APPROVED
AS MODIFIED
Mar 24, 2016
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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:
The Florida Department of Health and Maria José Miguez, MD, PhD has received a Certificate of Confidentiality from the government that will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, the subject may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

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 <u>may</u> 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

Western Institutional Review Board®
1019 39th Avenue SE Suite 120 | Puyallup, WA 98374-2115
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www.wirb.com

Certificate of Approval

THE FOLLOWING WERE APPROVED

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

BOARD ACTION DATE: 03/09/2017
PANEL: 1
STUDY APPROVAL EXPIRES: 03/21/2018
STUDY NUM: 1162896
WIRB PRO NUM: 20160469
ONLINE TRACKING:
INVEST NUM: 175357
WO NUM: 1-987576-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually
INST. NUM:

SPONSOR: Florida Department of Health
PROTOCOL NUM: 6JK04
AMD. PRO. NUM:
TITLE:
BIOBEHAVIORAL INTERVENTION FOR SMOKERS LIVING WITH HIV

APPROVAL INCLUDES:
Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

WIRB APPROVAL IS GRANTED SUBJECT TO:

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Florida Department of Health, 320C, 2585 Merchants Row Blvd., Tallahassee, Florida 32311

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada, when there is a local IRB and WIRB approved materials are reviewed by the local IRB and translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)
    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB unless other arrangements have been made and approved by WIRB.
    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Enrollment of limited readers and non-readers: unless consent has been waived or the protocol excludes enrollment of limited readers or non-readers, involve an impartial witness in the consent process when enrolling limited or non-readers and document the participation of the impartial witness using the designated signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard impartial witness form from www.wirb.com.

5. Enrollment of pregnant partners that do not have the capacity to consent for themselves and require consent be provided by a legally authorized representative: unless the protocol excludes the enrollment of pregnant partners that do not have capacity to consent for themselves, obtain consent from the pregnant partners legally authorized representative and document consent using the pregnant partner legally authorized representative signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard legally authorized pregnant partner form from www.wirb.com.

6. Obtain pre-approval from WIRB for changes in research.

7. Obtain pre-approval from WIRB for planned deviations and changes in research activity as follows:
   - If the research is federally funded, conducted under an FWA, or is a clinical investigation of a drug or biologic, then all planned protocol deviations must be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].
   - However, if the research is a clinical investigation of a device and the research is not federally funded and not conducted under an FWA, then only planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].

   The reason for these different requirements regarding planned protocol deviations is that the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) drug and biologic divisions have adopted the regulatory interpretation that every planned protocol deviation is a change in research that needs prior IRB review and approval before implementation; however, the FDA device division operates under a distinct regulation (See 21 CFR 812.150(a)(4).

   Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

8. Report the following information items to the IRB within 5 days:
   a. New or increased risk
   b. Protocol deviation that harmed a subject or placed subject at risk of harm
   c. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
   d. Audit, inspection, or inquiry by a federal agency
   e. Written reports of federal agencies (e.g., FDA Form 483)
   f. Allegation of Noncompliance or Finding of Noncompliance
   g. Breach of confidentiality
   h. Unresolved subject complaint
   i. Suspension or premature termination by the sponsor, investigator, or institution
   j. Incarceration of a subject in a research study not approved to involve prisoners
   k. Adverse events or IND safety reports that require a change to the protocol or consent
   l. State medical board actions
   m. Unanticipated adverse device effect
   n. Information where the sponsor requires prompt reporting to the IRB

   Information not listed above does not require prompt reporting to WIRB.

   Please go to www.wirb.com for complete definitions and forms for reporting.

9. Provide reports to WIRB concerning the progress of the research, when requested.

10. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact, Company

Chris Grayson, Florida International University
Maria José Miguez, MD, PhD, Florida International University
Clery Quiros, Florida International University

