Preoperative Cognitive Screening in Older Spinal Surgical Patients
NCT02922634
12/27/2019
Informed Consent Form

Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: Preoperative Cognitive Screening in Older Thoracic and Spinal Surgical Patients: Feasibility and Utility for Predicting Morbidity

Principal Investigator: Deborah J. Culley, MD

Site Principal Investigator: Same

Description of Subject Population: Patients 70 years of age and older undergoing an elective orthopedic or neurosurgical spine 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 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.

Key Information

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. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about postoperative delirium in patients 70 years of age or older seen for elective orthopedic or neurosurgical spine procedures.

How long will you take part in this research study?

If you decide to join this research study, it will take you about 45 minutes over 2 to 4 days to complete the study. During this time, we will NOT ask you to make any study visits to Brigham and Women's Hospital.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen: a brief memory test and assessments about your mood and health while you wait for your preoperative appointment today, brief cognitive assessments for up to three days after your surgery, a blood draw today and for up to three days after your surgery, and an optional follow up call six months after your procedure.

Why might you choose to take part in this study?

You will not benefit from taking part in this research study. Others with postoperative delirium may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include mild distress or fatigue from the cognitive testing; and bruising, soreness, or tenderness at the needle site from the blood draw.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

If you have questions or concerns about this research study, whom can you 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 Rachel Grasfield, BA at 617-525-7429 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 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Who will take part in this research?

We are asking you to take part in a research study because you are 70 years of age or older and are scheduled for elective thoracic or spinal surgeries that will require anesthesia. About 1,060 people will take part in this research study and all of them will be enrolled at Brigham and Women's Hospital. The NIH is funding this research.

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 and comorbidities, past history of delirium or other post-anesthetic complications, use of visual/hearing aids, medications, level of education, frailty, Activities of Daily Living, and Instrumental Activities of Daily Living. 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 administered the MiniCog memory test and a one-minute cognitive (thinking processes) screen called the Animal Fluency Test. The MiniCog is a quick and simple test will take 2-4 minutes to complete. The CANTAB Insight CE measures cognitive health across five key domains and is performed on an iPad.

A total of about 1 to 5 tablespoons of blood (20-80 ml) will be drawn throughout the study. These will be obtained if possible at the same time as your routine blood draw prior to your surgical procedure, with additional sampling on the first day following your surgical procedure. Delirium and cognitive impairment (CAM-3D), and possibly a blood draw (depending on your lab results) will be performed for up to three days after your surgery. This visit will last about 5-10 minutes. 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. Six to twelve 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 twelve months from the day of your surgery.

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 6-12 months after your surgery to get your

perspective on any complications. Do we have your permission to contact you in 6-12 months after your surgery?

_____No _____Yes: Phone number_____

Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be shared broadly and used for future research in a manner consistent with the participant's informed consent and all applicable federal and state laws and regulations.

As part of your routine care today, and after surgery as dedicated research blood draws, a phlebotomist or members of study staff will collect a total of about 1 to 5 tablespoons of blood (20-80 ml) throughout the study from you for testing.

We will perform a genome analysis on your DNA sample from these blood draws. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In this genome analyses, all or most of your genes are looked at and used by researchers to study links to the development of Alzheimer's Disease. Genetic results will not be shared with participants, nor entered into the medical record.

Staff at the bank will assign your sample a code number and store it in a freezer. They will not keep your name or other information that could identify you with your sample. They will use the code number to connect your sample to your health information that is stored in a computer database. The computer database is protected with a password. Only staff at the bank will know the password.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be de-identified by standards consistent with the Common Rule and HIPAA. Safeguards to protect the data according to Federal standards for information protection will be implemented. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Your samples will be made available to researchers at MGH (Massachusetts General Hospital), BWH (Brigham and Women's Hospital), and other Partners institutions, as well as non-Partners academic institutions. Occasionally, your samples may be shared with for-profit companies that are working with MGH, BWH or other Partners researchers on a specific research project. Your samples will not be sold to anyone for profit. The research staff will usually provide samples with limited information that does not directly identify you.

- As described above, all of the samples stored are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the tissue bank staff, and will be securely stored.

- Researchers at Partners institutions, whose studies have been approved by the hospital ethics board, may be allowed to review your medical record to collect more health information about you. The ethics board is a group that independently reviews and watches over all research studies involving people. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected.

- Researchers outside of MGH and BWH will not be given the key to the code that links your sample and medical information to your name or other direct identifiers.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses. All study documents are kept in locked filing cabinets, and any digital data is kept in password-protected files on Partner's encrypted computers.

Access to de-identified, individual-level participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose. Aggregate study information (including genomic summary results) and study analyses may be shared in the scientific literature or through other public scientific resources, such as data repositories or other data sharing resources that provide broad or unrestricted access to the information.

Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks due to computational methods, analytic technologies, or techniques (e.g., generation of information that could allow participants' identities to be readily ascertained).

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding postoperative delirium. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

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. 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 may 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.

If our questionnaires suggest that you have depression, we will offer to refer you to a psychiatrist or clinical psychologist.

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

You will not directly benefit from research conducted on your samples. We hope that research using the samples and information will help us understand, prevent, treat, or cure diseases.

There are no direct benefits to you and no monetary compensation is provided. No direct benefits to participants are expected from any secondary research on de-identified individual-level data or genomic summary results that may be conducted. 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 you still get medical care within Partners if you don't take part in this research study, or if you 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.

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 you do if you 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 you 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 will you have to pay for if you take part in this research study?

You will not have to pay anything out of pocket to participate in this research study, as it comprises of surveys and blood draws. Your health insurance provider will not be notified of your participation or be billed for your participation in the study.

What happens if you are 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 beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable 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 information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable 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 identifiable 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 identifiable 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 identifiable information for any mailing or marketing list. However, once your identifiable 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 identifiable information. Your permission to use and share your identifiable information does not expire.

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 identifiable 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 identifiable 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 identifiable 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, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable 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 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: 6/21/19