

SleepINNOVATE Consent

Brigham and Women's Hospital

Protocol Title: Sleep INNOVATE Study

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Sponsor: National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

What is the purpose of the research?

The purpose of the SleepINNOVATE study is to learn more about why patients get sleep disorders, how sleep disorders affect daily life, and how satisfied patients are with treatment. This study hopes to better understand sleep disorders to improve care and quality of life better for patients.

Why am I being asked to participate?

We are asking you to take part in this research study because you have had a sleep study, are scheduled to have a sleep study, or have a diagnosis of a sleep disorder. To participate in this study, you need to be 18 or older and read English.

How many people will participate?

We hope to enroll at least 2,000 people into the SleepINNOVATE study.

What happens if I decide to participate and how long will it take?

Health surveys and brain quizzes:

After you consent to the SleepINNOVATE study, you will create an ID and password to log into the study website. On the website, you will be asked to complete surveys and brain quizzes on our secure web portal.

- Health surveys will take less than 30 minutes for most people to complete. They will ask questions about demographics, health, general functioning, and sleep habits.
- Brain quizzes may take a total of 20-minutes to complete. The short quizzes will test different brain functions like concentration and memory. The quizzes are administered by The Many Brains Project (testmybrain.org), a non-profit organization that creates testing tools for research studies. The Many Brains Project will have access to the testing results but no information that could identify you.

We will give you feedback on how you did when you finish some of the surveys and when you finish the brain quizzes. We do not expect there to be any risks to you from taking the surveys or brain quizzes. For questions that might make you feel uncomfortable, you have the option to skip that question or decline to respond. You are also free to end the survey or brain quiz at any time.

We hope to track your progress for at least 2 years. This is very important to help understand how the health of sleep patients changes overtime. We will follow-up by email and ask you to complete the surveys after approximately 3 months, 6 months, 12 months, and 24 months. These reminder emails will not be encrypted; however, we will never send your personal information in an email. The reminder emails will be sent to the email address that you give us.

Will information be gathered from other sources?

Medical record health information:

In addition to the surveys and brain quizzes, we are asking for your permission to access to your health information and save this information on a secure research database:

- Sleep study data: summary sleep reports, the waveforms collected on the sleep study, CPAP adherence data (if you have had a sleep study or use CPAP type devices).
- Partners Health electronic medical records: extract information on your health conditions, treatments, health behaviors, hospitalizations, procedures, and laboratory results.

Partners Biobank:

If you have not already enrolled or declined to enroll, we will also invite you to enroll in the Partners Biobank. If you wish to participate, we will review a separate consent form with you.

How will sensitive information be handled and kept confidential and secure?

For your security, "identifying information" such as name and date of birth, will be removed from your information and then deposited in a research repository that will be accessed by other researchers. Information collected about you will be combined with the information of other people in the research study. Results will always report aggregate trends and never include personal information, like your name, without your specific permission.

The following parties may see, use, and share your identifiable health information:

- 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)

- We share your identifiable health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we 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.

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice and does not describe all details of this requirement (see Partners Privacy Notice*). During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

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.

What is the risk of a breach of confidentiality?

Although we will do our best to protect your study information, there is still a very small risk of loss of privacy. All study staff will be trained and certified in the ethical conduct of human subject research and how to keep all study information strictly confidential.

What are the benefits of participating?

We will introduce you to a sleep education website, MyApnea.Org. You can get more information on sleep disorders from the blog articles and learn from other patients and clinicians on the forum. We hope that your participation will help improve our understanding of sleep disorders and lead to improved treatments and diagnoses.

Will I be paid for participating?

If you are recruited to join the study while you are at the clinic or sleep laboratory, you will receive a parking voucher (worth up to \$10). When you complete each set of surveys and brain quizzes, you will be entered into a lottery to receive a \$50 gift

card. The lottery is drawn twice every 3 months. If you win, you will receive the gift card through email.

Is participation voluntary?

Participation is voluntary, and you can stop at any time. If you decide to drop out, please contact us to tell us. We may talk to you about follow-up care, if needed.

It is possible that you will be asked to drop out of the study before you finish it. If this happens, we will tell you why.

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

Deciding not to participate won't affect medical care you receive at Partners now or in the future, or any benefits you receive now or have a right to receive.

How do I contact the study team?

For general questions about the research study, email support@sleepinnovate.org or call Carolina dos Santos at 617-278-0746.

Susan Redline, MD, MPH is the person in charge of this research study. You can call her at 617-732-5859.

If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee 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.

We may contact you in the future to get additional information and ask if you are interested in joining other research studies.

Signature begins on next page

Signature

By (print name)

Date

/ /

MM / DD / YYYY