

## *Sample consent form language that would prepare for future sharing of data and specimen*

### **How will information be kept confidential and private?**

Information collected during the study and the results of the research tests will not be placed in your medical record. All study paperwork that includes identifying information such as your name and address, including this signed Consent, will be kept in a secure location. A copy of this Consent may be included in your/your child's medical record or in files at the blood collection laboratory. If you/your child have an echocardiogram or ECG for research purposes, the results of the examination will be reported in your/your child's medical record. For quality control purposes, the sponsor (xxxx) or its designee (xxxx), your doctor, and Medical Center Institutional Review Board (IRB) will be able to inspect your/your child's medical records and have access to confidential information which identifies you by name.

At no time will your personal information be revealed during any tabulation, presentation, or publication of the results of this research study.

The research interview and medical information, research test results, and blood, saliva and tissue samples collected during this study will be kept in special study databases and collection facilities (repositories). These data will be identified with a study number and will not contain identifying information. The data will be available to the study researchers, other persons with permission for related research, and the study sponsor. It is very unlikely that the study information will get out to others within the hospital, an insurance company or employer.

To help us protect you, your child and your family's privacy, there are many levels of security.

- First, no names will be attached to the information/data or samples collected. Samples and data will be given a unique study number and only this study number will be put on all of the study paperwork, data files, and samples.
- Second, the data centers storing all of the data, as well as the laboratories and study centers all have layers of security against hacking, mis-handling and unauthorized access.
- Third, all study doctors and their staff will follow hospital and study rules for keeping all study information private.

Last, the study has a *Certificate of Confidentiality* from the National Institutes of Health (NIH). With this Certificate, the researchers of this study cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a request for information from the United States government when it used for evaluating federally funded study projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA). The *Certificate of Confidentiality* does not prevent you or a member of your family from voluntarily releasing information about yourself/your child or your involvement in this research. *If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. You should understand that we will in all cases, take the necessary action and report to authorities, any indication of abuse, and to prevent serious harm to yourself, your child, or others as in the case of child abuse or neglect.* At each study center, a list

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will be kept that links the study number with your/your child's name and contact information (such as address and telephone numbers). This list will be kept in a password protected computer and will be kept separately from the study data. It will not be shared with researchers outside the study center. We use this list to contact you to discuss any clinically relevant findings, to review your/your child's medical status during the course of the study and to obtain new genetic samples, if the need arises.

**What is the long term plan for my information?**

The collected clinical [and genetic] information will be available indefinitely in a storage site (repository). The sample from blood or other fluid or tissue will be stored indefinitely in a 'biobank' (biorepository). The investigators want to use the sample for cell lines over an indefinite period. This gives the investigators a constant source of material to be used for medical, scientific, educational or research purposes.

Data and samples from these storage sites will be available to other researchers for future study of [disease targeted by this study] as well as other diseases.

Knowing that samples may be used by a research team in the future to study the other conditions may cause stress to some people. If you believe you will be bothered by this, talk with the study doctor/staff before you sign this form.