

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Indiana Familial Cancer Roster

You are invited to participate in the Indiana Familial Cancer Roster. You were selected as a possible subject because you and/or your family may have a familial predisposition (increased risk) for developing cancer. We request that you read this form and ask any questions you may have before agreeing to participate in the Roster.

The Indiana Familial Cancer Roster is being conducted by Gail H. Vance, MD, Professor, Department of Medical and Molecular Genetics, Indiana University School of Medicine, Indianapolis, Indiana.

STUDY PURPOSE

The purpose of this Roster is to collect and maintain information on families with a predisposition to cancer, in order to advance cancer research in Indiana and throughout the nation. A roster is a computer database of names and medical information. The purpose of this Roster is to include information which may be used by researchers in three ways:

1. Researchers may request statistical information from the Roster with no names or identifiers attached. Before the Roster releases this information, all information that could identify you or your family will be removed.
2. Researchers may also contact the Roster if they need genetic information or DNA from individuals predisposed to a certain type of cancer, again stripped of identifying information. Before the Roster releases this information, all information that could identify you or your family will be removed.
3. Researchers may contact the Roster in order to make contact with individuals/families that may be eligible to participate in his/her research study. If you or a family member fit the requirements of the research study, such as cancer type, age at the time of cancer diagnosis, or multiple family members affected with cancer, we will contact you with information of the study as well as send you a release form and stamped envelope addressed to us. If you wish us to release your name and contact information to the researcher in charge of the study, you will need to return to us the release form signed by you. The researcher in charge of the study will then contact you with details of the study. You will need to sign a separate "Informed Consent" form for each individual study in which you participate. **YOU ARE UNDER NO OBLIGATION** to participate in any research study.

All scientific requests from potential researchers for any of the studies listed above will be reviewed by a committee of doctors and other health professionals to make certain that the requests relate to cancer, are worthwhile studies and will not pose hardship to families who elect to participate in the study.

If you choose to participate in the Roster, information about you will never be released to any other individual, even your own family members, without your written permission. Your name or the names of any members of your family will never be involved in any report.

Participation in the Roster is indefinite. You may terminate your participation at any time by your written request.

If a DNA, serum, or blood sample has been collected for the purposes of this Roster, the sample will be kept indefinitely. The sample may be destroyed, at some indeterminate time, due to a lack of funding to support continued storage. A DNA, serum or blood specimen may be withdrawn from the study at any time by your written request.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 2000 subjects who will be participating in this Roster.

PROCEDURES FOR THE STUDY:

If you agree to participate in the Roster, we will ask you to do the following:

- 1) Complete a family history form, with emphasis on polyps, other tumors and cancers, diagnosed in yourself and/or biological family members.
- 2) Provide clinical information regarding polyps, other tumors and cancers in yourself and/or biological family members diagnosed with any of these. This information may include pathology reports, endoscopy reports,

oncology reports, or other relevant medical records. Death certificates may also be requested. Clinical information may also include physical findings suggestive of a cancer syndrome.

- 3) Consider providing a blood sample from which DNA and serum will be collected and stored. Two tubes of blood (7-10 ml each, about 4 teaspoons) would be collected from a vein in your arm. This would likely be a one-time occurrence.

The above procedures are considered to be standard and are not considered experimental.

RISKS OF TAKING PART IN THE STUDY:

Participating in the Roster may be associated with the following risks:

Family history form: There is a risk that you may experience increased emotional distress while documenting a family history of cancer and/or when learning you may have a hereditary condition predisposing to cancer. The chances of this occurring will differ from participant to participant. You may choose to complete the family history form at another time or to terminate your participation in the Roster.

Blood draw: the risks are minimal and include pain, bruising and slight chance of infection. Blood will be drawn by experienced technicians and whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered.

Confidentiality: There is a slight risk that someone could breach the security of the computer system containing demographic information; however, security measures are in place to ensure that only authorized individuals may access the database. During work-hours the computer system and files are in view of staff; consequently, non-staff members cannot access the charts or computer database. At the close of the working day, offices and the filing cabinets are locked. There is a slight risk that someone could break into the department or into the locked filing system and thereby, possibly gain access to the charts containing family history information.

BENEFITS OF TAKING PART IN THE STUDY:

There is no direct benefit to you by participating in the Roster. By participating, you may learn of relevant research studies for which you are eligible and thus, gain the opportunity of participating in research studies. By participating, society as a whole may benefit since information obtained from studies on hereditary cancer has advanced the understanding of the biology of the more common sporadic (i.e.: not inherited) forms of cancer.

ALTERNATIVES TO TAKING PART IN THE STUDY:

The only alternative is to not participate in this Roster. If you decide not to participate in this Roster, this decision will not affect your current or future relations with the Department of Medical and Molecular Genetics, Indiana University School of Medicine, Indiana University Hospital or IU Health.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports or published articles.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, study sponsor, and (as allowed by law) state or federal agencies (specifically the Office for Human Research Protections (OHRP)).

GENETIC INFORMATION

This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law which generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and discriminate against you based on your genetic information.

COSTS

There may be a small charge for a blood draw if done outside the Department of Medical and Molecular Genetics. There are no others costs associated with participation in this Roster.

PAYMENT

You will not receive payment for taking part in this Roster.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the Roster, contact the researcher, Dr. Gail Vance, at 317/278-0172 or the Roster coordinator, Mrs. Cindy Hunter, at 317/274-3060. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at 317/278-3458 or 800/696-2949. For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at 317/278-3458 or 800/696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this Roster is voluntary. You may choose to not take part and/or may leave the Roster at any time. Leaving the Roster will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this Roster will not affect your current or future relations with the Department of Medical and Molecular Genetics Department, Indiana School of Medicine, University Hospital or IU Health.

SUBJECT’S CONSENT

In consideration of all of the above, I give my consent to participate in the Indiana Familial Cancer Roster.

I will be given a copy of this informed consent statement to keep for my records.

SUBJECTS SIGNATURE: _____ Date: _____
(must be dated by the subject)

SIGNATURE OF PERSON OBTAINING CONSENT: _____ Date: _____

If the study involves children and they will be providing their assent on this form, use the following signatures:

(IF SUBJECT IS A CHILD:)

SIGNATURE OF PARENT: _____ Date: _____

SIGNATURE OF PARENT: _____ Date: _____

(If child will provide assent on this form)

SIGNATURE OF CHILD: _____ Date: _____

(unless the child will be signing an assent)

SIGNATURE OF PERSON OBTAINING CONSENT: _____ Date: _____