



CARDIAC SAFETY RESEARCH CONSORTIUM

June 8, 2017

To all interested cardiac screening groups:

The Cardiac Safety Research Consortium (CSRC) launched an initiative on the prevention of sudden cardiac death in the young (SCDY) and, in partnership with public screening groups including Parent Heart Watch, industry, academic institutions, and other interested participants, has convened three national meetings focused on developing a sustainable national health care resource on cardiac screening. This resource will consist of a data warehouse of information collected from the many screening efforts underway in this country. The accumulated data will enable powerful research and advocacy projects aimed to further understand SCDY and improve efforts for its prevention. Data collected across the diversity of our population will allow future improvements in the tools that are used, such as the ECG, to understand how age, gender, race, ethnicity, and activity level influence the detection and prevention of SCDY. The success of this initiative depends on partnership between the CSRC and screening groups across the country.

One of the first steps towards this success is to conduct a **nationwide pilot project**. The goal of this pilot project is to demonstrate that through the CSRC and screening group partnerships, reliable, uniform, digital data can be collected during screenings, regardless of group or location. The data that are collected during this pilot will enable the development of a sustainable national data warehouse.

We are at the point of submitting a protocol to a funding agency to secure limited funds to proceed with the national pilot screening project. We would like broad participation from a variety of screening groups. This would include grassroots foundations or parent groups who conduct a few small screenings each year, more established parent or foundation groups who have had years of experience in conducting ECG screenings and screen larger numbers on a yearly basis and those in between, industry groups who conduct screening efforts, and academic groups who oversee or perform ECG screenings. The participating screening groups and the other CSRC partners in this initiative will have access to these data through the CSRC.

The terms of participation will not necessarily require members to alter their methods or process of screening, but collection of uniform data elements that must be submitted electronically will be required. The participating screening groups will provide the required elements or Uniform Basic History form in a digital format. Additionally, ECG data must be digitally recorded and submitted. Follow up data for the first year of the pilot must also be obtained by the screening group (either by direct contact or by providing the parent of child or young adult with a contact link and guidelines). We expect that assistance with electronic collection and/or submission will be needed by some participating groups. The funds are not to be used to fund your screening efforts but to help with the additional work required to upload the digital Basic Uniform History form and the ECG data, and to provide the follow up



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information. The Pilot Study Leadership group will conduct site visits to help participants start this project and CSRC partners will assist with the digital transmissions and equipment, as needed.

If you or your group is interested and willing to participate in this pilot study, please complete the attached Interest Form and return by July 6, 2017. This form is also available on the CSRC website (www.cardiac-safety.org). We will conduct a group conference call or webinar to discuss the details of the pilot study and answer questions in early August. Given the nature of this pilot study, we would like to have 5-10 parent/foundation groups, 2-4 industry groups, and 3-5 academic groups as participants. Other interested groups will be able to join in future years, once the process has been created. We will select the final participants by the end of August and expect to launch the study between September and December of 2017.

We very much look forward to hearing from you and are excited about this important pilot study.

Sincerely,

CSRC Prevention of SCDY Leadership

Salim F. Idriss, MD PhD- Duke University Medical Center- Co-Chair

Theresa Wright, MD- Eli Lilly- Co-Chair

Mitchell Krucoff, MD- Duke University Medical Center- Co-Director CSRC

Stuart Berger, MD- Lurie Children's Hospital, Northwestern University- Working Group Chair

Tess Saarel, MD- Cleveland Clinic Foundation- Working Group Chair

Vicki Vetter, MD – Children's Hospital of Philadelphia – Working Group Chair

Valarie Morrow, MD- CSRC Project Manager

The Cardiac Safety Research Consortium (CSRC) is a multidisciplinary organization run by Duke University and the FDA whose purpose is to generate solutions to difficult problems related to cardiac safety by bringing together diverse partners to reach consensus solutions. The CSRC has a decade-long track record of many successes between public groups, academic professionals, industry partners, and other US and international governments regulatory representatives



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NATIONAL PILOT SCREENING PROJECT – INTEREST FORM

Complete and return by July 6, 2017

Organization Name _____

Contact Person _____

Street Address _____

City _____ State _____ Zip Code _____

Best Contact Number: _____

E-mail _____

Website _____ Text _____

Approximate number of children and young adults ages 5-25 screened per year
_____.

Comments or Suggestions _____

Return completed form to: cardiacsafety@dm.duke.edu

Thank you!