CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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PROJECT # 1212915

STUDY TITLE: DOES OPTIMIZED GENERAL ANESTHESIA CARE REDUCE POSTOPERATIVE DELIRIUM IN OLDER ADULTS UNDERGOING HIP FRACTURE REPAIR?

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you have A HIP FRACTURE THAT REQUIRES SURGERY UNDER GENERAL ANESTHESIA AND YOU ARE 65 YEARS OR OLDER.

This study is being sponsored by the Anesthesia Patient Safety Foundation.
In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if careful management of blood pressure, oxygen levels in the brain, and the amount of general anesthesia during surgery decreases mental confusion and improves recovery after surgery.

We are going to compare the effects (good and bad) of the strict control of blood pressure, the amount of anesthesia, and oxygen levels in the brain during general anesthesia for hip fracture surgery. We will compare general anesthesia administered in the normal way with general anesthesia administered using two monitors to adjust the amount of anesthesia and oxygen in the brain to see which is better. This research is being done because these two monitors are not routinely used during hip fracture surgery and we are trying to determine if patients will do better after surgery if these two monitors are used.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to enroll 250 patients to ensure that 160 patients will complete this entire study at the University Hospital at the University of Missouri.

HS IRB USE ONLY
Approval Date: 11/15/2017
Expiration Date: 12/10/2018

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in the study, you will receive the same medical care before and after surgery. If you have a high score on the memory test prior to surgery, you will be "randomized" into one of the two study groups described below on the day of surgery. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in any group. The two study groups are:

● Routine care group – you will receive general anesthesia during surgery and the amount of anesthesia you are given will be determined by the anesthesia provider using your blood pressure and heart rate to adjust the anesthesia during the surgery.

● Study care group – you will receive general anesthesia during surgery using the same medications as in the routine care group. Two monitors will be used to measure the amount of anesthesia being given and the amount of oxygen in the brain during surgery. These monitors will be used to determine the amount of anesthesia and oxygen you are given during surgery. Your blood pressure will also be kept within 20 percent of its preoperative level.

If you enroll in the study but do not have a high score on the memory test prior to surgery, you will not be randomized to a study group. You will have the same type of anesthesia that will be used in both study groups and the amount of anesthesia given will be determined by the anesthesia provider taking care of you in the operating room.

If you do not enroll in the study, you will have the same type of anesthesia that will be given in both study groups and the amount of anesthesia given will be determined by the anesthesia provider taking care of you in the operating room.

<u>If you take part in this study, you will have the following tests and procedures:</u>

● a short memory test prior to surgery - this memory test will take about 15 minutes.

● a short questionnaire to determine what you can do at home and if you are depressed – these questionnaires will take about 5 minutes

● a short questionnaire to review your medical history and activities at home

● a measurement of your grip strength in your dominant hand

● a daily visit by the research team after surgery to determine if you are confused

● a telephone call at 3 months and 1 year after surgery to find out how you are doing

<u>If you are in the study care group, you will have two additional monitors used in surgery</u>

● a Band-Aid type sticker placed on your forehead during surgery to measure the amount of anesthesia you are receiving. The amount of anesthesia will be adjusted using this monitor.

● a Band-Aid type of sticker placed on your forehead during surgery to measure the amount of oxygen in your brain. The anesthesia will be adjusted to keep the oxygen level in your brain at the same level that it was at prior to surgery.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for the entire time you are in the hospital. After you leave the hospital, we will call you at 3 months and 1 year after surgery to find out how you are doing.
Furthermore, we would greatly appreciate being able to contact you in the future about other studies by our research team.

□ Do you agree to allow us to contact you in the future about our next study?

The investigator and/or your doctor may decide to take you off this study if you become confused before you have surgery to repair the hip fracture.

You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits. If you decide to stop participating in the study, you are encouraged to discuss your decision with your doctor. There are no consequences of withdrawing from the study.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your doctor. There may also be other side effects that we cannot predict.

The risks associated with the procedures or monitors used in this study are not very likely but include:

● Performing the questionnaires and memory tests for the study will require approximately 15 to 20 minutes of your time at each of the three visits for these exams. While performing these questionnaires and memory exams, you may become frustrated or tired. The research person giving these tests will assist you in completing them. You may also ask for a break during this time if you need to rest before completing all of the exams.

● If you are in the group that has the monitors placed on your forehead, it is possible that you could develop a rash, but this has never been reported with these monitors.

For the reasons stated above the investigator will observe you closely while giving the treatment described and, if you have any worrisome symptoms or symptoms that the investigator or his associates have described to you, notify the investigator immediately. Dr. Johnson's telephone number is (573)-882-2568. For more information about risks and side effects, ask the investigator or contact Dr. Johnson at (573)-882-2568.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no direct medical benefit to you for participating in this study; however, you will be contributing to medical knowledge. We hope the information learned from this study will benefit other patients who need general anesthesia for their surgery in the future.

There is no guarantee that taking part in this research will result in any improvement in your condition.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:
An alternative is to not participate in this research study. You can have your hip fracture repaired using general or spinal anesthesia. You will receive the best medical care possible even if you are not in the study. Please discuss these and other options with the investigator and your doctor.

WHAT ABOUT CONFIDENTIALITY?

A copy of this consent will be placed in the medical record. Anyone accessing your record will be able to view the document and see that you have agreed to participate in the study. Medical information produced by this study will become part of your hospital medical record. Information that does not become part of your medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the University Hospital in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, the investigator must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this trial.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University Hospital will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

WHAT ARE THE COSTS?

There is no cost to you for your involvement in the study itself. However, you will be paying for the normal cost of anesthesia and surgery for repair of your hip fracture and your routine medical care. Any procedure related solely to research that would not otherwise be necessary will be explained. Some of these procedures may result in added costs and the additional costs will be paid with research funds.

You will not be charged for the memory tests that are part of this research study. You or your insurance company will, however, be charged for any other portion of your care that is considered standard care.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will receive no payment for taking part in this study.

WHAT IF I AM INJURED?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care in the University Hospital at the University of Missouri. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after he has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.

"A description of this clinical trial will be available on 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."

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Dr. Quinn Johnson at (573)-882-2568.

A copy of this consent form will be given to you to keep.

SIGNATURE

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

Subject/Patient*	Date
Legal Guardian/Advocate/Witness (if required)**	Date
Additional Signature (if required) (identify relationship to subject)***	Date

*A minor's signature on this line indicates his/her assent to participate in this study. A minor's signature is not required if he/she is under 7 years old. Use the "Legal Guardian/Advocate/Witness" line for the parent's signature, and you may use the "Additional Signature" line for the second parent's signature, if required.

**The presence and signature of an impartial witness is required during the entire informed consent discussion if the patient or patient's legally authorized representative is unable to read.

***The "Additional Signature" line may be used for the second parent's signature, if required. This line may also be used for any other signature which is required as per federal, state, local, sponsor and/or any other entity requirements.

"If required" means that the signature line is signed only if it is required as per federal, state, local, sponsor and/or any other entity requirements.

SIGNATURE OF STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

Study Representative****	Date

****Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the Study Representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the Study Representative may be a non-physician study investigator.

IF THE PATIENT IS INCOMPETENT TO GIVE CONSENT, COMPLETE THE FOLLOWING:

I, _____, hereby certify that I am _____
(Relationship to Patient)
of _____ and duly authorized to execute the foregoing.
(Name of Patient)

I consent to the *research study, experimental treatment, test, drug, etc.* as described in the attached consent form.

_____ _____
Legal Guardian/Patient Representative Date

_____ _____
Study Representative* Date

_____ _____
Witness (if required)** Date

*Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the study representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the study representative may be a non-physician study investigator.

**Regulations do not require the signature of a witness when the patient or patient's legally authorized representative is able to read and is capable of understanding the consent form document.

THE FOLLOWING REGULATION ONLY APPLIES WHEN AN ADULT PERSON, BECAUSE OF A MEDICAL CONDITION, IS TREATED AT A TEACHING HOSPITAL FOR A MEDICAL SCHOOL ACCREDITED BY THE AMERICAN OSTEOPATHIC ASSOCIATION OR THE AMERICAN MEDICAL ASSOCIATION AND SUCH PERSON IS INCAPABLE OF GIVING INFORMED CONSENT.

Persons authorized to consent when a patient is incapable of consenting to an experimental treatment, test or drug.

1. Legal guardian or
2. Attorney in fact (person appointed by durable power of attorney) or
3. A family member in the following order of priority:
    a. Spouse unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
    b. Adult child;
    c. Parent;
    d. Brother or sister;
    e. Relative by blood or marriage.

Such legal guardian, attorney in fact, or family member is not authorized to consent to treatment in contravention to such incapacitated person's expressed permission regarding such treatment.

If the patient is competent to consent but cannot write, do not use this proxy consent form. Please contact the IRB for directions in this situation.