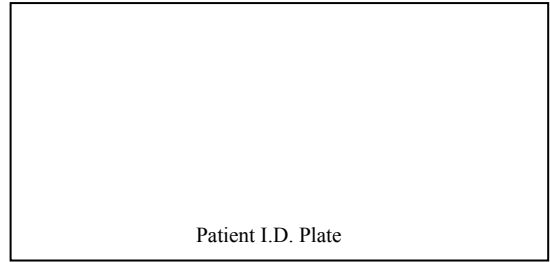


Sites of Research:



Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Molecular Genetics of Cystic Fibrosis

Application No. : 92-07-27-01

Sponsor: NIH

Principal Investigator: Garry R. Cutting, MD

Date: 10/16/03

Patient

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask questions about anything you do not understand now, or when you think of them later.
- You are a volunteer. If you do join the study and change your mind later, you may quit at any time without fear of penalty or loss of benefits.
- While you are in this study, the study team will keep you informed of any new information that could affect your decision to stay in the study.
- If children may join this study, the word “you” in this consent form will refer to both you and your child.

2. Why is this research being done?

You/your child has Cystic Fibrosis or clinical symptoms such as sinus infections, lung disease, pancreatic dysfunction or liver disease that can occur in Cystic Fibrosis. We would like you/your child to join a research study to find out if your/your child's symptoms are related to one or more genes. We will examine the genetic material from your/your child's blood (called DNA) for alterations in the gene for Cystic Fibrosis and for alterations in Modifier Genes that may affect the severity of your/your child's illness. Additionally, each sample may be analyzed for alterations in the DNA that have not yet been recognized and might be responsible for your illness. It is very helpful to also look at family members' DNA to determine how these markers have been transmitted. Therefore, to complete this genetic analysis, we may ask you to contact family members to we may obtain a blood sample from them. If you do not wish to contact family members, you may still choose to participate in the study.

3. What will happen if you join this study?

If you/your child agree to join this study, 2 tablespoons of blood (1 tablespoon for a child less than 5 years old) will be drawn from you/your child. Blood will be drawn by an experienced phlebotomist with sterile needles and syringes with as minimal discomfort as possible to you/your child. The blood sample will be assigned a number after it is obtained and the code will be kept confidential to protect your privacy.

- A. I do/do not wish to contact family members to participate in the study
- B. I do/do not wish to know my results.

4. What are the risks or discomforts of the study?

Mild discomfort and bruising may occur as a results of the blood drawing. Whenever possible, blood samples for the study will be obtained at the same time venipuncture is performed for medically indicated tests. If an alteration in the DNA is found, you may elect to receive the information. If you accept the information and wish to have genetic and supportive counseling, we will provide these services free of charge. If you/your child has cystic fibrosis, results of this study may become part of your/your child's medical record.

5. Are there benefits to being in the study?

Though it is our hope that some information may be obtained about your disease from these studies, helping us further characterize your illness and aid in its management, it is possible that you/your child will not receive any direct benefit from the study.

6. What are your options if you do not want to be in the study?

Your decision not to participate in the study or not to contact your family members or not to know your/your child's results will not affect the health care you receive at the Johns Hopkins Hospital in any way.

7. Will it cost you anything to be in this study?

The study procedures will be provided at no cost to you.

8. Will you be paid if you join this study?

No

9. Can you leave the study early?

Yes. Leaving this study early will not stop you from getting regular medical care.

10. What information about you will be kept private and what information may be given out?

Johns Hopkins has a policy to protect health information that may identify you. This section tells you what information about you may be used and given out in this study and who may give and receive the information. By signing this consent form, you agree that health information that identifies you may be used and/or given out as described in this form. Federal and state laws also protect your privacy. Johns Hopkins has procedures in place to support these policies and laws.

a. What information about you may be used or given out in this study?

Information that identifies you and relates to your health or medical condition may be used or given out as described in this form. Information that identifies you can include your name, address, telephone number, date of birth, Social Security number and other details about you. Information that relates to your health or medical condition includes:

- Information we get from you or from the activities and procedures described in this consent form, which may include:
- - i) things done to see if you can join this study, such as physical examinations, blood and urine tests and any other information that you share with us, including information about your health history and your family health history; and
 - ii) information obtained during the study, such as how you respond to the study activities or procedures, information we learn in study visits, phone calls, surveys, physical examinations, blood and urine tests, x-rays and other tests and any other medical information we learn from you as a participant in this study.
 - iii) Information regarding your family medical history
 - iv) Drawing and storing of blood (plasma and serum) for future testing and DNA testing.

b. Who may use and give out information about you?

Some people may see your health information and may give out your health information as needed to conduct this study. These people include the researcher and the research staff, the institutional review boards and their staff, legal counsel, audit and compliance staff, officers of the organization and other people who need to see the information to help this study or make sure it is being done as it should.

c. Who may see your health information?

Other organizations involved with protecting research participants, or just with this study, may see your health information. These include:

- Governmental entities that have the duty to protect research participants, such as the Office of Human Research Protections and the Food and Drug Administration
- The sponsor of this study and people that the sponsor may contract with for this study. The name of the sponsor is The Cystic Fibrosis Foundation and the National Institute of Health.

d. Why will this information be used and given out?

Your information will be used and given out to carry out this study and to evaluate the results of this study.

Your information may also be used to meet the reporting requirements of governmental agencies.

e. What if you decide not to give your permission to use and give out your health information?

You do not have to give your permission to use or give out your health information. However, if you do not give permission, you may not participate in this study.

f. How long does this privacy authorization last?

This authorization to use and give out health information does not end unless you cancel it. You may cancel your agreement to allow your health information to be used or given out as described in this form by sending a written notice to the Institutional Review Board Office, 1620 McElderry Street, Reed Hall, Suite B130, Baltimore, MD 21205-1911. If you do this, you are leaving this study. If you leave this study, no new health information about you will be gathered after the date that you leave. However, information gathered before that date may be used or given out if it is needed for this study or any follow-up for this study.

g. Is your health information protected after it has been given to others?

Even though Johns Hopkins has agreements with other organizations to protect the use of health information, if your health information is given to someone not covered by these policies and laws, that information may no longer be protected, and might be used or given out without your permission.

16. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of doctors, nurses, ethicists, non-scientists, and people from the local community. The IRB's purpose is to review human research studies and to protect the rights and welfare of the people participating in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Garry R. Cutting, at 410-95-1773.

c. What should you do if you are injured or ill as a result of being this study?

If you have an urgent medical problem related to your participation in this study, call Dr. Garry R. Cutting at 410-955-1773.

If you think you are injured or ill as a result of being in this study, call the principal investigator, Dr. Garry R. Cutting, at 410-955-1773.

The medical services at Johns Hopkins will be open to you as they are to all sick or injured individuals. Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. You are financially responsible for payment of any treatment or hospitalization. At your request, your insurance provider will be billed for payment of any treatment or hospitalization.

d. What happens to Data, Tissue, Blood and Samples that are collected in the study?

Johns Hopkins is dedicated to finding the causes and cures of disease. The data, tissue, blood and samples from your body collected during this study are important to this study and to future research. If you join this study, Johns Hopkins University or its outside partners in this research will own this data, tissue and blood samples. This material will be studied, tested, and used by medical scientists. If this material helps lead to the creation of a product or idea, whoever creates that product or idea will own it. You will not receive any financial benefit from the creation, development, use or sale of that product or idea.

e. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins is a group of organizations that includes: The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital and Johns Hopkins Community Physicians.

The Kennedy Krieger Institute is a separate legal entity that is not owned or controlled by The Johns Hopkins University or any of the other Johns Hopkins organizations. However, for studies where a Kennedy Krieger Institute protocol is reviewed by The Johns Hopkins University School of Medicine Institutional Review Board, "Johns Hopkins" also includes the Kennedy Krieger Institute.

Date: 10/16/03

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Principal Investigator: Garry R. Cutting, MD

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17. What does your signature on this consent form mean?

By signing this consent form, you are not giving up any legal rights. Your signature means that you understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM



Do not sign after the expiration date of: 11/20/2004

FOR ADULTS AND CHILDREN CAPABLE OF GIVING CONSENT:

Participant's Signature Date

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:

Signature of Surrogate/Guardian/Health Care Agent for Participant Date

Relationship of Surrogate to Participant: _____

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:

Signature of Parent Date

Signature of Parent # 2 (45 CFR 406 and 407 studies) Date

Signature of Legal Guardian (when applicable) Date

SIGNATURE(S):

Signature of Person Obtaining Consent Date
(Investigator or IRB Approved Designee)

Witness to Consent Procedures (Optional unless IRB or Sponsor required) Date

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.

FOR OFFICE USE ONLY: STUDY APPROVED FOR ENROLLMENT OF: ___ Adults Only ___ Adults and Children ___ Children Only
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