ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called Acute Effects of Cannabis on Cognition and Mobility in Older HIV-Infected and Uninfected Women. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Anjali Sharma, MD. You can reach Dr. Sharma at: **Office Address: 2100C White Plains Road Bronx, NY 10462** **Telephone #: 718-515-2593** For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.	The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail: Einstein IRB Albert Einstein College of Medicine 1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461
Support for this research study is provided by **National Institutes of Health (NIH)**	

Why is this study being done?

The goal of this study is to better understand the effects of cannabis use on balance, mobility, and cognition. An improved understanding of the effects of cannabis use and the risk of falling will help with developing tests and treatments for mobility impairment in aging women, with or without HIV, who use cannabis.

Why am I being asked to participate?

You are being asked to participate in this study because you are between the age of 40 and 65 and actively enrolled in the Women's Interagency HIV Study (WIHS).

How many people will take part in the research study?

You will be one of about **60** people who will be participating in this study. The screening visit questionnaires and MINI assessment will be conducted by phone, and the physical assessments (i.e. vital signs and ECG) will be in-person at the Bronx Clinical Research Site. The study visits will be conducted at the Columbia University Medical Center.

How long will I take part in this research?

We will ask you to make 2 study visits to Columbia University Medical Center.

What will happen if I participate in the study?

If you are eligible for the study, you will be asked to complete one (1) in-person and phone screening visit and two (2) in-person study visits. During the course of this study cannabis or a placebo (drug with no effect) will be administered. We will measure your level of mobility, balance and cognitive ability pre and post administration of the cannabis and placebo. You will be asked to smoke cannabis during both study visits. However, on one study visit you will be given a placebo. You will not be told if the cannabis you are smoking is a placebo or not.

Before each visit you will be asked to refrain from using any drugs or tobacco cigarettes at least 10 hours before your appointment. Additionally, you will be asked to abstain from drinking alcohol for at least 24 hours before your appointment.

On the day of your visit you a urine drug and pregnancy test will be performed. Breathalyzer and carbon monoxide testing will also occur.

Study staff will administer a series of questionnaires. Following this you will be asked to perform a series of tests that measure your mobility, balance and cognitive ability. There will be two rounds of these tests. After the first round of tests you will be given a break. After the break the study staff will provide you with medical cannabis. You will be instructed to smoke the cannabis. After smoking, you will again be asked to perform a series of tests that measure your mobility, balance and cognitive ability.

On your second visit you will be asked to perform the same series of test.

In total, each study exam day will be approximately 5 hours long. Breakfast and lunch will be provided.

A description of this clinical trial will be available on 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.

Specimen Banking (Future Use and Storage)

We will destroy the specimens and information about you when the study is complete. Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Genetic Testing

This study will not involve genetic research or genetic testing.

Information Banking (Future Use and Storage)

We will store information about you in a “bank”, which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies.
Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive $50 total for the in-person and phone screening visit and $75 per study session and an additional $50 upon completion of both study visits ($250 total). We will also cover transportation costs. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Anjali Sharma at 718-515-2593

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including “over-the-counter” remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.***

- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- the organization that funded the research, NIH
- organizations and institutions involved in this research: Columbia University. A copy of your consent will be sent to Columbia University.
- groups that review research (the Einstein IRB, and the Office for Human Research Protections)

These people, who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information then the researchers, may not use the Certificate to withhold that information.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.
In addition, you are advised not to drive after completing study visits. Participant will be provided with car service at the end of each visit.

Questionnaire

You may feel uncomfortable answering questions about mental health or drug use. You can choose not to answer questions that make you feel uncomfortable.

Risks of Taking Cannabis
Common side effects: sedations, gait disturbance, tiredness, sadness, anxiety, concentration difficulties, increased heart rate, palpitations, dizziness, sleep disturbance, changes in food intake, restlessness, confusion, sleepiness, clumsiness, gastrointestinal upset, headache, nausea, dry mouth, pallor, flushing, sweating, and slurred speech.

Risks to Women Who Are or May Become Pregnant
The effect of cannabis on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female subjects must have a negative pregnancy test before starting the study drug.

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be

removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process		Date	Time