Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Examining the Association Between Pre-existing Sleep Disturbance and Postoperative Delirium

Principal Investigator: Oluwaseun Johnson-Akeju, M.D., M.M.Sc

Site Principal Investigator:

Description of Subject Population: 100 patients age 60 and over, undergoing surgery at MGH

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.

Why is this research study being done?

We are doing this research study to understand the role of sleep disturbance on the incidence/severity of delirium after surgery.

We are asking you to take part in this research study because you are scheduled to undergo surgery at Massachusetts General Hospital (MGH). About 100 subjects will take part in this research study. We will enroll all 100 subjects at MGH.

How long will I take part in this research study?

Most of the study will be completed during your regular hospital stay. However, we will conduct questionnaires by phone or regular mail 1 month after your surgery. Therefore, it will take approximately 1 month to fully complete the study.

What will happen in this research study?

Pre-Operative Study Visit

On the day or days before your surgery, we will ask you to sign this consent form before we perform any study procedures. If you consent to the study, the study team may place polysomnogram (PSG) electrodes to monitor your sleep. These will be removed the morning before your surgery. A picture of the PSG device we will be using to monitor your sleep is included below.

Being a part of this study will not change the normal care that you will receive during your stay at MGH.

Peri-Operative Study Visit

We will ask you several questionnaires during your stay to help us understand if you develop delirium, had a good night's sleep, etc.

We will also take some blood samples, about 1 tablespoon of blood before surgery, and 1 tablespoon on the morning following your surgery. Your blood will be used to study whether there are any immune system differences between good hospital sleeping and poor hospital sleeping habits. Your blood may be stored for future testing to answer questions related to sleep disturbance and delirium.

Follow Up

A month after your surgery we will either call or send you questionnaires by regular mail. These questionnaires will tell us how you have recovered since leaving the hospital.

Stopping the Study
If you decide to stop taking part in the study for any reason, we will discuss the reasons why you are stopping the study.

Also, the study doctor may take you out of the study without your permission. This may happen because:

- The study doctor thinks it is best for you to stop the study
- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study.

Review of Medical Records from Hospital Admissions or Emergency Department Visits

MGH has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department for any reason. This alert will let the study doctors know why you are there. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

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

Questionnaires
We will ask you questions about your emotional or mental health (psychological questions). Some of these questions may make you uncomfortable. You do not have to answer questions that make you uncomfortable.

Medical information
Medical records will be checked to confirm your diagnosis. There is a small risk that your confidential medical information could be revealed or discovered by mistake. In addition, your samples and information will be coded and the key to the code will be kept in a separate, locked file. We won't share or publish any information that will identify you.

Risk of PSG Electrodes
There is a possibility that you may experience some redness or itching from placement of the

electrodes due to the glue used to attach them. This glue may have a mildly unpleasant odor and may annoy you.

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

You will receive no direct medical benefit for your participation in this study. What we learn in this study may help improve medical care for patients undergoing surgery 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?

You will not be paid to take part in this research study.

What will I have to pay for if I take part in this research study?

Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

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.

Oluwaseun Johnson-Akeju, MD is the person in charge of this research study. You can call him at 617-724-7200 Monday-Friday, 8am to 5pm. He can also be reached 24 hours a day at pager #13024.

If you have questions about the scheduling of appointments or study visits, call Reine Ibala at 617-643-2896 Monday – Friday 9-5, or you can reach her by e-mail at ribala@mgh.harvard.edu 24 hours a day, 7 days a week 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

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 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: 03/16/2018