

**AUTHORIZATION FOR USE AND DISCLOSURE OF
HEALTH INFORMATION FOR RESEARCH**

Principal Investigator: Garry R. Cutting, M.D.

Application Number: 92-07-27-01

Title of the Study: Molecular Genetics of Cystic Fibrosis Variants

This form relates to the Study. You also have been given a consent form that tells you about the Study, and any activities or procedures that are part of the Study. This form tells you what information about you may be used and given out in the Study and who may give and receive the information. By signing this form, you agree that health information that identifies you may be used and given out as needed in the Study. Johns Hopkins* has a policy to protect health information that may identify you. Federal and state laws also protect your privacy. Johns Hopkins has procedures in place to support these policies and laws.

1. What information about you may be used or given out in the Study?

Information that identifies you and relates to your health or medical condition may be used or given out in this Study. 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 obtained from the activities and procedures outlined in the Consent Form, which may include:
 - things done to see if you can join the 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
 - 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 the Study.
 - information regarding your family medical history

- drawing and storing of blood (plasma and serum) for future testing and DNA testing

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

Some people may see your health information and may give out your health information during the Study. These 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 the Study or make sure it is being done as it should.

3. Who may see your health information?

Other organizations may see your health information during the Study. These include:

- Governmental entities that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration
- Doctors and staff at other places that are participating in the Study
- The sponsor of the Study and people that the sponsor may contract with for the Study. The name of the sponsor is the Cystic Fibrosis Foundation and the National Institutes of Health.
- An outside institutional review board.

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

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

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

5. 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 the Study.

6. May you withdraw or cancel your permission?

You may cancel your agreement to allow your health information to be used or given out at any time by sending a written notice to the Institutional Review Board Office, 36 Turner, 720 Rutland Avenue, Baltimore, MD 21205-2196. If you do this, you are leaving the Study. If you leave the Study, no new health information about you will be gathered after that date. However, information gathered before that date may be used or given out if it is needed for the Study or any follow-up for the Study.

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

If your health information is given to someone not covered by these policies and laws, that information may no longer be protected, and may be used or given out without your permission.

8. Does this authorization have an end date?

This authorization to use and give out health information does not end.

9. Have you given up any legal rights by signing this form?

By signing this authorization form, you have not waived any of the legal rights you otherwise would have as a participant in a research study.

- * "Johns Hopkins" refers to The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital and Johns Hopkins Community Physicians. 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. Please note that the Kennedy Krieger Institute is a separate legal entity which is not owned or controlled by The Johns Hopkins University or any of the other Johns Hopkins organizations.

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 Subject Date
Relationship of Surrogate to Participant: _____

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:

Signature of Parent Date

Signature of Parent # 2 (when applicable) Date

Signature of Legal Guardian (when applicable) Date

NOTE: Children older than twelve who have signed an assent must sign this form in addition to their Personal Representative.

(Child)

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 CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PATIENT'S RECORD

