



## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** BIOBEHAVIORAL INTERVENTION FOR SMOKERS LIVING WITH HIV

**PROTOCOL NO.:** 6JK04  
WIRB® Protocol #20160469

**SPONSOR:** Florida Department of Health

**INVESTIGATOR:** Maria José Miguez, MD, PhD  
2302 Ridgewood Circle  
Royal Palm Beach, Florida 33411  
United States

**SITE(S):** Florida Department of Health  
320C, 2585 Merchants Row Blvd.,  
Tallahassee, Florida 32311  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** Maria José Miguez, MD, PhD  
305-348-4903

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

### SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) procedures, that are being tested for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

## **PURPOSE OF THE STUDY**

You are being asked to participate in this research study because you indicated that you smoke and you are ready to quit. The purpose of this study is to develop a smoking cessation strategy to address the specific needs of smokers living with HIV. The study will use nicotine replacement therapy, which in the United States is approved for regular use and can even be purchased over the counter. The protocol is checking if its use for longer periods of time (i.e. before quitting smoking and during relapse) and in doses specific to your nicotine levels in your blood can be more helpful. We are also providing you with important information about the risks of smoking and the current information we have about the use of mentholated cigarettes.

## **PROCEDURES**

If you decide to be in this study, you will be one of 500 people that will participate in this research study. The study will last for five years, but your involvement with the study will last for approximately one year and will include 5 visits to our research offices after you complete the initial assessment.

- We will ask you questions about your current use of tobacco, smoking history, quit attempts and what worked and did not work.
- We will ask you to complete some questionnaires. These surveys will take approximately 2-3 hours to be completed.
- We will perform a brief medical exam (weight, height, blood pressure, brief physical exam).
- We will draw blood (5 tubes) and ask for a urine sample. The collected blood will be used to evaluate your health status and to test for cotinine and carbon in your body (to confirm if you are smoking). This procedure will take a couple of minutes and will be done at each visit, including the first visit. If your treatment is not working, we will

examine the CYP2A6 gene as it has been associated with treatment failure and we will adjust your treatment accordingly. The urine sample will be used at the initial visit to test for illegal drugs.

- Once this visit is complete you will be part of one of two groups using a process like flipping a coin. Both groups will receive information and nicotine patches to assist you in your effort to quit cigarette smoking. The differences between the two groups is on the times for treatments or the amount that we will give you, and this mostly depends on your blood results.
- In the follow-up visits, we will also complete questionnaires, blood draw, a physical examination, and provide you with additional nicotine patches or gum.
- Medical Records: As part of this study, we will ask you to consent to let us view your medical records and we will ask you to bring your latest laboratory results

## **RISKS AND DISCOMFORTS**

There is a small risk during the process of drawing blood. You may feel a little discomfort as the needle goes through the skin. There may be some bruising at the site where blood is drawn. Pressing hard on the spot for 1 or 2 minutes after the needle is removed will help to prevent a bruise. Very rarely, the arm may become infected. Occasionally people feel lightheaded or even faint when their blood is drawn. If you feel faint, tell the person drawing your blood and she/he will have you lie down until the feeling goes away.

Nicotine Replacement: All nicotine products may cause side effects, particularly if we need to give you a high dose. Reducing the dose can prevent these symptoms. Side effects include:

Side effects of nicotine gum may include:

- A bad taste from the gum, but we are providing a flavored one.
- A tingling feeling on the tongue while chewing the gum.
- Hiccups.
- Upset stomach (nausea) or heartburn. This is sometimes caused by improper use, such as chewing the gum and without "parking" it between your cheek and gum; and
- Jaw pain caused by chewing.

Side Effects of Nicotine Patch May Include:

- A skin rash at the location of the patch.
- Sleep problems in the first few days, most often when using a 24-hour patch, such as having trouble sleeping or having especially vivid dreams. Removing the patch after 8 p.m. may help decrease this side effect.

You may feel embarrassed as we ask some personal questions such as use of tobacco, alcohol, drugs and illnesses, but you need to remember that we are health professionals, that your information is confidential and protected, and that these are common medical problems.

Women who are pregnant or nursing a child may not take part in this study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

**Other Risks**

Please note that similar to other research, there may be risks of participation and side effects which are still unknown. Your condition may not get better during this study.

Only you should take the study drug. It must be kept out of the reach of children or anyone else who may not be able to read or understand the label.

**NEW INFORMATION**

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.

**BENEFITS**

Your smoking addiction may improve while you are in this study; however, this cannot be promised. The results of this study may help people with smoking problems who are trying to quit in the future.

**COSTS**

The study will provide the nicotine patches and/or gums free of charge during your participation. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. Although unlikely, if injury or side effects should occur, treatment will be available. If you have insurance, your insurance may pay for these expenses. You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

**PAYMENT FOR PARTICIPATION**

At the end of each visit, after you have completed all procedures, you will be paid \$70 for time spent in the visit and \$5 for transportation costs (a total of \$75) if it is a long visit. If you refuse to provide the blood sample or we are not able to draw your blood you will be paid only \$40. If you agree to return for an additional blood draw, we will pay the additional \$30 plus \$5 for transportation. For a short visit, you will be paid \$30. If you do not finish the study, you will be paid only for the visits you have completed.

**ALTERNATIVE TREATMENT**

If you decide not to enter this study, there is other care available to you, such as Bupropion or Varenicline Tartrate. You can also receive nicotine replacement therapy without being in the study. The study doctor will discuss these with you. You do not have to be in this study to quit smoking.

## **INFORMATION ABOUT A CERTIFICATE OF CONFIDENTIALITY FOR THIS RESEARCH:**

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceedings.

There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse reported by the researcher
- if the investigator reports cases of contagious disease (such as HIV) to the state

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

### **What information may be used and given to others?**

The study doctor will get your personal and medical information. For example:

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

### **Who may use and give out information about you?**

The study doctor and the study staff.

### **Who might get this information?**

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

### **Your information may be given to:**

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Florida Department of Health,
- Florida International University Review Board,
- University of Miami Review Board,
- Western Institutional Review Board® (WIRB®).

**Why will this information be used and/or given to others?**

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

**What if I decide not to give permission to use and give out my health information?**

You will not be able to be in this research study.

**May I review or copy my information?**

Yes, but only after the research is over.

**May I withdraw or revoke (cancel) my permission?**

- Yes, but this permission will not stop automatically.

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

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**Is my health information protected after it has been given to others?**

There is a risk that your information will be given to others without your permission.

**Confidentiality**

The following entities may be looked at and/or copied for research or regulatory purposes by:

- the Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- governmental agencies in other countries,
- Western Institutional Review Board® (WIRB®), and
- Florida International University authorized personnel.

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

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.

## **COMPENSATION FOR INJURY**

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

## **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this 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.

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

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

## **SOURCE OF FUNDING FOR THE STUDY**

The sponsor Florida Department of Health will pay for this research study.

## **QUESTIONS**

Contact Dr. Maria Jose Miguez at 305- 348-4903 for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)  
1019 39th Avenue SE Suite 120  
Puyallup, Washington 98374-2115  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: Help@wirb.com

WIRB is a group of people who independently review research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

**CONSENT**

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

\_\_\_\_\_  
Subject Name (printed)

**CONSENT SIGNATURE:**

\_\_\_\_\_  
Signature of Subject (18 years and older)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Conducting Informed  
Consent Discussion

\_\_\_\_\_  
Date