Dr. Haney, 7/11/17
IRB#7475

SUMMARY SHEET

The following outline is meant to serve as a guide to help you learn about this research study and decide whether or not you want to take part. It does not replace the consent form that you will be asked to read and sign. The consent includes much more information you'll need to make a decision. Read the consent form carefully, ask questions and take your time to speak to others if you want to before you make your choice. Remember, even if you agree to take part in research you can change your mind at any time.

PURPOSE: To study how medications influence the effects of marijuana and your choice to smoke marijuana.

ALTERNATIVES: Since this is not a treatment study, the alternative is not to participate.

PROCEDURES:

- This study has two 11-day inpatient phases. Before each inpatient phase, you will be asked to briefly come into the laboratory for two consecutive days to start taking medication. On these two days, you will receive a morning capsule in the laboratory and then take your evening capsule at home. We will check your urine to confirm that you have taken your evening dose. After the 2nd day, you will move-in to the lab, and you will then spend 11 full days as an inpatient prior to move out.
- While you are inpatient, you will not be able to have your cell phone, make telephone calls, access the internet or news or receive visitors. Capsules will be administered every morning and evening.
- During the outpatient phase, you will not take capsules and you will not have to come to the laboratory.
- Marijuana cigarettes will be available on some inpatient days, but there will also be days when no marijuana is available.
- On the days marijuana is available, it will either be given to you by the investigators to smoke at set timepoints at no cost to you or you will have the option of purchasing individual puffs of marijuana (using your study earnings).
- You will never be required to spend your earnings on marijuana; this will always be your choice.

RISKS

- Smoking marijuana produces effects such as increased appetite, tiredness, shakiness, and heart pounding.
- Smoking less marijuana than you are used to can also produce side effects, such as irritability, trouble sleeping, restlessness, anxiety and loss of appetite.
- Most common side effects from the medications are headache, diarrhea, dizziness, constipation, cold-like symptoms, trouble sleeping, dry mouth and changes in appetite.
- You will be informed of any new findings that may affect your willingness to continue in this study.

BENEFITS: The study is not designed to benefit you directly.

NEW YORK STATE PSYCHIATRIC INSTITUTE

COLUMBIA UNIVERSITY DEPARTMENT OF PSYCHIATRY

CLINICAL INVESTIGATION CONSENT FORM

Purpose of Study

The purpose of this research is to study how medications influence the effects of smoked marijuana. You will receive any of three medications, all of which are approved by the Food and Drug Administration (FDA). You are being asked to participate because you regularly smoke marijuana, and if you are a woman, you are not pregnant. This study is funded by a grant from the National Institute on Health.

Participation is Voluntary

Participation in this project is voluntary, and you may refuse to participate or discontinue participation at any time without loss of benefits to which you are otherwise entitled. You will be informed of any new findings or risks that arise that may affect your willingness to continue in this study. A decision not to participate in this study or to withdraw at any time will not affect your present or future medical care at either the Columbia-Presbyterian Medical Center or the NYS Psychiatric Institute. The investigator may also decide that your participation should be discontinued, if he/she thinks that this is better for you.

Medications

As part of this study, we will ask you to smoke marijuana.

You may be given the following medications: (1) bupropion (ZYBAN®) used to help people quit smoking cigarettes, (2) lorcaserin (BELVIQ®) a weight loss drug, or (3) ondansetron (ZOFRAN®) used to prevent nausea and vomiting. You may also receive placebo capsules (sometimes called 'sugar pills'). Placebos look like the other capsules but have no active medicine. Neither you nor the research staff will know which capsules you got, but the investigators can find out. You and the other participants may not receive the same dose of medication at the same time.

Alternatives to Participation

This is not a treatment study; data are being collected for research only, to learn more about the effects of marijuana and medications, not to study you personally. The alternative is to not participate in the study. If you are interested in treatment, we will give you a referral to a treatment program.

Study Procedures

Before the Study Starts

We have told you what living in the Residential Laboratory is like to help you decide if you want to do the study. Women have been given a pregnancy test at screening and will be tested again before taking medications and prior to each inpatient phase. If pregnant, you will not be eligible to participate. If you think you might be pregnant, please tell the investigator. It is very important that women practice an effective method of contraception for the entire study, and you must agree to do so as part of your participation.

You will also have the opportunity to participate in an optional study to measure the influence of genetic or hereditary differences in how people respond to marijuana. In order to participate in this procedure, you will receive a separate consent form, asking you to provide a blood or buccal (cheek swab) sample for DNA testing. Your decision to participate in this procedure has no effect on your participation in the main study. You will also have the right to withdraw consent from this additional

procedure at any time by asking that your sample be destroyed, without affecting your participation in the main study.

Study Schedule

The study has two inpatient phases (where you sleep in the laboratory), each lasting eleven full days, plus a move-in and a move-out day. Before each move-in day, you will be asked to complete two brief outpatient sessions in our laboratory, where we will ask you to take your morning capsule and take home your evening capsule. We will test your urine to confirm you took your evening capsule.

During the inpatient phases and the outpatient dosing sessions, you will receive capsules twice/day. Between the two inpatient phases will be an outpatient phase lasting at least seven days (where you will be free to live as you currently do without taking capsules).

Each inpatient day is like a 9-5 workday. We will wake you up around 8AM. We will collect your urine each morning, weigh you and measure your heart rate and blood pressure. You will be given mood questionnaires and a series of computer tasks to complete at set periods throughout the day, and we ask that you complete the tasks as quickly and as accurately as you can. We will ask you to wear a small device on your wrist that looks like a watch that will record your sleep and activity level. In the evening, your time will be less scheduled. You can watch movies, play video games or relax in your room. Access to the recreation area will end at 10PM, and lights will go out at midnight. Study staff will watch you on cameras. No recordings will be made, but we will keep a record of how you spend your time. You will have privacy while sleeping and in the bathroom. You will always have bathroom access.

Marijuana cigarettes will be available on certain days and not others. On days of marijuana availability, you will either be given individual puffs of marijuana at no cost to you or you will have the option of using your study earnings to purchase individual marijuana puffs if you are interested in smoking (maximum of 18 puffs a day). You will never be required to spend your earnings on marijuana; this will always be your choice.

In order to complete the study, you will need to remain in the laboratory and follow the instructions we have given you. You can only eat and drink the items we have available. You cannot take any drugs other than those given as part of the study, and you will not be able to make telephone calls, access the internet, or receive visitors. We will examine your clothing and other belongings prior to each move-in and your room may be searched for drugs.

After the study

When the study is over, we will discuss study details with you that we were unable to discuss while you were in the study. We will also repeat your electrocardiogram.

Risks

You may experience side effects from the marijuana, which could include: increased appetite, sleepiness, anxiety, concentration difficulties, faintness, restlessness, confusion, lightheadedness, loss of coordination, clumsiness, shakiness, dizziness, stomach upset, headache, paleness, nausea, flushing, sweating, dry mouth, slurred speech, fatigue, itching, heart pounding, and changes in the pattern of heart beats.

You may also experience withdrawal if the amount of marijuana smoked in the study is less than what you normally smoke. Symptoms of marijuana withdrawal can include sleep difficulty, irritability, upset stomach, restlessness, anxiety and loss of appetite.

You may experience side effects from the capsules, which could include headache, dizziness, fatigue, nausea, dry mouth, constipation, cough, and back pain. Some rare but serious side effects include agitation, confusion, hallucinations, irregular heartbeat, heart valve disease, changes in your red or

white blood cells, depression, thoughts of suicide, and for men, an erection lasting longer than 4 hours. You should use caution if you drink alcohol, drive a motor vehicle or operate heavy machinery until you know how the capsules affect you. Since some of the capsules you may receive can affect serotonin levels in your body, you should not take any medications including dietary supplements, as this can lead to a potentially life-threatening drug reaction. We will watch you carefully throughout your participation to minimize the chance of any serious reactions.

Blood drawing may result in some discomfort at the site of needle entry, which could result in a small bruise. Finally, living in the residential laboratory may be boring.

The risk of using marijuana while taking study medications is not known. The medications listed above are safe when taken as recommended, but their effects in combination with marijuana have not been tested. They may increase, decrease or have no effect on how marijuana makes you feel.

Benefits

This study is not designed to directly benefit you. The benefits of participating in the research relate primarily to the general scientific value of gaining a better understanding of drug effects on behavior.

Compensation.

You will receive $25 for every screening, training, and outpatient dosing visit. You will be paid $40 for each move-in day and $25 for each move-out day, $45/inpatient test day and a bonus $45/inpatient test day if you complete the entire study. Study payments are made in cash upon completion of the second inpatient phase. In order to prevent a single large payment, you will receive half of your study pay in cash upon discharge. We will ask you to return to the laboratory for the second half of the payment the following week. Total payment (including screening pay) for your study participation will range from $1,850-$2,235, depending on how many screening and training visits you are asked to attend, how much money you choose to spend on marijuana, and whether you choose to participate in the genetic study.

Because payment is over $600, we are required by law to report your earnings to the IRS. Therefore, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. Please note that payment for this study may affect your eligibility for Medicaid and other city and state support services. No information about which study you participated in will be provided to the IRS.

Confidentiality. We will apply for a Federal Certificate of Confidentiality for this study, which protects the investigators from having to release the names or other identifying characteristics of research subjects. Investigators so authorized may not be compelled in any Federal, State or Local, civil, criminal, administrative, legislative or other proceedings to provide identifying information about research participants even if subpoenaed without your written consent. Although this certificate protects against involuntary disclosure, you may voluntarily disclose research data or information to physicians or other third parties. You may also authorize in writing the investigator to release the information to insurers, employers, or other third parties. Additionally, this certificate does not prevent the researchers from the voluntary reporting matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others. Such information will be reported to the appropriate authorities.

When results of this study are presented or published, your name will not be used. Your name and other personal identifying information will be stored in an electronically secure database at the New York State Psychiatric Institute. Research records will only be available to research staff and the Food and Drug Administration (FDA); signed consent forms will be kept in a locked file; electronic data will be maintained on password-protected computers. Once you are enrolled into the study, only your initials and

your assigned number will be used to identify you on all documents, including electronic documents that may be used for storage.

Research Standards and Participants' Rights

Compensation for Research Related Injuries:

Federal regulations require that we inform you about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact Dr. Haney at (646) 774-6153 so that you can review the matter and identify the medical resources that may be available to you. In case of injury, the New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital. In addition, we will provide assistance in arranging follow up care in such instances. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University, or by New York Presbyterian Hospital. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Questions:

The investigators will answer, to the best of their ability, any questions you may have now or in the future regarding study procedures or your response to them. You can call the principal investigator, Dr. Haney if you have any questions at (646) 774-6153. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). An IRB is a committee that protects the rights of participants in research studies. You may call the IRB main office at (646) 774-7155 during regular office hours.

You will be given a copy of this consent form to keep.

Statement of consent

I have discussed this study with _____ to my satisfaction. To the best of my knowledge, I am not pregnant. I understand that my participation is voluntary, and that I can withdraw from the study at any time without prejudice.

I have read the above, and I voluntarily agree to enter this research study.

_____

Signature of Subject

_____

Printed Name of Subject Date

Statement of the Investigator obtaining Consent

I have discussed the proposed research with this participant and, in my opinion, this participant understands the benefits, risks and alternatives (including non participation) and is capable of freely consenting to participate in this research.

Signature of Investigator obtaining consent Date

Printed Name of Investigator

Statement of the Physician Investigator

I have discussed the proposed research with this participant and, in my opinion, this participant understands the benefits, risks and alternatives (including non participation) and is capable of freely consenting to participate in this research.

Signature of Study Physician obtaining consent Date

Printed Name of Study Physician