INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Insomnia in HIV: Study I

You are being asked to take part in this research study because you are infected with the Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immunodeficiency Syndrome (AIDS), are under treatment for HIV, and may have insomnia (lack of adequate sleep). This study is supported by grants from Indiana University. The doctors in charge of this study are Dr. Samir K. Gupta and Dr. Jesse Stewart. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

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.

STUDY PURPOSE:

People with HIV infection often have problems with sleep. The preferred method to treat insomnia is not with medications, which can be addictive or lead to adverse interactions with other medications, but with a type of interactive therapy which gets to the root causes of insomnia and teaches patients how to get better sleep. Therefore, we wish to compare sleep improvement using a new interactive, internet-based therapy for insomnia with usual care as managed by your primary HIV provider. This internet-based treatment is called SHUTi. SHUTi is effective in persons without HIV infection, but it is unknown if it works in persons with HIV infection. As part of this study, we will also assess how insomnia is related to mood, memory, attention, and physical functioning.

STUDY PARTICIPANTS:

This trial will include patients who are at least 18 years old, have insomnia, and already are receiving antiretroviral therapy with viral loads (amount of HIV in the bloodstream) that are less than 75 copies per milliliter, or less than 75 HIV virus particles in a milliliter of blood.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate and are eligible for the study, you will be one of up to 40 HIV-infected people here at the Indiana University or Eskenazi Health Medical Centers who will be included in the study.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will be asked to participate in one Entry Visit and another visit 10 weeks later at the Infectious Diseases Research Clinic. If you are chosen to take part in the insomnia treatment program, then you will be asked to complete an additional six sessions (one per week) to receive this treatment. If you are chosen to receive usual care, then no other study related procedures or visits will take place until the Week 10 Visit.

Entry Visit

The Entry Visit will take no longer than two hours and will take place at the Infectious Diseases Research Clinic at the Fifth Third Office Building on the Eskenazi Health campus. At this visit, we will ask you about your medical and psychiatric history and the medications you take. We will also review your medical records to document your diagnoses and laboratory results as obtained in the clinic. We will measure your height, weight, blood pressure, and heartrate. You will then be asked to complete a series of surveys related to your sleep, mood, physical activity, fatigue, usual activities, alcohol use, tobacco use, and other substance use. You will also then complete tests of your memory and attention, strength, walking speed, and coordination.

At this time, you will be randomly assigned (as if by the roll of the dice) to one of two groups. The first group will receive the internet-based insomnia treatment during the next 10 weeks of the study. The second group will receive usual care from their primary HIV caregivers. Your primary HIV caregiver will be notified about the result of this randomization.

At the end of the Entry Visit, you will be given a sleep diary which you will complete over the next 3 days and nights. This diary is to show how much sleep you are getting. We will call you to receive the results of the sleep diary over the phone. You will also be provided a second sleep diary that we will ask you to complete for the 3 days after returning for the Week 10 Visit. We will again call you to receive the results of the sleep diary over the phone.

The Insomnia Treatment Used in This Study

If you are assigned to receive the study insomnia treatment called SHUTi, you will have the opportunity to complete six 40-minute therapy sessions, one per week. These sessions will take place at Dr. Stewart's office on the IUPUI campus, the Infectious Diseases Research Clinic at Eskenazi Hospital, or a location selected by you where you can access a computer with internet, such as your home, your work, a family member's/friend's home, or a public library. Your preference will determine the location of the SHUTi sessions. The SHUTi sessions will be performed between the Entry Visit and the Week 10 Visit.

The insomnia treatment is an interactive computer program; therefore, you will not be meeting face-to-face with a therapist. Through completing the sessions on a computer, you will learn techniques that have been shown to improve insomnia in other types of patients. These techniques include learning what causes your lack of sleep, how to improve your chances of better sleep, and how to avoid those things that cause your poor sleep. Please note that this program may be more effective in treating your insomnia if you are able to complete more of these sessions. You will then be given homework to complete before the next session; homework is to help you achieve better sleep.

As part of the SHUTi program, you will be asked to enter information regarding your particular sleep problem. This will help SHUTi make an individual treatment plan for you. You will not enter any information that can identify yourself. You will only be known to the program by a unique identification number.

Week 10 Visit

You will then be asked to return to the Infectious Diseases Research Clinic in approximately 10 weeks after the Entry Visit. You will be asked to return the second sleep diary at this visit. We will review your medical records and medications again, especially if your doctor has started any new insomnia treatments since your last visit. Your blood pressure, temperature, and weight will also be measured again. We will

also ask you to complete the same surveys regarding your sleep, mood, physical activity, fatigue, usual activities, alcohol use, tobacco use, and substance use. This visit will take no more than 1 hour.

At this time your participation in the study will be completed.

RISKS OF TAKING PART IN THE STUDY:

Risks of possibly experiencing emotional discomfort when completing surveys
The surveys will be given in private settings. You may choose not to answer any questions that make you feel uncomfortable.

The risks of possible loss of confidentiality
We will not tell others other than your main HIV caregiver that you are taking part in this study. All of your information will be identified with a coded number and without any personal identifying information. All test results will be locked in a cabinet and restricted.

If you choose to undergo the SHUTi insomnia treatment sessions at the Dr. Stewart's office or the Infectious Diseases Research Clinic, you will be in a private location where others, besides the study team members, cannot see you. But please note that if you choose to undergo the SHUTi treatment sessions in a public location, others around you may see that you are viewing an online insomnia treatment program. We will give you ear bud headphones, if you do not already have headphones, if you choose to complete the treatment sessions at a public location.

Risk of muscle soreness and falls
There is a minor risk of muscle soreness and of falling when performing some of the tests of physical functioning. Our team is well-trained to minimize these risks.

Suicidal thoughts
Because this study may involve people who have depression, some participants may report thoughts of being better off dead or of hurting themselves. This could happen during a phone call or an in-person visit. IF this occurs, our protection plan will be used. You will first be asked a series of questions. If it is determined that immediate care is needed, the study team will contact Dr. Stewart and/or Dr. Gupta to determine the right course of action. If we believe that you are in imminent danger of harm, we will have to report it, potentially to authorities, including the police, for your own protection. We may contact your primary doctor, your primary HIV caregiver, and your HIV social worker or care coordinator. We may also consult with Midtown Community Mental Health Center and escort you to the Crisis Intervention Unit at Eskenazi Health Hospital.

If you prematurely terminate a phone call after reporting suicidal thoughts, the study doctors will be notified to determine the right course of action. We will try to contact you back to obtain additional information. If it is determined that immediate care is needed and that you are in imminent danger of harm, we will have to report it, potentially to authorities, including the police, for your own protection. We may contact your primary doctor, your primary HIV caregiver, and your HIV social worker or care coordinator. We may also consult with Midtown Community Mental Health Center and refer you to the Crisis Intervention Unit at Eskenazi Health Hospital.

We may also then decide in this situation that is important for your own safety to end your participation in this trial.

BENEFITS OF TAKING PART IN THE STUDY:

You may receive no direct benefit from participating in this study. However, you may receive benefits if the insomnia treatment program improves your sleep and also your mood, memory, attention span, and physical function. Information learned from this study may help others who have HIV.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you have the option not to participate and choose to seek other types of insomnia treatment through your primary HIV caregiver. The most common alternative treatments for insomnia are medications and psychotherapy. If you choose not to participate, your decision will not affect your regular medical care or your relationship with the study doctor.

CONFIDENTIALITY:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his research associates, the sponsors - Indiana Center for AIDS Research and Indiana Clinical and Translational Sciences Institute, the Indiana University Institutional Review Board or its designees and the Office for Human Research Protections (OHRP).

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent.

COSTS:

The costs of all study-related tests will be provided by the study. However, taking part in this study may lead to added costs to you or your insurance company in the event of physical or emotional injury resulting from your participation in this research. Please ask your insurance provider about any expected added costs or insurance problems.

PAYMENT:

You will receive payment for taking part in this study. If you are eligible, you will receive $75 for the Entry Visit and $50 for the Week 10 Visit. If you complete the entire study, you may then receive a total of $125. You will be paid at the completion of each visit. You will be paid with a pre-paid gift card from Kroger or Walmart. You will not be provided compensation for attending the insomnia treatment sessions. Free parking or bus fare vouchers will be provided for all study sessions and for all insomnia treatment sessions.

COMPENSATION FOR INJURY:

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your

health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

CONTACTS FOR QUESTIONS OR PROBLEMS:

You are encouraged to ask questions any time during the study. In the event you experience a side effect or have further questions about the study, you may call the clinic at 317-944-8456. You may also call Dr. Samir K. Gupta at 317-274-7926 or at 317-274-8114 or you may reach Dr. Jesse Stewart at 317-274-6761. If you cannot reach anyone during regular business hours (i.e. 8:00AM-4:00 PM), please call the Indiana University Human Subjects Office at 317-278-3458 or 800-696-2949. On nights, weekends, or holidays, and as a 24-hour contact, you may reach the Infectious Diseases physician on call at 317-944-5000.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the Indiana University Human Subjects Office at 317-278-3458 or 800-696-2949.

VOLUNTARY NATURE OF STUDY:

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Not taking part will not affect your general health care. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

The study doctor may need to take you off the study without your permission if he feels that it is not in your best interest for you to participate.

PARTICIPANT'S CONSENT:

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent statement to keep for my records.

SUBJECT'S SIGNATURE:

_____ Date:_____
(must be dated by the subject)

_____
(Printed Name)

SIGNATURE OF PERSON
OBTAINING CONSENT:

_____ Date:_____

_____
(Printed Name)