

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Dr. John Day

IRB Use Only

Approval Date: April 22, 2015

Expiration Date: February 17, 2016

Protocol Title: Subject Database and Specimen Repository for Neuromuscular and Neurodegenerative Disorders - **Biobank**

Please check one of the following:

_____ You are an adult participant enrolling in the Biobank.

_____ You are the parent or guardian granting permission for a child to enroll in the Biobank.

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."

DESCRIPTION: You are being asked to enroll in the Biobank. The purpose of this enrollment is to collect, store, and give out to other researchers any tissue(s) that you are willing to donate to the Stanford Neuromuscular Biobank. This could include, but not limited to, surgical specimens of brain tissue, spinal cord, cerebrospinal fluid, heart, muscle, and other organs or post-mortem tissue if your family consents after your death. Before you decide whether or not to take part, please read the information below and ask questions about anything you do not understand. Your participation is entirely voluntary.

Your clinical care will stay the same whether you choose to contribute to the Biobank or not.

Up to 1000 people per year could enroll or donate for an indefinite number of years in this Biobank.

RISKS AND BENEFITS: Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability.

Researchers can use the post mortem tissue and information to have a better understanding of the neurological diseases being researched. This could result in new discoveries about the disease which could produce potential treatments that might benefit others affected by the same disease in future. We cannot and do not guarantee that you will receive any benefits from enrolling in the Biobank.

TIME INVOLVEMENT: The Stanford Neuromuscular Biobank is a tissue bank which collects and stores human tissue, DNA, RNA, various cell lines, protein, medical history and/or clinical test results in order to use it in future research. The samples may be kept until they are used up, or Dr. Day decides to destroy them.

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PAYMENTS: You will receive no payment for enrolling in the Biobank. There will be no cost to you for any tissue/data collected and stored.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to enroll in this Biobank, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue enrollment at any time without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw your consent, postmortem tissue will not be collected from you. The results of research using the tissues that you donate to the Biobank may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

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 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 research. 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 Biobank is to collect, store, and give out to other researchers any tissues that you are willing to donate to the Biobank. More specifically, your Protected Health Information may be collected, used, and shared with others. This would help us learn more about various neurological conditions. Your information may also be presented at meetings or in articles written about the research (publications) on the tissues you donated to the Biobank. You will not be identified by name in any presentation or publication that uses your research or health information.

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 enroll in this Biobank. Signing the form is not a condition for receiving any medical care outside your enrollment in the Biobank.

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

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If you decide to enroll in this Biobank, 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 any research, 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, you must submit your request in writing to the investigator: Dr. John Day Department of Neurology, Stanford University Medical Center, 300 Pasteur Drive, A342, Stanford, CA 94305, (650)-725-4341.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this Biobank, may be used or disclosed in connection with this research, including, but not limited to, your health information related to the neurological condition you are having which will include information abstracted from medical records. However, your identity will not be revealed, and will not be linked to the health information in any publication or public presentation.

Who May Use or Disclose the Information?

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

- The Protocol Director (Dr. John Day)
- Study team
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

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 Biobank:

- Other researchers at Stanford
- The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration Act
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments

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Your identifying information will not be disclosed to the recipients of information from us, so they will not be in a position to reveal your identity.

When reviewing your records, confidentiality will be maintained to the extent possible according to privacy regulations. Please be aware that there is a possibility that your identifiable information may be shared with other entities and may no longer be protected by applicable privacy laws and regulations.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end in 2100 or when the research project ends, whichever is earlier.

Name of participant

Signature of Participant

Date

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

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, Dr. John Day at 650-725-7622. You should also contact him at any time if you feel you have been hurt in any way by being a part of this Biobank.

Independent Contact: If you are not satisfied with how this Biobank 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.

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Alternate Contact: If you cannot reach the Protocol Director, please call the Page Operator 650-723- 6661 and ask for the Investigator’s pager number or the pager number of the On-Call Neurology Resident. You can also contact the research coordinator Shirley Paulose at 650-724-3792, or the research coordinator Jennifer Perez at 650-497-3079 or the co-Protocol Director Katharine Hagerman at 650-723-9574

Name of Participant

Signature of Adult Participant

Date

Signature of LAR (Parent, Guardian or Conservator)

Date

Authority to act for participant

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date