

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

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

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SITE(S): The Critical Path Institute
Suite 200
1730 East River Road
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**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 you will participate in it, if you consent 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 participation and can decide to participate or not participate in a free and informed manner.

PURPOSE

You are being invited to participate in the above-titled research project. The purpose of this project is to develop a registry containing voluntarily information about patients, such as you, 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

You are being invited to participate because you have 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 to participate, you will be asked to allow your physician to place information about your medical history and reaction to the medication in a computer file. A special code number will be used to replace your name so that the information cannot be linked to you personally. This will include information from your medical record and your electrocardiogram (ECG), an electronic tracing of your heart. In addition, the following procedures will be performed on you:

- a small brush or cotton swab will be rubbed against the inner cheek of your mouth to scrape some cells that contain your genetic material (DNA), and
- You will have about 2 teaspoonsful of blood taken from a vein in your 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 physician, or one of his/her assistants will contact the Registry and obtain a code number for your medical information. Your physician or one of his/her staff will then send a copy of your medical information and ECG to the study doctors at The Critical Path Institute.

Your DNA will be used for tests to determine which proteins are present in your body that control the electrical activity of your heart and how it is likely to respond to certain medicines. Your DNA will not be tested for any other purpose without first obtaining your permission. You will not be informed of the results of the tests because it will not be of medical value to you. You 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 you have blood collected, insertion of the needle into your arm vein may cause bleeding, bruising, pain and infection.

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

BENEFITS

You will not get any personal benefit from participation, but the information gathered may benefit others.

PARTICIPATION COSTS

You will not be charged for any of the procedures listed above.

SUBJECT COMPENSATION

You will not be paid for your participation.

COMMERCIAL ISSUES

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

ALTERNATIVES

Your alternative is to not be in this study.

CONFIDENTIALITY

The medical information about you 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 name. Only authorized study personnel will have access to the information you provide.

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 participation in this study, or if at any time you feel you have 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 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. You do not give up any of your legal rights by signing this consent form. In the event that you require or 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 participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

NEW FINDINGS

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

If you agree 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 from the study at any time without causing bad feelings.

I freely consent to be in this research study.

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

Consent and Assent Instructions:

*Consent: Subjects able to provide consent must sign on the subject line below
Consent is provided by the Legally Authorized Representative for subjects unable to consent*

Assent: Is required for subjects able to provide assent

Printed Name of Subject

Subject's Signature (Ages 18 and over)

Date

OR

Signature of 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 subject the nature of the above study. I hereby certify that to the best of my knowledge the subject who is signing this consent form understands the nature, demands, benefits, and risks involved in his/her 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

ASSENT SIGNATURES, For Subjects with a Legally Authorized Representative:

Assent:

For subjects who have a legally authorized representative, I confirm that:

- I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.
OR
- The subject is not able to assent due to lack of mental capacity.

Signature of Person Conducting Assent Discussion

Date

----- Use the following only if applicable -----

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.