

**PATIENTINFORMATION FOR IKKE ENGELSK TALENDE PATIENTER**  
**DEN GENETISKE OG MOLEKYLÆRE BAGGRUND FOR HJERTEARYTMIER**  
 UNDERSØGELSEN FOREGÅR PÅ DEN MEDICAL MADISON FORSKNISNGS LABORATORIUM

Kære

De anmodes hermed om at deltage i et videnskabeligt projekt.

Før du tager stilling til dette bør du informeres om følgende:

- (i) om projektets formål og varighed, og hvilke undersøgelser indgå i projektet
- (ii) hvis der skulle indgå nogle undersøgelser, der er eksperimentelle
- (iii) en orientering om risici og ubehag forbundet med undersøgelsen, ligeledes om undersøgelsens fordele
- (iv) hvis der i fremtiden skulle være nogle yderligere undersøgelser eller eventuelle behandlinger, du kan komme i betragtning til
- (v) om den fortrolige behandling af dine data
- (vi) hvis der skulle være tilfældet, at man kan komme i betragtning til kompensation eller behandling, hvis noget uheld skulle ske som følge af undersøgelsen
- (vii) hvis det kan være tale om nogle uventede risici
- (viii) om eventuelle omstændigheder som kan påkræve, at lægen standser undersøgelsen
- (ix) hvis det skulle være uventet udgifter for dig
- (x) hvad det sker, hvis du ønsker at stoppe din deltagelse i dette studie
- (xi) hvad det sker, i tilfælde af nye, uventede oplysninger, der muligvis ville kunne ændre din beslutning
- (xii) hvor mange patienter ville i alt deltage i studiet

Hvis du indvilliger at deltage i projektet skal du efter at have modtaget ovenstående såvel mundtligt som skriftligt information, underskrive dette dokument sammen med et lille resume om selve undersøgelsen. I tilfælde af supplerende spørgsmål er du velkommen til at kontakte RAMON BRUGADA, Direktør hos Director of Molecular Genetics, Masonic Medical Research Laboratory, 2150 Bleecker St, Utica, NY, 13501 USA tel (315) 735 2217. Du er også velkommen til at kontakte LUCILLE ROTUNDO, BSN, OCN, Faxton-St. Luke's Healthcare, IRB Secretary at (315) 624-4390, i tilfælde af spørgsmål om rettigheder for patienter der deltager i videnskabelige projekter. Jeg er informeret om, at det er frivilligt at deltage, og at jeg når som helst kan trække mit tilsagn om deltagelse tilbage, uden at dette vil påvirke min nuværende eller fremtidige behandling. Ved at skrive under på dette dokument betyder, at du såvel mundlig som skriftlig, har fået ovenstående information, og eventuelle spørgsmål har været besvaret på tilfredsstillende vis.

\_\_\_\_\_

Patient

\_\_\_\_\_

Dato

\_\_\_\_\_

Vitterlig personen

\_\_\_\_\_

Dato

\_\_\_\_\_

forbindelsen/relationen til patienten

\_\_\_\_\_

Lægens signatur (underskrift) der har formidlet oplysninger

\_\_\_\_\_

Dato

\_\_\_\_\_

Viden

\_\_\_\_\_

Dato

\_\_\_\_\_

Translatør (hvis dette er tilfældet)

\_\_\_\_\_

Dato

**BØRNS TILSAGN**

Ved at skrive under på denne patientinformation bekræfter du, at dit barn

\_\_\_\_\_ har på sin vis, indvilliget i at deltage i denne videnskabelige undersøgelsen (har sagt, ja ), hvilket ville sige, at man ville vurdere barnets accept i lyset af :barnets alder, modenheden og psykologiske tilstand.

**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.

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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.

_____	_____	
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.

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