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 The PITCH Study. 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 Dr. Deepika Slawek. You can reach Dr. Slawekat:

Office Address:
Montefiore Medical Center
111 East 210 Street
Bronx, New York 10467

Telephone #:
718-920-3786

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@einsteinmed.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 the National Institute of Health (NIH)

Why is this study being done?

The goal of this study is to understand how medical cannabis use affects symptoms over time in people living with HIV.

Why am I being asked to participate?

You are being asked to participate in this study because you are certified to receive medical cannabis, have pain, and are living with HIV.

What will happen if I participate in the study?

You will be required to come in for 2 research visits across 14 weeks. You will be asked to complete a survey on a computer. These surveys can take anywhere from 30 minutes to 1 hour to complete.

You will also be asked to complete 15 web-based questionnaires every week (over 14 weeks) using a smartphone. If you do not have a cell phone or home computer that can access the internet, weekly surveys will be completed verbally over the phone.

Computer surveys and web-based questionnaires will ask questions about pain, cannabis (marijuana) use, medication use, other substance use, mental health symptoms, and adverse events.

You will be asked to provide urine and blood samples at both in-person research visit. Urine will be tested for drugs and medications. You will be asked to provider blood specimens at the beginning and end of the 14-week study. Blood samples will be tested for HIV viral load, T-cell count, and levels of inflammation. To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein 5 tubess of blood will be drawn, about 5 tablespoons.

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.

As part of this study we will review your medical records and put the information we collect in our research records.

How many people will take part in the research study?

You will be one of about **100** people who will be participating in this study.

Specimen Banking (Future Use and Storage)

We will store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue and blood) from many studies. These specimens and information cannot be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose, or treat disease, including genetic research. Your specimens and 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 biobank 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 specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me 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.

Information Banking (Future Use and Storage)

Will I be paid for being in this research study?

You will be assigned a debit card when you join the study. You will receive a total of $42.50 for each in-person visit ($27.50 for visit and an additional $15 for visits with blood draws or urine collection) and $3 for each of 15 web-based surveys. Over the course of the study, you may be paid up to $130. 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.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc. In addition, the researchers wish to review information pertaining to your HIV records. By law, you must specifically authorize access to these records:

☐ Yes, I authorize the use and disclosure of my information pertaining to HIV testing and HIV status.

Initial: _____ Date: _____

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself (i.e., suicidal) or that you may hurt someone else (i.e., homicidal) we are required to report this circumstance to a mental health care provider or primary care physician for evaluation and/or referral.

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.

Questionnaire
You may feel uncomfortable answering questions about pain, cannabis (marijuana) use, other substance use, mental health symptoms, and adverse events. It is possible that such questions produce discomfort or anxiety. You can choose not to answer questions that make you feel uncomfortable.

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless "black and blue" may develop. Very rarely, fainting may occur.

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.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. However, the information learned from this study may, in the future, benefit other people with the same medical condition.

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 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/he] 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
Printed name of the person conducting the consent process	Signature	Date