

Consent Form for Human Subject Research
Conducted at the Masonic Medical Research Laboratory
Molecular Genetics Laboratory
Molecular Genetic Basis for Brugada Syndrome – MMRL-002

IRB Reapproval 3/6/03

Background

Some diseases are inherited, or passed from parent to child in some families. The material that is transmitted from parents to children is called DNA. The DNA contains some segments, called genes, which, when damaged, can cause disease to the patient. It is now possible to locate these genes in the DNA and analyze them for abnormal function. Identification of these altered genes in the individuals can help understand how the abnormal gene causes the disease. Identification of these genes requires the study of multiple individuals in families affected with the disease. This research study is sponsored by Doris Duke Charitable Foundation, American Heart Association and National Institutes of Health.

Purpose

The purpose of this study is the identification of abnormal genes responsible for familial inherited cardiac diseases like Brugada syndrome, Long QT syndrome, atrial fibrillation or familial bundle branch block. The information obtained will help advance the understanding of the disease being studied. The study will be recruiting individuals for the next 5 years and enroll about 500 patients.

Procedures

You will be one of approximately 500 subjects to be asked to participate in this trial. Adult individuals will be asked to donate blood (1-2 teaspoons). Children under 14 will be required maximum 1 teaspoon. DNA obtained will be used to determine whether the markers follow the disease gene within their particular family. While the individual will have completed his or her role in this project after giving blood, the linkage (or mapping) studies may go on for years before significant results are obtained. On occasion, if DNA is used up, that person may be asked to donate a small sample of blood once again. The samples will be stored in the form of DNA or cell lines in Dr Brugada's laboratory at the Masonic Medical Research Laboratory. As part of the genetic analysis different candidate genes will be analyzed over time. The DNA will only be used to identify genetic risk factors for cardiac arrhythmias. If the patient decides to withdraw from the study, or if the study is completed, the DNA will be returned or discarded per patient indication. The samples will not be sold or transferred to a third party or made available for other use. Because there is worldwide recruitment, my primary physician will explain the consent and the procedure and answer any questions that I may have.

Potential Risks and Discomforts

The only physical risk present in this study involves drawing blood from a vein, usually from the arm. Rarely bleeding (usually a very small amount) or infection, just like any other small scratch may occur. If any other procedure that requires drawing blood is already being performed, no

Molecular Genetic Basis for Brugada Syndrome

added risk will occur due to this study. There is a potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk for disease.

Potential Benefits

You have been told that the benefits of participating in this study may be: that the information obtained during this study might result in improved diagnosis in myself, some of my family members, or the general population at some time in the future. In this case, I will be offered the opportunity to be informed of the results, but may decline if I wish. However, I (or my family) may receive no benefit from participating in the study. The results of the testing will be made available to me or to my physician of my designation per my request. The primary physician will be in charge of providing genetic counseling or referring the patient to a genetic counselor if so I desire. However, you may receive no benefit from participating in this study.

Alternatives

The only alternative to this study is non-participation.

Subject Costs and Payments

There are no costs to you subject to your participation in this research study.

Subject's Rights

There may be unknown risks/discomforts involved. You will receive any new information discovered during the course of this study, concerning significant treatment findings that may affect your willingness to continue participating in this research study.

Every effort will be made to maintain the confidentiality of your study records. The data from the study may be published; however, you will not be identified by name. The confidentiality of the data will be maintained within legal limits. In the event of injury resulting from this research, Masonic Medical Research Laboratory is not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community. Your signature below acknowledges your voluntary participation in this research project. Such participation does not release the investigator(s), institution(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to you.

You may refuse to participate or may discontinue your participation AT ANY TIME, without penalty, loss of benefits, or change in present or future care. The investigator has the right to withdraw you from the study at any time. Your withdrawal from the study may be for reasons related solely to you (e.g. not following study-related directions from the Investigator, a serious adverse event reaction) or because the entire study is terminated. The Sponsor has the right to terminate the study or the Investigators participation in the study at any time.

Molecular Genetic Basis for Brugada Syndrome

The investigator, RAMON BRUGADA, and/or his designee has attempted to answer all of your questions. If you have further questions or concerns, please address them with the study representative now. In the event of a research-related injury or if any other problems arise, you may contact: LUCILLE ROTUNDO, BSN, OCN, Faxton-St. Luke's Healthcare, IRB Secretary at (315) 624-4390. If questions/concerns arise during the course of the study, you may speak with the principal investigator, RAMON BRUGADA at (315) 735-2217.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

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|--|-------|-------------------------|
| _____ | _____ | |
| Subject | Date | |
| _____ | _____ | _____ |
| Legal Representative or Next of Kin | Date | Relationship to Subject |
| _____ | _____ | |
| Investigator or Designee Obtaining Consent | Date | |
| _____ | _____ | |
| Witness (if applicable) | Date | |
| _____ | _____ | |
| Translator (if applicable) | Date | |

CHILDREN CONSENT

Your signature on this consent form attests to the fact that your child _____ has, within limits imposed by age, maturity, and psychological state, given his/her assent (affirmative agreement) to participate in this research project.
