

Coordination of Rare Diseases at Sanford (CoRDS) Frequently Asked Questions (FAQs)

What is a patient registry and what is the purpose of the CoRDS registry?

A patient registry can be defined as system designed to collect and store information that can be used to evaluate outcomes for a group of individuals and can be used to inform scientific clinical and policy purposes.

The Coordination of Rare Diseases At Sanford (CoRDS) is a registry that collects information on patients diagnosed with a rare disease to help accelerate research into rare diseases. It was developed because access to information about rare diseases presents a challenge to researchers, patients and their families. CoRDS provides a way for researchers conducting clinical trials to search for individuals who would be able to participate in their clinical trial, and keeps individuals aware of the opportunities to participate in clinical trials.

Why would I want to enroll?

A rare disease registry like CoRDS:

- Provides researchers with a resource for identification and recruitment of potential research participants
- Provides individuals an opportunity to know about
- Has the potential accelerate research into rare diseases, an area where there is a need for research

I have already enrolled in a rare disease registry. Why should I enroll in CoRDS?

- The questionnaire is very brief and includes 8 questions asking about contact information, demographic information, diagnostic information and confirmation of the diagnosis.
- CoRDS personnel update this information annually to maintain accurate information which can be useful to researchers.
- This information can be collated (organized) in a registry with all rare diseases. Since treatments are based on symptoms and symptoms sometimes overlap among the rare diseases, having a registry for all rare diseases increases the numbers who might be eligible for a clinical trial and presents individuals with opportunities for clinical trials that they might not know about through the registry in which they are already enrolled.

What type of information are you collecting?

- The CoRDS questionnaire asks questions about contact information, demographic information, clinical diagnosis, how the diagnosis was confirmed and if the participant has interest in participating in future research studies.

Who has access to the information in the CoRDS database?

Any researcher with Institutional Review Board (IRB)¹ approval and approval from an advisory board convened by Dr. Pearce. The researchers will only be able to see “de-identified² patient data.

What happens to my information once I enroll?

The information provided will be stored in a secure database at the Sanford Children’s Health Research Center in Sioux Falls, SD. A subset of de-identified information collected CoRDS participants may be shared with other databases if they have IRB approval and have been approved by an advisory panel convened by Dr. Pearce. We will combine our data with other databases in order to develop a better understanding of rare diseases that may lead to new research studies, clinical trials, and clinical treatments. We want to merge this data with other databases in an effort to promote collaboration among existing rare disease organizations and research efforts.

Will my information be kept confidential?

The CoRDS registry has to follow rules to protect information about the participant. Federal and state laws also protect the participant’s privacy. All confidential electronic information will be stored in our Velos eResearch Clinical Research Management System using a secure computer. Any confidential paper information (consent forms, questionnaires) will be stored in secure, fireproof cabinet. Every possible effort will be made to maintain confidentiality. In the unlikely event that there was a breach in the database, all participants will be notified.

How will I be contacted about future research studies?

When a researcher would like to contact potential participants for a clinical trial, they will search for eligible participants in the CoRDS registry and then complete a request for contact form. CoRDS personnel will then contact those individuals on behalf of the researcher. The CoRDS participant can decide whether or not they would like to participate

¹ An IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the **IRB**

² De-identified data has been stripped personal identification such as name and contact information)

in the clinical trial. If interested, the participant can contact the researcher about the research study.

Is there a cost?

No, there is no cost to enroll in the CoRDS registry.

Do I have to participate in a research study if I join CoRDS?

No, the participant will never have to participate in a research study if he/she does not want to.

What if I change my mind about being in CoRDS?

The participant can withdrawal from the CoRDS registry at any time. Simply contact CoRDS personnel at 605-312-6413 or via email at cords@sanfordhealth.org. Once the participant withdraw from CoRDS, all of the participant's identifiable information will be removed and future researchers who are searching the registry would not see the participant's de-identified record. The participant may still be able to be contacted by those researchers the participant have already released the participant's contact information.

I would like to join the CoRDS registry. How Do I Enroll?

Individuals contact CoRDS personnel indicate the best phone number and time at which to reach them. CoRDS personnel will contact the individual to discuss the CoRDS registry and gather mailing information to send them consent forms and a brief questionnaire. If individuals are unable to make contact over the telephone, we are also able to send the forms via email. Once the appropriate signed consent forms and completed questionnaires are received, CoRDS personnel will enter patient information into our CoRDS database.

I have more questions about CoRDS. Who Do I contact?

We would be happy to hear from potential participants and answer any questions they have about the CoRDS registry. Please contact Cords@sanfordhealth.org or 605-312-6413 to talk with a member of the CoRDS team.

Learn more about the CoRDS registry on our website www.sanfordresearch.org/cords.

Can I share information about CoRDS?

Yes. If you know of anyone who would be interested in enrolling, they may send their contact information to CoRDS personnel via email cords@sanfordhealth.org or by phone at 605-312-6413. Anyone can learn more CoRDS about at www.sanfordresearch.org/cords.

About Sanford Children's Health Research Center

Sanford Children's Health Research Center is a two-site campus researching a childhood diseases at locations in Sioux Falls, SD, and La Jolla, CA. The La Jolla site is located within the Sanford-Burnham Medical Research Institute. A unique partnership is in place with the Sanford-Burnham Medical Research Institute (La Jolla, CA), as well as national and international research relationships through Sanford Children's Hospital. We're actively using interdisciplinary approaches and establishing collaborations on a national level to understand the underlying basis of a number of childhood diseases and maladies.

About Sanford Research

Sanford Research is a non-profit research organization formed between Sanford Health and the University of South Dakota. In 2007, a transformational gift of \$400 million by Denny Sanford has allowed for an expansion of current goals and will enable Sanford Research to become one of the premiere research institutions in the United States and the world. Sanford Research is composed of several research centers, including Cancer Biology, Cardiovascular Health, Health Disparities, Methodology and Data Analysis, Sanford Children's Health, and the Sanford Project.

About Sanford Health

Sanford Health is an integrated health system headquartered in Fargo, ND and Sioux Falls, SD and consists of two long-standing organizations that merged in 2009. Sanford is now the largest, rural, not-for-profit healthcare system in the nation with a presence in 110 communities in eight states. In addition, Sanford Health is in the process of developing international clinics in Belize and Ireland. Sanford Health includes 30 hospitals, 111 clinic locations and more than 800 physicians in 70 specialty areas of medicine. For more information, visit www.sanfordhealth.org.