Washington State University

# ASSESSING THE PHARMACOKINETICS AND DRUG INTERACTION LIABILITY OF KRATOM, AN OPIOID-LIKE NATURAL PRODUCT

NCT04392011

Document date: 20 August 2020

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**WASHINGTON STATE UNIVERSITY**
Department of Pharmaceutical Sciences, College of Pharmacy and Pharmaceutical Sciences

# Research Study Consent Form

**Study Title:** Assessing the pharmacokinetics and drug interaction liability of kratom, an opioid-like natural product

**Researchers:** Mary F. Paine, RPh, PhD; Principal Investigator; Associate Professor, Department of Pharmaceutical Sciences, College of Pharmacy; 509-358-7759 (office); 24-hour emergency telephone: 919-259-5020

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Victoria Oyanna, PhD student; Study Assistant

**Sponsor:** National Institutes of Health

## KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
- Study Purpose – The purpose of this study is to determine whether or not kratom, a natural product currently available in the U.S., has an effect on enzymes that are responsible for breaking down drugs in the body.
- Major Activities of Subject Participation – If you are asked to participate in this study, you will be asked to avoid consuming dietary/herbal supplements and citrus juices for several weeks. You will also be asked to avoid consuming caffeinated beverages or other caffeine-containing products the evening before and the morning of a study day. You will be asked to avoid consuming alcoholic beverages for at least 1 day prior to the study day and during the study day. If you are female, you will be asked to use an acceptable method of contraception that does not include oral contraceptive pills (such as abstinence, copper IUD, or condoms).

  During the study, you will first present for a screening visit at the Nursing Building or Sleep and Performance Research Center on the WSU Spokane campus. During this visit, you will read, understand, and sign this consent form. You will have a medical history and physical exam completed. You will have blood drawn during this visit. If you are female, you will be asked to provide urine for a pregnancy test. If your results indicate that you are fit for the study, you will be asked to participate.

  The study is broken into two study arms: Arm 1 and Arm 2. Arm 2 is further broken down into Arm 2a and 2b. For the first day of each study arm, you will be asked to present for one 14-hour inpatient visit, where blood will be drawn through an intravenous (IV) line before and after you are given the study drugs (midazolam and dextromethorphan) with or without kratom. After an initial blood draw, you will be given kratom alone (Arm 1), a combination of study drugs alone (Arm 2a), or a combination of kratom with study drugs (Arm 2b). Overall, blood will be drawn at 11 different time points during the visit, and a total of approximately 60 milliliters (about one-fourth of a cup) of blood will be collected. You will not be allowed to eat until after the 4-hour blood draw. You will also be asked to collect urine throughout this visit by voiding into a jug.

  Depending on which study arm(s) you choose to participate in, you will be asked to return to the clinical research unit once every day for 6 days after the inpatient visit (Arm 1), or once after the inpatient visit (Arm 2a and 2b). Blood will be drawn through an IV line or needlestick during these visits. About 5 milliliters (one teaspoonfuls) of blood will be taken on each day. If you choose to participate in Arm 2 (2a and/or 2b), you will be asked to wait at least one week before starting either arm.
- Duration of Participation – This study is divided into two arms: Arm 1 and Arm 2. The duration of participation will depend on which arm(s) you choose to participate in. Those who complete Arm 1 only will participate for a minimum of 7 days. Participation time for those who complete Arm 2 only (Arm 2a and 2b) will be at least 12 days. Participants who choose to complete both study arms will be a part of the study for at least 5 weeks, with flexibility of completion time of up to 6 months.
- Significant Risks – Risks pertaining to this study can include bruising, pain, or bleeding at the site of blood draw; inflammation of the vein; fainting, allergic reactions to the study drugs (midazolam, dextromethorphan) or kratom; stimulant-like effects; drowsiness; dizziness; low blood pressure; confusion; excitement; irritability; nervousness; dizziness; somnolence (sleepiness); or serotonin syndrome, defined as

an excessive amount of serotonin that is characterized by symptoms including but not limited to diarrhea, shivering, and fever. If you are female and are pregnant or become pregnant, there may be unforeseeable risks to the embryo/fetus.
- Potential Benefits – There are no direct benefits to you. However, the information learned from the study may help people, such as those in your community, in the future.
- This is a clinical trial and should not be considered medical treatment.

**What you should know:**

You are being asked to take part in a research study carried out by Dr. Mary Paine. This form explains the research study and your part in it if you decide to participate in the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. Your participation in the study is strictly voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide not to take part in the study or quit later. This study has been approved for human subject participation by the Washington State University (WSU) Institutional Review Board (IRB).

**What is the purpose of this study?**

The effects of dietary/herbal supplements and other natural products, including foods, on drug concentrations in the body represent an understudied area of research. It is typical for doctors and pharmacists to check for potential drug-drug interactions when prescribing or dispensing medicines to patients, but they may not always check for potential natural product-drug interactions. The researchers believe this is because there is still little information on how natural products interact with drugs. St. John's wort is one example of a natural product that is known to change the way some drugs are broken down in the body, and patients are warned not to take St. John's wort when these drugs are prescribed to them. Grapefruit juice is another natural product that is known to change the way some drugs are broken down in the body, and patients are advised to avoid consuming grapefruit juice when taking many different drugs.

This research study is being done to determine whether another natural product, kratom, has an effect on the enzymes of the body that break down (metabolize) drugs. This is a clinical study and should not be considered medical treatment.

You are being asked to take part in this study because you:
- Are from 18-55 years old and healthy
- Are not taking any medications (prescription and non-prescription) or dietary/herbal supplements that can interfere with your ability to eliminate the study drugs and kratom
- Are willing to abstain from consuming dietary/herbal supplements and citrus juices for several weeks
- Are willing to abstain from consuming caffeinated beverages or other caffeine-containing products the evening before and the morning of the first day of each study arm

- Are willing to abstain from consuming any alcoholic beverages for at least 1 day prior to any study day and during the study day
- Are willing to use an acceptable method of contraception that does not include oral contraceptive pills or patches (such as abstinence, copper IUD, condom)
- Have the time to participate
- Consume kratom intermittently (not regularly) and are willing to abstain from taking it for at least two weeks prior to beginning the study
- Do not carry genes that make you a poor metabolizer of one of the test drugs

You cannot take part in this study if you:

- Are under 18 or over 55 years old
- Are taking medications or dietary/herbal supplements that can interfere with your ability to eliminate the study drugs and kratom
- Have never taken kratom
- Have a chronic illness such as (but not limited to) kidney disease, liver disease, diabetes mellitus, high blood pressure, coronary artery disease, chronic obstructive pulmonary disease, cancer, or HIV/AIDS
- Have a hematologic (blood) disorder
- Have a history of drug or alcohol addiction or major psychiatric illness
- Have a need for chronic opioid pain medications
- Have used opioid pain medications within the last 3 weeks
- Have an upcoming need for opioid pain medications (e.g., planned dental or surgical procedure)
- Have a history of allergy to midazolam, dextromethorphan, or related drugs
- Have a history of intolerance or allergy to kratom or opioids
- Are pregnant or nursing
- Carry genes that make you a poor metabolizer of one of the test drugs

**What will I be asked to do if I am in this study?**

Taking part in the study will last from anywhere from 6 days to 6 months, depending on your schedule. The study will require no more than 47 hours of active participation, including minimal time commitment at home while collecting urine.

If you take part in the study, you will be asked to:

- Present for a screening visit at the Nursing Building or Sleep and Performance Research Center on the WSU Spokane campus. This visit will last approximately 2 hours and will include the following:
  - Reading, understanding, and signing this consent form
  - Undergoing a medical history and physical exam
  - Having about 1 tablespoonful of blood drawn for routine laboratory testing
  - Having about one-half teaspoonful of blood drawn to determine if you are a poor metabolizer of one of the test drugs
  - Providing urine for routine laboratory testing and test for multiple common drugs of abuse, including several opioids
  - Providing urine for a pregnancy test if you are female

- If your lab tests come back normal, the drug test comes back negative, you do not have the genes that make you a poor metabolizer of one of the test drugs, and if you are female and your pregnancy test comes back negative, you will be asked to participate in the study.
- The study will be divided into 3 separate arms. Arm 1 will enroll 6 subjects and last 7 days. Arms 2a and 2b will enroll 12 subjects. Arm 2a will consist of one inpatient visit and one outpatient visit. Arm 2b will consist of one inpatient visit and two outpatient visits.
- Arm 1 will last 7 study days (20 hours in total across 7 days) and will take place in the clinical research unit in the Nursing Building or Sleep Performance Research Center. You will be asked to remain in the clinical research unit for about 14 hours on study day 1 and then return daily over the next 6 days (for less than 1 hour each day).
- Each Arm will be separated by at least one week.
- The 6 subjects who participate in Arm 1 will have the option to participate in Arms 2a and 2b. Arm 2a will require approximately 15 hours of active participation. Arm 2b will require approximately 16 hours of active participation.
- Kratom or the study drugs (midazolam, dextromethorphan) may alter your ability to drive. You must arrange a safe ride home on all inpatient study days (*i.e.* day one of Study Arm 1, 2a, and 2b). This includes requesting a family member or friend to drive you home, calling a taxi, or using ride-share applications.

The study arms will include the following:

- **Study Arm 1:**
  - This Arm will include 1 inpatient visit lasting up to 14 hours, subsequent 1-hour visits on the following 5 days, and 1 additional 1-hour visit a few days later.
  - You will be asked to void your bladder before coming in for the study day.
  - Your vital signs (blood pressure, pulse, respirations) and oxygen saturation will be checked and recorded on case forms when you arrive.
  - An intravenous (IV) line will be placed in one of your arms. One blood sample (5 mL or one teaspoonful) will be drawn through the IV line.
  - You may be asked to provide one additional blood sample (< 3 mL, or about one-half a teaspoonful) that will be drawn through the IV line.
  - You will be asked to take kratom (2 g) by mouth as a tea.
  - You will begin collecting your urine by voiding into a jug as needed.
  - Blood (5 mL, or about 1 teaspoonful) will be drawn at the following times after you take kratom: 15 minutes, 30 minutes, 1, 1.5, 2, 3, 4, 6, 8, and 12 hours.
  - A total of approximately 60 mL (one-fourth of a cup) will be drawn during the 14-hour visit. Every attempt will be made to use your IV line for the blood draws.
  - You will not be allowed to eat until after the 4-hour blood draw. You will then receive lunch.
  - You will be discharged as soon as possible after the 12-hour blood draw and given a urine jug to take home and void into until you come back to the clinical research unit the next morning.
  - You will be asked to return to the clinical research unit for a blood draw 24 (day 2), 48 (day 3), 72 (day 4), 96 (day 5), and 120 (day 6) hours after you take kratom.

The blood will be drawn through a needlestick in your arm. You will drop off your urine jug the mornings of days 2-6.

- You will be asked to return to the clinical research unit for a 5 mL (about 1 teaspoonful) blood draw up to 7 days after the 120-hour blood draw.
- If you choose to participate in Arm 2, you will wait at least 1 week before starting Arm 2a. You will be asked not to take any dietary/herbal supplements (with the exception of the study herbal product) or consume citrus juices for the duration of the study.
- If you choose not to participate in Arm 2, you will receive a follow-up call 5 days later from a member of the study team.

- **Study Arm 2a:**
  - This Arm will include 1 inpatient visit lasting up to 14 hours and 1 outpatient visit lasting up to 1 hour.
  - You will be asked to void your bladder before coming in for the study day.
  - Your vital signs (blood pressure, pulse, respirations) and oxygen saturation will be checked and recorded on case forms when you arrive.
  - An IV line will be placed in one of your arms. Two blood samples (3 mL, or less than one teaspoonful, plus 5 mL, or about 1 teaspoonful) will be drawn through the IV line.
  - You may be asked to provide one additional blood sample (< 3 mL, or about one-half a teaspoonful) that will be drawn through the IV line.
  - You will be asked to take a drug “cocktail” (combination) consisting of midazolam syrup (2.5 mg) and 2 capsules (15 mg each; 30 mg total) of dextromethorphan by mouth with 240 mL of water.
  - You will begin collecting your urine by voiding into a jug as needed.
  - Blood (5 mL or about 1 teaspoonful) will be drawn at the following times after you take the drugs: 15 minutes, 30 minutes, 1 hour, 1.5, 2, 3, 4, 6, 8, and 12 hours.
  - A total of approximately 60 mL (about one-fourth of a cup) will be drawn during the 14-hour visit. Every attempt will be made to use your IV line for the blood draws.
  - You will not be allowed to eat until after the 4-hour blood draw. You will then receive lunch.
  - You will be discharged as soon as possible after the 12-hour blood draw.
  - You will be asked to return to the clinical research unit for a blood draw 24 hours after you take kratom. The blood will be drawn through a needlestick in your arm.
  - You will be asked to collect your urine and drop off your urine jug upon returning to the clinical research unit for the 24-hour blood draw.
  - After completing Arm 2a, you will wait at least 1 week before starting Arm 2b. You will be asked not to take any dietary/herbal supplements (with the exception of the study herbal product) or consume citrus juices for the duration of the study.

- **Study Arm 2b:**

- This Arm will include 1 inpatient visit lasting up to 14 hours and 2 outpatient visits, each lasting up to 1 hour. The first outpatient visit will occur at the 24-hour mark and the second outpatient visit will occur within the week following the first outpatient visit. The timing of the second outpatient visit will be flexible depending on your schedule.
- You will be asked to void your bladder before coming to the clinical research unit for the study day.
- Your vital signs (blood pressure, pulse, respirations) and oxygen saturation will be checked and recorded on case forms when you arrive.
- An IV line will be placed in one of your arms. One blood sample (5 mL, or about 1 teaspoonful) will be drawn through the IV line.
- You may be asked to provide one additional blood sample (< 3 mL, or about one-half a teaspoonful) that will be drawn through the IV line.
- You will be asked to take kratom (2 g) by mouth as a tea, as well as a drug "cocktail" consisting of midazolam syrup (2.5 mg) and 2 capsules (15 mg each; 30 mg) of dextromethorphan by mouth with 240 mL of water.
- Blood (5 mL or about 1 teaspoonful) will be drawn at the following times after you take kratom and the drug "cocktail": 15 minutes, 30 minutes, 1 hour, 1.5, 2, 3, 4, 6, 8, and 12 hours.
- A total of approximately 60 mL (one-fourth of a cup) will be drawn during the 14-hour visit. Every attempt will be made to use your IV line for the blood draws.
- You will not be allowed to eat until after the 4-hour blood draw. You will then receive lunch.
- You will be discharged as soon as possible after the 12-hour blood draw.
- You will be asked to return to the clinical research unit for a blood draw 24 hours after you take kratom. The blood will be drawn through a needlestick in your arm.
- You will be asked to collect your urine and drop off your urine jug upon returning to the clinical research unit for the 24-hour blood draw.
- After completing Arm 2b, you will receive a follow-up call 5 days later from a member of the study team.

If you choose to participate in Arm 1 only, your total participation time in the study will be a minimum of 7 days. If you choose to participate in Arm 2 only, your total participation time in the study will be a minimum of 12 days. If you choose to participate in Arms 1 and 2, your participation time in the study will be a minimum of 5 weeks. However, the researchers recognize that you may not be able to meet these tight schedules and can be flexible, as long as you can complete the entire study within 6 months.

If significant new findings develop during the course of the research which may relate to your willingness to continue participation, these will be provided to you and you can decide whether to continue participating.

**Are there any benefits to me if I am in this study?**

There is no direct benefit to you from being in this study. However, the information learned from the study may help other people, such as those in your community, in the future. The knowledge gained from the study will benefit society because the information will provide

important insight into how a commonly consumed natural product can alter drug disposition, and ultimately, drug response.

**Are there any risks to me if I am in this study?**
The potential risks from taking part in this study are:

- You might experience bruising, pain, or bleeding at the site of the blood draw, inflammation of your vein, or fainting.
- You might have an allergic reaction to midazolam, dextromethorphan, or kratom.
- You might experience stimulant-like effects, including increased energy and alertness, decreased appetite, increased sociability, and heightened libido as a result of kratom. These effects should be minimal because you will be receiving a single low dose.
- You might experience drowsiness, dizziness, or low blood pressure as a result of midazolam. These effects should be minimal because you will be receiving a single low dose.
- You might experience confusion, excitement, irritability, nervousness, dizziness, somnolence (sleepiness), mild fatigue, and serotonin syndrome (defined as an overaccumulation of serotonin, characterized by symptoms including but not limited to diarrhea, shivering, and fever) as a result of dextromethorphan. These effects should be minimal because you will be receiving a single dose.
- As with any experimental procedure, there may be adverse events or side effects that are currently unknown, and it is possible these unknown risks could be permanent, severe, or life-threatening.
- A description of this clinical study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, it will include a summary of the results. You may search this website at any time.
- If you are female and are pregnant or become pregnant, there may be unforeseeable risks to the embryo or fetus.
- Hardcopies containing personal/medical information about you may be misplaced.
- If you experience any adverse effects or injury, you should contact the principal investigator (Dr. Mary Paine), study physician (Dr. Matthew Layton), or any of the researchers listed at the top of this form. If you require additional assistance or would like to report any concerns, you should contact the Washington State University Institutional Review Board at (509) 335-3668, or e-mail irb@wsu.edu, or regular mail at: Neill Room 427, PO Box 643143, Pullman, WA 99164-3143.

The researchers will make every attempt to minimize these potential risks, including:

- Having only trained personnel (nurse, physician, physician's assistant, pharmacist, pharmacy student) draw blood.
- Monitoring your respirations, blood pressure, pulse, and oxygen saturation each study day.
- Study personnel will ask you how you are feeling throughout the study day and will address any concerns you may have.
- Having the anti-allergy medication, diphenhydramine; the opioid antidote, naloxone; and an Epi-kit available if needed. If you experience a severe adverse reaction, you

will be given diphenhydramine, naloxone, and/or epinephrine, 911 will be called, and you will be transported to a local emergency room.
- Allowing only members of the study team to collect and store, as hardcopies, your personal/medical information. These hardcopies will be kept in a locked office and cabinet. Your personal information will not be entered on a computer.
- Having the study physician or authorized licensed designee available at all times during the study in case you experience serious adverse events.

**Will my information be kept private?**
The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. The federal Food and Drug Administration (FDA) may also review the study data.

The researchers will make every attempt to keep your information private, including:
- Private conversations will occur only in closed-door offices or rooms.
- Your personal information will be kept in hardcopy format in a locked office and cabinet. Such information will not be entered on a computer.
- Data collected from you (clinical labs, vital signs) will not be linked to you and will be stored on a password-protected computer and in hardcopy format in a locked office.
- Only members of the research team will have access to the data.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

Identifiers might be removed from the identifiable private information or identifiable specimens and then the information or specimens could be used for future research studies or distributed to other researchers for future research studies without your additional permission. If you do not agree to this, you may choose not to join the study.

The data for this study will be kept for 7 years. One blood sample will be retained indefinitely for genetic analysis if future research indicates a genetic variation may affect the way the body responds to any of the study drugs or components in kratom. The genetic analysis would only be conducted for the specific genes associated with the way the body responds to any of the study drugs and their metabolites, or components in kratom.

A description of this clinical trial will be available on http://www.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.

**National Institutes of Health Certificate of Confidentiality**
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as

evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Complementary and Integrative Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the FDA. You should understand that 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 provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. For example, if child abuse and neglect or harm to self or others is suspected, the researchers are required to report this information to relevant authorities.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including research data in the medical record.

**Are there any costs or payments for being in this study?**

There will be no costs to you for taking part in this study.

Please review the table on the next page for a breakdown of compensation for participating in this study.

***TABLE 1.*** *Payments for participation*

| **STUDY VISITS** | **PAYMENT TOTAL** |
|---|---|
| Screening | $25 |
| Arm 1 Inpatient | $300 |
| Arm 1 Outpatient (6 visits) | $150 |
| Arm 1 Urine Collection (five 24-hour collections) | $200 |
| Arm 2a Inpatient | $300 |
| Arm 2a Outpatient | $25 |
| Arm 2b Inpatient | $300 |
| Arm 2b Outpatient (2 visits) | $50 |
| **Total** | **$1,350** |

If you complete only Arm 1, you will receive a total of $475; if you complete and return your 24-hour urine collections every day on days 2-6 of Arm 1, you will receive a total of $675. If you miss any of the 24-hour urine collections in Arm 1, you will forfeit the additional $200. If you complete only Arm 2, you will receive a total of $700. If you complete all study arms, you will receive a total of $1,150. If you complete all study arms and return your 24-hour urine collections every day on days 2-6 of Study Arm 1, you will receive a total of $1,350.

You also will receive food and drink during each study day. If you decide to quit the study at any time, you will receive payment based on the number of study days you have completed and as soon as possible after your last study day. There will be no penalty for discontinuing participation at any time.

If you receive payment for taking part in this study, you will be asked to provide your home address and social security number because this payment may be taxed as income. If you are a nonresident alien, a 30% withholding tax will apply to your payment per Washington State University's Business Policies and Procedures Manual (BPPM 45.53; https://policies.wsu.edu/prf/index/manuals/45-00-contents/45-53-incentive-payments-research-participants).

**Who can I talk to if I have questions?**
If you have questions about this study or the information in this form, please contact the primary researcher, Dr. Mary Paine, by phone (509-358-7759), e-mail (mary.paine@wsu.edu), or regular mail (WSU College of Pharmacy and Pharmaceutical Sciences; PBS 323, 412 E Spokane Falls Blvd; Spokane, WA 99202-2131). If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.

**What if I have a study-related injury or want to withdraw?**
If you have a study related injury, illness, distress and want to report this to the researchers, contact the primary researcher, Dr. Mary Paine, by phone (509-358-7759), e-mail (mary.paine@wsu.edu), or regular mail (WSU College of Pharmacy and Pharmaceutical Sciences; 412 E Spokane Falls Blvd, PBS 341; Spokane, WA 99202-2131). To withdraw your previously collected data from the study, you must contact the primary researcher by e-mail or regular mail within 10 days of the incident, requesting that your collected data be withdrawn from the study.

**What are my rights as a research study volunteer?**
Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records.

**What does my signature on this consent form mean?**
Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved
- You are giving your voluntary consent to take part in the study

**Statement of Consent**

| **Yes, I agree** | **No, I disagree** | The researcher may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in de-identified form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity. I will not be re-contacted for permission to use the samples. |
|---|---|---|
| _____ | _____ | |

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

**Statement Confirming Driver Availability**

I confirm that a driver will be available to take me home after I am discharged from all of the inpatient study days.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant