Assent Script
In-person/Mail/Email/Online/Telephone

Assent for Children 7-17 Years of Age and Adults Unable to Consent
Sanford Children’s Health Research Center

Protocol Title: Coordination of Rare Diseases at Sanford (CoRDS)
Principal Investigator: Angela Van Veldhuizen, RN, BSN
Department: Sanford Children’s Health Research Center
2301 E. 60th Street N, Sioux Falls SD 57104
Email: cords@sanfordhealth.org
Phone: (877) 658-9192

Instructions for Parents and Legally Authorized Representatives: If the participant is between the ages of 7-17 or is an adult unable to consent, we ask that you read to them, or have them read, the following information before you enroll them in the CoRDS Registry. If your child/the participant does not agree to participate, you may not enroll them in the CoRDS Registry.

Introduction
We would like to tell you about a research study we are asking you to be in. A research study is like a big science project. The research study will help scientists and doctors help people that are sick. If it is okay with you, we will ask your parent(s)/legally authorized representative(s) a few questions about you and use this information for our study.

The scientists and doctors may ask you to help them again in another research study in the future. If you don’t feel like doing this right now, just tell us. Even if your parent(s)/legally authorized representative(s) say(s) that it is okay to be in this research study, you don’t have to. If you let us put your name and information in the study, you can always ask us to erase them at any time by letting us know.
Affected Adults, Parents/Guardians, Legally Authorized Representatives Consent Form
Participation in Research for Affected Adults/Affected Minors
Sanford Research

Protocol Title: Coordination of Rare Diseases at Sanford (CoRDS)
Investigator: Angela Van Veldhuizen, RN, BSN
Department: Sanford Children’s Health Research Center

Instructions: If you have previously completed a CoRDS Informed Consent Form, please read carefully as the terms may have changed.

The current Informed Consent Form and Assent Form are available on the CoRDS website (http://www.sanfordresearch.org/cords/), online within the online portal, and via mail, email, or telephone per participant request. CoRDS encourages participants to review the Informed Consent Form and Assent Form regularly for any revisions. It is your responsibility to ensure you have read the current Informed Consent Form and Assent Form.

What is the purpose of this study?
The purpose of the Coordination of Rare Diseases at Sanford (CoRDS) is to establish an international rare disease patient registry. The CoRDS Registry is a de-identified, searchable list of people affected by rare, uncommon, or undiagnosed conditions. CoRDS’ goal is to provide a valuable resource of de-identified information, and to accelerate patient recruitment into research studies and clinical trials.

Who can participate?
Any individual affected by a rare, uncommon, or undiagnosed disease is welcome to enroll in the CoRDS Registry. A parent or guardian may register a child who is under the age of 18, or a Legally Authorized Representative (LAR) may register on behalf of an adult who is unable to consent.

What will happen in this study?
If you choose to enroll, you will be asked to complete a brief questionnaire(s). The questionnaire(s) requests your basic contact, socio-demographic, and health information, as well as your communication and research preferences. This information will be saved under a unique coded identifier. CoRDS will send a reminder if your questionnaire has not been completed, and will send an annual reminder to remind you to update your information or confirm that it is up to date.

Unless you withdraw from the study, your information will be stored indefinitely. If you are a parent or guardian enrolling a child, CoRDS will contact your child when they turn 18 to obtain their consent directly. If CoRDS cannot reach your child after three attempts, all identifiable information will be removed and data will be stored in the registry indefinitely.

Is this study voluntary? Is it possible to withdraw from the study?
Participation in CoRDS is voluntary. You are free to withdraw at any time, for any reason. To withdraw, please contact CoRDS by mail or email and select one of the following options.
1. Leave identifiable information in CoRDS, but do not contact me again;
2. Remove identifiable information and leave de-identified information in CoRDS;
3. Remove all information from CoRDS.

You will have 30 days to decide what you wish to do with your data. CoRDS will contact you to confirm that your data has been modified/deleted according to your wishes. If CoRDS does not hear from you within 30 days, your identifiable information will be removed and data will be stored in the registry indefinitely.

What are the benefits of this study?
There is a chance that you will receive no direct benefits for participating in CoRDS, and CoRDS cannot guarantee that a researcher will request to contact you. However, the data you contribute could help research that provides benefits to a wider population. In addition, you may be contacted about research opportunities.

Is the information kept confidential? What are the risks of participation?
CoRDS will make every effort to keep all information gathered in the registry confidential, but this cannot be guaranteed. There is a minimal risk associated with the loss of confidentiality.

How will my information be accessed? Can I choose how my information is shared?
On the questionnaire(s), you can choose how you would like CoRDS to share your information. Information in the CoRDS Registry may be accessed in the following ways:
1. Researchers may access de-identified information if they have obtained approval from their Institutional Review Board (or equivalent approval in their country) and the CoRDS Scientific Advisory Board. If you enter a disease-specific registry for a Patient Advocacy Group (PAG), that PAG may ask to be involved in the review process. If a researcher wishes to notify you about a research opportunity, CoRDS Personnel will contact you on their behalf. There is no obligation to participate – it is always up to you to contact the researcher.
2. A subset of de-identified information may be shared with certain other databases in order to avoid a duplication of efforts and to increase knowledge and understanding of rare diseases.
3. Patient Advocacy Groups (PAGs) representing individuals with rare or uncommon diseases may have access to information that may or may not be identifiable for non-research purposes. These PAGs have signed a contract stating they will not use the information for research purposes.

Who should I contact if I have questions?
- For general questions about CoRDS or enrollment: call (877) 658-9192 or email cords@sanfordhealth.org
- If you feel you have been harmed: Angela Van Veldhuizen, (605) 312-6426
- If you have questions about your rights as a research participant: Sanford Health Institutional Review Board (IRB), (605) 312-6430