CONSENT FORM

Title of Research: **The Effect of Guanfacine on Delirium in Critically Ill Patients**

UAB IRB Protocol #: **IRB-300004839**

Principal Investigator: **Andrew B. Barker, MD**

Sponsor: **Department of Anesthesiology and Perioperative Medicine, Division of Critical Care Medicine**

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in this consent form.
Purpose	The purpose of this study is to test how well the drug Guanfacine can help treat critically ill patients diagnosed with delirium in the Intensive Care Unit (ICU).
Duration & Visits	The study drug or placebo will be given up to 14 days or until discharge from the ICU.
Overview of Procedures	This is double blinded randomized controlled trial. This means that If you decide to take part in this study, a computer will assign you by chance to one of the study drugs. This is called randomization. You will either get the drug Guanfacine or a placebo. After you receive either, your doctor and study team will watch you for side effects as described below. Double blinded means neither you nor your doctor will know if you get the drug guanfacine or placebo.
Risks	The medication used in this study, Guanfacine hydrochloride (Tenex), is a medication usually used to treat high blood pressure. You may experience some side effects from taking the study drug. The side effects of Guanfacine are: • Slower heart rate • Lower blood pressure • Sleepiness • Dizziness • Dry mouth • Constipation The placebo being used in this study's control group is made from sugar. The amount of sugar used in this pill is too small to have any effect. You will be assigned to either group by chance. It is not known if treatment with Guanfacine will prove to be effective or have more side effects than no treatment or non-study alternatives.
Benefits	You may or may not benefit directly from taking part in this study. However, this study may help us better understand how to treat delirium symptoms in critically ill patients in the future.
Alternatives	There is currently no standard drug to treat delirium. Current management is based on trying to prevent delirium. The alternative to participating in this study is to be treated with the hospital's usual care approach.

Purpose of the Research Study

We are asking you to take part in a research study because you (or the individual for which you are the legal representative) have been diagnosed with delirium during your Intensive Care Unit stay. Delirium is a common problem in critically ill patients, and is associated with increased agitation, and an inability to correctly orient to person, place, time, and situation. Several risk factors associated with delirium include: advanced age, substance abuse, sleep disturbances, and other body metabolism disturbances.

The purpose of this research study is to test how well the drug Guanfacine, currently FDA approved to treat high blood pressure and Attention Deficit Hyperactivity Disorder (ADHD) symptoms, can help treat critically ill patients diagnosed with delirium in the Intensive Care Unit (ICU). This study will enroll approximately 200 participants at UAB Hospital.

Study Participation & Procedures

If you agree to join the study, you will have an equal (50/50) chance of being assigned to the group receiving the study drug Guanfacine, or a placebo (sugar pill). A placebo does not have any active medicine, so it should not have any effect on you. You will be assigned randomly (by chance, like the flip of a coin) in a 1:1 ratio between the two study groups. The randomization scheme will be generated by the study statistician using a statistical software program. This is a double-blind study. This means neither you nor your doctors will know which study drug you are taking. If necessary, the doctor can find out which you are taking.

- You will take your assigned study medication by mouth (or if you already have a small tube inserted through your nose into your stomach) once nightly if indicated for up to 14 consecutive days or until ICU discharge, whichever comes first.
- A member of the study team will conduct a brief mental alertness assessment with you twice daily (in the morning and evening) while you are taking the assigned study medication.
- If you are entered and complete the entire study, you will be in the study for up to 90 days.
- If you are discharged from the hospital before Day 28, you will be contacted by a member of the study staff on Days 28 and 90 to complete a brief follow-up assessment.

Additional Information:

Your de-identified information that we collect (private information with all personal identifiers removed) may be used for future research studies or used by another researcher for future research studies without additional informed consent.

Risks and Discomforts

The medication used in this study, Guanfacine, is a medication usually used to treat high blood pressure. You may experience some side effects from taking the study drug.

The side effects of Guanfacine are:

- Lower heart rate
- Lower blood pressure
- Sleepiness
- Dizziness
- Dry mouth
- Constipation

The placebo being used in this study's control group is made from sugar. The amount of sugar used in this pill is too small to have any effect on you.

You will be assigned to either group by chance. It is not known if treatment with Guanfacine will prove to be effective or have more side effects than no treatment or non-study alternatives.

Benefits

You may or may not benefit directly from taking part in this study. However, this study may help us better understand how to treat delirium symptoms in critically ill patients in the future by increasing the healthcare professional's overall awareness and treatment options for delirium.

You will be assigned to either group by chance, which may prove to be more or less beneficial than the other study group.

Alternatives

There is no standard medication for treating delirium. Current management is based on trying to prevent delirium. One alternative may be not to participate in this study. In which case, the hospital's current usual care approach will continue to be used and include non-medication based approaches to maintain wakeful days and restful nights, early mobilization activities, timely removal of physical restraints, and optimal pain control.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on 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.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:
- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but the use of your personal health information will continue until you formally cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All drugs related to this study will be provided to you at no cost during the 14-day study period. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation

You will not be paid for your participation in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional

If you are discharged from the hospital before Day 28 (after study enrollment), the study staff will contact you to complete a brief follow-up assessment on Days 28 and 90.

Initial your choice below:

_____ **YES**, I agree to allow the study staff to contact me for a follow-up assessment after my hospital discharge.

_____**NO**, I do NOT agree to allow the study staff to contact me for a follow-up assessment after my hospital discharge.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Andrew B. Barker at (205) 934-4699 or after hours by paging him at: UAB Paging (205) 934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Legally Authorized Representative Date

_____

Signature of Witness Date

_____

Signature of Person Obtaining Consent Date