Protocols Title: Predicting Obstructive Sleep Apnea in Down Syndrome
Principal Investigator: Brian Skotko, MD, MPP
Site Principal Investigator:
Description of Subject Population: Participants in the Down Syndrome Program at Massachusetts General Hospital

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.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, “you” always refers to the person who takes part in the study.
Why is this research study being done?

Our goal is to identify a set of measures that would help doctors predict whether patients with Down syndrome have obstructive sleep apnea (OSA). OSA is a condition in which the flow of air pauses or decreases during breathing while you are asleep because the airway has become narrowed, blocked, or floppy. Many people with Down syndrome also have OSA.

By doing this research, we hope that patients with Down syndrome might one day be able to receive treatment for obstructive sleep apnea without having to have a sleep study.

We are asking you to take part in this study because you have Down syndrome, are between 3 and 35 years old, and are already attending the weekly Down Syndrome Program at Massachusetts General Hospital (MGH).

We will enroll about 100 subjects in this study. The Maternal and Child Health Bureau of the Health Resources and Services Administration of the U.S. Department of Health and Human Services is paying for this research study to be done.

How long will I take part in this research study?

You will take part in this study for 2 study visits. One part will occur during your regularly scheduled visit to the MGH Down Syndrome Program. The other part will require an overnight stay for you and your parent(s) or guardian. The overnight visit will take place at the Sleep Laboratory, which is located at the Massachusetts Eye and Ear Infirmary (MEEI), 243 Charles Street, Boston, MA.

What will happen in this research study?

We will ask you to sign this consent form before we do any study tests or procedures. Before the visit, we will give your parent or guardian two questionnaires to fill out about your sleep habits.

Visit 1
This visit will take place at the same time as a regularly scheduled visit to the Down Syndrome Program. Taking part in the study will add about 10 minutes to your regular visit. At this visit, we will:
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- Give you a physical examination. This physical examination would be performed anyway as part of your routine visit to our Down Syndrome Program. We plan to use information from the exam for our research. It will not add any time to your visit at the Down Syndrome Program. The findings from the physical examination will be included in your medical record.

**Visit 2**
This visit will take about 12 hours. It will take place at the sleep laboratory.

You will have a sleep study at Massachusetts Eye and Ear Infirmary (MEEI). This sleep study will take place on a different day than your regular visit to the Down Syndrome Program. A coordinator from the Sleep Laboratory will call you to schedule a night that is most convenient for your schedule. You will be asked to arrive in the evening of your scheduled sleep study and go home the next morning. A sleep study allows physicians to learn a great deal about how your brain and body behaves during a night of sleep. As you sleep in a comfortable, controlled environment, different equipment allows technologists and physicians to monitor brain activity, muscle activity, breathing, blood oxygen levels, and eye movement. During this sleep study, an EKG will be performed. This test checks the electrical activity in your heart. The technicians will place several small, sticky pads on your chest, arms, and legs. Each pad has a wire attached. The wire connects to a machine that makes a recording of your heart rhythm.

We will also do an EEG. This test checks the electrical activity in your brain. We will place small sticky pads on your head. Each pad has a wire attached. The wire connects to a machine that makes a recording of your brain activity. These tests do not hurt. None of these measurements are invasive, meaning that at no time will your blood be taken. The results of the sleep study will be placed in your medical record.

During this sleep study, you will also be asked to wear a wristband oximeter, which is a device that looks like a wristwatch. This device (Nonin Wrist Ox₂ Model 3150) will measure the oxygen levels in your fingertips, without doing anything invasive. This wristwatch does not hurt. The results of this wristband oximeter will not be placed in your medical record.

On the evening before your sleep study, we will collect a urine sample first thing in the morning. The results of the urine tests will not be placed in your medical record.
What are the risks and possible discomforts from being in this research study?

EEG/EKG Leads

The risks are having electroencephalogram (EEG) and electrocardiogram (EKG) leads (sticky pads with wires attached) applied and removed for the sleep study. Sometimes, these leads can cause skin irritation.

Sleep Study

There is a small risk that you could fall out of bed during the sleep study. Some people also feel uncomfortable sleeping away from home.

Confidentiality

Some medical information (parent questionnaire, physical examination, sleep study results, X-rays) collected during this study may become part of your hospital record. In addition a copy of this informed consent document will be filed in your medical record.

We will assign you a study number. We will label study information with the study number instead of your name. The key to the study number connects your name to the study information. The study doctor will keep the key that links personal information to the study number. Only the study doctor and members of the research team will be able to see this information. This information will be kept on a password-protected computer that is kept in a locked office. The information will be read only by the study staff and will not contain anything that could identify you.

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

During this study, we will find out if you have obstructive sleep apnea. If you do, we will refer you to a specialist who can treat it. Others with Down syndrome may benefit from what we learn from this study in the future.

What other treatments or procedures are available for my condition?

If you do not wish to participate in this research study, you will continue to receive your regular care at the Down Syndrome Program at MGH. This would include a sleep study, if your doctor thinks you should have one.
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.

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

If you choose to stop taking part in the study, we will give you a questionnaire asking why you do not wish to finish the study.

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

We will not pay you for taking part in this research. However, as a token of our appreciation, we will be giving you a $25 gift certificate after the completion of their sleep study.

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

Study funds will pay for certain study-related items and services. However, we will bill your health insurer for 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.

The physical examination is a standard part of a regular visit to the Down Syndrome Program. Therefore, that part of the Study Visit 1 will be billed to your insurance.
If this is your first sleep study, then it will be billed to your insurance. Likewise, if you have had a prior sleep study and have signs and symptoms of obstructive sleep apnea, the sleep study will be billed to your insurance.

If you have had a prior sleep study and do not have signs and symptoms of obstructive sleep apnea, the sleep study will be paid for by the research study.

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.

Brian Skotko, MD, MPP, is the person in charge of this research study. You can call him at 617-643-3196, M-F, 9-5.
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. We share your 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.

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 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.

_________________________________________        Date/Time
Study Doctor or Person Obtaining Consent

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.

IF SUBJECT IS AN ADULT (18 years and older)…

Signature of Adult Subject, if able to Consent

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.

_________________________________________        Date/Time
Subject

OR

Assent of Adult Subject, if unable to Consent

Statement of Person Giving Assent
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- 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.

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

__________________________________________  Date/Time

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.

__________________________________________  Date/Time

Print Name (check applicable box on the next page)

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

__________________________________________  Date/Time

Relationship to Subject:

IF THE SUBJECT IS BETWEEN 14 AND 17 YEARS OF AGE…

Assent for Child:

Statement of Person Giving Assent
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- 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.

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

______________________________    ______________________________
Child, Ages 14-17          Date/Time

Signature of Parent(s)/Guardian for Child:

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

______________________________    ______________________________
Parent(s)/Guardian for Child          Date/Time

IF THE SUBJECT IS YOUNGER THAN 14 YEARS OF AGE…

Assent for Child: (Please sign separate Assent document, if appropriate)

Signature of Parent(s)/Guardian for Child:

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

______________________________    ______________________________
Parent(s)/Guardian for Child          Date/Time
Consent of Non-English Speaking Subjects Using the “Short Form” in the Subject’s Spoken Language

Statement of Hospital Medical Interpreter
As someone who understands both English and the language spoken by the subject, I interpreted, in the subject’s language, the researcher’s presentation of the English consent form. The subject was given the opportunity to ask questions.

_________________________________________   _________________
Hospital Medical Interpreter               Date/Time

OR

Statement of Other Individual (Non-Interpreter)
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

_________________________________________   _________________
Name                                           Date/Time

Witness to Consent of Subjects Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above
☐ Other means _____________________________________________

(fill in above)

_________________________________________   _________________
Witness                                         Date/Time

Consent Form Version: 31 October 2012