Differences in Cannabis Impairment and its Measurement Due to Route of Administration

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If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Differences in Cannabis Impairment and its Measurement Due to Route of Administration**

Application No.: **IRB00122849**

Sponsor: **National Institute of Justice (NIJ)**

Principal Investigator: **Ryan Vandrey, Ph.D.**
5510 Nathan Shock Dr.
Baltimore, MD 21224
Phone: 410-550-4036
Fax: 410-550-0030

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to measure the effects of both oral and vaporized cannabis (marijuana), at different doses, on your ability to perform certain tasks such as balancing, eye tracking, and computerized measures of memory and attention. We will also collect biological fluids (urine, blood, saliva/spit) after cannabis is eaten or vaporized to see if there are markers in those fluids that can predict how you do on the tasks. The results of this study will help us better understand the effects of using cannabis, and to help identify behaviors and/or substances in the body that relate to cannabis impairment.

The use of cannabis in this research study is investigational. The word "investigational" means that cannabis is not approved for marketing by the FDA and is still being tested in research studies. The FDA is allowing the use of cannabis in this study. The cannabis used in this study has been provided for research purposes by the NIDA Drug Supply Program.

People aged 18-45 years who have used cannabis previously, but not during the past 30 days, may join this study.

How many people will be in this study?

Up to 30 people will be enrolled in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screening

You will be asked to answer some questions and complete some tests to see if you are eligible to take part in this study. This is called "screening" and will take about 3 hours to complete. During the screening visit:

- You will be asked to tell us about yourself (for example, your full name and date of birth) and to answer questions about your medical history and past use of legal and illegal drugs.
- We will measure your weight, blood pressure, heart rate, and will conduct a routine physical examination.
- You will be asked to give us urine, blood (5mL or 2 teaspoons), and saliva samples for testing and drug screening, and to give us a breath sample to see if you drank alcohol recently. If you are female, the blood sample also will be tested to see if you are pregnant. Positive tests for drug use or pregnancy would make you ineligible for the study.
- We will also obtain an electrocardiogram (ECG), which is a measure of how healthy your heart is. The ECG measures the electrical activity of your heart. The test involves putting small sticky electrodes, like Band-Aids®, on your chest. Sometimes these sticky electrodes are also put on your arms and legs.
- You will be asked to answer questions about how you are feeling and have felt recently. Most of the questions will be done on a computer, but some will be done as an interview.

You will not be exposed to any study drug during the screening visit.

If you are not eligible for this study, your study participation will end after the screening visit.

Study

If you are eligible for the study based on the screening, and decide to continue to take part in this study, participation will consist of the following things:

- ***Study location***
  The study will take place at the Johns Hopkins Bayview Medical Center (JHBMC). You will be asked to come to JHBMC a total of 7 times: A 3-hour session for the screening assessment and six 1-day drug administration sessions.

- ***Study measures***
  Each time you arrive at JHBMC for a screening or drug administration session, you will be asked to give us a urine sample for drug screening and to take a breath test to see if you have recently used alcohol. If you are female, the urine sample also will be tested to see if you are pregnant. Positive tests for alcohol, drug use, or pregnancy will disqualify you from the study at that time.

  While at JHBMC, you will be asked to answer questions about how you are feeling, complete tasks that test skills like attention, memory, thinking, reaction time, balance, eye tracking, and hand-eye coordination, have your vital signs (for example, heart rate, blood pressure) measured by research staff, and provide blood (6 mL; 1.2 teaspoons), urine, and saliva samples several times throughout each day.

  During the study, you will be asked to wear a device on your chest that measures the electrical activity of your heart and movement during the time you are here. You will put this device on yourself or with the assistance of research staff. It gets attached to you with 2 sticky electrodes.

  We will use an eye tracking video recorder to check your eye movements.

  For research purposes, a video recording will be made of the balance, eye tracking, and hand-eye coordination tasks that you complete. The purpose of this recording is to make sure that your ability to do these tasks is scored correctly. These recordings will be used for the purposes of this research, will be stored on password secured and encrypted computers, and will not be shared without your written permission.

- ***Cannabis exposure***
  You will be asked to self-administer cannabis during six drug administration sessions. For three of these sessions you will be asked to consume a chocolate brownie containing either placebo or one of two doses of cannabis (containing 10mg or 25mg THC). For the other three sessions, you will be asked to inhale vaporized cannabis containing placebo or one of two doses of cannabis (containing 5mg or 20mg THC). A placebo is a substance that looks like the study drug but that contains no active ingredients. In this study we will compare the study drug to placebo. The doses of cannabis used in this study are similar to the amount of found in about 1/10 to 1/4 gram of average potency (10% THC) cannabis. One gram of cannabis is the amount commonly found in one cigarette (joint, blunt). You will be given 5 minutes to eat each brownie and 10 minutes to inhale the vaporized cannabis. The dose of cannabis or placebo you receive is selected at random, like picking numbers

out of a hat. You will not be told which dose you are given on any session day, and study staff will also not know this at that time.

- ***Biological specimen collection***
  We will collect some of your blood, urine, and saliva, at certain times. A small amount of blood (6mL or 1.2 teaspoons) and saliva will be collected when you arrive and again several times throughout the day. On days that cannabis is eaten, additional blood specimens will be collected 1, 2, 3, 4, 5, 6, and 8 hours after you finish eating the brownie. On days when cannabis is vaporized, additional blood specimens will be collected immediately after and 1, 2, 3, 4, 6, and 8 hours after you finish inhaling the cannabis vapor. A small catheter will be placed in your arm so that blood can easily be collected and only one needle stick is needed. We will collect 60 mL of blood during each session. The total amount of blood we collect during the study (288 mL) is less than what would be collected during a routine blood donation (473 mL). Your body should be able to replace the blood that is collected quickly and without effects on your health.

  We will collect all urine that you produce while you are at JHBMC during the drug administration sessions.

- ***Other drug use***
  Please let us know if you plan to take any new over-the-counter or prescription medication, or change the dose of any medication that you already take while you are in the study. You will also be asked not to use any illegal drugs, including cannabis not provided to you as part of the study, until you have completed all study visits.

  If your urine drug test is positive for any drug when you arrive at JHBMC for your study visit, you will no longer be allowed to take part in this study.

How long will you be in the study?
Following the screening visit, if you are eligible, you will be asked to complete 6 drug administration sessions spaced about 1 week apart. For each of those sessions you will be asked to spend about 10 hours (about 7:30am-5:30pm) at JHBMC.

4. What are the risks or discomforts of the study?

Cannabis
Cannabis can cause a number of effects and include getting dizzy, loss of balance, change in heart rate or blood pressure, red or irritated eyes, feeling tired, pounding in chest or heart, dry mouth, jitters, headache, upset stomach, vomiting, sore throat, increased appetite, trouble concentrating, memory problems, confusion, depression, feeling paranoid, rash, trouble sleeping, blurry vision, ringing in the ears, diarrhea, and hallucinations. Vaporizing cannabis can also produce throat irritation. Smoking cannabis may cause respiratory problems and harm, including bronchitis, emphysema and laryngitis, and increase risk for cancers of the mouth and lungs. It is believed that vaporization reduces this risk relative to smoking, but harm associated with inhalation remains possible. Cannabis is not known to cause overdose or death.

During the telephone interview, you described yourself as having previously used cannabis, but that you have not used it in the past 30 days. If you quit using cannabis because you had problems related to use in the past, exposure to cannabis in this study might create an increased desire to begin using it again.

Use of cannabis has been associated with an increased risk of developing serious mental health problems such as psychosis and schizophrenia, especially for people with a family history of those types of problems. There may be additional risks related to the use of cannabis that are not currently known. You should consider these risks before agreeing to take part in this study.

Other risks or discomforts

The risks of answering the questions and completing tasks in this study are not greater than the risks of everyday life. You may get tired or bored when we are asking you questions or you are doing tasks. You do not have to answer any question you do not want to answer.

The device used to measure the electrical activity of your heart should not be used by people who have a pacemaker or heart defibrillator. If you have either one of these devices, please let us know right away so we know not to attach this device to you.

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection. We will use sterile equipment to collect blood from you, reducing the risk of infection. Steps will be taken to minimize discomfort.

If you are subject to random drug testing as a condition of your employment, it is possible your participation in this study could cause a positive drug test.

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

If you are pregnant, you will not be able to take part in this study. You must be willing to take a pregnancy test during the screening visit and on arrival at JHBMC for the study.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. By taking part in this study you will help us better understand the effects of cannabis exposure, and under what conditions and for how long that may impact different types of drug testing.

7. What are your options if you do not want to be in the study?

This is a voluntary research study. You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

The only cost to you for being in this study is the cost of traveling between your home and the Johns Hopkins Bayview campus.

9. Will you be paid if you join this study?

You will be paid for being in this study. You will be paid $30 for completing the screening visit and an additional $2300 for completing the entire study. Total possible earnings will be $2330. A more detailed breakdown of study compensation is displayed below.

Screening Visit:	$30
Drug Administration Sessions:	$300/completed session
Completion Bonus:	$500
	$2330

If you show up for the study and have a positive test for drugs, pregnancy, or alcohol, you will not be allowed to take part and you will not be paid for that visit.

If you leave the study before completion, you will only be paid for study days that were completed prior to the day you leave the study and you will not receive the completion bonus.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. The JHU IRB may need access to study records to ensure the welfare of study participants. People outside of Johns Hopkins (Federal government agencies such as the Food and Drug Administration, the Drug Enforcement Administration, and the Office of Human Research Protections) may need to see or receive your information for this study. This can be part of routine monitoring or audit of research studies, for protection of human subjects in research, or in response to a problem with this study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. Are there additional privacy protections?

The identifiable data collected in this study can only be used for research purposes, and no other purpose without your consent. (42 USC 3789g) The researchers have an approved Privacy Certificate from NIJ that protects the data collected in this study. (28 CFR Part 22) This means that the identifiable information collected from you is immune from legal process, cannot be released by the researchers under subpoena, and can not be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceedings without your consent. De-identified data from this study will be archived at the National Archive of Criminal Justice Data (NACJD).

Confidentiality can be broken if you indicate to us that you intend to harm yourself or someone else or if we suspect abuse, neglect or abandonment of a child or vulnerable adult. In such a situation, we may need to intervene or to report this to the appropriate authorities. For us to make a report, your consent for reporting is needed. Please see the separate consent for reporting. If you do not sign the consent for reporting, you may not participate in this study.

15. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

16. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Ryan Vandrey at 410-550-4036 (office) or 802-310-7956 (cell). If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Annie Umbricht at 410-550-1917 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call the on-call physician at 410-550-0052 during regular office hours, after hours, and on weekends.

In the event of an emergency, please call 911 right away and then call Dr. Umbricht at 410-550-1917 and Dr. Vandrey at 410-550-4036 after you have received emergency care.

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

17. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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