KEY INFORMATION FOR NUTRITIONAL THERAPY FOR DELIRIUM IN ELDERLY HOSPITALIZED SUBJECTS

We are asking you to choose whether to volunteer for a research study about older people who sometimes get delirious (short-term confusion) after being admitted to the hospital with an infection. For people who are hospitalized and already have delirium, we are asking their Legally Authorized Representative (LAR) or, if one is not established, their surrogate decision maker or caregiver to consider enrolling them into our study. A surrogate decision maker is any person designated orally or in writing to the supervising healthcare provider, as a surrogate for an adult. In the absence of an alternate decision maker designated by the individual, the surrogate decision maker is a person designated as a surrogate decision maker by the individual's supervising healthcare provider.

This page gives you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if a nutritional product will reduce the severity or duration of delirium. Your participation in this research will last up to four days.

If a delirious person is enrolled into the study, they will be interviewed twice daily by study staff to determine the level of delirium, have a fasted blood sample drawn each day for up to four days. Some people in this study will receive a nutritional supplement each day for up to four days while in the hospital. Other people will continue to receive standard medical treatment as ordered by their doctor, but no supplement. The active ingredients in this supplement (essential amino acids) have been recognized as generally safe by the U.S. Food and Drug Administration (FDA). This study is being done to test their effectiveness.

If a non-delirious person enrolls into this study, they will have a fasted blood sample taken for two consecutive days and be interviewed twice daily for up to four days by study staff to determine if the participant has delirium or not. These individuals will not receive the supplement.

WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

Delirium can cause you to stay in the hospital longer, can cause you and your family much stress, and could greatly increase the cost of your healthcare. If this nutritional supplement can help shorten or lessen

the severity of delirium, that would be good for all elderly people who are admitted to the hospital. We do not know if the supplement will be helpful.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

We will draw several blood samples from your arm or IV catheter during this study, which you would not have to do if you were not in the study. For a complete description of risks, refer to the full Consent.

DO I HAVE TO TAKE PART IN THE STUDY?

No. It is okay to say no. 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.

If you are a student or employee of UAMS, nothing about your academic plan or employment will change no matter what you decide.

Tell the study team if you have decided you don't want to be in the study. It is perfectly okay to say no.

University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **Please take as much time as you need to read this form and decide what is right for you.**

Why am I being asked to be in this research study?

- We want to learn more about delirium that may happen to elderly people during a hospital stay, and the effects of a nutritional supplement.
- We are asking people like you who are currently in the hospital with an infection to help us.
- Up to 60 people, ages 60 and older will be part of this study.

What if I don't understand something?

- This form may have words you don't understand. If you'd like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you like before you decide whether you want to be in this study.

What will happen if I say yes, I want to be in this study?

If you qualify, we will do these things:

- review your medical record for what medicines you take and your medical history
- draw a teaspoon of blood from a vein in your arm or from your IV catheter at each blood draw.
- conduct a brief interview to see if you presently have delirium.
- **<u>If you are delirious on the day that you join the research study:</u>**
  - Your legally authorized representative or surrogate decision maker will be contacted about having you participate in this study
  - You will have the choice of being in the study supplement group or standard treatment group. If you choose the study supplement group, you will receive a nutritional supplement twice each day for up to four days. If you choose to be in the standard treatment group, you will receive the standard treatment for delirium by the physicians (no supplement). If one of these

two groups has already been filled when you join the study, you will need to join the group that is still enrolling participants (that is, you will no longer be able to choose your group).

- Each day you are in the hospital, we will perform the delirium interview twice each day.
- We will also ask to draw a blood sample one time a day (up to 4 days). each morning before you have had breakfast or anything to eat, except on the second morning we will draw a second blood sample one hour after you eat.
- There is one supplement: the recipe we are testing is a mix of amino acids, flavors, and a sweetener.

- **If you are not delirious on the day that you join this research study**, you will be placed in the Control group, have your blood drawn one time each morning for two consecutive days and asked the interview questions twice a day for up to 4 days.
  - If you become delirious before completing the 2 days of study procedures, you will be removed from the study.

How long will this study take?

Your part will take up to 4 days in total.

What if I say no, I do not want to be in this study?

- Nothing bad will happen.
- You can still get medical care at UAMS.

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen.
- You can still get medical care at UAMS.
- If you decide to stop being in the study, you can call Dr. Gohar Azhar at UAMS at 501-454-8797, OR Patricia Savary at UAMS at 501-526-5701, OR Shakshi Sharma, Ph.D. at 501-526-6547, OR Ethan Bradford at 501-686-8762.

Will it cost me anything to be in the study?

There are no anticipated costs to you and/or your insurance provider for participating in this research study. The study supplements will be provided at no cost to you or your insurance provider. The study will also pay for the research procedures (blood draws) for this Study.

You (and/or your insurance provider) will be responsible for your regular medical care (meaning you would receive this care whether or not you are in the research study), as usual. You will be responsible for any co-payments and/or deductibles as required by your insurance provider. Your insurance provider may or may not agree with the determination of what are routine tests and procedures and may determine some charges as research related. In that case, they may deny payment, and you will be responsible for any charges that are not paid for by research study. There is never any guarantee with any service that you will not incur some financial liability. Study staff will be available to assist you with contacting your insurance provider to answer any questions you may have about insurance coverage relating to this study.

Will I be paid for being in the study?

Yes. Payment will be provided to you by Amazon gift card. You will be mailed a $25 Amazon gift card after your last study visit.

UAMS and Sub-investigator Robert R. Wolfe, Ph.D. have a financial interest in the supplement being studied. The value of this interest may go up or down, depending on what studies like this one find. This financial interest has been reported to the appropriate institutional committee and will be managed to prevent the chance of the study results being influenced for monetary gain.

Will being in this study help me in any way?

Being in the study may or may not help you but may help people at risk for delirium in the future. What we learn may help in the following ways:

- If the test supplement seems promising, then it may lead to larger studies in the future, and may eventually prevent complications such as problems with memory and thinking, falls and longer hospital stays.
- If the supplement is helpful, this potentially mean less days in the hospital.

What are the risks of being in this study?

The risks are:

- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- Pain, bruising, redness, swelling, lightheadedness, and small chance of infection with the blood draws if they need to be done by needle stick.
- We will draw less than 4 tablespoons of blood in total.

What if I get sick or hurt while I'm in this study?

- If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and/or follow-up care.
- If you are not here and get hurt or sick, and think it is because of the study, do these things:
  - ✓ call your doctor or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study Nutritional Therapy for Delirium in Elderly Hospitalized Subjects
    - the name of the head researcher for this study Dr. Gohar Azhar
    - a copy of this form if you have it
  - ✓ call Patricia Savary at 501-526-5701, OR Shakshi Sharma Ph.D. at 501-526-6547, OR Ethan Bradford at 501-686-8762.
- This treatment may be billed to you or your insurance company in the normal manner. No other form of payment is available.

What are the alternatives to being in this study?

You do not have to be in this study.

There are no alternatives to being in this study, as it does not involve treatment or other procedures that may help you.

If your LAR or surrogate decision maker has signed you up for this study and you regain the ability to make your own medical decisions before completing the study, you have the right to continue or stop participating.

Can I be taken out of the study even if I want to continue?

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- You do not take the study product for 2 days (we will still monitor you and collect blood samples, but you will not continue the study product).
- You were not delirious when you signed up but became delirious before finishing the study procedures.
- It is not in your best interest to continue.
- The study is stopped for any reason.

What information will be collected about me in the study?

During the study, we will need to learn private things about you, including

- General information about you such as name, age, race, ethnicity, and other demographic information.
- Medical information about you, such as the medications you use as well as your level of confusion or delirium; lab tests of your levels of essential amino acids, muscle proteins, and immune system; and your response to the supplement and any side effects.
- We will collect blood samples from you, either by needle stick or from your IV catheter.
- We will not use the samples we collect from you for commercial profit. They will only be used to help us learn if delirium can be managed by the supplement.

Who will see this information? How will you keep it private?

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off information and study samples that we collect from you during the study.
- When we share the results of the study in medical journals, we will not include your name or anything else that identifies you.

- There are people who make sure the study is run the right way. These people may see information from the study about you. They are
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires we tell the authorities if we learn
  - about possible child or adult abuse
  - that you might hurt yourself or someone else

Where and how long will my information and samples be kept?

- We will remove your name for the study information and samples and use a code number instead; the key that links your name to the study information will be kept separately in a locked computer file. Only study staff will be able to link your information to you.
- We will not put information about you from the study in your medical record.
- Your blood samples will be kept in a freezer in the principal investigator's lab on the UAMS campus. A portion of the blood may be sent to a commercial testing lab for analysis at a later date.
- Your samples and data will be destroyed about 7 years after the completion of this study.

If I stop being in the study, what will happen to any information or samples collected from me in the study?

- If you wish to have your information or samples taken out of the study, call Patricia Savary at 501-526-5701, OR Shakshi Sharma Ph.D. at 501-526-6547, OR Ethan Bradford at 501-686-8762.

Will my information or samples from the study be used for anything else, including future research?

- No. Your information and samples will be used only for purposes of this study. It will not be used for future research or anything else unrelated to this study.

Will you tell me the results of the study?

- No. We will not directly notify people in the study about what we find. We will, however, publish the results in an academic journal (though, what we publish will not include anything that can identify you).

Will you tell me anything you learn that may impact my health?

- Yes. If we learn something about you that might be important for your health, we will tell you.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about being in the study.
- The study team will let you know by calling you or your legally authorized representative or surrogate decision maker.

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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 any time.

What if I have questions?

- Please call the head researcher of the study Dr. Gohar Azhar at UAMS at 501-526-5821 if you
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team or want to speak to someone not directly involved with this study or have questions about your rights as a research participant. To do so call the UAMS Institutional Review Board at 501-686-5667.

HIPAA RESEARCH AUTHORIZATION

We are asking you to take part in the research described in the consent form. To do this research, we need to collect health information that identifies you. We may collect the following information from your UAMS medical record:

- Your name.
- Your age, gender, ethnic and racial background.
- Lifestyle information; health and medical history.
- Your study treatments and response to study treatments.
- Your biological samples and data resulting from testing your biological samples.

We will only collect information that is needed for the research. Participating in this research study will create the following new health information: results from the delirium interviews and blood samples. For you to be included in this research, we need your permission to collect, create and share this information.

We will, or may, share your health information with people at the University of Arkansas for Medical Sciences (UAMS) who help with the research or things related to the research process, such as the study staff, the UAMS Institutional Review Board and the research compliance office at the University of Arkansas for Medical Sciences. Additionally, we may need to share your health information with people outside of UAMS who make sure we do the research properly, such as the Office for Human Research Protections or the Food and Drug Administration. We believe that those involved with research understand the importance of preserving the confidentiality of your health information. However, some of the people outside of UAMS may share your health information with someone else. If they do, the same laws that UAMS must obey may not apply to others to protect your health information.

By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others.

How long will your personal information be used?

Your personal information will be used for only as long is needed for the study and further research, with your consent. This authorization to collect, use and share your health information expires at the end of the research period and will be destroyed 7 years after the completion of this study.

If you sign this form, you are giving us permission to create, collect, use and share your health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, you cannot be in the research study. You need to sign this form if you want to be in the research study.

If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to the person and the address listed by "Principal Investigator" on the first page of this form. The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or change your mind later, this will not affect your current or future medical care or benefits at the University of Arkansas for Medical Sciences.

By signing the document, I am saying:

- ✓ I understand that joining this study is voluntary.
- ✓ I agree to be in the study.
- ✓ Someone talked with me about the information in this document and answered all my questions.

I know that:

- ✓ I can stop any and all parts of the study at any time and nothing bad will happen to me.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my rights by signing this form.
- ✓ My decision will not change my medical care at UAMS.

I agree to be part of this study:

My health information can be collected and used by the researchers and staff for the research study described in this form. *If you are signing this consent form as a LAR/Surrogate Decision Maker, please leave the 2 lines below blank and skip to the Box Section to complete the LAR/Surrogate Decision Maker section.*

_____
Participant's Name (Please Print)

_____ _____
Participant's Signature (*if applicable)* Date

LAR/SURROGATE DECISION MAKER COMPLETE IN THIS BOX *(if applicable)*:

Print Participant's Name:_____

_____
Print Name of Participant's Legally Authorized Representative (LAR)/Surrogate Decision Maker

_____
LAR's/Surrogate Decision Maker's Relationship to Participant

_____ _____
Signature of Participant's LAR/Surrogate Decision Maker Date

_____
Person obtaining consent- printed name

_____ _____
Person obtaining consent- signature Date