

You must consent to the information in the **Recruitment Statement** and the **HIPAA Authorization Form** in order to participate in the CSCDP.

**SAINT LOUIS UNIVERSITY**  
**Recruitment Statement for Research Participation**

Dear Potential Research Participant,

Meg Hefner, Adjunct Associate Professor of Pediatrics, and her research team would like to invite you to participate in a research study on CHARGE syndrome (CS). The study is being conducted at Saint Louis University (SLU). It is called the CHARGE Syndrome Clinical Database Project (CSCDP). You may participate if you or your child has been diagnosed with CS.

Although this is a long statement, it is very important. Please read through the whole Recruitment Statement before agreeing to the study. We really want you to read this so you know what we are doing with your/your child's data.

**Background**

CSCDP is an Internet web-based questionnaire designed to collect data (information) on CS. This research is being supported in part by the CHARGE Syndrome Foundation, Inc. We have many goals for this project. Goals of the project are to:

- Collect information on people with CS of all ages from all over the world
- Use the collected data to understand more about CS and how it affects different individuals. For example, we can use the database to answer questions like
  - How many people with CS develop seizures and at what ages?
  - How many people with CS take growth hormone and has it helped?
- Find new features that have not yet been recognized as part of CS
- Follow individuals with CS over time to see what problems come up at different ages
- Help with other CS research by identifying people with specific issues.
- Create a registry of baseline information to simplify participation in other CS research studies. Once data is entered into the CSCDP, it can be made be available for other research through a Data Use Agreement (DUA) with SLU. For example, say Scientist A wants to study the effect of cochlear implants in CHARGE. Once a DUA is in place, data from CSCDP can be transferred to Scientist A as a starting point. Scientist A will then only need to ask you questions about cochlear implant -- you will not have to re-answer all of the baseline questions to participate in that research project.

This statement explains:

1. Who is eligible to participate
2. What you are agreeing to if you consent
3. How you can participate
4. How your data will be used
5. How we protect your data and keep it private
6. The benefits and risks of participation

7. Your options and how to withdraw
8. Whom to contact if you have questions

**1. Who can participate?**

You are eligible to participate if you are the parent or guardian of an individual with CS or an independent adult with CS. You need to have a valid email address and access to the Internet to participate. The survey is in English only. All data entered needs to be in English.

**2. What am I agreeing to?**

When you check the “I ACCEPT” box, you agree to let CSCDP researchers use the data you enter for CS research at SLU. You also agree to permit CSCDP to share your data with other studies through a DUA between SLU and other researchers (see sections 4 and 5 below). “Data” includes all of your answers to the survey questions. It also includes any photographs or documents you choose to upload. You must enter the name and birthdate of the person with CS. Beyond that, none of the data items are “required.” You may choose to not answer any questions or upload photographs or documents. The CSCDP researchers and other approved studies may use any data you choose to enter for research, publications and teaching.

**3. How do I participate - what is involved?**

Your participation in this research project is completely voluntary. If you choose to participate, you agree to (1) enter data, (2) allow the CSCDP research team to use and share the data as described above and (3) allow CSCDP to contact you by email. You will access the questionnaire on the Internet using your computer at home. You will be given a link for entering your data. There are many sections to the questionnaire. At the end of each Section, you have the option of stopping and returning later (“Save and Return”) or Submitting that Section (“Submit”).

**a. What information is REQUIRED? How will you use my email address?**

You may choose not to answer individual questions. Other than your name and the name and date of birth of person with CS, none of the questions are Required – you may choose to not answer some questions. We will use your email address to contact you:

- We may send emails to remind you to complete the survey sections
- We may occasionally send emails to ask for updates on the person with CS
- When we add a new Section, we may send an email to invite you to complete the new section
- We may send you an email to alert you to a CS research project that may interest you

**b. What kinds of questions are asked?**

For a more complete description of what is asked in each Section, including what sort of questions will be asked and estimated time to for completion, click here or go to the Research Tab at [chargesyndrome.org](http://chargesyndrome.org)

#### SECTIONS

Information and Consent  
Demographics  
Birth History  
Major Features of CHARGE  
Minor Features of CHARGE and Other Findings  
Genetic Testing  
Surgeries and Hospitalizations  
Vision  
Hearing  
Milestones and Growth  
Neurology  
Medication, Bone Health and Sleep  
Summary: Additional Photos and Comments

There are several opportunities to upload photographs (e.g. face) and specific documents (e.g. genetic testing, growth charts, audiograms). You can see the section descriptions and other details in the CSCDP link at the Research tab at the CHARGE Syndrome Foundation website ([chargesyndrome.org](http://chargesyndrome.org)). Looking over each description before starting it will help you be prepared to enter data into that section. For example, for in Genetic Testing, you will be asked for results of CHD7 gene testing and any other genetic testing that was performed.

#### **c. Is it all online? How do I submit the information?**

This is a web-based questionnaire. You will need email and Internet access to be able to complete the consent information and to enter data for the project. For detailed information on data entry, see the Frequently Asked Questions (FAQ) for CSCDP in the Research tab of the CHARGE Syndrome Foundation website: [chargesyndrome.org](http://chargesyndrome.org).

#### **d. How long will it take? Can I start and stop?**

Completing all of the survey sections will take several hours. This can be done in multiple sittings. For details on how to start, stop and save, see FAQ.

#### **4. How will my data be used?**

The collected data will be used to more fully understand the features and natural history of the CS and as a registry of baseline information for other CS research. Data will be shared with CS research projects through Data Use Agreements (DUA) between SLU and the other investigators. Before a DUA is signed and data are transferred, the external (recipient) investigator must provide copies of recruitment and consent materials and proof of human subjects approval, including provisions for privacy and confidentiality. Although identifiable information can be shared with a DUA, no identifiable information will be released or published by SLU or other investigators. We

hope the data will eventually aid in developing treatments or predicting risks related to CS. Findings based on data collected through the CSCDP may be published and/or presented at conferences. Publications may include medical journals and CHARGE Syndrome Foundation publications. Presentations may be at professional conferences and CHARGE Syndrome Foundation conferences. Names and identities will not be revealed and records will remain confidential even when shared with other investigators through DUAs.

**5. How do you keep my data protected and private?**

The data will be stored on a secure computer system at SLU. As described above, data (including identifying information) will be shared with other approved CS research projects through DUAs. Every DUA will require the recipient organization to have provisions for privacy and confidentiality such that your identity will not be revealed. The only other times individual or identifying information will be released are

- If required to do so by law, CSCDP investigators may release the individual-level information.
- The Institutional Review Board and government officials responsible for monitoring this study may inspect the study records.

**6. What are the benefits and risks of participating?**

**Benefits:** Participation in the CSCDP will probably not directly benefit you/your child. We hope it will make it easier to participate in future CS studies. One of the goals of the CSCDP is to make meaningful contributions to CS research. If CSCDP investigators publish study results in peer-reviewed journals, there may be an indirect benefit to you as understanding of CS increases.

**Risks:** There are some potential risks to participating in the CSCDP, as described below:

- Some questions may make you uncomfortable. You may choose not to answer questions that make you uncomfortable.
- Your questionnaire responses, and/or personally identifying information may be stolen in the event of a security breach. Even the best electronic Protected Health Information (PHI) storage system cannot be 100% secure from all possible threats. We have strong measures in place to minimize the possibility of a breach. We cannot provide a 100% guarantee that your data will be safe.
- Nothing about this project is invasive or experimental. The procedures involved do not involve more than the minimal risks described above. No compensation or treatment is available as a result of participation.

**7. How long will this study last? Can I withdraw from this study?**

It is important to know that we are not telling you to take part in this project. Your participation is voluntary and you can choose not to participate. Whether or not you participate in the CSCDP will have no effect on your relationship with the CHARGE Syndrome Foundation or SLU. If you decide not to participate, there will not be a penalty to you or loss of any benefits to which you are otherwise entitled. You may stop

participating in the CSCDP at any time. Even if you do consent to participate in this project, you may still choose not to complete any question or section of the questionnaire. At any time, you may choose to withdraw from the project. To withdraw, send an email specifically requesting to withdraw from CSCDP to Meg Hefner directly at [hefnerma@slu.edu](mailto:hefnerma@slu.edu) and to CHARGE-survey@slu.edu. Any research on your data that has been performed or published prior to this date will not be reversed, undone, or withdrawn. Information that you have already submitted will remain in the database. The CSCDP is intended to be long term: there is currently no end date. We hope to gather longitudinal data (information over time), including into teen and adult years.

Parents/guardians must consent and enter data for children under 18 and wards.

**Independent adults with CHARGE must provide their own consent.** As youths with CHARGE become independent adults, they will be required to consent to the project if they wish to continue to have additional data collected.

#### 8. **Whom do I contact if I have questions?**

If you have questions, please email CHARGE-survey@slu.edu or contact Meg Hefner directly at hefnerma@slu.edu or (314) 991-9638. If you have questions about your rights as a research participant, you may call the SLU Institutional Review Board at (314) 977-7744.

#### **I want to participate. What do I do now?**

If you have read this entire Recruitment Statement and wish to participate

- Consent to all of the information in this Recruitment Statement by choosing "I Accept" below
- Read the HIPAA (privacy) statement below and choose "I Accept"

If you Accept both documents and Submit, you will be taken to Section 1 - Demographics

Q1.2 By selecting "I Accept", I certify that I have read the CSCDP Recruitment Statement and have been able to ask questions and state any concerns. The researcher has responded to any questions and concerns. I believe I understand the CSCDP and the potential benefits and risks that are involved. I give my informed and voluntary consent to take part in the CSCDP.

- ☐ I Accept (1)
- ☐ I don't Accept (2)

If Don't Accept Is Selected, Then Skip To End of Survey