Informed Consent:
Preoperative Cognitive Screening in Older Surgical Patients Utility for Predicting Morbidity, NCT 02598050, Document date 03/01/2021

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Preoperative Cognitive Screening in Older Orthopedic Surgical Patients

Principal Investigator: Deborah J. Culley, MD

Site Principal Investigator: Same

Description of Subject Population: Patients between the ages of 45-60 years or 65 years and older undergoing an elective orthopedic surgical procedure requiring anesthesia

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are asking you (or your surrogate if they will be signing your surgical consent) to take part in a research study because you are either 65 years of age or older or between the ages of 45 and 60 years and are scheduled for elective lower extremity joint replacement surgery that will require anesthesia. Older patients often experience difficulty with concentration and memory after

surgery and anesthesia and have a higher rate of other complications but it is difficult to know who is at risk for these problems because, unlike the testing we do for the heart, lungs, and blood, we don't specifically evaluate brain function prior to surgery. We are trying to find a way to do that simply and easily and to determine whether such testing can be used to predict postoperative complications, and possibly, changes in the immune system. About 290 people will take part in this research study and all of them will be enrolled at Brigham and Women's Hospital.

How long will I take part in this research study?

It will take about 10-15 minutes to complete several surveys. An additional 2-8 minutes will be required to do the memory testing and complete the study blood draw. This can all be done while you are here at the Preadmission Testing Center at the Brigham and Women's Hospital. You will not be required to make any additional follow-up visits for the purpose of this study but we would like your permission to contact you prior to your surgery to administer a survey and also at 6-12 months after your surgery to assess cognitive and physical functioning. Do we have your permission to contact you prior to your surgery and 6-12 months after your surgery?

_____No _____Yes: Phone number_____

What will happen in this research study?

It will take about 15 to 20 minutes to complete the questions for this study. We will gather information about your past medical history, medications, level of education, mood, social support, alcohol consumption, health and functional status, and pain. Some of this information will be gathered from you during an interview and the remainder will be gathered from your medical record. During that time you will be asked to do two cognitive tests (which involve thinking processes such as memory). A total of six 10 ml vials of blood (about twelve teaspoons full) will be drawn throughout the study. These will be obtained at the same time as your routine blood draw prior to your surgical procedure, with additional sampling throughout your surgical procedure, and on the first day following your surgical procedure. You can withdraw from the study at any time. Your participation or withdraw will have no effect on the care you receive as a patient in this hospital. One to six months after your discharge from the hospital we will gather information for your patient record about in hospital complications and treatments, where you were discharged to when you left the hospital and length of hospitalization. We will collect information from your medical record for six months from the day of your surgery.

What are the risks and possible discomforts from being in this research study?

It is possible that during the course of cognitive testing that you may become uncomfortable with your ability to perform the test or fatigued from the surveys. Although it is hoped that you will answer all questions in the surveys, you may skip over any questions you choose not to answer. If you or one of the investigators believe that it is in your best interest to stop your participation in the study you can be immediately withdrawn from the study without any effect on the care you receive.

You will have a blood sample drawn as part of this study. Side effects from blood draws include bruising, soreness or tenderness at the needle site. Rarely, people faint during or after having blood drawn. Very rarely, an infection occurs at the site where the blood is drawn, but this can be treated.

What are the possible benefits from being in this research study?

There are no direct benefits to you and no monetary compensation is provided. However, results of this study will help advance understanding of how preoperative cognitive performance affects perioperative outcomes. This study has the potential to aid and improve decision-making by physicians and patients in the future.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Deborah J. Culley, MD is the person in charge of this research study. You can call her at 617-732-7330 Monday-Friday 9-5. You can also call Dominique Cheung, MA and Rachel Grasfield, BA at 617-525-6719 Monday-Friday 9-5 with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:
- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research

- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

Signature | Date | Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult | Date | Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent Form Version: 1/31/2017