Official Title: A Human Laboratory Study of n-Acetylcysteine for Alcohol Use Disorder
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CONSENT TO PARTICIPATE
IN A RESEARCH STUDY
University of Kentucky Medical Center

TITLE OF STUDY:
Behavioral Effects of Drugs: Inpatient (34) (Alcohol and N-Acetylcysteine)

INVESTIGATOR INFORMATION:

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WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about the effects of drugs on behavior. You are being asked to participate because you are 21-55 years old with a recent history of alcohol use. You are also being asked to participate because you have expressed interest in participating in this study, you passed the medical screen, and it is unlikely that you will react badly to the laboratory setting or to the drugs you will take. You must be at least 21 years of age to participate in this research study and you will be asked to provide legal proof of age. If you volunteer to take part in this study you will be one of about 25 people to do so over the next two years at the University of Kentucky.

WHO IS DOING THE STUDY?

This study is being conducted under the scientific and administrative supervision of William W. Stoops, Ph.D., Department of Behavioral Sciences at the University of Kentucky College of Medicine and the medical supervision of Lon R. Hays, MD, M.B.A. and Abner O. Rayapati, M.D., Department of Psychiatry**,** at the University of Kentucky College of Medicine. There may be other people on the research team assisting at different times.

WHAT IS THE PURPOSE OF THIS STUDY?

This medication development experiment is testing the effects of placebo (a blank, no drug) or n-acetylcysteine (a medication used to treat acetaminophen overdose) on the subjective, cognitive and physiological effects of alcohol. We are also interested in determining whether n-acetylcysteine impacts whether you like alcohol and want to choose to drink it. The purpose of this research is to gather information on how safe n-acetylcysteine and ethanol are. The results of this study will be shared with the sponsor providing financial support for the study (the National Institute on Alcohol Abuse and Alcoholism), the Food and Drug Administration and other federal agencies, if required.

You should understand that this is a research project, not a treatment program. The procedures of the study are designed to provide scientific information in a way that is relatively safe and comfortable for you, but not to provide benefits. **If you are seeking treatment, do not agree to participate in the study. This study will not help you stop using alcohol.** The investigators can arrange for referral to an appropriate treatment program if you so desire.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not participate if you have a history of serious physical disease, current physical disease, impaired cardiovascular functioning like heart attack or stroke, high blood pressure, chronic obstructive pulmonary disease, history of epilepsy or seizure, diabetes, current or past histories of serious psychiatric disorder. You should not participate if you have a history of other significant medical problems.

You should not participate if you are seeking treatment for your drug or alcohol use, are currently in treatment for your drug or alcohol use, or are currently in successful remission from your drug or alcohol use. If you have ever been addicted to drugs or alcohol, you should discuss this with the research staff before agreeing to participate.

If you are a female, you should not participate if you are pregnant or plan on becoming pregnant during your participation in this experiment. You must be using an effective form of birth control (e.g. birth control pills, surgically sterilized, IUD, cervical cap with a spermicide, condoms, or abstinence), and you must be willing to take a pregnancy test before being accepted into the research study. You will also be required to take a pregnancy test prior to each experimental session. Should one of these tests show that you are pregnant, your participation will be terminated immediately. If you are female, you should not participate if you are lactating or breast feeding a baby.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky Laboratory of Human Behavioral Pharmacology (LHBP) and at the Inpatient Unit of the Clinical Services Core (CSC) at the University of Kentucky Medical Center. Your participation in this study will last approximately one month as outlined in Table 1 below.

Day	Table 1: Overall Participation Timeline
0	Practice Session at the LHBP. The timeline of this session matches that of experimental sessions, except no alcohol will administered, nor will you stay overnight at the CSC. You will be provided with doses to take at 7:00 PM and 7:00 AM through Day 5. Doses will be provided in a Wisepill® device that will monitor when you take the doses.
1-5	Placebo or n-acetylcysteine maintenance. On day 1, you will take your oral dose of placebo or n-acetylcysteine at approximately 7:00 AM. You will then take doses to take at 7:00 PM and 7:00 AM through Day 5.
5	Experimental Session 1 at the CSC inpatient unit. The Experimental Session timeline is outlined in Table 2. You will stay on the inpatient unit overnight after completing this session.
6-12	Discharge from the CSC on the morning of Day 6, followed by a 7 day washout period in which you do not take placebo or n-acetylcysteine.
13-17	Placebo or n-acetylcysteine maintenance. Details are the same as Days 1-5 above.
17	Experimental Session 2 at the CSC inpatient unit. Details are the same as those for Day 5 above.
18-24	Discharge from the CSC on the morning of Day 18, followed by a 7 day washout period in which you do not take placebo or n-acetylcysteine.
25-29	Placebo or n-acetylcysteine maintenance. Details are the same as Days 1-5 above.
29	Experimental Session 3 at the CSC inpatient unit. Details are the same as those for Day 5 above.
30	Study is completed after discharge from the CSC on the morning of Day 30.

Over the course of your approximately month-long participation, you will be asked to complete 4 total sessions as outlined in Table 1 above. They will consist of 1 practice session at the LHBP and 3 experimental sessions at the CSC. Experimental sessions will be completed after a period of maintenance on placebo or n-acetylcysteine. Each of these sessions will last about 5 hours, but you will be required to stay at the CSC overnight after completing each experimental session as outlined in Table 2 below.

Approximate Time	Table 2: Experimental Session Timeline
2:00-3:00 PM	Arrival at the LHBP. If you drove to the LHBP, your car keys will be collected. Urine sample collected and analyzed for drugs for all and pregnancy for females. Breath alcohol level, field sobriety test, vital signs assessment, self-reported times of maintenance dosing, questionnaires about drug and alcohol use completed. You will need to abstain from alcohol for at least 12 hours prior to your arrival at the LHBP.
3:00-3:30 PM	Transport to, admission and acclimation to the CSC. You will receive a light snack.
3:30-4:15 PM	Baseline subjective, physiological and cognitive-behavioral measures completed.
4:15-5:30 PM	Sampling phase. During this time you will sample a dose of alcohol. Subjective and physiological measures will be completed at 10, 20 and 30 minutes after this sample dose. Cognitive-behavioral measures will be completed 30 minutes after this sample dose.
5:30-6:30 PM	Choice Phase 1. During this time, you will be able to choose between drinking 4 alcohol doses and $3.00. That is, for each alcohol dose you choose not to drink, you will earn $3.00 that will be added to your study payment. Subjective and physiological measures completed every 30 minutes during this time.
6:30-7:30 PM	Choice Phase 2. During this time, you will be able to choose between drinking 4 alcohol doses and $3.00. That is, for each alcohol dose you choose not to drink, you will earn $3.00 that will be added to your study payment. Subjective and physiological measures completed every 30 minutes during this time.
7:30-7:45 PM	Side Effects Rating Scale completed. Session ends. You will then receive dinner.
7:45-11:00 PM	During this time you may engage in recreational activities.
11:00 PM	Lights out.
7:00 AM (the next day)	At this time, you will receive breakfast.
7:30-8:00 AM	Sobriety test and breath alcohol level measured.
8:00 AM	After passing the sobriety test and having a breath alcohol level of 0.000, you will be discharged from the CSC and returned to the LHBP to receive payment and your car keys. You may depart for your home after returning to the LHBP and being paid.

During your time on the CSC you must agree to follow the general rules of the CSC and share in the routine responsibilities of keeping the unit and yourself neat, clean and orderly. You will be provided a detailed list of the CSC rules before being admitted as an inpatient. You should understand that during the time that you spend on the CSC that you will not be allowed to leave the unit unsupervised, nor will you be allowed to have visitors. You will be allowed to make telephone calls.

You should also understand that upon arrival to the LHBP on experimental session days, the LHBP staff will take your car keys and will return them when you are released from the hospital the following morning. Should you leave the hospital prior to that time, you will need to arrange transportation (e.g., have a friend pick you up, arrange a taxi). You must agree to follow the investigator's advice about caution and refrain from operating dangerous machinery if you leave the hospital. Your car keys will be returned the morning following the experimental session upon successful completion of a field sobriety test.

WHAT WILL YOU BE ASKED TO DO?

Before participating in this research study, it will be necessary for you to have a physical and psychiatric examination. During the time you participate, you must agree to participate as an outpatient at the LHBP for 1 practice session and an inpatient at the CSC for 3 experimental sessions over approximately 1 month. During the time you participate, you should refrain from using any illicit substances. Also, please refrain from drinking alcohol 12 hours prior to coming to the laboratory and consuming food or caffeine 4 hours prior to a session. The first session will be a "practice" session to make you familiar with the various tasks and procedures of the experiment. The remaining experimental sessions will occur as outlined in the tables above. Sessions will last approximately 5 hours each, but you will be asked to stay as an inpatient at the CSC overnight until you are no longer affected by any of the alcohol you consume. During the sessions we will collect data concerning your physiological status and your subjective status. That is, we will record your heart rate, blood pressure, and temperature. We will also repeatedly ask you to answer various questionnaires about how you feel and about what kind of drug effect you feel. Finally, you will also have the opportunity to choose to consume alcohol during two 1 hour blocks as outlined in Table 2 above. The scheduled tasks pose no hazard or risk to you. You must agree to complete these forms and to do the tasks to the best of your ability and at the scheduled times. At the end of sessions, you will be paid the $40 for completing the session and whatever money you earned for choosing to not consume alcoholic beverages in the two choice phases described in Table 2 above. The morning after each session, you will be discharged from the CSC, provided that you meet appropriate release criteria (i.e., pass a sobriety test and have a breath alcohol level of 0.000).

During the active treatment phase (i.e., drug maintenance periods of the study), you will be given a device called a Wisepill® that will contain medications for you to take and that will monitor when you take the medication. We ask that you take the medication at the specified time (i.e., 7:00 AM and 7:00 PM) and that you return the device to us undamaged and in good working condition. We ask that you take that medication at the time specified, as well, returning at intervals noted in Table 1 for additional medication.

During your participation, you should not use any illicit drug. There will be urine checks and breathalyzers prior to each experimental session. These urine and breath checks will be conducted at the LHBP and CSC. If a urine screen or breathalyzer shows that you used other drugs or you have them in your possession, you may be dropped from the study. If you are dropped from the study because you used other drugs, or had them in your possession, you will lose a substantial portion of the money you might have earned.

Daily experimental procedures. On your first session, you will complete a practice session. This practice session is to familiarize you with the experimental routine. Every other session will be an experimental session. If you smoke tobacco cigarettes, you should understand that you will not be allowed to smoke during the experimental session which will last approximately 5 hours. We have included a table above to help you better understand the study protocol.

Drugs and Drug Administration. During the experiment you will be given doses of commonly prescribed drugs or recreational drugs. Drugs will be administered by mouth. The drugs tested will be placebo (a blank, no drug), an acetaminophen overdose treating medication (n-acetylcystine [Acetadote®]) and alcohol.

The prescription drugs will be administered in doses approved by the Food and Drug Administration (FDA). These drugs will be administered alone and in combination.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

The physiological measures, cognitive-behavioral tasks and subjective-effects questionnaires present no risks exceeding those of everyday experience. The primary risks to participation are those specifically related to the ingestion of the study drugs. The drugs under study occasionally produces side effects and these are outlined in the tables below. We will monitor for these side effects during experimental sessions at CSC. If you feel you are experiencing any of these side effects, you should

tell the nursing staff or physician. In addition to the risks listed below, you may experience a previously unknown risk or side effect.

Possible Risk or Side Effect of Alcohol	How often has it occurred?	How serious is it?	Can it be corrected?
Drowsiness, slurred speech, headache, gastrointestinal upset, breathing difficulties, distorted vision and hearing, impaired judgment and decreased perception and coordination	These are likely to or will occur.	Somewhat serious	These side effects are likely to decrease over time as the medications clear from your system.
Blackouts (memory lapses, where the drinker cannot remember events that occurred while under the influence), anemia, unconsciousness and coma	These are extremely uncommon.	Very Serious	No.

Possible Risk or Side Effect of n-acetylcysteine	How often has it occurred?	How serious is it?	Can it be corrected?
Nausea, vomiting, diarrhea, constipation, rash, fever, headache, drowsiness, reduced blood pressure	These are likely to or will occur.	Somewhat serious	These side effects are likely to decrease over time as the medications clear from your system.
Liver damage	This is extremely uncommon.	Very Serious	This may go away with treatment.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Understand that you are not a patient receiving medical treatment and that you will not receive any direct benefits from this study. However, the knowledge gained will contribute to a better understanding of alcohol effects and may result in improved therapeutic treatments. If you are seeking treatment, please notify the investigator now and he will make the necessary referral.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

Participating in this research study will not cost you anything. The clinical laboratory tests, physical examination and psychiatric screen described above will be paid by a grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the sponsor (the NIAAA).

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

Every effort will be made to maintain the confidentiality of your study records. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential, unless you give prior written approval or unless it meets our disclosure criteria (i.e., about communicable diseases, abuse of a child or elderly person or that you intend to harm yourself or others). Your name, address, and social security number will be listed on the receipt for payment that you receive, as required by the Internal Revenue Service; but no information about your participation in this research project will be released. We will be collecting your social security number for payment purposes. You cannot participate in this research if you withhold your social security number. A certificate of confidentiality has been obtained from the Department of Health and Human Services (DHHS). This certificate protects the investigators from being forced to release any research data that identifies you, even under a court order or subpoena. This protection, however, is not absolute. The investigators will report certain communicable diseases, abuse of a child or elderly person or that you intend to harm yourself or others to the appropriate authorities. Also, because this research is regulated by the National Institute of Health (NIH), the Food and Drug Administration (FDA) and The University of Kentucky, staff from these and other DHHS agencies may review records that identify you. However, it is the policy of these agencies and of these investigators that every attempt will be made to resist demands to release information that identifies you. When results of this study are published, your name will not be used.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

You can discontinue your participation in this study at any time. If you choose to withdraw from the study, you will be required to remain in the facility until the investigators are satisfied that you are no longer affected by the drug. During this time, you will be free to spend your time engaged in activities that are not part of the study. You should understand that you must remain in the facility in order to protect yourself and others from the effects of the drug and that your judgment while you are affected by the drug may be impaired sufficiently to necessitate that you remain in the facility.

You should understand, however, that if you decide to withdraw from the study early you will not receive any of the completion allowance described below. You will receive the $40 per session completion allowance for each of the experimental sessions you completed.

You should understand the principal investigator on this project, William W. Stoops, Ph.D., can terminate your participation for the following reasons: 1) failure to adhere to patients rules for CSC, 2) if you verbally or physically assault another volunteer, patient, or staff member on the CSC, 3) if your behavior is disruptive to other ongoing studies that are conducted on the CSC, 4) if your behavior is disruptive to the other volunteers, patients, research staff, or medical staff on the CSC, 5) failure to comply with the alcohol, drug, and food restrictions, 6) failure to comply with the pregnancy restrictions, 7) failure to take the doses as prescribed or complete a scheduled experimental session, 8) failure to perform the behavioral tasks to the best of your ability, 9) if you leave the hospital against the advice of the principal investigator or the medical doctors. If you are terminated for any of these reasons, it will be deemed that you did not complete all of your scheduled experimental sessions and you will not receive the completion allowance described below.

You should also understand that the medical doctors on this project, Lon R. Hays, MD, M.B.A. and Abner O. Rayapati, M.D., can terminate your participation if they do not feel that it is medically safe for you to continue. If your participation is terminated for medical reasons, you will receive the $40/session completion allowance for each of the experimental sessions you completed.

If you choose to withdraw from the study early, the data collected until that point will remain in the study database and may not be removed. The individuals conducting the study may need to withdraw you from the study and the study intervention and/or medication will no longer be provided by the investigator and may not be accessible commercially. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons. It is not

expected that withdrawing from the study will lead to risks in your health and welfare, but investigators may request follow up appointments if you withdraw.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET SICK OR HURT DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lon R. Hays, M.D., M.B.A. at (859) 323-6021 x 79015 or Abner O. Rayapati, M.D. at (859) 257-9175 immediately. You can also call 911 in the case of an emergency. Dr. Hays or Dr. Rayapati will determine what type of treatment, if any, is best for you at that time. The medical costs related to your care and treatment because of research related harm will be your responsibility.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will be paid for your participation in this experiment. You will earn payments for attending visits, making certain selections during experimental sessions, and taking medications as directed. Specifically, you will earn $40 for each practice and experimental session that you finish. This will be paid to you upon completing that session. If you complete the entire study (i.e., complete 1 practice session and 3 experimental sessions over approximately one month), you will earn an additional $40 per session bonus at the end of the study. You can also earn money based on how you choose alcohol (or not) during experimental sessions. During each experimental session, as outlined in Table 2 above, you will have the opportunity to choose between 8 alcohol doses and money. For each alcohol dose you do not choose, $3.00 will be added to your session completion payment. So, if you do not choose to drink any of the alcohol during an experimental session, you can earn an additional $24. Thus, the maximum amount of money you can earn from completing practice and experimental sessions is $392 ($160 [session completion payment] +$160 [study completion bonus] +$72 [total amount available if you do not choose alcohol doses during any experimental sessions]).

You will earn $10 for coming to pick up your study doses at the outset of each maintenance period as outlined in Table 1. You will also earn money if you take the doses given to you as prescribed. Specifically, on the first day of maintenance that you take your doses at 7:00 AM and 7:00 PM, as verified by the Wisepill®, you will earn $5 for that day. For each consecutive day that you take doses as prescribed, that payment will increase by $2 (e.g., you will earn $7 on the second day in a row that you take your doses at 7:00 AM and 7:00 PM as verified by the Wisepill®).

If you complete the entire study, attending each visit as scheduled and taking each dose as directed, you can earn up to approximately $707.

You should understand that if you make more than a total of $600 by participating in research projects, the University of Kentucky will report your earnings to the appropriate state and federal government agencies (i.e., Internal Revenue Service [IRS]). You should further understand that it is your responsibility to determine how these earnings might affect your personal financial situation.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in this research study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can

contact the investigator, William W. Stoops, Ph.D., at (859) 257-5388. If you have questions about your rights as a volunteer in this research study, contact the staff in the Office of Research Integrity at the University of Kentucky at (859) 257-9428 or toll free at 1-866-400-9428. We will give you a copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT MY DECISION TO PARTICIPATE?

If the investigators on this project, William W. Stoops, Ph.D., Lon R. Hays, MD, M.B.A. and Abner O. Rayapati, M.D., learn of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study. If you choose not to continue, you will not lose any of your earnings. That is, you will receive the completion allowance for each of the experimental sessions you completed.

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Dr. Stoops or his staff regarding your willingness to participate in future research studies about how to prevent, detect, or treat substance use disorders?

☐ Yes ☐ No _____Initials

WHAT ELSE DO YOU NEED TO KNOW?

This research is supported by a grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA [R21 AA 026129]). 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.

There is a possibility that the data/specimens/blood collected from you may be shared with other investigators in the future. If that is the case the data/specimen/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. This form describes how researchers may use your information. Please read it carefully.

Your health information will be used and/or released (disclosed) for the following research study: Behavioral Effects of Drugs (Inpatient) (34).

You allow William W. Stoops, Ph.D. and his research staff at the University of Kentucky to create, access, use, and release your health information for the purposes listed below.

Your health information that may be used and released includes:

- Demographic information (for example, information about your race, gender, socioeconomic status, and age)
- Results of physical examinations
- Results of psychiatric screening tests
- Results of questionnaires and study procedures
- Results of blood tests and urine screens
- Medical history

Your health information will be used for:

- A study coordinated by William W. Stoops, Ph.D. examining the effects of stimulant drugs. Your protected health information is necessary to conduct this line of research, as well as to meet legal, institutional, and accreditation requirements.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity,
- University of Kentucky Medical Center, Investigational Drug Service, Center for Clinical and Translational Sciences, Clinical Services Core, and Clinical Research Organization
- The National Institute on Alcohol Abuse and Alcoholism,
- The Food and Drug Administration

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If your revoke the authorization:

- You will send a written letter to: William W. Stoops, Ph.D. 465 E. High Street, Suite 204B, Lexington, KY 40507 to inform him of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You will not be allowed to participate in the study.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-9817.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____

Signature of research subject or *research subject's legal representative — Date

_____ _____

Printed name of research subject or *research subject's legal representative — Representative's relationship to research subject

*(*If, applicable)* Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

_____ _____

Name of person obtaining informed consent/HIPAA authorization — Date

_____

Signature of Investigator