RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Prion Registry

PROTOCOL NO.: None
WIRB® Protocol #20170944

SPONSOR: Prion Registry Consortium

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STUDY-RELATED PHONE NUMBER(S): CJD Foundation HelpLine
(+1) 800-659-1991

A person who takes part in a research registry is called a participant. In this consent form "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" means the participant.

SUMMARY

You are being invited to participate in a research registry. The purpose of this consent form is to help you decide if you want to be in the research registry.

You should not join this research registry until all of your questions are answered.

Things to know before deciding to take part in a research registry:

- The main goal of a research registry is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research registry will not cause you to lose any medical benefits. If you decide not to take part in this registry, your doctor will continue to treat you.

PURPOSE OF THE RESEARCH REGISTRY

The "Prion Registry" initiative is a participant-driven effort, overseen by prion disease patient advocates, which will empower people suffering from, or at risk for, prion disease, and their families to help transform research and treatment of the disease through participation in research.

Our ultimate goal is to further the development of life-saving therapies to cure, treat, prevent, or delay prion disease. We created this research registry to make it easier for patients to:

1) be counted,
2) find research studies to participate in, and
3) share their data with researchers,

This research registry will also help qualified researchers recruit study participants and gather data.

PROCEDURES

- You will answer some questions about how prion disease has affected you and/or your family.
- If you agree, you may choose to be contacted about future research studies and/or clinical trials in which you may be eligible to participate. You may choose not to receive these invitations or decline to participate in future studies.

RISKS AND DISCOMFORTS

There is a potential risk that information you provide, such as health, genetic, or contact information, could be seen by unauthorized individuals. An accidental release of your information could be used to identify you or your family members. However, we have tried to minimize this risk by carefully limiting access to the computers that would house your information to the staff of this research initiative as well as by creating secured access-controlled software that will hold information about your personal identity (e.g. name, date of birth, address) in an encrypted manner.

The medical questionnaire may ask about sensitive or emotional subjects, and filling out the questionnaires could lead you to feel uncomfortable or upset, in which case please tell the registry staff. You have the right to refuse to answer any questions.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this registry. You may be asked to sign a new consent form if this occurs.

BENEFITS

Participating in this initiative is unlikely to directly or immediately improve your own health. The information we collect will hopefully aid in research efforts to one day provide better prion disease treatment and prevention options. Your participation may also one day allow researchers to recruit you for experimental treatment trials, which could potentially result in health benefits to you. Registry staff will not be able to provide you with any specific information about your own health, genetic status, or other medical information.

COSTS

There are no costs to participate in this registry.

PAYMENT FOR PARTICIPATION

You will not be paid for being in this registry.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to participate.

CONFIDENTIALITY

After removing your name and any other readily identifiable information, registry staff will share statistics regarding de-identified data with researchers interested in launching research studies. For example, staff may provide researchers with information regarding the number of individuals in the registry who qualify for a potential research study, based on age, genetic mutation status, location, and/or other information.

Qualified researchers who have received approval from an ethics committee will also be able to post studies for which you will be notified of your eligibility. An ethics committee is a group that independently reviews and watches over all research studies involving people. The board follows local laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected. It will then be your choice whether to contact these researchers and share your identity in order to enroll in their studies; researchers will not be able to directly view your contact information in the registry.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this registry is voluntary. You may decide not to participate or you may leave the registry at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

SOURCE OF FUNDING FOR THE REGISTRY

The sponsor, Prion Registry Consortium, will pay for this research registry.

QUESTIONS

For any of the following types of questions:

- if you have any questions about your participation in this research registry,
- if you feel you have been harmed by the research registry, or
- if you have questions, concerns or complaints about the research.

You may contact one of our member organizations as follows:

Australia — CJDSGN HelpLine — (+61) 298998905 / toll free 1800052466
India - CJD Care India (+91) 9167004979
Italy — Italian Association on Prion Diseases (+39) 3939874016
U.S. and elsewhere — CJD Foundation HelpLine — (+1) 800-659-1991

If you have questions about your rights as a research registry subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some registry specific questions, such as questions about appointment times. However, you may contact WIRB if the registry staff cannot be reached or if you wish to talk to someone other than the registry staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this registry, please print copy of this consent form for your records.

AGE DECLARATION

I am of the legal age of majority in my location of residence and able to give consent.

YES __ NO __

PARTICIPATION OPTIONS

The registry may contact me with follow-up research questionnaires and invitations to participate in additional studies. I may choose to ignore these questionnaires and invitations.

YES __ NO __

CONSENT

I have read this consent form (or it has been read to me). All my questions about the registry and my part in it have been answered. I freely consent to be in this research registry.

I authorize the release of my data for the purpose of this registry.

By signing this consent form, I have not given up any of my legal rights.

Adults able to independently consent:

_____
Subject Name

_____
Date

Adults <u>unable to consent for themselves:</u>

Consent is provided by the Legally Authorized Representative for subjects unable to consent

_____
Subject Name

_____ _____
Name of Legally Authorized Representative Date

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject