



## **Inform Congenital Heart Disease (InformCHD)**

*A Patient-Reported Database*

Sponsored by Conquering CHD

***Before completing an InformCHD survey, it is important that you understand how your information will be protected and used, both now and in the future.***

***If you have questions or concerns about your participation, you may contact the database coordinator at [InformCHD@conqueringchd.org](mailto:InformCHD@conqueringchd.org).***

### **What is Inform Congenital Heart Disease (Inform CHD)?**

InformCHD is Conquering CHD's unique patient-powered database for the congenital heart community. InformCHD collects information from people with congenital heart disease longitudinally – this means it will gather information over the years.

The information we collect allows us to educate patients and the medical community, create and build programs, better advocate and inform future research.

### **What are InformCHD's goals?**

InformCHD will gather information directly from those who are affected by congenital heart disease. This provides a unique and very valuable perspective.

InformCHD will help researchers understand what it means to live with congenital heart disease from your point of view – with a goal of observing trends, improving outcomes and quality of life and identifying future research activities that are important to people with CHD.

InformCHD has been created to meet the immediate need to better understand trends, outcomes and future research needs related to COVID-19, but Conquering CHD plans to support the gathering of data through InformCHD indefinitely, as part of our commitment to patient-engaged research.

### **Who can participate?**

The information provided to InformCHD is open to any person with congenital heart disease of any diagnosis, age, race or ethnic background. Participation is entirely voluntary, and persons can opt out at any time. However, persons completing the survey must be at least eighteen (18) years of age, have the capacity to consent to participation and agree to comply with the privacy policy.

### **How do I participate?**

Information is collected mostly through online surveys.



If the person with CHD is under the age of eighteen (18) or not able to complete the surveys by themselves, a parent or guardian should complete the survey on their behalf. This will be noted on the survey.

An enrollment survey will be sent out upon request and may also be found on our website at [conqueringchd.org/InformCHD](http://conqueringchd.org/InformCHD). The enrollment survey takes 2-3 minutes and involves answering a few questions about yourself (such as name, email address, date of birth, gender, race/ethnicity, zip code, diagnosis and severity of your CHD).

Sub-surveys will be sent out periodically. Sub-surveys are shorter and focused on areas of interest, for example acute health, pain, women's issues, etc. These surveys should only take 5-10 minutes to complete. Participation in each survey is entirely voluntary and you can opt out at any time.

\*Note – due to the time sensitive response to COVID-19 the enrollment survey will be combined with a sub-survey as noted below. In an effort to understand the impact of COVID-19 over time, multiple related sub-surveys will be shared over the next 6-12 months.

#### **How is my information stored and reported?**

Conquering CHD has contracted with [ArborMetrix](#), an independent, outside organization that provides secure collection, storage and analytical support for all information gathered by InformCHD.

The information collected will be kept confidential and will only be reported in a de-identified and aggregate manner. De-identified means that we will replace your name with a coded number and have all personal identifiers (such as name, date of birth, emails, zip code, and any other information that might identify you) removed. Aggregate refers to combining de-identified information gathered from all other InformCHD participants. Information will always be reported in groups and percentages, never individually.

#### **How will the information collected be used in research?**

Conquering CHD will regularly review the de-identified and aggregate (combined) information gathered by surveys to look for relationships and trends. These findings may prompt Conquering CHD to dig deeper into a topic by either doing a more complete review, creating an additional survey to better understand the topic, and/or identifying helpful programs. Researchers outside of Conquering CHD (external researchers), may apply to have access to InformCHD's de-identified and aggregated data only, meaning none of the data shared will have any personally identifiable information. Both internal and external research will be overseen by Conquering CHD staff and will be evaluated by a multidisciplinary review committee that includes researchers, clinical experts and members of the congenital heart disease community. Examples of external researchers that may apply to have access to limited de-identified and aggregate data includes college/university students performing work in the



CHD community, academic researchers, pharmaceutical industry organizations and health insurance payors.

Benefits of research activities are generally indirect; research finding may benefit the congenital heart community in general, but not individual participants.

Conquering CHD is committed to sharing research findings with both the participants and the community in a clear and understandable manner through summaries and key findings.

### **Do I have to participate in InformCHD?**

Taking part in InformCHD is completely voluntary. You do not have to share information unless you want to. If you decide not to join us, there is no penalty to you or your family. No one will be informed of your decision. You will still be a part of the Conquering CHD community and have access to all our other activities and programs, both nationally and locally.

If you decide to participate in InformCHD, you can choose for how long and which surveys to answer. You can also change your mind at any time.

If you change your mind and no longer want to be part of InformCHD, you can stop answering the surveys (opt-out of them) or contact the InformCHD Coordinator at [InformCHD@conqueringchd.org](mailto:InformCHD@conqueringchd.org) and request that your account be deactivated. If you decide to deactivate your account, you will not need to offer a reason and will not be penalized or lose any benefits to which you are otherwise entitled.

*NOTE: Any de-identified information previously shared for a research study prior to an opt-out/account delete request cannot be retrieved or removed from the InformCHD database.*

### **Compensation and Cost to Participate**

There are no costs to join InformCHD. You will not be paid for participating in InformCHD.

### **What are the risks of joining InformCHD?**

The risks of taking part in InformCHD are very low and do not change over time. By agreeing to participate in InformCHD, you may learn information that is difficult or upsetting to you. ***It is important to recognize that each person with congenital heart disease is unique and any health concerns should be addressed by your healthcare provider.***

### **Security and Confidentiality of the Information**

Conquering CHD takes the safety, confidentiality and security of your information very seriously. Conquering CHD will never share your personal information with any third parties for research, marketing or any other purposes.



Although small, the loss of your private or confidential information is a risk. In the unlikely event of an information breach, we will let you know right away. Conquering CHD has contracted with [ArborMetrix](#), an independent, outside organization that specializes in data collection, visualization and measurement of clinical trends and outcomes. ArborMetrix will provide technical expertise including significant security protections to mitigate the risks associated with data loss, corruption and/or breaches. ArborMetrix uses a variety of encryption tools and security features to protect against data breaches and incorporates those security protections into InformCHD.

Among the security tools that InformCHD uses are software maintenance, continuous security monitoring and anti-virus updates; regular evaluations done by independent, outside security experts; multiple levels of restricted access to certain data (such as names and contact information), user access (for example, a password is needed to enter InformCHD), application access (meaning only staff with specific roles can access certain features or audit trails), and hosting services (including firewall and secure socket layers).

While we are using many tools and practices to ensure the security of information saved in InformCHD, we cannot guarantee the security of the information on your computer or mobile device. We also cannot guarantee the security of data while it is being sent to the InformCHD database from your computer or mobile device. To decrease this risk, we recommend you send information to InformCHD via a secure Wi-Fi or cellular connection.

Most Conquering CHD and ArborMetrix individuals with access to the information gathered by InformCHD view it in a de-identified and aggregate manner. However, the InformCHD coordinator and a handful of ArborMetrix staff have access to identified information. This access is required to ensure proper functioning of the infrastructure and dashboard. Access to identified information will be highly controlled and limited to essential personnel (based solely on need to know, job function and role) trained to protect participant's privacy.

Conquering CHD and ArborMetrix staff with access to identified information follows strict guidelines for confidentiality. Some of these access controls include human subjects certification, multi-factor authentication, single sign-on, and a strict "least-privileged" authorization policy.

Least privileged is a powerful security principle which states that no single person or entity should be able to access information or exercise privileges beyond what is necessary to perform their assigned role. Each entry into the database is user, date and time stamped for monitoring purposes.

For more details, please see the privacy policy [hotlink].



### **How do I benefit by participating in InformCHD?**

Participants of InformCHD will help improve the future of people living with congenital heart disease and their immediate family members, although the direct benefit to the participant is minimal. The participants will be able to benefit by utilizing the information and tools offered by InformCHD to take control of their health. These include:

- **Shared decision-making:** the information provided to InformCHD can be printed and shared. You can provide this information to your healthcare professional such as your cardiologist, nurse or emergency room staff. This survey report would provide details of your individual medical condition encouraging shared decision making when evaluating treatment options with your care providers.
- **Resources:** InformCHD will direct you to trusted, up-to-date, relevant and evidenced-based information about congenital heart disease and health. It will also help connect you to research opportunities.

### **Who is sponsoring InformCHD?**

InformCHD is a program of Conquering CHD. Conquering CHD is primarily funded by the generosity of individual donors. However, we do receive some support from medical institutions and industry partners. For more information please see our complete and current list of supporters.

There will never be an opportunity for any donor, sponsor or grantee to access patient level data.

External researchers will have the opportunity to query de-identified, aggregate information and be able to present research protocols that invite InformCHD participants to enroll. They will never have access to, or receive any identifiable information, including names, dates of birth or zip codes. These queries will be done through Conquering CHD's Research Program for a nominal fee in order to continue to support the InformCHD infrastructure.

For more information about proposals from external researchers, see section, "How will the information collected be used in research?"

### **Whom should I contact if I have any questions?**

If you have any questions about InformCHD or about your rights as a participant, contact the InformCHD Coordinator by email at [InformCHD@conqueringchd.org](mailto:InformCHD@conqueringchd.org).

By clicking the box below, you are stating you have read and understand this participant agreement.

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Conquering CHD