Stanford Center for Narcolepsy Research
Donor Program

PART 1

INFORMATION ABOUT THE DONOR PROGRAM
I. Introduction

The Stanford Center for Narcolepsy Research is primarily funded by the National Institute of Health. The Center for Narcolepsy was established in the early 1980s and is now directed by Drs. Emmanuel Mignot and Seiji Nishino. The Center for Narcolepsy is part of the Department of Psychiatry and Behavioral Sciences and has published more than 100 articles on narcolepsy. It is the world leader in narcolepsy research. Several hundred patients with the disorder are currently treated at the Center or participate in various research protocols. Amongst the Center’s many notable achievements, CNR can claim the discovery of both the tight association between narcolepsy and DQB1*0602 gene and the relationship between hypocretin deficiency and narcolepsy-cataplexy.

We have recently identified hypocretin (orexin) deficiency as the cause of most cases of human narcolepsy. The most likely cause is an autoimmune attack against the 70,000 or so hypocretin containing cells located in the brain. Our goal is now to understand this process and to find a way to prevent and reverse it. We are also studying the hypocretin system at the molecular and pharmacological level, with the goal of finding new treatments. The establishment of the brain donor program is a necessary component to identifying and understanding the cause of narcolepsy from all angles.

Thank you for your interest in the Stanford Brain Donation Program and sleep research.

II. This Donor Packet

Please read all of the instructions in this packet carefully before sending in any enrollment forms. Please call Mali Einen, Clinical Research Coordinator at (650) 721-7550, if you have any questions.

The donor packet is divided into two parts. Part 1 contains information for your records. Part 2 contains enrollment forms and instructions for completing the forms.

Please send completed enrollment packet to:
Mali Einen
Stanford Center for Narcolepsy Research
450 Broadway, M/C 5704
Redwood City, CA 94063
You may expect to receive notification of entry into the donor program. However, all applicable portions of the donor packet need to be completed in order to enroll. Please allow at least 2 weeks for processing of forms.

III. After Enrollment is Complete

I will send a copy of the donor registration, donor card, and contact names to your family physician as well as to others listed on the donor registration form. We will contact you about once a year to update your medical history and personal information. It is very important that if you move, change doctors, or have any other pertinent information change that you notify us immediately. Your donation is vital, therefore current information is crucial.

You are free to withdraw consent for brain donation at any time.

IV. At The Time of Death

It is necessary to contact the appropriate individuals immediately following the donor’s death, since we strive to perform the tissue removal within six hours. Please encourage family or those you expect to be close to you in event of your death to notify us even prior to passing as this gives us more time to make arrangement to ensure a timely removal. Upon the donor’s death (or before), the family or nursing staff should immediately notify either: (please try to contact in order listed)

**Mali Einen, Clinical Research Coordinator:**
During business day: (650) 721-7550
Home (cell) (650) 804-1658

**Emmanuel Mignot, M.D., Ph.D., Director:**
After Hours: (650) 323-6264
Cell Phone: (650) 799-1565

**Roman Karp, Prosecutor of PathServe**
Pager: (415) 719-0526
(using a touch-tone phone, leave your phone number with area code and then hang up)
When death occurs, our staff will most often travel to the mortuary to perform the tissue removal or a qualified local pathologist will be found. If the mortuary is not able to offer facilities for our staff to perform the removal, then an alternative plan for removal of tissue and transportation will be made by the Stanford Center for Narcolepsy.

The brain donor program involves no additional expense to the family. Funeral arrangements and related expenses will continue to remain the responsibility of the family. The brain donation procedure will in no way interfere with an open-casket funeral. Please do not hesitate to contact us if you have any questions.

Please remember that CNR relies on notification from the donor's family, friends or appointed professionals to alert us at or preferably even before the time of death. It is most important that those people close to you know of your intentions to donate your brain to our program and that they be provided our contact information.

V. Follow-Up

All data collected will be used anonymously by researchers from the Stanford Center for Narcolepsy Research and Stanford University.

Please address inquiries regarding neuropathology reports to:

Mali Einen
Center for Narcolepsy Research
450 Broadway, M/C 5704
Redwood City, CA 94063
Stanford Center for Narcolepsy Research
Donor Program

PART 2

ENROLLMENT FORMS AND INSTRUCTIONS
I. Donor Registration Form Instructions

The Donor Registration Form should be self-explanatory. Below are few notes that may answer questions about special circumstances.

Donor's Name: Please write in your full name, if it does not already appear in this box.

Patient's Current Residence: This refers to where you *actually* live, even if it is a nursing home or an extended care facility.

Caregiver (Next of Kin): self-explanatory.

Current Primary Care Physician: The primary care physician is the doctor who is currently most involved with your medical care on a long-term basis. If you have been placed in a nursing home, the doctor on staff will most likely be the one who can offer the most relevant information regarding your condition. Therefore, this name should be listed as the current primary physician.

Funeral Arrangement Information: We encourage you to choose a mortuary or cremation service early to avoid a complication or delay at the time of death. Please confirm these arrangements prior to listing them on the donor registration form.

*** It is important that we are notified of any changes to the donor registration application ***

*** If not all information is available currently (ie. You haven’t yet chosen a funeral home) please return with the information that is available to date. In later updates this information can be completed.

II. Donor Cards

Four donor cards are included. One card is for you to keep. The second is for your family. The third and fourth cards included in this section must be sent back to the SCFN (Stanford Center for Narcolepsy Research) along with all other applicable forms. If
possible, the donor cards should be signed by both the donor and one witness. If the donor is unable to sign his/her name, three witnesses must sign the donor card and a letter of consent must be filed with the SFCN (see Letter A or Letter B provided for this purpose).

III. Letter of Consent
(If Donor is unable to sign Donor Card)

Letter A

If the donor cannot physically sign his/her name, he/she may sign the card with an "X". Three witnesses must also sign the donor card and a statement that declares the donor is mentally able but not physically able to sign his/her full name must be attached. Form letter A is provided for this purpose.

Letter B

In the case where the donor may not be able to make an "X", the next of kin must sign the donor’s name on the donor card. If the next of kin has a power of attorney, the correct signature would read: "John Smith by Mary Smith, attorney in fact." Three witnesses must sign the card, and a formal letter stating this fact must be on file with the SFCN. Form letter B is provided for this purpose.

***Please only fill out the letter appropriate to the donor’s situation. Both letters do not need to be completed.***
IV. Releases of Information

Two releases of information are included so that we may request medical records from facilities outside Stanford University. These medical records are crucial for documenting a donor’s clinical history. Signed releases will be kept in the donor’s chart until such time as they are needed. Releases should be received along with other contents of the donor packet.

V. Mailing Checklist for Completed Forms

___1. Donor Registration application
___2. Donor Card (Keep one for yourself, one for your family and mail two)
___3. Letter A OR Letter B, if donor is unable to sign donor card.
___4. Medical Release Requests (return both)
___5. Information Face Sheet (Contains contact and demographic information on donor)

Please send the fully completed packet to:

Mali Einen
Stanford Center for Narcolepsy Research
450 Broadway Street, M/C 5704
**Donor Registration Form**

<table>
<thead>
<tr>
<th><strong>Donor Name:</strong></th>
<th>Last Name</th>
<th>First Name</th>
</tr>
</thead>
</table>

**Patients Current Address:**

- Facility (if applicable): ____________________________
- Street Address: ____________________________
- City, State Zip: ____________________________
- Phone: ____________________________
  - home
  - work
  - mobile

**Caregiver (Next of Kin):**

- Name: ____________________________ Relationship: ____________
- Street Address: ____________________________
- City, State Zip: ____________________________
- Phone: ____________________________
  - home
  - work
  - mobile

**Current Primary Care Physician:**

- MD Name: ____________________________
- Street Address: ____________________________
- City, State Zip: ____________________________
- Phone: ____________________________
  - office
  - fax

**Funeral Arrangement Information:**

- Facility Name: ____________________________
- Street Address: ____________________________
- City, State Zip: ____________________________
- Phone: ____________________________

Stanford Center for Narcolepsy Research (SFCN)
Pursuant to the Uniform Anatomical Gift Act, I hereby give, effective upon my death, Donation of my Brain to the SCFN/ACRC for the purposes of clinical research.

Date __________________________

Signature of Donor

________________________________________

Age of Donor _______________________
Date of Birth _______________________
Signature of Witness(es)

________________________________________

________________________________________


Donor Card
Patient/Family Copy
Pursuant to the Uniform Anatomical Gift Act, I hereby give, effective upon my death, Donation of my Brain to the SCFN/ACRC for the purposes of clinical research.

Date______________________________

Signature of Donor

______________________________

Age of Donor________________________
Date of Birth________________________
Signature of Witness(es)

______________________________

______________________________

______________________________

Donor Card
Patient/Family Copy
Pursuant to the Uniform Anatomical Gift Act, I hereby give, effective upon my death, Donation of my Brain to the SCFN/ACRC for the purposes of clinical research.

Date________________________________________

Signature of Donor

____________________________________________

Age of Donor___________________________

Date of Birth____________________________

Signature of Witness(es)

___________________________________________

___________________________________________

___________________________________________

Donor Card

ACRC Copy(return to Stanford)
Pursuant to the Uniform Anatomical Gift Act, I hereby give, effective upon my death, Donation of my Brain to the SCFN/ACRC for the purposes of clinical research.

Date__________________________

Signature of Donor

______________________________

Age of Donor_____________________
Date of Birth_____________________
Signature of Witness(es)

______________________________

______________________________

______________________________

Donor Card
SFCN Copy (return to Stanford)
Dear Roman Karp:

This letter is to inform you that

___________________________
(name of patient)

is physically unable to sign the Stanford Center for Narcolepsy Research donor card, but has made an "X" to represent his/her name. This mark is also to represent consent to participate in the SCFN donor program.

Sincerely,

X___________________________

Next of Kin
Dear Roman Karp:

This letter is to inform you that ___________________________ (name of patient) is unable to sign the Stanford Center for Narcolepsy Research donor card, but has consented to participate in the SCFN donor program.

Sincerely,

X____________________________________

Next of Kin
# STANFORD CENTER FOR NARCOLEPSY RESEARCH

## BRAIN DONOR PROGRAM

## CONTACT NAMES AND TELEPHONE NUMBERS

<table>
<thead>
<tr>
<th>Primary Contact Name</th>
<th>Telephone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SCFN Clinical Research Coordinator: Mali Einen</td>
<td>(650) 721-7550</td>
</tr>
<tr>
<td>During business day: (9am-5:00 pm)</td>
<td></td>
</tr>
<tr>
<td>Evening/home:</td>
<td>(650) 323-7207</td>
</tr>
<tr>
<td>Cell Phone #</td>
<td>(650) 804-1658</td>
</tr>
</tbody>
</table>

If you do not receive a reply from Mali Einen, call these numbers until you reach the first available person:

<table>
<thead>
<tr>
<th>Back-up Contact Name</th>
<th>Telephone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. SCFN Director: Emmanuel Mignot, M.D., Ph.D.</td>
<td>(650) 323-6264</td>
</tr>
<tr>
<td>Evenings or Weekends (home phone):</td>
<td></td>
</tr>
<tr>
<td>Weekdays work and cell:</td>
<td>(650) 725-6517</td>
</tr>
<tr>
<td></td>
<td>(650) 799-1565</td>
</tr>
</tbody>
</table>

| 3. ACRC Director: Jerome Yesavage, M.D. | (650) 493-5000 ext.65147 |
| During business day: (8am-5:00 pm) | |

| 4. Roman Karp, Prosector of PathServe | (415) 719-0526 |
| Pager (using a touch-tone phone, leave your phone number with area code and then hang up) | |

| 5. PathServe Answering Service | (415) 664-9686 |

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*Face-Sheet*
NAME: ___________________________ 
___________________________
last first middle initial

PERMANENT ADDRESS:

______________________________________________________________

street address

city state zip code

TELEPHONE: (____)____________ (____)_________________ (____)____________

home work cellular

E-MAIL: ___________________________ OCCUPATION: ___________________________

DATE OF BIRTH: _____/_____/_____ AGE: ______ GENDER: ___ M ___ F

MARITAL STATUS: _____ Married _____ Single

With which of the following major ethnic groups do you identify?
Check ALL ETHNICITIES THAT APPLY and specify the country/countries of origin of yourself and ancestors for each group checked. For example, if you consider yourself Asian, specify whether Chinese, Korean, etc. If you consider yourself American, please specify your family’s country/countries of origin prior to immigrating to the United States. Please list your country/countries of origin, if known.

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Country/Countries of Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>___________________________</td>
</tr>
<tr>
<td>Caucasian</td>
<td>___________________________</td>
</tr>
<tr>
<td>Latino/Black</td>
<td>___________________________</td>
</tr>
<tr>
<td>Latino/Am. Indian</td>
<td>___________________________</td>
</tr>
<tr>
<td>American Indian</td>
<td>___________________________</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>___________________________</td>
</tr>
<tr>
<td>Other</td>
<td>___________________________</td>
</tr>
</tbody>
</table>

Have you ever had a polysomnogram (overnight sleep study) or MSLT (napping test)? YES NO

SLEEP CENTER: ___________________________

ADDRESS: ____________________________________________

street address city state zip code

TELEPHONE: (____)_________________ DATE OF STUDY: ________________________
In order to properly evaluate the brain that a donor provides, the Center for Narcolepsy Research (CNR) must have a complete understanding of that individual’s health. Particularly, CNR needs to know if the donor suffers from any condition (acute or mild, temporary or chronic) that might affect the constitution of the brain. As such, CNR requires access to each donor’s relevant medical history.

- Authorization to Use Your Health Information for Research Purposes
  - Please carefully read through this form before signing. CNR provides you with this information in order to inform you of your rights as a participant in research and to educate you on the protocol and purpose of this particular project.

- Authorization for Release of Protected Health Information
  - Via the Health Insurance Portability and Accountability Act (HIPAA), all of your health information is protected by federal law. As such, CNR cannot acquire copies of your medical history from your physicians without your express written consent. As such, please fill-out each release form in its entirety and sign where appropriate.
  - If you believe that CNR will need to contact more than one physician/organization to acquire records that paint a complete picture of your health, please complete one release form for each physician/organization.
  - If you believe that CNR can acquire records that paint a complete picture of your health from a single physician/organization, please complete a single release form for that physician/organization. On the remaining release forms, please fill-in all of the fields except the name and address of the physician/organization.
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?**

Current evidence indicates hypocretin deficiency as the cause of most cases of human narcolepsy. The most likely cause is an autoimmune attack against the roughly 10,000 hypocretin containing cells located in the brain. Our goal is to understand this process and find a way to prevent and reverse it. We are also studying the hypocretin system at the molecular and pharmological level, with the goal of finding new treatments. The establishment of the brain donor program is a necessary component to identifying and understanding the cause of narcolepsy from all angles. In order for your donation to be of use, however, we must know and have documentation of your health. As such, we require your health information in order to identify sleep disorders or other conditions which may affect the constitution of your brain.

**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. 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 contact: Professor Emmanuel Mignot or Mali Einen at 650-721-7550.

**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: blood samples, lab results, sleep related records (including sleep studies and physician’s notes), Stanford Sleep Inventory questionnaire, and other questionnaires.

**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, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
  - The Protocol Director, Emmanuel Mignot, MD, PhD.
The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The Study Coordinators and Research Team
- The National Institute of Health (NIH)
- Other research institutions working in conjunction with the NIH
- Study Collaborators

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 Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health
- The Food and Drug Administration
- Other research institutions working in conjunction with the NIH
- Other collaborating research institutions

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, 2057

________________________________________
Signature of Participant

________________________________________
Name of Participant (print)

________________________________________
Signature of Legally Authorized Representative (if necessary)

________________________________________
Date

________________________________________
Description of Representative's Authority to Act for Subject (if necessary)

AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

Patient Name: ____________________________ Date of Birth: ______________ SS#: __________________
Patient Address: _________________________________________________________________
Telephone #: _____________________

I, the undersigned, hereby authorize (clinic/physician/sleep center name and address):

__________________________________________________________
__________________________________________________________
__________________________________________________________
__________________________________________________________

and any of its parents, subsidiaries, or affiliates and their respective agents and subcontractors, to disclose confidential health information about me, ________________________________.  
(patient name, please print)

I UNDERSTAND THAT THIS AUTHORIZATION IS VOLUNTARY.

I authorize you to release a copy of my sleep related medical records to:

Center for Narcolepsy Research  
450 Broadway, MC #5704  
Redwood City, CA 94063  
(Attn: Mali Einen)

This data is required for a narcolepsy research project in which I am participating.

The researchers conducting this study are requesting copies of the results of any overnight polysomnogram or MSLT, or any sleep related records, including initial evaluations and follow-up visits, particularly those records pertaining to periods of hypersomnia.

If you have any questions concerning this request, please contact the Clinical Research Coordinator, Mali Einen (800-49-SLEEP). You may also contact Emmanuel Mignot, M.D., Ph.D., the project manager (650-725-6517).

IMPORTANT: Your signature below means that you understand and agree to the following:
I understand that the Information provided under this authorization may include Protected Health Information which could contain diagnosis and treatment information including information pertaining to chronic and/or communicable diseases. I understand that the information to be disclosed is protected by law and that the same information may be re-disclosed by the recipient and may no longer be protected by the same law(s) that applied in the first instance. I understand that the permission that this form grants expires two years from the date of signature. I understand that I may revoke this Authorization at any time by requesting such in writing.

(Patient Signature) (Date)
(Medical Record #, if known) (approximate date of service)

AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

Patient Name: ___________________________ Date of Birth: ___________________________ SS#: ___________________________  
(mmm/dd/yyyy) (optional)

Patient Address: _________________________________________________________________ Telephone #: _____________________

I, the undersigned, hereby authorize (clinic/physician/sleep center name and address):

__________________________________________________________
__________________________________________________________
__________________________________________________________
and any of its parents, subsidiaries, or affiliates and their respective agents and subcontractors, to disclose confidential health information about me, _____________________________.

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(Patient Signature)  
(Date)

(Medical Record #, if known)  
(approximate date of service)