INFORMED CONSENT DOCUMENT

Project Title: **Huntington's Disease Registry**

Principal Investigator: **Jane Paulsen, PhD**

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- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word "you" in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are a teenager reading this document because you are being invited to be in this study, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.
- If you are the legally authorized representative of a person who is being invited to be in this study, the word "you" in this document refers to the person you represent. You will be asked to read and sign this document to give permission for the person you represent to participate in this study.

This form provides important information about what you will be asked to do while on the registry, about the risks and benefits of the registry, and about your rights as a research participant.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose, such as family or friends.
- Do not sign this form unless the study research team has answered your questions and you decide that you want to be part of this registry.

WHAT IS THE PURPOSE OF THIS REGISTRY?

You are being invited to participate in a registry (list) of people interested in Huntington's disease (HD) research. It may be that you have a family member or other loved one with HD, or that you may have or are at-risk for HD. If you agree to participate in the registry, your name will be added to a list of people who will be invited to participate in future research studies on Huntington's disease.

The purpose of this registry is to allow Dr. Jane Paulsen's HD research team to contact individuals on the list who may fit a study's eligibility requirements. On a separate sheet of paper, there are some questions we would like you to answer. These answers will help us identify in which research studies you may be able to participate. However, for some studies, we may need to call you to ask about some

current protected health information. For example, we may need to know if you are currently participating in a research study, or if you have previously participated in a research study at our HD Center of Excellence. We may also need to know what medications you are currently taking, or whether you have experienced any recent outpatient or inpatient medical events (e.g., surgeries, hospitalizations, etc.). Answering these questions helps us determine your eligibility for our research studies. None of the information you provide us will be used to provide you with clinical care. We will not be creating any medical record or adding any information to an existing medical record for you at the University of Iowa Hospitals and Clinics. Rather, as part of your participation in this registry, the information you provide us is used **only** to check for your eligibility to participate in our research.

We would also like to keep a written summary of any interaction we have with you while you participate in this registry. For example, if we mail you information, we would like to record the date and type of information we sent you. If we have a phone conversation with you, we would like to record a written summary of the conversation. These summaries help our staff track your requests for information and ensure our communication with you is efficient. All information you provide us will be kept on a password protected website which is housed on a secure server that is only accessible to members of our research team.

If an individual meets the requirements for a study, we will send information on the study and invite him/her to participate. There is no obligation to take part in any future research, and you may request to have your name removed from this contact list at any time. Other members of your family are invited to participate in this registry as well.

By participating in this registry, you will also receive information on local support groups and newsletters letting you know what is happening in HD research. This list of names will only be used for Huntington's disease research and communication. With this registry, we hope to increase the understanding of this disease and discover ways of treating it.

To be on the registry, please complete the attached information sheet. In order to send you information and contact you about study involvement, please complete the section titled "Contact Information" with your name, phone number, address, and email (if applicable). Additionally, we would like your date of birth, handedness, and years of education. The section titled "Medical Information" includes information on your HD gene status, and completing this section is **optional**. All of this information will help the research team decide for which studies you are eligible. Information from this registry is stored on a password-protected computer file accessible only to Dr. Jane Paulsen and her HD research team. Your medical records will never be accessed for the registry.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 2100 people will take part in this study at the University of Iowa.

WHO IS ELIGIBLE TO PARTICIPATE IN THIS REGISTRY?

All individuals interested in Huntington's disease (HD) research are eligible to participate in this registry. It may be that you have a family member or other loved one with HD or that you yourself may have or be at-risk for HD.

HOW LONG WILL I BE ON THIS REGISTRY?

If you agree to take part in this registry, your involvement will last until you terminate your participation by contacting Dr. Jane S. Paulsen or one of her research assistants at (319) 335-1611 or (319) 384-4912.

WHAT ARE THE RISKS OF BEING ON THIS REGISTRY?

As with any registry, there is a risk to confidentiality. Information we gather will remain confidential unless otherwise governed by law. All information collected for this registry is stored on a password-protected computer file accessible only to Dr. Jane Paulsen and her HD research team.

ARE THERE ANY UNFORSEEN RISKS?

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being on this registry.

WHAT ARE THE BENEFITS OF BEING ON THIS REGISTRY?

There may be no personal benefit from participating in this registry. However, it is hoped that this registry will be of use to research studies that will benefit future Huntington's disease families. It will help us to better understand the disease and its progression, and it will hopefully provide a greater chance of understanding and eventually curing the disease. It may also lead to a better understanding of this disease for you and your family.

WILL IT COST ME ANYTHING TO BE ON THIS REGISTRY?

You will not have any costs for being on this registry.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being on this registry.

WHO IS FUNDING THIS REGISTRY?

The University of Iowa and the research team are receiving no payments from other agencies, organizations, or companies to keep this registry.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this registry confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in the registry. For example, federal government regulatory agencies, people who use the registry, auditing departments of the University of Iowa, and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these

records could contain information that personally identifies you.

To help protect your confidentiality, we will keep your information in locked filing cabinets and storage areas, and use password-protected computer files.

IS BEING ON THE REGISTRY VOLUNTARY?

Taking part in the registry study is completely voluntary. You may choose not to take part at all. If you decide to be in this registry, you may stop participating at any time. If you decide not to be on the registry, or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the registry itself, please contact: Dr. Jane S. Paulsen or one of her research assistants at (319) 335-1611 or (319) 384-4912.

If you have questions, concerns, or complaints about your rights as a research participant or about research related injury, please contact the Human Subjects Office, The University of Iowa, Hardin Library for the Health Sciences, 600 Newton Road, Office 105, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research participant can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed): _____

_____ _____

(Signature of Participant) (Date)

Parent/Guardian or Legally Authorized Representative's Name and Relationship to Participant:

_____	_____
(Name - printed)	(Relationship to Participant - printed)
_____	_____
(Signature of Parent/Guardian or Legally Authorized Representative)	(Date)

Legally Authorized Representative (for adult participants who cannot consent for their own participation):
In studies conducted in the state of Iowa, the first person on the list below who is reasonably available and competent must sign as the legally authorized representative even if another person on the list is more conveniently available.

1. The designated proxy (such as a Durable Power of Attorney for Health Care)
2. Court-appointed guardian
3. Spouse (does not include "Common-law" spouse)
4. Adult child
5. Parent
6. Adult sibling

Check the method by which consent is being obtained:

□ Consent is being obtained by mail without a discussion between a research team member and the subject. (Research team member does not sign this document)

□ Consent is being obtained in person or by mail after a discussion between a research team member and the subject. (Research team member signs below.)

Statement of Person Who Obtained Consent

(This line is only to be signed by a research team member after discussion with participant.)

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

_____	_____
(Signature of Person Who Obtained Consent)	(Date)