CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMED CONSENT DOCUMENT

Challenging the Huntington Disease Paradigm: Evaluation of Psychosocial Issues in Persons at-risk for Genetic Prion Disease

You are being asked to participate in a research study about the psychosocial experience of being at-risk for a genetic prion disease**.** You were selected as a possible participant because you are at least 18 years old, you have been identified as being at-risk for a genetic prion disease due to a family history and have either not undergone predictive testing, or have a testing-confirmed mutation. Please read this form and ask any questions that you may have before agreeing to be in the research.

Researchers at Case Western Reserve University are conducting this study.

Purpose

The purpose of this research is to assess the psychosocial experience of being at-risk for a genetic prion disease (gPrDs).

Procedures

If you agree to be a participant in this research, we would ask you to do the following things: create a profile on www.prionregistry.org. Once done you will be able to navigate to the questionnaire for this study from the Study Listings page. Once you have accessed the study, you will be asked to answer questions in a survey.

You can choose to stop participating for any reason at any time. If you wish to stop participating, simply do not submit the completed questionnaire.

Foreseeable Risks and Discomforts

There are no known risks, harms or discomforts associated with this study beyond those encountered in normal daily life. Some of the activities we will ask you to complete might make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time. The possible risks and/or discomforts associated with the procedures described in this study include: anxiety or distress when answering questions. There is a possible risk of losing confidentiality; however, your answers will not be shared with anyone and will be reported only as summary statistics. If you do not wish to answer a question, please skip it and go on to the next question. You may choose to end your participation at any time if you become uncomfortable for any reason.

If at any point during the questionnaire you become emotionally distressed, please seek support from the appropriate mental health resources in your area.

Anticipated Benefits

You will not directly benefit from participation in this study. Your participation may help genetic counselors and other healthcare professionals to better understand the experience of individuals at risk for genetic prion diseases.

Compensation

There will be no costs to you for study participation.

You will not be compensated for your participation in this research study.

Alternative(s) to Participation

You have the option to not participate.

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University. There is no penalty or loss of benefits for not participating or for discontinuing your participation.

Confidentiality

The records of this research will be kept confidential. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies.

Data Storage

Research data will be stored electronically in an encrypted file and is password protected.

Data Retention

The researchers intend to keep the research data until analysis of the information is completed;

Contacts and Questions

The researchers conducting this study are Anne Matthews and Madeline Williamson. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact them by email at **alm14@case.edu** or mlw124@case.edu or by phone at (216) 368 1821.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; (1) questions, concerns or complaints regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact Case Western Reserve University's Institutional Review Board at (216) 368-4514 or write: Case Western Reserve University; Institutional Review Board; 10900 Euclid Ave.; Cleveland, OH 44106-7230.

You will be given a copy of this form for your records.

Statement of Consent

By continuing with this survey you certify the following:

- You are at least 18 years of age. You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.