Drug-gene-nutraceutical interactions of cannabidiol and tacrolimus

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Drug-gene-nutraceutical interactions of
cannabidiol and tacrolimus
IRB Protocol Number: 12763
PI: Michael T. Eadon, MD

ABOUT THIS RESEARCH
You are invited to participate in a research study. Scientists do research to answer important questions, which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form and ask any questions you have before agreeing to be in this study.

STUDY SUMMARY
The commercial availability of cannabidiol, or CBD oil, has increased in the United States. This supplement has the potential to interact with other drugs, including tacrolimus, a medicine commonly used to prevent rejection in transplant recipients. Cannabidiol is now FDA approved and marketed as Epidiolex, which is the form of drug used in this study. This study has three phases where we test for the amount of drug in your body after taking tacrolimus alone, cannabidiol alone, or both together. The information learned in this study will help to inform doctors as to how to appropriately adjust doses of cannabidiol and tacrolimus in order to improve health outcomes and long-term treatment success for transplant recipients.

WHY IS THIS STUDY BEING DONE?
This study is done to see how your liver breaks down tacrolimus (a medication typically used to prevent rejection in transplant recipients) and cannabidiol (sometimes called CBD oil) by two enzymes called CYP3A4 and CYP3A5. These enzymes (substances in your liver) play an important role in the way your body breaks down tacrolimus and cannabidiol. It also plays a role in helping to remove these medicines out of the body. While both drugs are FDA approved, it is investigational to determine whether they interact when taken together. It is suggested that when tacrolimus is taken with cannabidiol, it may increase the amount of tacrolimus in your body by slowing down your liver's ability to get rid of tacrolimus. We are asking you if you want to be in this study because you are an 18- to 75-year-old male or female who is healthy or with stage 3 or 4 chronic kidney disease (CKD).

The study is being conducted by Michael T. Eadon and the Indiana University School of Medicine Department of Medicine. The study is funded by the National Institutes of Health (NIH).

HOW MANY PEOPLE WILL TAKE PART?
You will be one of 72 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

The study is broken down into three phases with a total of 3 inpatient days and 6 outpatient visits as detailed below in the STUDY CALENDAR. All study days and visits will be performed at the Indiana Clinical Research Center (ICRC), a research unit at Indiana University Hospital. The study will take a total of 26 days to complete. The total amount of blood drawn for this study, including screening and exit laboratory tests, will be slightly under 650 ml or approximately two and one-half cups over 26 days. In comparison, this amount is similar to the amount one would give if donating blood one time.

Note: The study physician may request a repeat screening and /or exit laboratory results to verify the findings. Prior to giving you the study medications, we will collect a baseline blood and urine sample and an electrocardiogram (EKG), and request you to fill out a brief questionnaire on how you are feeling.

STUDY CALENDAR

<table>
<tr><td colspan="5">Phase 1</td></tr>
<tr><td>Day 1 Inpatient ICRC
Tacrolimus Single Dose
5 mg</td><td>Day 1 (cont.):
-IV placed and blood drawn through the IV 7 times
-Collect urine
-Eat ICRC diet
-Estimated length: 12 hours</td><td>Day 2:
Outpatient ICRC
-Blood draw and vitals
-Collect urine
-Estimated length: 30 min.</td><td colspan="2">Day 3:
Outpatient ICRC
(Last blood draw for phase 1)
-blood draw and vitals
-Estimated length: 30 min.
Days 4-7: Wash-out: allow tacrolimus to leave your system</td></tr>
<tr><td colspan="5">Phase 2</td></tr>
<tr><td>Day 8 Inpatient ICRC*
Cannabidiol Single Dose
5 mg/kg</td><td>Day 8 (cont.):
-IV placed and blood drawn through the IV 7 times
-Collect urine
-Eat ICRC diet
-Estimated length: 12 hours</td><td>Day 10:
Outpatient ICRC
-Blood draw and vitals
-Collect urine
-Estimated length: 30 min.</td><td colspan="2">Day 12:
Outpatient ICRC
-Last blood draw for phase 2 with vitals
-Estimated length: 1 hour.
<u>Phase 3 begins</u>
*Begin taking first dose of cannabidiol 2.5 mg/kg twice daily</td></tr>
<tr><td colspan="5">*Minor rescheduling of visits is allowed, and subsequent visits would be adjusted accordingly</td></tr>
<tr><td colspan="5">Phase 3 (cont.)</td></tr>
<tr><td>Day 12-14: take cannabidiol 2.5 mg/kg twice daily</td><td>Day 15-23: take cannabidiol 5 mg/kg twice daily</td><td>Day 24: Inpatient ICRC*
Continue cannabidiol 5 mg/kg twice/day on day 24-26
-Take tacrolimus 5 mg once
-IV placed and blood drawn through the IV 14 times
-Collect urine
-Eat ICRC diet
-Estimated length: 12 hours</td><td>Day 25:
Outpatient ICRC
-Blood draw and vitals
-Collect urine
-Estimated length: 30 min.</td><td>Day 26:
Outpatient ICRC
-Last blood draw for phase 3 with vitals
-Collect urine
-Estimated length: 30 min.</td></tr>
<tr><td colspan="5">*Minor rescheduling of visits is allowed, and subsequent visits would be adjusted accordingly</td></tr>
</table>

SCREENING (this visit):

- A blood sample (~15 ml) will be obtained for laboratory tests and a urine sample will be obtained for urine analyses.
- Laboratory tests will include a urine drug screen, urine analysis, and blood tests to see your blood counts, electrolytes, liver function, and the ability of your blood to clot.
- We will ask you about any medications you take and your demographic characteristics (self-identified race, bodyweight, height, gender/sex, age).
- If you are a female volunteer, a urine pregnancy test will be given. This test must be negative (not pregnant) to take part in the study.
- Your basic measures of general health (e.g., temperature, heart rate, breathing rate and blood pressure), weight, and EKG (electrical tracing of your heart) reading will be obtained. A clinical provider will be available for consultation.
- You may be asked to stop certain dietary supplements or over-the-counter medications that are not essential to your health.
- A blood sample (~10 mL) will be obtained if a genetic test for CYP3A4 and CYP3A5 function is not available in the medical record, this test will be performed from your blood sample to know how fast you metabolize (break down) cannabidiol and tacrolimus. The study needs an equal number of people who are fast and slow metabolizers, so you may not be selected to complete the study if there are already too many people with fast or slow metabolism.

PHASE 1:

Day 1 (Inpatient stay)

- You will be requested to arrive in the morning at ICRC (about 7 a.m.) on the first inpatient study day after an overnight fast. On the evening prior to the inpatient study Day 1, it is important that you have nothing to eat or drink after 11 pm except for water.
- If you are a female volunteer, a urine pregnancy test will be given. This test must be negative (not pregnant) to take part in the study.
- Your basic measures of general health (e.g., temperature, heart rate, breathing rate and blood pressure), weight will be obtained. A physician will be available for consultation
- An intravenous catheter (small, flexible, plastic tube) will be placed in a vein in one of your arms for blood collection.
- Prior to dosing with tacrolimus, blood (about 2 teaspoons) and urine samples will be collected. You will also be asked to fill a questionnaire about how you feel.
- Then, you will receive one dose of tacrolimus by mouth (5 mg tacrolimus) with a standardized breakfast and 250 ml water. A standard lunch will be served 4 hours after taking tacrolimus.
- We will obtain 7 blood samples (about 2 teaspoons each) at the following times: 20, 40, and 60 minutes and 2, 4, 6, 12 hours after dosing with the medications. In addition to blood sampling, we will have you save all your urine in provided urine containers for the entire inpatient stay.
- You will be discharged to go home after the 12-hour blood draw.

Day 2 (outpatient visit).

- You will be requested to return to ICRC on Day 2 (24 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), collect urine sample, and to fill out the brief questionnaire on how you feel.

Day 3 (outpatient visit).

- You will be requested to return to ICRC on Day 3 (48 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), and to fill out the brief questionnaire on how you feel. If you have CKD, your kidney function and potassium level will be re-checked from the blood sample.

PHASE 2:

Day 8 (Inpatient stay)

- You will be requested to arrive in the morning at ICRC (about 7 a.m.) on inpatient study Day 8 after an overnight fast. On the evening prior to the inpatient study Day 8, it is important that you have nothing to eat or drink after 11 pm except for water.
- Your basic measures of general health (e.g., temperature, heart rate, breathing rate and blood pressure), weight will be obtained. A physician will be available for consultation
- An intravenous catheter (small, flexible, plastic tube) will be placed in a vein in one of your arms for blood collection.
- Prior to dosing with cannabidiol, blood (about 2 teaspoons) and urine samples will be collected. You will also be asked to fill out a questionnaire about how you feel.
- Then, you will receive one dose of cannabidiol by mouth (5 mg/kg in a liquid form) with a standardized breakfast and 250 ml water. A standard lunch will be served 4 hours after taking cannabidiol.
- We will obtain 7 blood samples (about 2 teaspoons each) at the following times: 20, 40, and 60 minutes and 2, 4, 6, 12 hours after dosing with the medications. In addition to blood sampling, we will have you save all of your urine in provided urine containers for the entire inpatient stay.
- You will be discharged to go home after the 12-hour blood draw.

Day 10 (outpatient visit).

- You will be requested to return to ICRC on Day 10 (48 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), collect urine sample, and to fill out the brief questionnaire on how you feel.

Day 12 (outpatient visit).

- You will be requested to return to ICRC on Day 12 (96 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), and to fill out the brief questionnaire on how you feel.
- You will be given 2.5 mg/kg of cannabidiol in the ICRC to start Phase 3. You will be instructed to take cannabidiol 2.5 mg/kg twice daily with food continued for 3 total days (5 more doses) and then take 5 mg/kg twice daily with food, continued for 9 additional days (12 total days of cannabidiol).
- You will receive a diary to record the time the medication was taken and symptoms such as lethargy, somnolence, sleep disorder, diarrhea, or any other feelings or side effects experienced during the course of the study. You will be asked to take cannabidiol with meals and avoid grapefruit.

PHASE 3: **(Note:** Phase 3 starts when you take your first dose of cannabidiol on Day 12)

Days 12 to 14 (at home).

- Continue taking 2.5 mg/kg cannabidiol twice daily with meals for the next consecutive 3 days (until Day 14). It is important that you take the study medication approximately the same times each day. In the event you miss a dose, it is very important that you notify the research coordinator for further instructions.

Days 15 to 23 (at home).

- Take 5 mg/kg cannabidiol twice daily with meals for the next consecutive 9 days (through Day 23). It is important that you take the study medication approximately the same times each day. In the event you miss a dose, it is very important that you notify the research coordinator for further instructions.
- We reserve the right not to increase the dose up to 5mg/kg twice daily based at the discretion of the PI/MD with consideration given to your safety, tolerability, and individual response to treatment.

Day 24 (Inpatient stay)

- We will conduct a medicine check to ensure you have taken the correct amount and check your blood to see if the drug is present on Day 24.

- You will be requested to arrive in the morning at ICRC (about 7 a.m.) on Day 24 after an overnight fast. On the evening prior to the inpatient study Day 24, it is important that you have nothing to eat or drink after 11 pm except for water.
- Your basic measures of general health (e.g., temperature, heart rate, breathing rate and blood pressure), weight will be obtained. A physician will be available for consultation
- An intravenous catheter (small, flexible, plastic tube) will be placed in a vein in one of your arms for blood collection.
- Prior to dosing with cannabidiol and tacrolimus, blood (about 2 teaspoons) and urine samples will be collected. You will also be asked to fill out a questionnaire about how you feel.
- Then, you will receive a dose of cannabidiol by mouth (5 mg/kg in a liquid form) and tacrolimus (5 mg capsule) with a standardized breakfast and 250 ml water. A standard lunch will be served 4 hours after taking tacrolimus.
- We will obtain 14 blood samples (about 2 teaspoons each) at the following times: 20, 40, and 60 minutes and 2, 4, 6, 12 hours after dosing with the medications. In addition to blood sampling, we will have you save all your urine in provided urine containers for the entire inpatient stay.
- You will receive a second dose of cannabidiol by mouth (5 mg/kg in a liquid form) before discharge.
- You will be discharged to go home after the 12-hour blood draw.

Day 25 (outpatient visit).

- You will be requested to return to ICRC on Day 25 (24 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), collect urine sample, and to fill out the brief questionnaire on how you feel.
- You will receive a dose of cannabidiol by mouth (5 mg/kg in a liquid form) and reminded to take an additional dose in the evening.

Day 26 (outpatient visit).

- You will be requested to return to ICRC on Day 26 (48 hours) for a brief outpatient visit to have your basic measures of general health checked, draw blood sample (one tube, approximately 2 teaspoonful), collect urine sample, and to fill out the brief questionnaire on how you feel.
- If you have CKD, your kidney function and potassium level will be re-checked from the blood sample.
- This visit completes the study.

If you participate in this study, we may learn things about you from the study procedures that could be important or interesting to you. Depending on the information, you might need to meet with professionals with expertise to help you decide what to do with the information. We do not have money or funds available to cover the costs of any follow-up consultations or actions. We will share the following information with you:

- Any information that might be immediately critical to your health will be shared with you or your health care provider.
- The screening laboratory tests and EKG (electrocardiogram) may suggest you have a disease that could be treated. If these tests are abnormal, the results will be shared with you because this information may be helpful for your health in the future.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

The risks of participating in the studies are related to blood draws and to the pharmacological effects of test drugs: tacrolimus and cannabidiol.

1) Venipuncture: Venipuncture may cause slight pain, bruising, and bleeding from the site of the needle puncture into the vein, and in rare cases, fainting and infection. To minimize these discomforts and risks, only trained and experienced nurses, physicians, or technicians in the ICRC will place the intravenous catheter in the vein or perform venipuncture to collect blood samples.
2) Blood Loss: The total amount of blood drawn for this study, including screening and exit laboratory tests, will be slightly under 650 ml or approximately two and one-half cups over 26 days. In comparison, this amount is similar to the amount one would give if donating blood one time. To minimize the impact of blood loss, you will be screened to ensure you have a hemoglobin count of 10.0 g/dl or above.
3) EKG: There are generally no risks associated with an EKG. However, the adhesive used to attach the pads may cause a rash or skin irritation.
4) Loss of information: There is a risk someone outside the study team could get access to your research or medical information from this study. More information about how we reduce this risk is below.
5) Cannabidiol has been approved by the food and drug administration (FDA). It can cause sleepiness, decreased appetite, diarrhea, fatigue, rash, and poor-quality sleep. A small number of individuals will feel a euphoric mood (feeling of increased energy or happiness). In about 1 in 100 individuals taking cannabidiol for over 4 months, the medicine can affect the liver. The likelihood of cannabidiol affecting your liver is less because of the shorter duration you will take the drug. The function of your liver (blood test) and the medications you take will be screened at the start of the study to see if you are at higher risk. You will not be able to participate in the study if you have abnormal liver function. We will ask you about side effects at every visit. If you experience sleepiness or fatigue, you can choose to continue the study at a lower dose of cannabidiol (2.5 mg/kg twice daily instead of 5 mg/kg twice daily). Taking cannabidiol with tacrolimus should not increase the amount of cannabidiol in your system or increase the risk of side effects.
6) Tacrolimus has been approved by the food and drug administration (FDA). Tacrolimus is generally well tolerated and taken twice daily by many transplant recipients for years. Common side effects include suppression of your immune system, kidney problems, and high potassium. These side effects generally only occur when the amount of tacrolimus in your system is high, which usually happens when you take more than 4 consecutive doses. Since you will only receive a single dose of tacrolimus on two occasions 20 days apart, the risk of side effects is low (less than 1 in 1000). We are testing to see whether cannabidiol can double the amount of tacrolimus in your system, but even if this happens, the amount of tacrolimus in your system will likely still be too low to cause high potassium or kidney problems. Your kidney function and potassium will be screened on enrollment and after taking tacrolimus to ensure there is no significant change in your kidney function.

There also may be other side effects that we cannot predict.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

All procedures, tests, ICRC visits, and study medications that will be done as part of this research will be covered by the study team; this study will incur no cost to you or your insurance company.

If you are injured as a result of participating in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We do not think you will have any personal benefits from taking part in this study, but we hope to learn how cannabidiol affects tacrolimus to help other people in the future. You may receive some benefit from the EKG and laboratory screening tests completed.

WILL I BE PAID FOR PARTICIPATION?

You will receive a total compensation of up to $1050 for your time. We will reimburse you for parking and provide your meals during the three inpatient days.

Study Visit	**Payment**
Screening	$50
Inpatient Day 1	$200
Outpatient Day 2+3	$50+$50
Inpatient Day 8	$200
Outpatient Day 9+10	$50+$50
Inpatient Day 24	$200
Outpatient Day 25+26	$50+$50
Full Study completion bonus	$100
Total	**$1050**

You will be compensated corresponding to your participation for the portions of the study which are completed. Compensation will be issued at the completion/withdrawal of the study. The principal investigator reserves the right to withdraw you from the study without your consent if your risks in participating in this study outweigh your best interest in terms of safety or if you are unable to adhere to the study requirements.

If you receive $600 or more in one calendar year from Indiana University, you will need to complete a form giving us your Social Security number (SSN) or tax identification number (TIN). You will receive a 1099 tax form the following January from Indiana University and will need to report this payment as income on your federal and state tax returns. You are responsible for paying any local, state, or federal taxes. If you have questions about how this impacts your tax return, please contact a tax professional. If you do not have an SSN or TIN, the Internal Revenue Service (IRS) requires Indiana University to deduct 30% from your research payment to pay required taxes on your behalf.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION AND SPECIMENS BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the criteria to be in this study, gathering information about your medical history to include in the research data, and reviewing results of your medical tests for safety purposes, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include all of your medical records. Those records may contain information related to mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians [Internal Medicine]
- IUMG – Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
    - The Indiana Clinical Research Center (ICRC)
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)
    - The United States Food and Drug Administration (FDA)

Information and specimens collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations. The Certificate also does not stop sharing of information required by the Food and Drug Administration (FDA).

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WHAT WILL YOU DO WITH MY GENETIC INFORMATION?

The specimens collected in this study may be used to predict the function of the enzymes that metabolize (break down) tacrolimus and cannabidiol in the liver using a genetic test for CYP3A4 and CYP3A5, the proteins which metabolize the drugs. We will not use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. You will not receive testing for any genetic diseases.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, or a research-related injury, contact the principal investigator, Michael Eadon, MD, at 317-274-2502, weekdays (8:00am-5:00pm). After business hours, please call 317-962-2000 and ask for the nephrology physician on call. In the event of emergency, you should search for immediate treatment in the emergency room nearest to you. If you are unable to reach the investigator at the above number(s) in an emergency, you may contact the University Hospital pharmacy at 317-944-0362 and ask them to page the IDS pharmacist on call.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you.
If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University Health or Eskenazi Health.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, you can contact the study team at 317-274-2502. You may withdraw from this study at any time without penalty. Leaving the study will not result in any penalty or loss of benefits to which the subject is entitled. The decision of any subject to participate or not to participate will not affect current or future relationship with the research team.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Michael Eadon, 950 W. Walnut St, R2 Suite 202, Indianapolis, IN 46202 or by email at meadon@iupui.edu. If you withdraw your authorization, you will not be able to continue in this study.

However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

The researchers may stop your participation in the study even if you do not want to stop if your risks in participating in this study outweigh your best interest in terms of safety or if you are unable to adhere to the study requirements. This study may be terminated by the National Institute of Health for unforeseen reasons (e.g., lack of funding), by the DSMB or IRB at their discretion.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

Agreement to be Contacted by Text and/or Email

We would like to communicate with you about this study by text message and/or email. We might use text or email to send you reminders about upcoming visits or appointments, check on how you are doing, or tell you about the progress of the research.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study

Phone number for this communication: _____

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

Participant's Signature:_____Date:_____

Participant's Address:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____Date:_____