CoRDS Registry

Coordination of Rare Diseases at Sanford

Coordination of Rare Diseases at Sanford (CoRDS):

An international patient registry at Sanford Research

Catie Olson

CdLS Foundation Webinar

January 20, 2015

SANFORD RESEARCH

About CoRDS

Mission: To accelerate research into rare diseases

Goal: To establish an international rare disease patient registry for all rare diseases

- Create resource of contact information and clinical data on individuals diagnosed with any rare disease to enable a comparative analysis across diseases
- Provide a mechanism by which researchers can identify and contact patients interested in participating in research

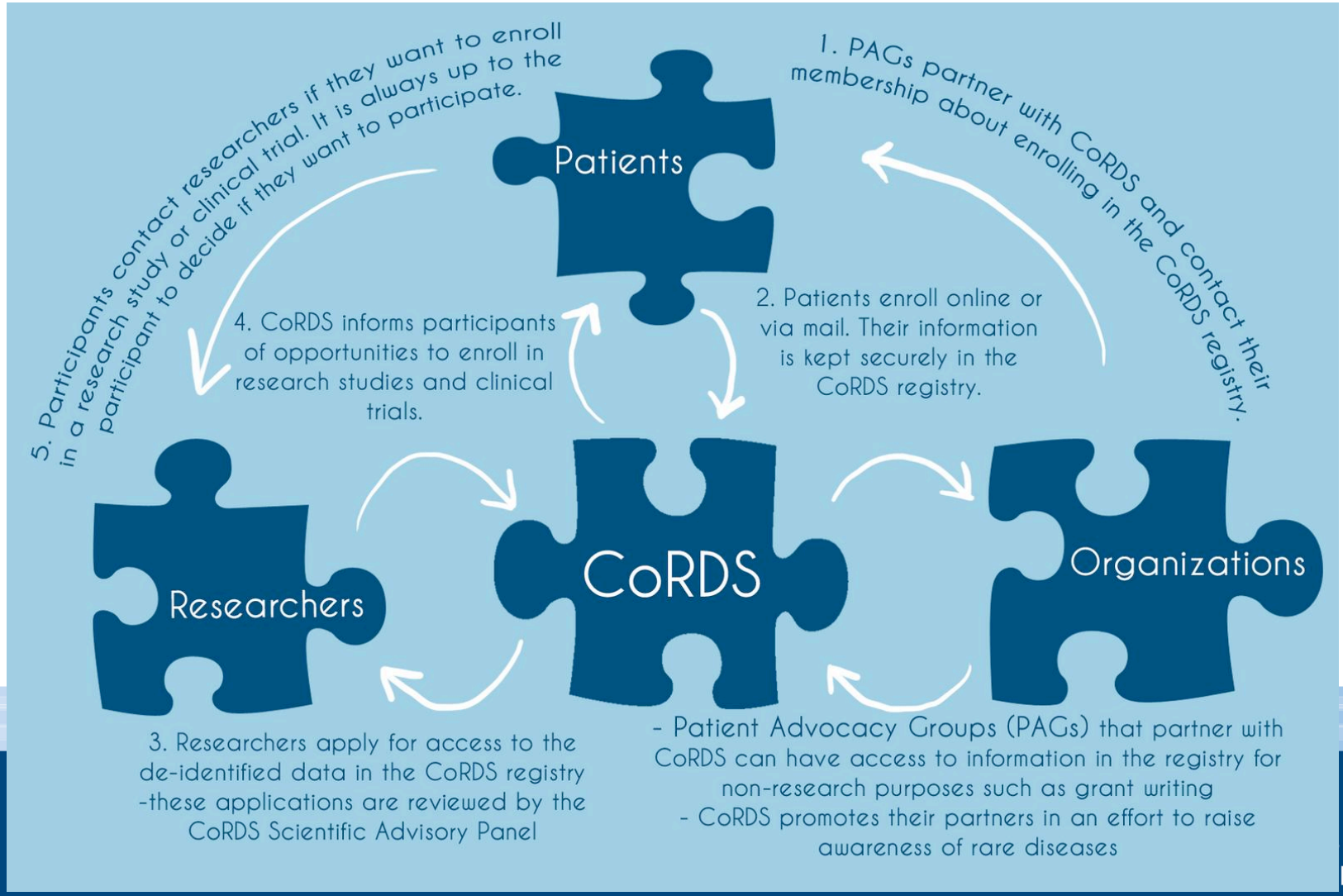
*The term “disease” is used to encompass all rare conditions.

What makes CoRDS unique?

- First of its kind; central resource for all rare diseases; allows for comparative analysis across diseases
- Unique collaboration with patient groups to establish a registry and customize a questionnaire
- Any researcher with IRB approval would have access to the information pending review from advisory panel
- Enrollment option for individuals who are not represented by a rare disease organization and those who are undiagnosed
- **No cost** for patients and families to enroll, no cost for researchers to access, no cost for patient groups to start a registry

Who is involved?

Patients, Researchers & Patient Groups



How are patients & families involved?

- Participants that enroll can contribute information to the CoRDS database by filling out a brief questionnaire
- Participants may learn about research opportunities for which they are eligible
- When notified about research opportunities, they have the ability to decide whether or not they would like to participate

Why would an individual want to participant in CoRDS?

- Provides individuals an opportunity to be informed of research studies and clinical trials for which they are eligible
- Provides researchers with a central resource for the identification and more rapid recruitment of potential research participants
- Has the potential to accelerate research into rare diseases
- No financial cost, not difficult or time consuming to enroll

What is involved after enrollment?

- CoRDS requests and reminds participants to complete their enrollment & update their information annually.
- There is no cost to enroll
- No obligation to participate in research - participants are free to decline any or all research opportunities
- Participants can change preferences and withdraw at any time.

How do researchers access CoRDS?

- Submit brief application to CoRDS Scientific Advisory Board
- Login and access de-identified data
- Identify participants that are eligible for specific research studies
- CoRDS personnel contact participants on behalf of the researcher

How are Patient Groups involved?

- Organizations without a registry can partner to catalog important data
- Flexible to accommodate needs of stakeholder ie customized questionnaires, access to data for non-research purposes, etc.
- No cost for organization to establish a registry
- IRB and IT personnel in-house, software infrastructure for secure data collection & management

CoRDS Patient Registry for the Cornelia de Lange Syndrome Foundation

- Launched August 2014
- Disease-specific registry for individuals diagnosed with Cornelia de Lange Syndrome
- Utilizes common data elements, as well as disease-specific data elements
- Cornelia de Lange Syndrome Foundation has access for non-research purposes and is involved with researcher review process

CoRDS-CdLS Registry Metrics

- Currently the Cornelia de Lange Syndrome Foundation's disease-specific registry includes:
  - 41 fully enrolled participants
  - 44 participants in screening
- Participants have enrolled from
  - 22 US States
  - 2 Countries (United States and India)

Enrollment Options

1. Online Enrollment
   - Web-based enrollment platform (April 2012)

2. Mail-Based Enrollment

3. In-person Enrollment
   - Patient Advocacy Group annual meetings
   - Sanford Health clinics

How do I enroll?

Step 1:

- Participant completes CoRDS Registry Screening form on CoRDS website: sanfordresearch.org/cords
- Participant receives unique username & password via email or receives their forms by mail

CoRDS Registry

Coordination of Rare Diseases at Sanford

CoRDS Registry Form

If you are interested in enrolling in the Cords Registry, please complete the brief screening form below and click submit. You may indicate below if you'd like to enroll online or by mail.

After submitting this form, CoRDS personnel will send you the information you need to complete to enroll if you would like to enroll online, cords personnel will send you an email with a username and password needed to log-in and enroll on the secure site. If you would like to enroll by mail, cords personnel will send you the forms necessary for you to enroll.

Please submit the following:

*Participant First Name:

*Participant Last Name:

*Participant Date of Birth(MM/DD/YYYY):

*Diagnosis:

Parent or Legally Authorized Representative Name:

*Phone Number:
(Please enter your 10-digit phone number i.e. xxx-xxx-xxxx)

*Best time to call:

*Time Zone: Select

*Email:

Preferred Method of Enrollment: Select

If your preferred enrollment method is mail-based, please provide your mailing address below. (Street address, City, State, Zip code, Country)

Street Address:

City/Town:

State: Choose Your State Here

Postal Code:

Country:

*Referred by (Name of Organization/Healthcare Provider):

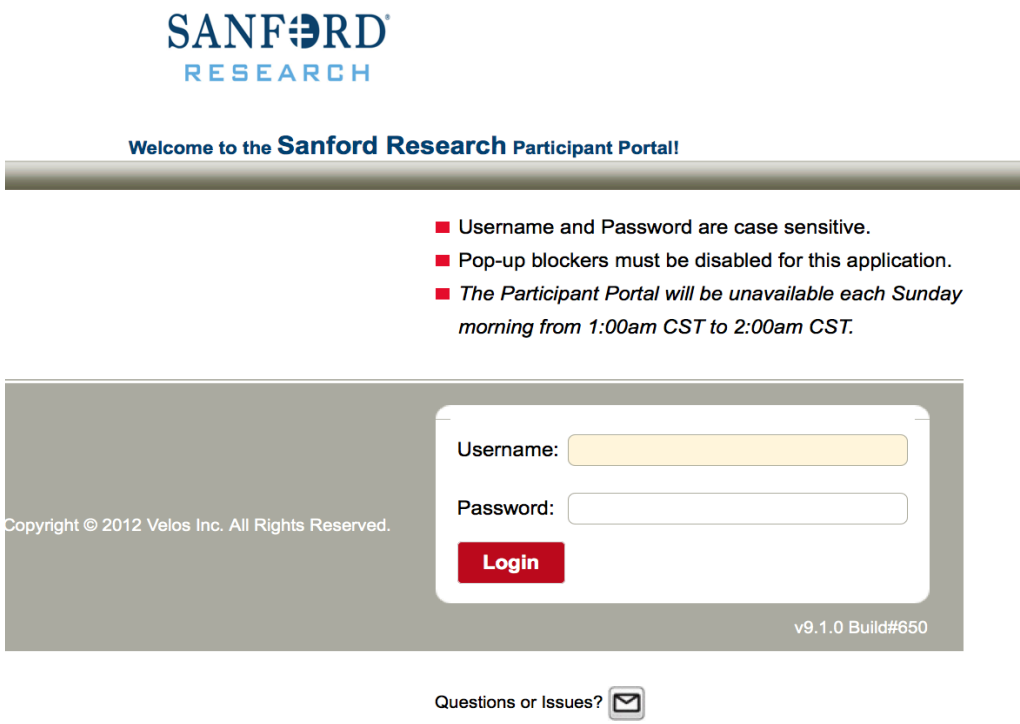
RESEARCH

Online Enrollment

Step 2:

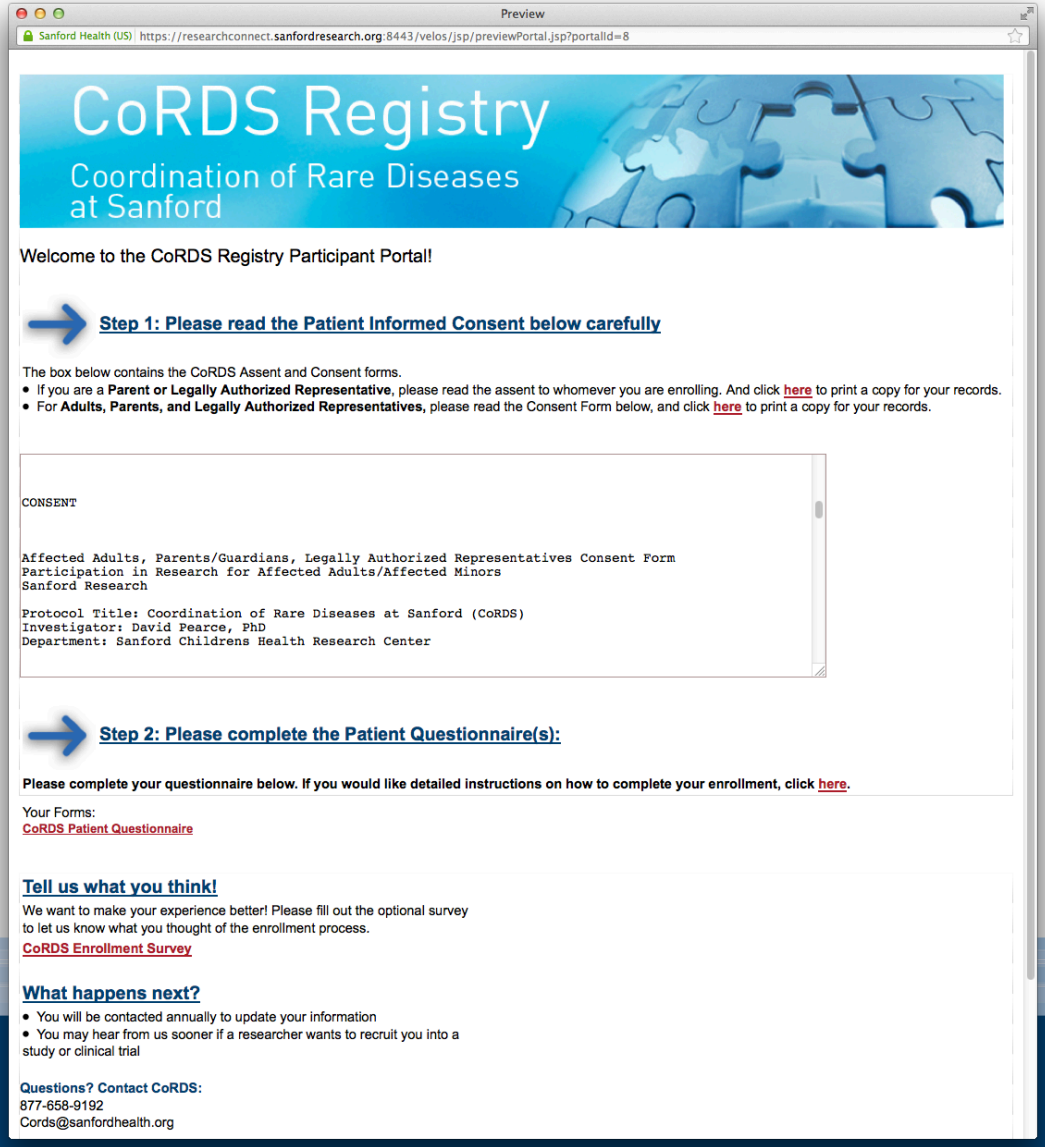
- Participant logs in with their username & password
- Participant reviews Informed Consent and completes questionnaire

*CoRDS contacts participants annually to update their information. Participants may login anytime to update their information



SANFORD RESEARCH

Informed Consent



SANFORD RESEARCH

Cornelia de Lange Syndrome Questionnaire

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.

Step 2: Please complete the Patient Questionnaire(s):

The Cornelia de Lange Syndrome (CdLS) Registry is broken up into several forms, allowing you to answer some or all of the questions in one sitting.
If you would like detailed instructions on how to complete your enrollment, click here. A glossary of medical terms can be found below.

For best results, use Internet Explorer or Mozilla Firefox to login to the secure web portal. **In the past, participants have encountered problems while completing the form with Google Chrome.** If you typically use Google Chrome as your web browser, we would recommend that you switch to Internet Explorer or Mozilla Firefox to access the portal.

Your Forms:
CoRDS Enrollment Form
CdLS Registry Form 1 of 5
CdLS Registry Form 2 of 5
CdLS Registry Form 3 of 5
CdLS Registry Form 4 of 5
CdLS Registry Form 5 of 5

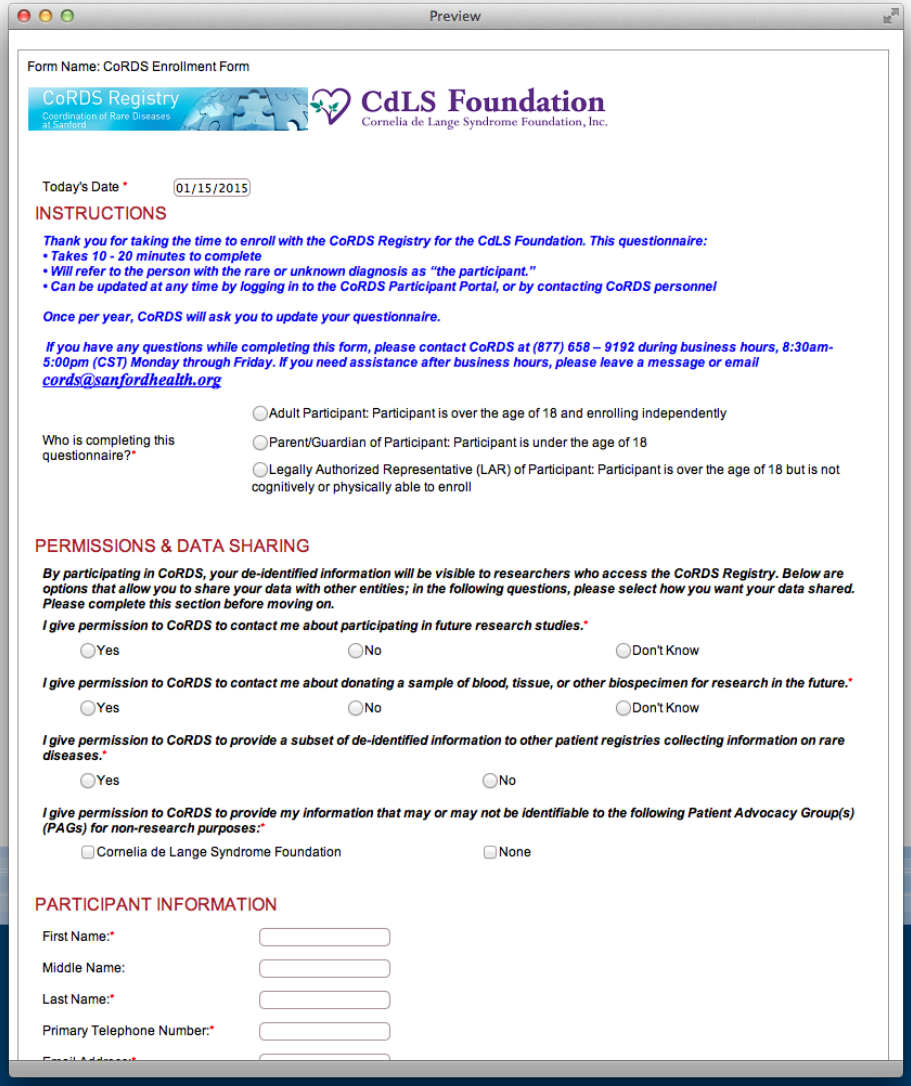
CdLS Questionnaire Glossary

Tell us what you think!

We want to make your experience better! Please fill out the optional survey to let us know what you thought of the enrollment process.
CoRDS Enrollment Survey

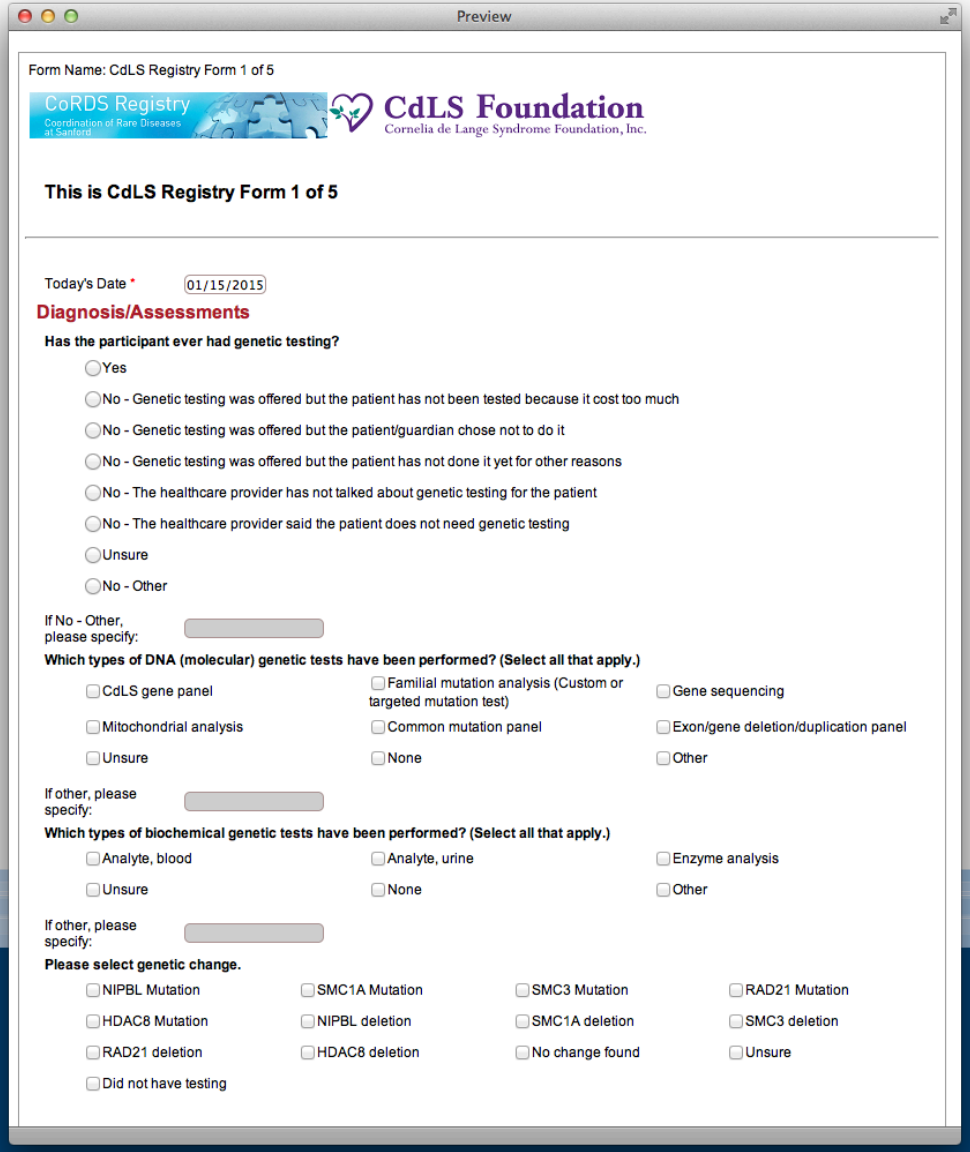
SANFORD RESEARCH

CoRDS Enrollment Form



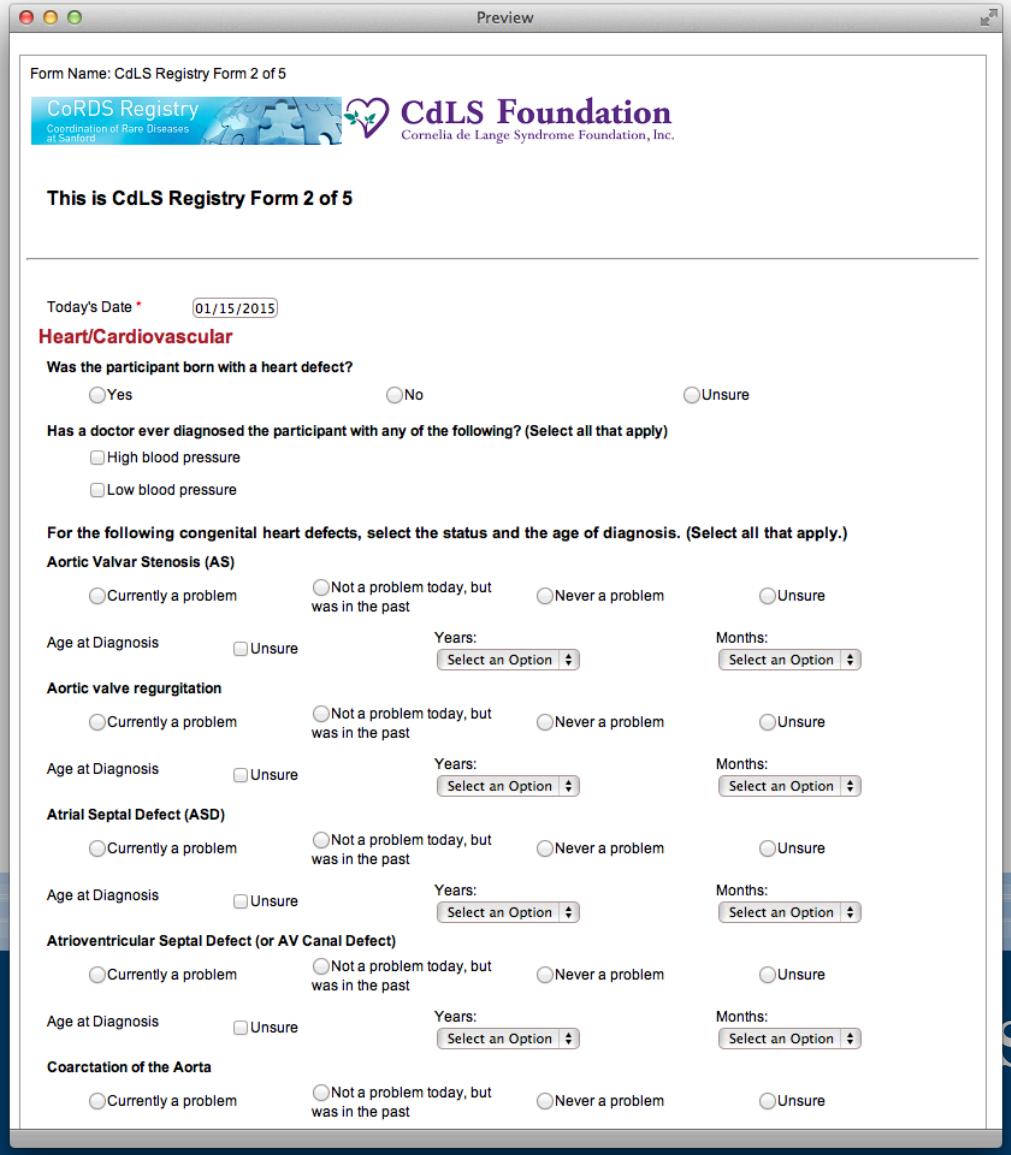
SANFORD RESEARCH

CdLS Registry Form 1 of 5



SANFORD RESEARCH

CdLS Registry Form 2 of 5


Preview

Form Name: CdLS Registry Form 2 of 5

CoRDS Registry
Coordination of Rare Diseases at Sanford

CdLS Foundation
Cornelia de Lange Syndrome Foundation, Inc.

This is CdLS Registry Form 2 of 5

Today's Date * 01/15/2015

Heart/Cardiovascular

Was the participant born with a heart defect?

Yes No Unsure

Has a doctor ever diagnosed the participant with any of the following? (Select all that apply)

High blood pressure

Low blood pressure

For the following congenital heart defects, select the status and the age of diagnosis. (Select all that apply.)

Aortic Valvar Stenosis (AS)

Currently a problem Not a problem today, but was in the past Never a problem Unsure

Age at Diagnosis Unsure Years: Select an Option Months: Select an Option

Aortic valve regurgitation

Currently a problem Not a problem today, but was in the past Never a problem Unsure

Age at Diagnosis Unsure Years: Select an Option Months: Select an Option

Atrial Septal Defect (ASD)

Currently a problem Not a problem today, but was in the past Never a problem Unsure

Age at Diagnosis Unsure Years: Select an Option Months: Select an Option

Atrioventricular Septal Defect (or AV Canal Defect)

Currently a problem Not a problem today, but was in the past Never a problem Unsure

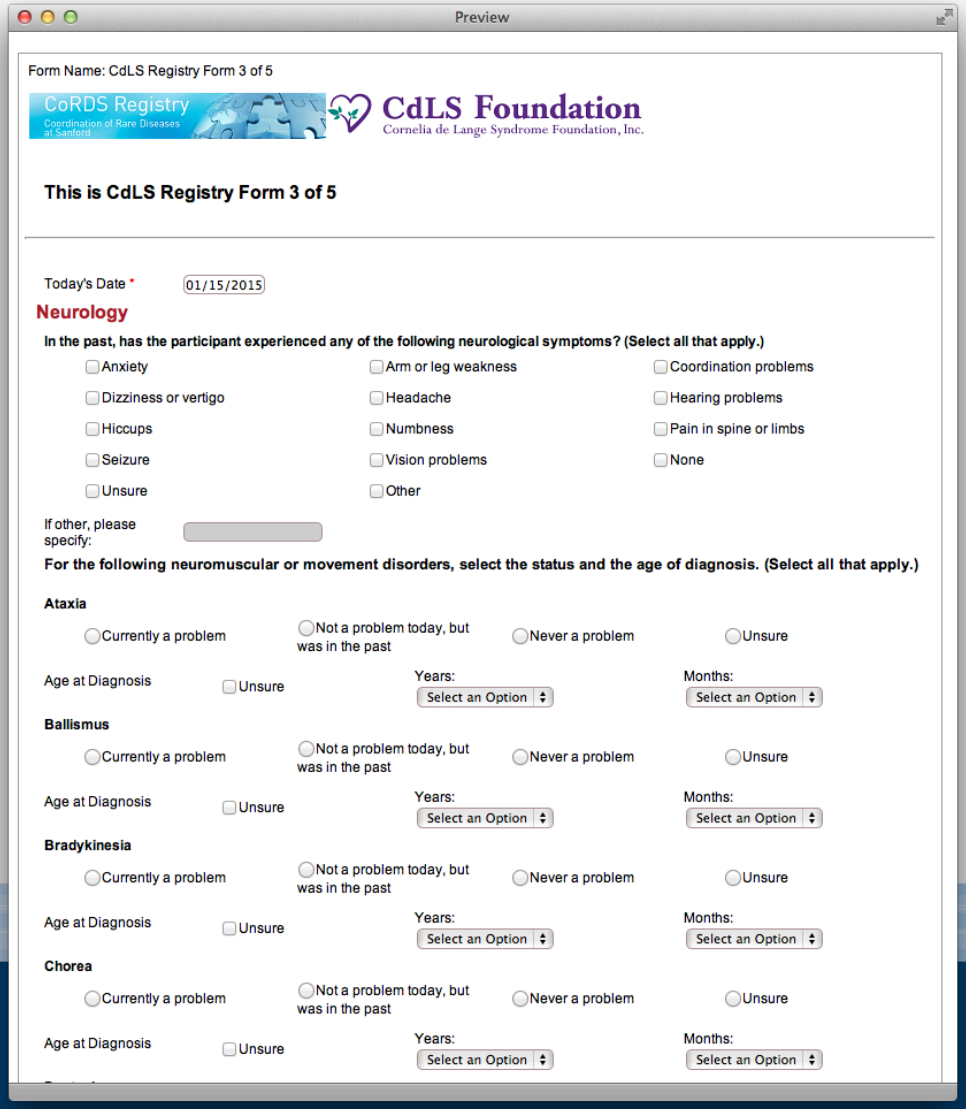
Age at Diagnosis Unsure Years: Select an Option Months: Select an Option

Coarctation of the Aorta

Currently a problem Not a problem today, but was in the past Never a problem Unsure

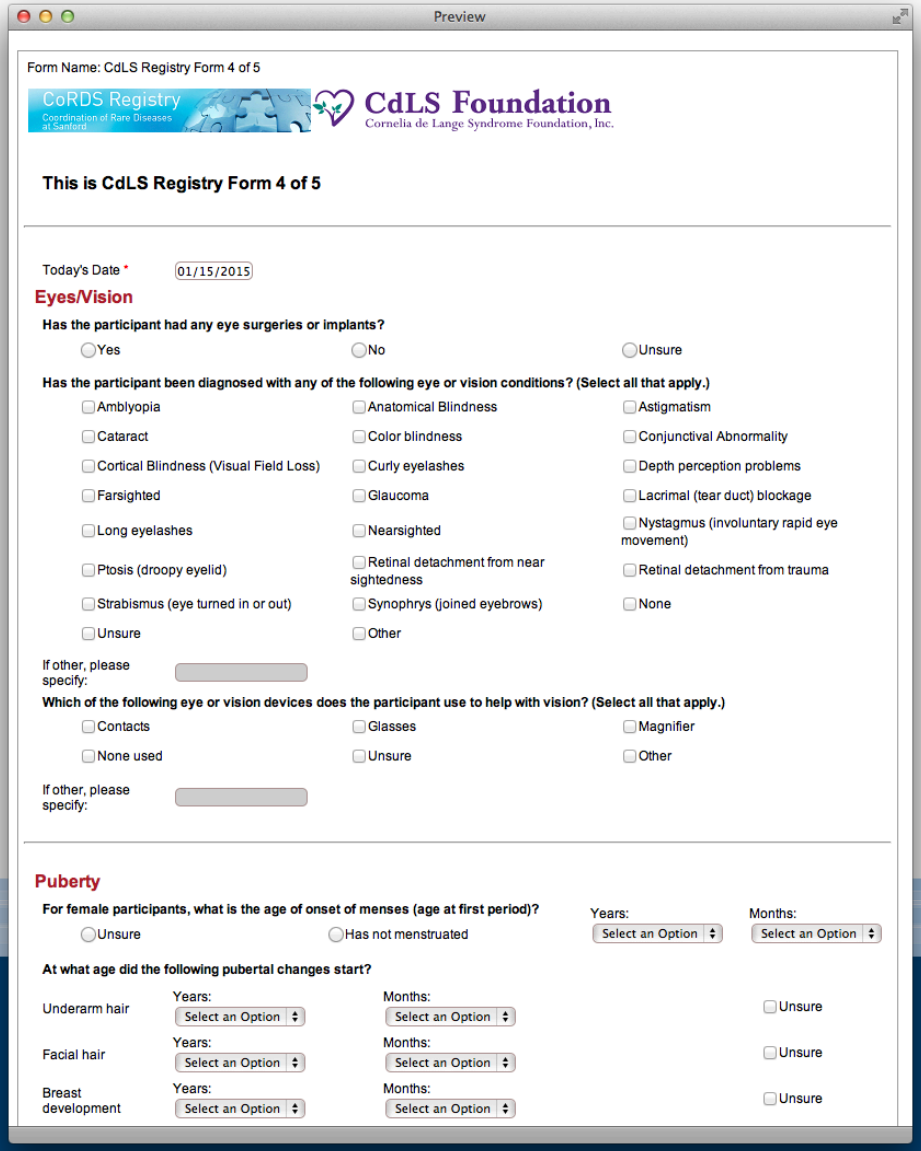
SANFORD RESEARCH

CdLS Registry Form 3 of 5



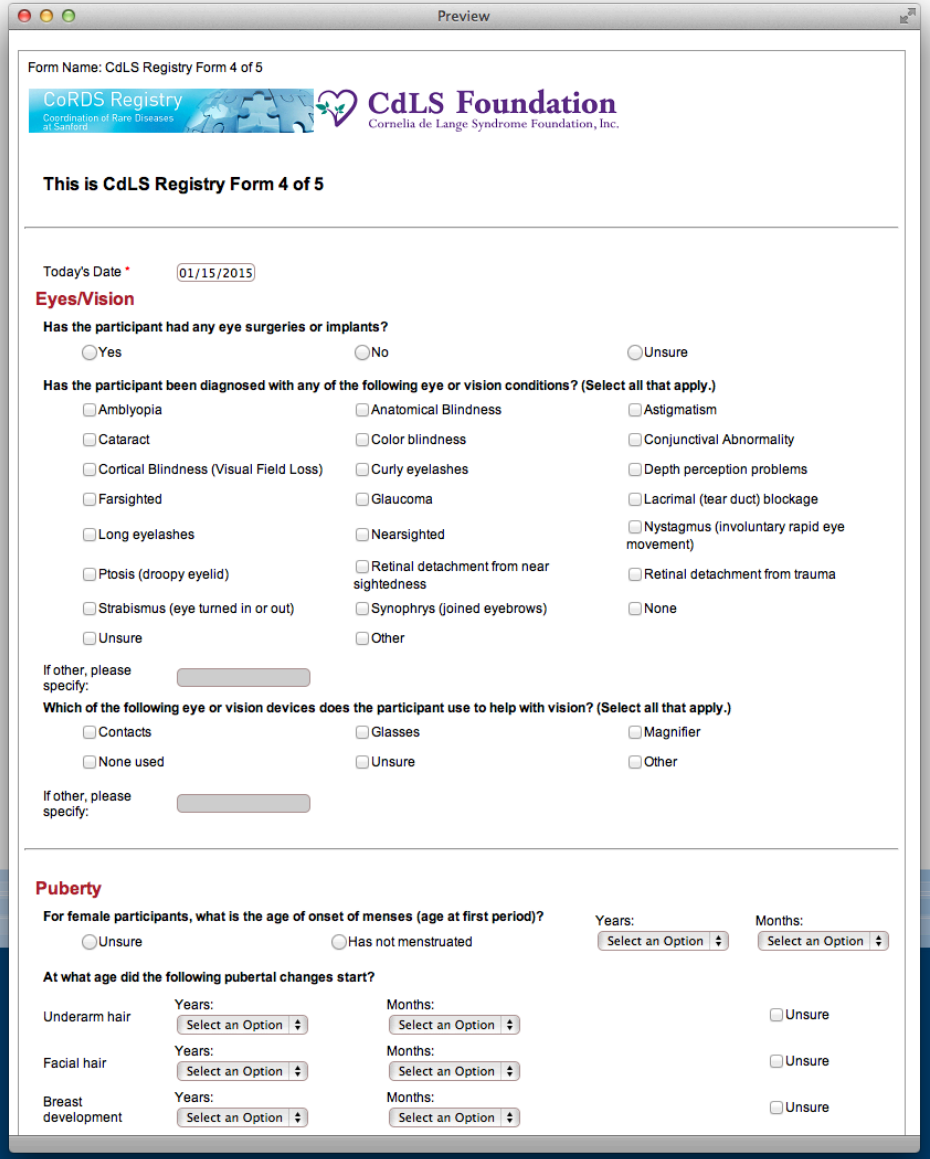
SANFORD RESEARCH

CdLS Registry Form 4 of 5



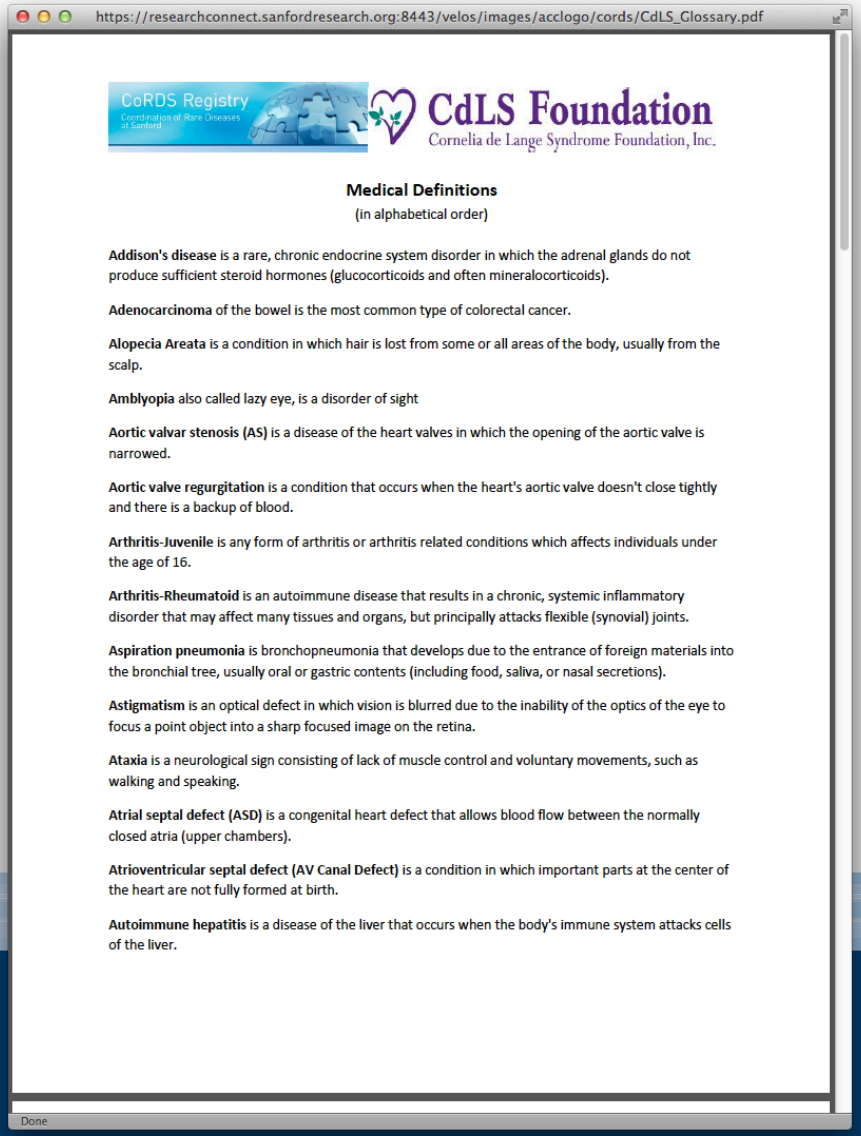
SANFORD RESEARCH

CdLS Registry Form 5 of 5



SANFORD RESEARCH

CdLS Questionnaire Glossary



SANFORD RESEARCH

What information is collected in the CoRDS module?

Demographic information:

- Name
- Date of birth
- Gender
- Race
- Contact information
- Data-sharing preferences

*Includes Common Data Elements (CDEs) as recommended by the National Institute of Health (NIH).

What information is collected in the disease-specific modules?

Clinical diagnosis information

- Diagnosis
- Symptoms
- When/where testing occurred
- How diagnosis was made
- Family history

SANFORD RESEARCH

Data Management

- Velos E-Research Software
- Centralized, relational database of rare disease data
- Provides a mechanism to securely collect, modify, display, & report data
- Secure patient portal allows for online enrollment
- Easily searchable using common data query (SQL) commands
- Supports multiple languages, data curation

CoRDS Partners

Research and Resource Group, Inc.

Lowe Syndrome Association

FMD Chat

National Ataxia Foundation
www.ataxia.org

ML4 FOUNDATION
Mucolipidosis IV Foundation

CHILDREN'S® PROJECT

CdLS Foundation

SIP

ABDA
American Behcet's Disease Association

the global genes project

Kawasaki Disease Foundation

madisons FOUNDATION

BATTEN DISEASE SUPPORT & RESEARC ASSOCIATIO
A LIGHT IN A WORLD OF DARKN

XLH NETWORK

TEAM Sanfilippo FOUNDATION

Glut1 Deficiency Foundation
www.G1DFoundation.org

SANFORD Children's

PVNH
support & awareness™
the international neuronal heterotopia disorders community

APS Foundation of America, Inc.

rkng14 USA OUTREACH

Mowat-Wilson Syndrome

1p36Deletion
SUPPORT & AWARENESS

SANFORD RESEARCH

CoRDS Registry

Coordination of Rare Diseases at Sanford

Questions?

Catie Olson
Director, CoRDS
605.312.6413
Catherine.Olson@sanfordhealth.org
www.sanfordresearch.org/cords

SANFORD RESEARCH