

CLINICAL INVESTIGATION CONSENT FORM

The Johns Hopkins Medical Institutions
(The Johns Hopkins Hospital
The Johns Hopkins Bayview Medical Center, etc.)

Title of Research Project: Genetic Studies of Crohn's Disease
and Ulcerative Colitis

Explanation of Research Project to Subject:

Adult Consent
(Blood Drawing)

Consent 1

Purpose of the study: The purpose is to find out why Crohn's disease and ulcerative colitis occurs in some families. Specifically, we wish to use some of your blood cells to help find the genes which may be responsible for Crohn's disease or ulcerative colitis to occur in families, such as your own. This is the reason we are asking patients and their relatives to participate by providing information and some blood cells.

Procedures: If you agree to become part of this study, you will be asked to give a blood sample from a vein in your arm (less than two tablespoons) which will be used to help search for genes and other proteins associated with these diseases. A portion of the samples will be sent to the Johns Hopkins Genetics Core laboratory to be used to establish a library of cell types. There will be no charges to you for these tests and for any part of the study.

Confidentiality as to your name will be maintained. The samples contain only a code number which is only known to Dr. Bayless and his research assistant. Your name or identifying characteristics will never be used in public or in publications describing the research results.

As with other research conducted at the Johns Hopkins University School of Medicine, the samples and any products and processes that result from the study of these samples are the property of Johns Hopkins University.

Risks-Discomforts: The risks of drawing blood from a vein (the procedure used in all laboratories) may be slight discomfort from the needle, bruising, and rarely, an infection where the needle enters the skin. There are no other risks.

this page. You should, at the investigator's, or other name of institution that are available to you and to others. You should ask the principal investigator listed below any questions you may have this research study. You may ask him/her questions in the future if you do not understand something that is being done. The investigators (or doctors) will share with you any new findings that may develop while you are participating in this study.

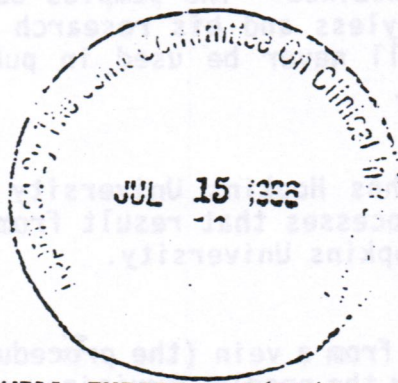
The records from this research study will be kept confidential and will not be given to anyone who is not helping on this study, unless you agree to have the records given out. If the study uses a new drug or device that is under the jurisdiction of the Food and Drug Administration (FDA), the FDA government officials may look at the relevant part of your medical records as part of their job to review new drug and device studies.

If you want to talk to anyone about this research study because you think you have not been treated fairly, or think you have been hurt by joining the study, or you have any other questions about the study, you should call the principal investigator, Theodore M. Bayless, M.D. at 955-4916 or call the Office of the Joint Committee on Clinical Investigation at 955-3008 or call The Johns Hopkins Bayview Medical Center Institutional Review Board for Human Research at 550-1853. Either the investigator or the people in the Committee office or IRB office will answer your questions and/or help you to find medical care for an injury you feel you have suffered. The Johns Hopkins University, The Johns Hopkins Hospital, The Johns Hopkins Bayview Medical Center, _____ and the Federal Government do not have any program to provide compensation to you if you experience injury or other bad effects which are not the fault of the investigators.

You may withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from it, you will still have the same quality of medical care available to you at Johns Hopkins or the Johns Hopkins Bayview Medical Center.

If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
COMMITTEE OR IRB STAMP
OF CERTIFICATION



PROTOCOL WILL EXPIRE: 3/26/97

RPN NO. 96-01-31-06

Subject's signature
(including children, when applicable)

Signature of Parent or Guardian (when applicable)

Witness to Consent Procedures *

Signature of Investigator or Approved Designee

Date

*Optional unless subject is illiterate, or unable to sign.

NOTE: Signed copies of this consent form must be a) retained on file by the Principal Investigator; b) deposited in the patient's medical record; and c) given to the patient.

Revised: 6/94