KEY INFORMATION FOR BEHAVIORAL EFFECTS OF DRUGS: INPATIENT (36)

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 (i.e., have used alcohol in the past week). 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.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

This medication development experiment is testing the effects of methylphenidate (a medication used to treat Attention Deficit Hyperactivity Disorder [ADHD]), duloxetine (a medication used to treat depression) and their combination on the subjective and physiological effects of alcohol. We are also interested in determining whether methylphenidate, duloxetine or their combination impacts whether you like alcohol and want to choose to drink it.

Your participation in this research will last about eight weeks. The research procedures will be conducted in the Laboratory of Human Behavioral Pharmacology (LHBP) at the University of Kentucky. During the time you participate, you must agree to participate as an outpatient at the LHBP. You will be asked to complete 1 practice session, 4 experimental session days, and 3 post-study follow-ups.

The purpose of this research is to gather information on the safety and effectiveness of methylphenidate, duloxetine, and their combination on the behavioral, subjective and physiological effects of alcohol.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR 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 the nature of effects of these drugs and may result in improved therapeutic treatments for patients taking these drugs. If you are seeking treatment, please notify the investigator now and he will make the necessary referral. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The primary risks to participation are those specifically related to the ingestion of the study drugs. Two types of risk are associated with the administration of these drugs to human volunteers. First, the drugs under study occasionally produce side effects. The drugs will be administered in combination, which may change the side effect profile. Second, there is a slight risk that habituation or tolerance will develop. If you develop habituation or tolerance to the medications administered in the study, the effects of these medications would be decreased if they were administered to you at therapeutic doses. For a complete description of risks, refer to the Detailed Consent.

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

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 services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Craig R. Rush, Ph.D. of the University of Kentucky, Departments of Behavioral Science, Psychiatry, and Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 859-257-5388

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not participate if you have a history of serious physical disease, current physical disease, impaired cardiovascular functioning, 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 alcohol or drug use, are currently in treatment for your alcohol or drug use, or are currently in successful remission from your alcohol or drug use. If you have ever been addicted to alcohol or drugs, 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). Your participation in this study will last approximately one month and a half as outlined in Table 1 contained in the Appendix. During the time you participate, you must agree to participate as an outpatient at the LHBP. You will be asked to complete 1 practice session, 4 experimental session days, and 3 post-study follow ups. You must agree to follow the general rules of the LHBP. You should understand that during the time that you spend at the LHBP that you will not be allowed to leave the office unsupervised, nor will you be allowed to have visitors. You will not be allowed to make telephone calls during the practice and experimental sessions, and the follow-ups.

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, 4 experimental sessions, and 3 post-study follow-ups over approximately 1 month and a half. 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 as outlined in Table 2 in the Appendix. The remaining experimental sessions will occur following periods of taking a maintenance medication. Sessions will last approximately 4 hours each, but you will be asked to stay as an outpatient at the LHBP 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. 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 the adherence bonus for that week during medication maintenance (described on page 5). In the evening after each session, you will be discharged from the LHBP, provided that you meet appropriate release criteria (i.e., pass a sobriety test and have a breath alcohol level below 0.02 g/dl). On the day following from the last experimental session (Day 29) or following your last day of study participation – should you choose to withdraw from the study early– (described in Table 2), research staff will escort to the University of Kentucky Medical Center to undergo additional medical screening. It will be necessary to take a small amount of blood from a vein in your arm (i.e., about 1 ounce or 35 ml). You will be scheduled for an appointment that would best suit your schedule.

This appointment is anticipated to last approximately 1 hour. These tests will be used to determine if your heart, kidney, liver, and immune system function are normal. These tests, however, will not allow us to detect the presence or absence of specific diseases (for example, hepatitis). If your liver enzymes are abnormal, you will be notified and the study physicians will be notified for consultation on a course of action. The investigators may request repeat tests until your liver enzymes return to normal. If desired, copies of these tests may be provided to you.

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., 9:00 AM) 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. All study medications will also be encapsulated with the dietary supplement riboflavin to assess adherence via fluorescence detection. Presence of riboflavin in a provided urine sample will be verified prior to experimental sessions using a hand-held ultraviolet light detector.

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. 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 may lose portions of your completion bonus money you could 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 practice or experimental session which will last approximately 4 hours. We have included a table in the Appendix 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 (an inactive substance, no drug), an ADHD medication (methylphenidate [Metadate CD®]), an anti-depressant (duloxetine [Cymbalta®]), 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 AND 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 Appendix tables. We will monitor for these side effects during experimental sessions at the LHBP and while you are taking these medications on an outpatient basis. If you feel you are experiencing any of these side effects, you should tell the research staff or physician. In addition to the risks listed in the Appendix, you may experience a previously unknown risk or side effect.

As noted above, it will be necessary to take a small amount of blood from a vein in your arm. You may experience some discomfort from having the needle inserted into the vein in your arm. There is some risk of bruising, soreness, infection, bleeding, pain, irritation from the insertion of the need in to the vein in your arm. However, these risks are minimal since standard sterile procedures will be used. You should be aware that some people faint while blood is being taken.

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.

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).

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

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.

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 National Institute of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (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.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY 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, Craig R. Rush, Ph.D., can terminate your participation for the following reasons: 1) failure to adhere to subject rules for the LHBP, 2) if you

verbally or physically assault another volunteer, patient, or staff member at the LHBP, 3) if your behavior is disruptive to other ongoing studies that are conducted at the LHBP, 4) if your behavior is disruptive to the other volunteers, patients, research staff, or medical staff at the LHBP, 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 LHBP 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 HURT OR SICK 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.

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 4 experimental sessions over approximately one month), you will earn an additional $40 per session bonus after the end of the study on Day 29 (see Table 1 in appendix). Thus, the maximum amount of money you can earn from completing practice and experimental sessions is $400.

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 9:00 AM, 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 9:00 AM as verified by the Wisepill®). You will also receive $50 for each of the three post-study follow up appointments that you attend.

If you complete the entire study, attending each visit as scheduled and taking each dose as directed, you can earn up to approximately $1,446.

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 NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the investigators on this project, Craig R. Rush, Ph.D., William W. Stoops, Ph.D., Joshua A. Lile, 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.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Do you give permission for Craig R. Rush, Ph.D. to contact you with information about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes

☐ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Craig R. Rush, Ph.D. 465 E. High Street, Suite 204B, Lexington, KY 40507.

WHAT ELSE DO YOU NEED TO KNOW?

This research is supported by a grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA [DA 026255]).

If you volunteer to take part in this research, you will be one of about 40 people to do so nationally, and one of about 40 to do so at the University of Kentucky.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs. 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.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

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): 36 (Alcohol, Methylphenidate, and Duloxetine).

- You allow Craig R. Rush, 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) pertaining to the study.
- Results of physical examinations pertaining to the study.
- Results of psychiatric screening tests pertaining to the study.
- Results of questionnaires and study procedures pertaining to the study.
- Results of blood tests and urine screens pertaining to the study.
- Medical history pertaining to the study.

Your health information will be used for:

- A study coordinated by Craig R. Rush, Ph.D. examining the effects of alcohol. 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 Research Unit, and Clinical Research Organization,
- The National Institute on Alcohol Abuse and Alcoholism,
- The Food and Drug Administration

If you become pregnant anytime during the study or within 7 days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

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: Craig R. Rush, 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 about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

Appendix: Study Visits/Procedures

WHAT WILL YOU BE ASKED TO DO?

Day	Table 1: Experimental Procedures
0	Practice Session at the LHBP. The timeline of this session matches that of experimental sessions (see Table 2 below).
1-6	Drug maintenance. On Day 1, you will take your oral dose of methylphenidate, duloxetine, and/or placebo at approximately 9:00 AM and continue through Day 6. Doses will be provided in a Wisepill® device that will monitor when you take the doses.
7	Experimental Session 1 at the LHBP. The Experimental Session timeline is outlined in Table 2.
8-13	Drug maintenance on your oral dose of methylphenidate, duloxetine, and/or placebo. As described in Days 1 – 6.
14	Experimental Session 2 at the LHBP.
15-20	Drug maintenance on your oral dose of methylphenidate, duloxetine, and/or placebo. As described in Days 1 – 6.
21	Experimental Session 3 at the LHBP.
22-27	Drug maintenance on your oral dose of methylphenidate, duloxetine, and/or placebo. As described in Days 1 – 6.
28	Experimental Session 4 at the LHBP. Following discharge, you will receive taper medications to take for 2 weeks that you will being taking on morning of Day 29.
29 + 3 weeks	Medical screening repeated on Day 29. Follow-up visits scheduled weekly for 3 weeks following participation.

Day	Table 2: Experimental Session Activities
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	Baseline subjective, physiological and cognitive-behavioural measures completed.
3:45-4:15 PM	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.
4:45 PM	Subjective and physiological measures will be completed.
5:15 PM	Subjective and physiological measures will be completed.
5:45 PM	Subjective and physiological measures will be completed.
6:00 PM	Physiological measures collected. After passing the sobriety test and having a breath alcohol level below 0.02 mg/dL, you will receive the WisePill® device containing your doses for the next 7 days (or taper doses no if last experimental session), your payment, and your car keys, and will be discharged from the LHBP

Appendix: Risks

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

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 Methylphenidate	How often has it Occurred?	How Serious is it?	Can it be Corrected?
anxiety, restlessness, difficulty sleeping, loss of appetite, changes in heart rate, dizziness, faintness, irritability, shaking, nausea or other gastrointestinal discomfort, headache, increased blood pressure, performance impairment, flushing and sweating	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.
heart attack, stroke, psychotic episodes, seizure, death	These are extremely uncommon.	Very Serious	No

Possible Risk or Side Effect of duloxetine	How often has it occurred?	How serious is it?	Can it be corrected?
changes in vision, agitation, anxiety, body aches or pain, cough, dizziness/lightheadedness, constipation, diarrhea, difficulty with breathing, dry mouth, ear congestion, changes in urination, headache, fainting, increased blood pressure, weakness, loss of appetite, loss of voice, muscle aches, nausea, nervousness, rash, itchiness, changes in sexual function, sleepiness or unusual drowsiness, sleeplessness, sneezing, sore throat, swelling, stuffy or runny nose, sweating, tremor and weight change	These commonly occur.	Somewhat serious	These side effects are likely to decrease over time as the medications clear from your system.
angle-closure glaucoma, unusual bruising/bleeding, seizures, hallucinations, worsening of existing depression or suicidal thoughts and Stevens-Johnson syndrome.	These are extreme-ly uncommon.	Very serious	These may go away with treatment.

INFORMED CONSENT SIGNATURE PAGE

You are a participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendices**

You will receive a copy of this consent form after it has been signed.

_____ _____
Signature of research subject **Date**

_____
Printed name of research subject

_____ _____
Printed name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Principal Investigator or Sub/Co-Investigator