

**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: Benjamin Forred
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. CoRDS' goal is to collect and provide a valuable resource of information, and to accelerate patient recruitment into research studies and clinical trials.

Who can participate?

Any individual with a rare, uncommon, or undiagnosed disease, as well as those who are unaffected carriers are welcome to enroll in the CoRDS Registry. A parent or guardian may enroll a child who is under the age of 18. A Legally Authorized Representative (LAR) may enroll an adult over the age of 18 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 update your information or confirm that it is up to date.

Sometimes, it is important for researchers to know how many members of a family are affected by a given condition and how diseases are inherited within a family. You will have an option to link your account with other family members who are enrolled in CoRDS. By linking your account to a family member's account, you are agreeing to have your name, date of birth, city/state residence, and family relation shown to the family member to which you would like to be linked. You will not be able to look at or edit each other accounts. Researchers will not be able to identify who the individuals are; rather they will only know that you are related to the family member you have linked to.

Is this study voluntary?

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 are no direct benefits to participating in CoRDS but the data you contribute may help advance research for rare diseases which would benefit a wider population. By participating in CoRDS you may be contacted about research opportunities you qualify for, and can decide at that time if you would like to participate, however CoRDS cannot guarantee that a researcher will request to contact you.

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 CoRDS may be accessed in the following ways:

1. Researchers may access de-identified information once they are approved by the CoRDS Scientific Review Committee. 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. CoRDS ensures that all research study referrals have been reviewed and approved by an IRB as applicable.
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: Benjamin Forred, (605) 312-6416 If you have questions about your rights as a research participant: Sanford Health Institutional Review Board (IRB), (605) 312-6430