

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM  
PARENTAL**

**TITLE:** An International Registry for Patients with Drug-Induced Arrhythmia

**PROTOCOL NO.:** None  
WIRB® Protocol #20061523

**SPONSOR:** Agency for Healthcare Research and Quality  
Rockville, Maryland  
United States

**INVESTIGATOR:** Raymond L. Woosley, M.D., Ph.D.  
Suite 200  
1730 East River Road  
Tucson, Arizona 85718  
United States

**SITE(S):** The Critical Path Institute  
Suite 200  
1730 East River Road  
Tucson, Arizona 85718  
United States

**STUDY-RELATED**

**PHONE NUMBER(S):** Raymond L. Woosley, M.D., Ph.D.  
520-547-3440  
1-888-826-3847

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You are being asked to read the following material about this research study and how your child will participate, if you consent for him/her to do so. Signing this consent form will indicate that you have been so informed and that you give your consent. Federal regulations require written informed consent before participation in this research study so that you can know the nature and risks of your child's participation and can decide to participate or not participate in a free and informed manner.

## **PURPOSE**

You are being requested to allow your child to participate in the above-titled research project. The purpose of this project is to develop a registry containing information about patients, such as your child, who have had medication-induced changes in heart rhythm. This reaction to medication is called an arrhythmia. The long-term goal is to develop a genetic test that could identify people at risk for having such unwanted reactions to medications.

## **SELECTION CRITERIA**

Your child is eligible to participate because he/she has been diagnosed with a medication-induced arrhythmia. Approximately 1000 subjects worldwide will be enrolled in this study; locally approximately 100 subjects will be enrolled.

## **PROCEDURES**

If you agree for your child to participate, he/she will be asked to allow his/her physician to place information about your child's medical history and his/her reaction to the medication in a computer file. A special code number will be used to replace your child's name so that the information cannot be linked to him/her personally. This will include information from your child's medical record and his/her electrocardiogram (ECG), an electronic tracing of his/her heart. In addition, the following procedures will be performed:

- a small brush or cotton swab will be rubbed against the inner cheek of your child's mouth to scrape some cells that contain genetic material (DNA), and
- he/she will have about 1 teaspoon, of blood taken from a vein in his/her arm.

More DNA can be obtained from a blood sample than from the cheek cells so having a blood sample reduces the chance that too little DNA would be obtained to complete the tests. DNA, deoxyribonucleic acid, is the substance in cells that carries genetic information.

Your child's physician, or one of his/her assistants, will contact the Registry and obtain a code number for your child's medical information. Your child's physician, or one of his/her staff, will then send a copy of your child's medical information and ECG to the study doctors at Critical Path Institute.

Your child's DNA will be used for tests to determine which proteins are present in his/her body that control the electrical activity of your child's heart and how it is likely to respond to certain medicines. Your child's DNA will not be tested for any other purpose without first obtaining your permission. Neither you nor your child will be informed of the results of the tests because it will not be of medical value to either of you. Your child should not take any medications that could cause arrhythmias no matter what the results of this test are.

## **RISKS**

Participation in this research may involve the following risks:

When your child has blood collected, insertion of the needle into his/her arm vein may cause bleeding, bruising, pain and infection.

Genetic information obtained in this study from your child's DNA may not have any importance for your child's medical care or treatment at this time. However, like some other types of medical information, the results from your child's participation in a genetic study may cause an employer or insurance carrier to discriminate against your child. The risk that the information he/she provides or the results of your child's tests will be learned by others is very small.

## **BENEFITS**

Neither you nor your child will get any personal benefit from participation, but the information gathered may benefit others.

## **PARTICIPATION COSTS**

Neither you nor your child will be charged for any of the procedures listed above.

## **SUBJECT COMPENSATION**

Neither you nor your child will be paid for your child's participation.

## **COMMERCIAL ISSUES**

There may someday be commercial gain associated with the development of this test. There are no plans for either you or your child to receive any financial compensation from your child's participation.

## **ALTERNATIVES**

Your alternative is to not allow your child to be in this study.

## **CONFIDENTIALITY**

The medical information about your child related to the registry will remain confidential. Records will be stored in a separate locked file cabinet and only entered into a computer database with a confidential ID number and not with your child's name. Only authorized study personnel will have access to the information your child has provided.

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA;
- Department of Health and Human Services (DHHS) agencies;
- governmental agencies in other countries; and
- the Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

## CONTACTS

If you have any questions concerning your child's participation in this study, or if at any time you feel your child has experienced a research-related injury, contact the study doctor, Raymond L. Woosley, M.D., Ph.D., at 520-547-3440 or Marietta Anthony, Ph.D., at 520-547-3440. If calling long distance, you may call 1-888-826-3847.

If you have questions concerning your child's rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, Washington 98502  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: ClientServices@wirb.com.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

## **LIABILITY**

Side effects or harm are possible in any research study. Known side effects have been described in this consent form. However, unknown harm also may occur and require care. Neither you nor your child gives up any of your child's legal rights by signing this consent form. In the event that your child requires or you are billed for medical care that you feel has been caused by the research, you should contact the study doctor, Raymond L. Woosley, M.D., Ph.D., at 520-547-3440. If calling long distance you may call 1-888-826-3847.

## **SOURCE OF FUNDING**

Funding for this research study will be provided by the Agency for Healthcare Research and Quality.

## **VOLUNTARY PARTICIPATION/WITHDRAWAL**

Your child's participation in this study is voluntary. You may decide not to allow your child to participate or your child may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which your child is entitled.

## **NEW FINDINGS**

New information developed during the course of this study which may change your decision to allow your child to be in this research study will be given to you as it becomes available.

If you agree to allow your child to be in this study, a copy of this signed consent form will be given to you.

## **CONSENT**

I have read the information in this consent form (or it has been read to me). Before giving my consent by signing this consent form, the methods, inconveniences, risks and benefits have been explained to me and my questions have been answered. I may ask questions at any time and I am free to withdraw my child from the study at any time without causing bad feelings.

I freely consent to allow my child to be in this research study.

By signing this consent form, I have not given up any of my/my child's legal rights.

***Consent and Assent Instructions:***

*Consent: Is provided by the Legally Authorized Representative*

*Assent: Is not required for subjects 6 years and younger*

*Is required for subjects ages 7 through 12 years using the Assent section at the end of this consent form*

*Is required for subjects ages 13 through 17 years using the Assent Section below*

\_\_\_\_\_  
Subject Name

**CONSENT SIGNATURE:**

\_\_\_\_\_  
Signature of Parent/Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority of Subject's Legally Authorized Representative or Relationship to Subject

\_\_\_\_\_  
Signature of Witness (if necessary)

\_\_\_\_\_  
Date

**INVESTIGATOR'S AFFIDAVIT**

I have carefully explained to the parent/legal guardian the nature of the above study. I hereby certify that to the best of my knowledge the person who is signing this consent form understands the nature, demands, benefits, and risks involved in his/her child's participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator (if different than above)

\_\_\_\_\_  
Date



