1. _____ I do not have a financial conflict of interest with this proposal.
2. _____ I do have a financial conflict of interest with this proposal but it is within the de minimus as defined by the PHS guidelines (less than $10,000).

Signature of Person Obtaining Consent: _____

Printed Name of above: _____

Date: _____

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