

Attachment 5 – Informed Consent

Flesch-Kincaid reading level: 8.3

RESPONSIBLE ORGANIZATIONS:

Participating sites (TBD), National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC), and March of Dimes.

PURPOSE:

People born with heart conditions are living longer because of better care. However, little is known about the daily life of adults who were born with heart conditions. Thus, the (fill in the site name), the March of Dimes, and the CDC are asking adults born with a heart condition to complete a brief survey. This survey asks questions about your access to care and quality of life. Your answers may help identify unmet needs of adults born with a heart condition. This information may also help families who have children with heart conditions plan for the future.

PROCEDURES:

Completing the survey is up to you. Nothing will happen if you decide not to complete the survey. If you decide to take part in this survey, you can either complete the survey and mail it back in the postage paid envelope, or you can complete the survey online by logging onto XXXXXXX. We will take your return of the completed survey as your consent to be part of this project. The survey will take about 20 minutes, but the exact time depends on your answers. It would be helpful if you completed the entire survey. However, you can refuse to answer any question and you can stop at any time.

RISKS:

There are no known risks to you for completing the survey. If you do not want to answer a question, you do not have to. All personal information (name, date of birth, address, and contact person's address) will be kept private and never linked to your answers.

BENEFITS:

There is no benefit to you for completing the survey, but your answers are important to adults and families of children born with heart conditions. The survey information may help identify unmet needs of adults who were born with heart conditions. Additionally, this information may help families of children born with heart conditions plan for the future. We will share what we learn at meetings and through papers and reports. We will never share information that could identify you.

CONFIDENTIALITY:

We are contacting adults who were born with a heart condition. We are asking for your name and contact information to confirm we have reached the correct person and to re-contact you in the future. You may decline to be re-contacted now or at any time in the future.

All of the answers you provide will be kept private to the extent allowed under federal laws [Privacy Act of 1974 (5 U.S.C. § 552a)]. These laws do not prevent the project staff from reporting information needed for evaluating or auditing the project.

We will assign your survey a number. We will remove your name and address and that of your contact person and keep that information separate from your answers to the survey questions. Only certain project staff will

have access to the information. None of your answers will be linked to your name or address. Your answers will be combined with the answers from everyone else that took part in the survey.

All of the completed surveys will be kept at the CDC in locked cabinets in locked rooms with limited access by the project staff. All the computer files will be kept on a secure, password-protected server.

COSTS/COMPENSATION:

We know your time is valuable. As a thank you, we included a \$5.00 gift card for you in this survey packet. Please keep the gift card, whether or not you complete the survey. If you choose to return your completed survey via mail or complete it online, we will send you another gift card worth \$10.00 to thank you for the additional time and effort spent.

RIGHT TO REFUSE OR WITHDRAW:

Your participation in this survey is up to you. Nothing will happen if you decide not to take part. You can refuse to answer any questions and you can stop at any time. If at any time you would like to have your survey answers destroyed or removed from the project, please call xxxxxx.

If you have any questions, please contact:

Dr. Sherry Farr
National Center on Birth Defects and Developmental Disabilities, CDC
800.xxx.xxxx

If you have questions about your rights as a participant in this project, please call the CDC's Office of the Deputy Associate Director for Science at 1-800-584-8814. Leave a message including your name, phone number, and refer to protocol xxxxx, and someone will call you back as soon as possible.