Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Development of a Novel Cannabis Brief Intervention for Frequently-Using Emerging Adults: Pilot Randomized Trial

Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to understand how and why emerging adults (age 18-25 years) use cannabis and how to help prevent harmful or problematic cannabis use in emerging adults.

The study is five visits over the course of six months. You will be randomly assigned to receive one of two brief interventions that focus on healthy behaviors in emerging adults. A brief intervention is short-term counseling that helps people change a behavior and improve their health. The brief interventions are 2 sessions long. Each session is 40-50 minutes. You will also answer questions about your substance use and overall mood, as well as provide saliva samples.

There are risks of participation including the loss of confidentiality. You may also feel uncomfortable answering some questions or talking about personal things in the brief intervention. The researchers will code all research information in order to protect your privacy.

There is no guarantee or promise that you will receive any benefit from participation in this study. However, you will learn about healthy behaviors. You may also reduce your cannabis use if you choose.

You may choose not to participate in this study. If you are interested in learning about treatment for problematic substance use, study staff can provide information about other options. You may also choose to follow up with your own healthcare provider.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you completed the Entryway Intake and are between the ages of 18 and 25 and use cannabis regularly. This study is being conducted to test two different approaches to help learn more about how to help prevent the harmful or problematic use of cannabis in emerging adults. Neither of the two intervention approaches are part of standard care. The study is sponsored by the National Institutes of Health (NIH). The investigator in charge of this study at MUSC is Dr. Kathryn Gex. The

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study is being done at one site, the Medical University of South Carolina. Approximately 62 people will take part in this study.

B. PROCEDURES

If you agree to be in this study and sign this informed consent to participate, the following will happen:

1. You will first complete a series of questionnaires about your substance use and overall mood. Completing these questionnaires should take about 30-45 minutes. Some data collected during your Entryway Intake visit will be carried over and included in order to avoid repeating questionnaires. You will also provide a saliva sample to be tested for cannabinoids.
2. Next, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (*Health Education*) and Group B (*Values in Action*).
4. Group A will receive two sessions of *Health Education*, 1 session a week for 2 weeks. Group B will receive *Values in Action*, according to the same schedule. You will meet with the same study counselor for both sessions. Each session is expected to last about 40-50 minutes. Your sessions with your study counselor will be audio recorded. Audio recordings are done for supervisory purposes to ensure that your counselor is conducting the sessions appropriately.
    i. *Health Education* includes a discussion about healthy sleep habits, maintaining balanced eating and nutrition habits, stress and stress management, and healthy relationships.
    ii. *Values in Action* includes a discussion about personal values and goals, your reasons for cannabis use, and strategies for relaxation and stress management.
5. At the end of your second session, you will complete a short set of questionnaires asking you to rate and provide feedback about your assigned intervention. This should take about 15-30 minutes. You will also provide a saliva sample to be tested for cannabinoids.
6. Approximately 1 month, 3 months, and 6 months after your second session, you will complete follow-up assessments with a series of questionnaires similar to your first study visit. These questionnaires will ask about your substance use and overall mood. The assessments should take between 30-45 minutes each. You will also provide saliva samples at each of these follow-up study visits to be tested for cannabinoids.

You may be withdrawn from this study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures. You may withdraw from the study at any time.

D. RISKS AND DISCOMFORTS

There are risks involved with participating in this study, including risks associated with study procedures and loss of confidentiality.

1. Loss of Confidentiality: There is a chance that your personal information may not be kept

confidential. However, the researchers will take all steps to protect your information. Some answers you give during the study visits (like whether you use illegal drugs) may put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records to the extent allowed by law. We will keep all your personal information in locked file cabinets and in password-protected servers. Only research staff will be able to access your personal information.

2. Interview/Rating Scales (Questionnaires): You may be asked questions that could make you feel uncomfortable because you feel they are private. You may refuse to answer any question(s) that you do not wish to answer.

3. Brief Interventions: You may discuss topics that are personal or private during the intervention sessions. If you find this to be uncomfortable or distressing, you should tell your study counselor in the session. You may choose not to discuss the topic further.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

The potential benefit to you is that the intervention you receive may prove to be more effective than the other study intervention or than other available interventions. However, this cannot be guaranteed.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you can earn up to $200 for participation in this study.

You will be compensated $60 for Week 1 study visit. You will be compensated $40 for Week 2. You will be compensated $30 each at the 1-month and 3-month visits, and $40 at the 6-month visit.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $2000.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study. If you choose not to participate in this study and are interested in learning about treatments for substance use disorder, study staff

can provide information about other options. Alternative treatment options are available at the Medical University of South Carolina and through other providers in the community. Staff can aid in a referral to MUSC's Center for Drug and Alcohol Programs, and the Charleston Center, as desired or recommended.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

If there are significant new findings during the course of the study, you will be notified.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O. CLINICAL TRIALS.GOV

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.

P. COLLECTION OF SPECIMENS

We will collect saliva for laboratory tests for analysis of THC, CBD, and other substances found in the cannabis plant. The samples will be coded using a study identification number in order to protect your identity.

As part of this study, we would like to store saliva specimens collected from you for future research on cannabis use. This future research may be conducted by Dr. Kathryn Gex or by other researchers who obtain IRB approval for their research. This research will not involve genetic studies. There are several things you should know before allowing your (tissues, cells, urine, and/or blood) to be studied or to be stored.

1. The specimens will be labeled with a code that only study personnel can link back to you. Researchers outside of this study will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.
2. In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.
3. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.
4. In this study, investigators will not tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or later develop.

Q. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment,

the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Dr. Kathryn Gex at (843) 792-4904***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

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