INFORMED CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Contigency management trial for cannabis for persons living with HIV

Full Study Title: Feasibility and impact of a 28-days of monitored abstinence based from cannabis use on symptoms of distress, inflammation, and HIV viral load

Study Sponsor: National Institute of Health/National Institute on Drug Abuse

Principal Investigator: Chukwuemeka Okafor, PhD, MPH, Assistant Professor, Division of Infectious Diseases and Department of Psychiatry and Behavioral Sciences, University of Texas Health Science Center at San Antonio (UT Health San Antonio)

Study Contact: Chukwuemeka Okafor, PhD, MPH, Principal Investigator, 857-225-3923

You are being invited to take part in a research study. Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part, at any time. The purpose of the study is to determine how feasible it is for you to stop using cannabis for 28 days and to learn more about how stopping cannabis impacts your health. If you choose to participate in this study, you will be asked to stop using cannabis for 28 days. At every study visit, we will ask you to provide a urine sample to confirm that you stopped using cannabis. We will also use a needle to take about 10 ml of blood from your arm during three of the study visits. Finally, at every study visit, we will ask you to complete a questionnaire on a computer about your mood, behaviours, and other symptoms. The total amount of time you will be in this study is about six weeks, with eight clinic visits over the duration of the study. Each clinic visit will take between 1-2 hours.

There are potential risks involved with this study that are described in later this document. Some known risks include feeling uncomfortable answering questions or questionnaires and potential bruising related to blood draws.

You may not benefit directly from your participation in this study; however, the information gained from your participation may benefit others in the future.

The alternative to this study is not to participate. Deciding not to participate will not affect your future medical care or participation in a future study in any way.

If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the UT Health San Antonio.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of the study is to determine how feasible it is for you to stop using cannabis for 28 days and to learn more about how stopping cannabis impacts your health. The study will test how feasible it is for you to stop using cannabis if we provide financial incentives to you, if we confirm that you stopped using cannabis. Each time we confirm that you stopped using cannabis, we will provide you a financial incentive.

The National Institute of Health/National Institute of Drug Abuse is paying UT Health San Antonio for their work on this study.

This trial may be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

Who is being asked to take part in this study?

You are being asked to take part in this research study because you are living with HIV and you indicated that you use cannabis regularly. This study is being conducted at the Pinnacle Clinical Research Building, 5109 Medical Drive, 4th Floor, San Antonio, TX 78229 UT Health, San Antonio , Texas. About 25 people will take in the study at the clinic site.

What will happen if you take part in this study?

We will ask you to stop using cannabis for 28 days. We will ask you to come for eight clinic visits over the duration of the study. Each clinic visit should take between 1 to 2 hours. During all the clinic visits, will ask you to provide a urine sample to confirm that you stopped using cannabis. We will also ask you to provide a blood sample during three clinic visits to monitor your safety and health including your HIV viral load and immune system. During all the clinic visits, we will ask you to complete questionnaires on a computer. The questionnaire will ask you questions about your substance use, mood, pain, sleep, and adherence to medications. In addition, you will be asked questions on whether you have considered committing suicide or whether you have tried or attempted to harm yourself or commit suicide.

For blood samples – You will have about 10 ml of blood drawn from a vein in your arm three times during the study period. The total amount of blood withdrawn during your participation will be about 30 ml. We do not plan to tell you what we find when we analyze your blood. When we finish the tests, we will destroy any leftover blood.

Your identifiable information such as your name or medical record number will not be included on the blood sample. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent. If study results are published, you will not be identified in the publication.

Most tests done on biological samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, we will contact you to let you know what they have found. A study team member will call you on the phone to provide the results.

How long will you be in the study?

If you agree to take part, your participation will last for 42 days or six weeks and will involve eight clinic visits.

What choices do you have other than this study?

The alternative to this study is not to participate. Deciding not to participate will not affect a participant's future medical care or participation in a future study in any way.

What are the risks of taking part in this study?

There are risks to taking part in this study. It is important for you to think carefully about these as you make your decision.

Questionnaires and interviews: You may feel uncomfortable with questions that ask you about your substance use behaviors and mood symptoms. You may get tired when we ask you questions, or when you are competing questionnaires. You do not have to answer any questions that you do not want to answer.

Blood draws: There is a slight risk of pain, dizziness, fainting, bruising and on rare occasions infection after the blood draw procedure.

Urine collection and drug testing: There are few risks to urine collection. Participants who test positive for substances of abuse or who report distress due to their substance use, will be refereed and encouraged to seek assistance from drug abuse treatment agencies.

Confidentiality: There is a risk of loss of confidentiality. To maintain confidentiality, all information you will provide in this study will not be provided to anyone outside the research team unless you give us written permission to do so. The only exceptions to this are reports of child abuse or if you have serious suicidal thoughts. You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is collected during this study will remain confidential to every extent of the law. A special identification number will be used to identify you in the study and only the investigator will know your name.

What are the benefits to taking part in this study?

There may be no benefits to you from participation in this study. You may experience personal satisfaction that you are helping in advancing important clinical research related to substance use (particularly cannabis) and HIV infection.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Emeka Okafor at 857-225-3923.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section “Contact Information” for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

You should report any such injury to Emeka Okafor at 857-225-3923 and to the Committee for the Protection of Human Subjects at 713-500-7943.

What are the costs of taking part in this study?
The sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care.

If you receive a bill that you believe is related to your taking part in this research study, please contact Emeka Okafor at 857-225-3923 with any questions.

Will you be compensated for taking part in this study?
During the entire study, participants will receive bus passes and parking vouchers ($5 each for up to 8 visits) to cover transportation costs for each clinic visit. During the study, you can earn a monetary amount in the form of a Mastercard for each time you attend a clinic visit. The monetary amount will be $5 at the first visit. This amount will increase by $5 for each consecutive clinic visit that you attend. In other words, if you attend the first three consecutive schedule clinic visits, you will earn $5, $10, and $15 at each visit, because the monetary amount increased by $5.

Additionally, you can earn a monetary amount each time you submit a urine sample that we confirm is negative for cannabis (i.e. cannabis free). The first time you provide a urine sample that is cannabis-free you will receive a monetary amount worth $15. This amount will increase by $10 for each consecutive cannabis-free urine you submit. For example, if you provide 3 cannabis-free urine samples in a row, you will earn a monetary amount worth $15, $25, and $35 at each visit because the monetary amount increases by $10 for each cannabis-free urine that is submitted. Also, unscheduled visits that are completed will be compensated at $15 each.

The staff will tell you more about the incentives. The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each study visit. Your name, address and date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Please indicate your willingness to receive study-related messages:

___**Yes,** I would like to participate (please select the best method(s) for communication)

- □ Cell Phone (text messages)
- □ Email

___**No,** I choose not to participate

All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

If you are paid, the money you receive may be taxable. When the total payment is $600 or more in one calendar year, the institution must report the amount to the IRS. The IRS considers it earned income and treats it like any other income.

How will privacy and confidentiality be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UT Health San Antonio to use and disclose (release) your protected health information (PHI). Protected Health Information is information about a person's health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study.

The health information that we may use or disclose for this research includes results of physical examinations, medical history, lab tests, or other health information. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care. We will get this information by asking you and by looking at your chart at UT Health San Antonio.

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study that are sent outside UT Health San Antonio for review or testing. We will use appropriate information security safeguards that meet applicable state and/or federal laws, rules, regulations designed to protect your data when it is being collected, stored and transmitted. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

We may share your health information with people and groups involved in conducting and overseeing this research study including:

- The sponsor of the study, National Institute of Health/National Institute of Drug Abuse, and the entities that they use to monitor, administer, or conduct the research
- The following collaborator at other institutions that are involved with the study: UT Health Houston
- Members of the local research team
- The Institutional Review Board and the Compliance Office of UT Health San Antonio, and other groups that oversee how research studies are carried out
- The Research offices at UT Health San Antonio
- Quest Laboratory and Principle Health Systems
- TigerConnect, university approved texting platform
- Law enforcement agencies

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. . If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in this research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

Do you have to allow the use of your health information?

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UT Health San Antonio may not withhold treatment or refuse treating you if you do not sign this Authorization. You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact the PI, Emeka Okafor, in writing at 5109 Medical Drive, 4th Floor, San Antonio, TX 78229. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

How long will your PHI be used?

This Authorization will expire 15 years after the end of the study.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact the Principal Investigator, Emeka Okafor at 857-225-3923 as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center, Houston has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

The University of Texas Health Science Center at San Antonio is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

E-mail Authorization Agreement

The research team would like to communicate with you regarding your research visits via email. In order to do this, we will ask that you sign a separate Email Authorization Agreement.

Texting

The research team would like to communicate with you regarding your participation via text message. In order to do this, we will share your name and phone number with TigerConnect. Standard text messaging rates will apply if you do choose to receive the text messages.

If you agree to receive texts from the research team, we will use a messaging system called “TigerConnect” which uses an “encrypted” method of messaging. When one of the research team messages you via TigerConnect, you will receive a text that says “you have received a secure message from” UT Health San Antonio Department of Medicine with a link. When you click on the link it will take you to a secure website where you can read the text and reply.

Please indicate your willingness to receive study-related text messages:

- □ **Yes,** I agree to receive texts from the research team
- □ **No,** I do not agree to receive texts from the research team

SIGNATURES

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM

Printed Name of Witness	Signature of Witness	Date	Time AM PM

☐ *Check if consent and authorization obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. Have witness initial below.*

Declaration of witness: I was present for the entire consent process. _____←(initials of witness)

Printed Name of Person Obtaining Authorization	Signature of Person Obtaining Authorization	Date	Time AM PM

☐ Check if authorization was obtained from this individual who can understand & comprehend English but is physically unable to talk or write. The method used for communication with the subject was: _____. The specific means by which the subject communicated agreement to participate was:_____