Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here:

_____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study allowing us to save and store the biological samples (cerebral spinal fluid and blood) that your physician had ordered for diagnostic testing. Normally, when lab tests are completed samples are destroyed after testing is completed. Instead we would like your permission to keep your samples for further research. We hope through the further study of samples such as yours that we may discover the cause for hypocretin destruction, or other biological markers responsible for narcolepsy or other disorders of excessive sleepiness. You were selected as a possible participant in this study because we have received your samples for diagnostic testing.

Your participation in this study is entirely voluntary.

Participant ID:

STUDY

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Mali Einen at 650.721-7550.

This research study will bank the samples of approximately 2,000 subjects with narcolepsy or other disorders of excessive sleepiness. Samples are sent to us for diagnostic testing from across the United States and abroad. We will enroll all willing participants. Over several years, Stanford University expects to enroll 2,500 research study participants.

DURATION OF STUDY INVOLVEMENT

This research study is expected to continue the banking of samples for 3 to 5 years. Your participation involves your agreement allowing us to store and save your sample (10 minutes) and the completion of a questionnaire asking you about your sleep habits and symptoms (30 minutes). No further time is required for your participation. Your cerebral spinal fluid and blood samples will be banked (saved and stored) for use in further research testing indefinitely or until the sample is used.

PROCEDURES

If you choose to participate, Emmanuel Mignot and his research study staff will assign your samples with a database ID and store them in the lab freezers for possible further research. The information form your completed questionnaire will also be collected and entered into our database.

Your samples may be sent outside of Stanford for analysis.

Tissue Sampling for Future Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored under an assigned number or code and de-identified or not linked to any of your personal identifying information. The key to linking your personal information to your samples will only be known to the principle investigator, Dr. Emmanuel Mignot and his clinical coordinator, Mali Einen.

You have the right to refuse to allow your tissues to be studied for future study at any time even if you initially agree today. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Complete your questionnaire as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

Because your participation in this research study, involves your agreement allowing the banking of samples drawn by your physician for clinical diagnostic procedures, your involvement does not affect your participation in any other research project.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide that you would no longer like to allow the banking of your spinal fluid or blood for other possible research please inform us directly and we will immediately destroy your remaining sample(s) at that time. Please contact Mali Einen at 650-721-7550 or Einen@stanford.edu .

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.

- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

- Completing the required questionnaire can take 30 minutes and may be difficult for someone who is sleepy.
- It is possible that the knowledge that research tests may yield results about you that you may not know could be psychologically distressing.

POTENTIAL BENEFITS

It is possible that the further study of your samples may lead to a greater understanding about your disorder. Discoveries could lead to possible improved treatments for narcolepsy or other disorders of excessive sleepiness; however this may be a very long term process

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

The alternative is to not participate in allowing the banking of your samples for possible further research. In this case your samples will be destroyed after the diagnostic testing results have been provided to the physician requesting the testing.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You may refuse to answer any particular question or questions and still participate in the study.

If you decide not to participate, tell the Protocol Director. You will still receive the results of your testing, care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to bank or store samples of spinal fluid and blood that we have received for diagnostic testing purposes, allowing us to use the samples for use in possible further research studies. Further testing may result in the discovery of the cause of hypocretin cell destruction in narcolepsy, may lead to the discovery of the cause of other diseases of excessive sleepiness or could lead to possible improved treatments.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.
Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Emmanuel Mignot, MD, 450 Broadway, M/C # 5704, Redwood City, CA 94063, 650-721-7550, Mignot@stanford.edu

What Personal Information Will Be Used or Disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, biological samples, sleep related records, Stanford Sleep Inventory Questionnaire, or any other relevant clinical information you may provide.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Emmanuel Mignot, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The study coordinator and Research Team.

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire on December 31, 2028.

_____
Signature of Participant

_____
Signature of Legally Authorized Representative

_____
Date

_____
Description of Representative's Authority to Act for Subject

Participant ID:

STUDY

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.

Costs
There is no cost to you for participating in this study.

Sponsor
The National Institutes of Health is providing financial support and/or material for this study.

Consultative or Financial Relationships
There are no consulting or financial relationships associated with this protocol.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. Because this study only involves your giving permission for the use of samples drawn for clinical purposes, there is no risk of medical complications or injury due to your participation.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Emmanuel Mignot. You may contact him now or later at 650-725-6517.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Participant ID:

STUDY

Alternate Contact: If you cannot reach the Protocol Director, please contact Mali Einen at 650-721-7550.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I consent to my samples being saved for future research	[ ] Yes	[ ] No
Are you participating in any other research studies?	[ ] Yes	[ ] No
May we contact you about future studies that may be of interest to you?	[ ] Yes	[ ] No

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____
Signature of Adult Participant Date

_____ _____
Signature of Parent, Guardian or Conservator Authority to act for participant Date

_____ _____
(If available) Signature of Other Parent Authority to act for participant Date

The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date

Participant ID:

STUDY