

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title	Identification and Analysis of Hereditary Gastrointestinal Cancer and Polyposis Syndromes
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Why am I being asked to volunteer?

You are being invited to participate in a research study due to your personal and/or family history of gastrointestinal cancer and/or gastrointestinal polyposis. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. If a family member is interested in the study, please have them contact our program. No medical information pertaining to you will be provided to any of your relatives. Family members will never be directly contacted by the study group without your permission.

You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form, and you will receive a copy of the consent form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. You do not have to participate in any research study offered by your doctor, and you will not lose any of your legal rights as a research subject by signing this consent form.

What is the purpose of this research study?

The purpose of this study is to enroll appropriate patients into the Gastrointestinal Cancer and Polyposis Registry. Patient who are eligible include those who either have or are at risk of having a hereditary gastrointestinal cancer or polyposis syndrome.

How long will I be in the study?

You will be enrolled into the Gastrointestinal Cancer and Polyposis Registry indefinitely, or until you request removal from the registry.

What am I being asked to do?

The purpose of the Gastrointestinal Cancer and Polyposis Registry is to store your medical and family history information, including genetic testing information (if applicable), to facilitate research on gastrointestinal cancer and polyposis syndromes. Additionally, being part of the registry will give our program the option to potentially contact you if and when the following opportunities arise:

- 1) We have updated information on any of your genetic testing results.
- 2) New testing options become available that may benefit you or your relatives.
- 3) There are new research opportunities available that may benefit you or your relatives.
- 4) There are clinical trials or new therapies that you may be eligible for.
- 5) There are other new opportunities or advances related to your condition, genetic testing results, or your familial risk, that may benefit you or your family.

It is important to note that enrollment in this registry does not assure that all updates to your genetic testing results will be communicated to you, nor does it assure that you will automatically be updated on new clinical recommendations or opportunities that may affect your care. Therefore, you may need to continue to contact the Gastrointestinal Cancer Risk Evaluation Program on at least an annual basis for updated information and recommendations about your health. In addition, we recommend that you directly notify your physician(s) and/or genetic counselor if there are changes to your personal and/or family history of cancer and/or gastrointestinal polyps. Providing the research team with updated information about changes to your personal/family history does not automatically update your clinical medical record.

What are the possible risks or discomforts?

There are no additional health risks that result from enrollment in the registry. Although extreme care is taken to maintain the confidentiality of this registry, there is always a small risk of a breach of this confidentiality with regards to your genetic testing results and other personal and family history information. Additionally, in terms of general risks associated with genetic testing, learning about genetic risk for cancer could cause worry, anxiety, depression or fear for the future. This information could be upsetting to family members and could possibly strain personal relationships. There is a possibility if multiple family members are tested, that genetic testing could reveal non-paternity, non-maternity or undisclosed adoption. Finally, learning about the presence of genetic risk for cancer could lead to concerns about insurance or employment discrimination. Fortunately, the Genetic Information Non-Discrimination Act (GINA), which was passed in 2008, provides significant protection against genetic discrimination in health insurance and employment. However, the protection of GINA does not cover life, disability, or long-term care insurance.

What are the possible benefits of the study?

Enrollment in the registry may help you learn about new testing and treatment options, as well as enable us to potentially update you if the information about any of your genetic test results change. Registry enrollment may also facilitate future research to better understand, diagnose, and treat hereditary conditions related to gastrointestinal cancer and/or polyposis.

IRB Approved: 20-Feb-2018 To: 29-Oct-2018

What other choices do I have if I do not participate?

Your participation in the Gastrointestinal Cancer and Polyposis Registry is not mandatory, and will not affect your access to medical treatment now or in the future. If you decline to participate in the registry, you can still pursue clinical genetic testing.

Will I be paid for being in this study?

No

Will I have to pay for anything?

No

When is the Study over? Can I leave the Study before it ends? Can I change my mind about giving permission for use of my information?

Given the long term goals of the registry, this study is expected to continue data collection indefinitely. If you decide to participate, you are free to leave the study at any time. Withdrawal from the registry will not interfere with your future care. You may withdraw by sending written notice to the Principal Investigator for the Gastrointestinal Cancer and Polyposis Registry. This study may also be stopped at any time by the Principal Investigator.

What information about me may be collected, used or shared with others?

Information that will be collected as part of your participation in the registry includes:

- 1) Name, address, phone number, date of birth, email and certain other demographic information
- 2) Medical record number
- 3) Personal and family medical history, including results from tests and procedures
- 4) Genetic test results (if applicable)
- 5) Tumor test results (if applicable)

Why is my information being used?

Your personal and family information that will be entered into the registry, will be used to contact you about certain clinical developments or opportunities if deemed necessary by the study team, and will also be used to perform research on hereditary gastrointestinal cancer and polyposis syndromes.

Who may use and share information about me?

The following individuals may use or share your information for this research study: The Principal Investigator for the study, other members of the study team, and other authorized personnel at the University of Pennsylvania including offices that support research operations.

Who, outside of the School of Medicine, might receive my information?

As part of your participation in the registry, the Principal Investigator, Co-Investigators, and Gastrointestinal Cancer and Polyposis Registry team may disclose your personal health information, including the results of tests and procedures, to collaborating sites for research purposes and/or inclusion in larger multi-center registries. Any information shared will be disclosed in a completely de-identified manner, unless disclosure of a direct identifier is required by law. Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information will be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless you have given written authorization, The University of Pennsylvania's Institutional Review Board grants permission, or as permitted by law.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be included in this registry.

How will my personal information be protected?

The data from this registry is secure and password protected. It is only accessible to members of the Gastrointestinal Cancer Risk Evaluation Program. The registry is not accessible to other hospital employees, or insurance companies. If information from the registry is ever used for research purposes, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. We will take all precautions to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy, as your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania with any questions, concerns or complaints by calling 215-898-2614.

How can I request more information?

You may ask more questions about the registry at any time. A member of the Gastrointestinal Cancer Risk Evaluation Program will be available to answer questions as they arise, and our clinic office can be reached at 215-349-8222. If you want further information about your rights as a participant in the clinical registry, you may contact the Office of Regulatory Affairs at 215-898-2614.

You have read this consent form and you will receive a copy of this consent form. You agree to participate and accept the risks. You agree to the information provided in this document and you have had the opportunity to ask questions you might have about participation in the Gastrointestinal Cancer and Polyposis Registry. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution, as well as outside our institution in a de-identified manner.

_____	_____	_____
Name of participant (Print)	Signature of participant	Date

_____	_____	_____
Name of person obtaining consent(Print)	Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	_____
Name of authorized subject representative(Print)	Signature of authorized subject representative	Date

_____	_____	_____
Name of person obtaining consent(Print)	Signature	Date

Provide a brief description of the above person’s authority to serve as the subject’s authorized representative.
