Research Consent Form for Social and Behavioral Research

Protocol Title:
Epidemiology of Syndromic GI Stromal Tumors

DF/HCC Principal Research Investigator / Institution:
JUDY E. GARBER, MD, MPH, DANA-FARBER CANCER INSTITUTE

DF/HCC Site-Responsible Research Investigator(s) / Institution(s):
JUDY E. GARBER, MD, MPH, DANA-FARBER CANCER INSTITUTE

(Family Members Consent 1B)

A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "subject" or "participant". This research study is evaluating the genetic and other features that are associated with inherited forms of GIST (gastrointestinal stromal tumors). The study is called **Project FLAG (Families Learning About GIST).** Members of your family have been involved in this research study and thought you might be interested in participating too.

It is expected that a total of about 800 people will take part in this research study, enrolling through their oncologist's office at Dana-Farber, or another participating program, or through a GIST support website (GIST Support International or the Life Raft Group).

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is the National Cancer Institute (NCI), a division of the National Institutes of Health (NIH), which is providing funding for this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research subject. The decision to participate or not is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

We encourage you to take some time to think this over and to discuss it with other people and to ask questions now and at any time in the future.

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B. WHY IS THIS RESEARCH STUDY BEING DONE?

GISTs are very rare tumors. The majority of GISTs do not occur in families. However, some families have inherited a greater tendency to develop GISTs, sometimes in association with certain skin findings or a tendency to other cancers as well.

In this project, researchers are exploring the inherited forms of GIST. Scientists have found that certain changes in the DNA pattern in GIST genes may be passed down from generation to generation in some families. Families who have a DNA change in these genes appear to be more likely to be diagnosed with the inherited forms of GIST. There may be other genes that can confer risk of GIST as well. We are hopeful that the information that we collect in this study can be used to assess a person's risk of GIST, and to develop good cancer screening recommendations for people at high risk of developing GIST.

Finally, individuals who enroll in this study may consent to have their information become part of a registry of GIST families who may wish to participate in related research to address issues that may not be completely explained in the course of this study.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following options:

- Decide not to participate in this research study
- Participate in another research study
- Obtain genetic counseling and/or genetic testing through available clinical programs

Whether or not you decide to participate in this study, you may still be able to obtain genetic counseling and/or genetic testing through clinical programs at this center or at other centers. If you decide not to participate in this study, your care at the institutions participating in the project will not be affected.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

You are eligible to participate in this component of the FLAG study because one of your family members has or has had a GIST and is a participant in the same research study. Your relative thought that you might be interested in the study, too. According to the family history your relative provided to us, you have had cancer or another condition that may make it more likely that there is some inherited component to your relative's GIST. Your information is, therefore, valuable to the study, as we try to identify features of the family or personal health history that may be connected to hereditary GIST.

We would therefore welcome your decision to participate in this study. You may participate in this research in several ways:

1. We request that you give us permission to obtain and review your medical records and pathology specimens pertaining to your diagnosis of cancer or a non-cancerous condition that may be linked with inherited forms of GIST, so that we can be precise about these diagnoses.
2. We request that you consider giving us a specimen of blood or saliva for research. We will study the DNA from your sample as part of our effort to understand which conditions are part of hereditary GIST – which other cancers? Which skin conditions? Are there other features? The sample will be stored in a bank with samples from other patients with GIST and their family members. Genes potentially related to hereditary GIST will be analyzed. However, your samples are analyzed for research only. No results from this analysis will be given back to you.

If your relative who has had GIST agrees to further investigation, we will want to analyze his/her genes. If an alteration in the gene is found, we would want to study the DNA of other family members to learn whether shared genetic changes link the GIST to the type of cancer or other condition you have had. This is what research is all about. If a genetic alteration is identified in your relative, he or she will have the option of notifying you and offering to have your DNA re-tested through the study. At this time you will be mailed **Consent #3** and be asked to provide another specimen of blood or saliva if you agree to genetic testing. Once we receive your signed **Consent #3** and your blood or saliva sample, it will be sent to a clinical laboratory. This latest testing is clinical, meaning that you would receive the results (if you decide to do so, after talking with a genetic counselor), which you could share with your physician and family members.

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E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

Your length of participation in this research study will vary by how much you choose to participate. If you provide medical records only, and decline to be contacted in the future, your involvement will be brief. If you agree to enroll in the study, and provide a sample for research, the specimen may be stored in the bank and analyzed over months or years. You may stop participating at any time for any reason. Your decision to stop participating in the study will not affect the care that you receive at any of the participating institutions.

The research team may decide to take you off the research study for many reasons including if:

- It is considered to be in your best interest
- The study procedures are found to be unsafe or ineffective
- There is any problem with following study procedures
- There are any problems with research funding
- Or for any other reason

If you are removed from the research study, the research Investigator will explain to you why you were removed.

In addition, you can stop participating in the research study at any time for any reason. Please notify us in writing if you wish to do so.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are physical and perhaps emotional risks to taking part in any research study.

1. Blood Draw: The risks of blood drawing are small and include superficial bruising or bleeding at the needle site.

2. Certain emotional consequences may result from participating. You may find talking or thinking about the issues raised in this study to be distressing. You may also find that discussing your personal or family medical history and the concept of inherited GIST or other cancer susceptibility may stress your relationships with family members or friends. We are prepared to talk with you about these issues, and to assist you in identifying an appropriate professional counseling if you need additional support.

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During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

There may also be side effects other than those listed above that we cannot predict.

For more information about risks and side effects, contact your genetic counselor or Dr. Judy Garber at (617) 632-2282.

During the research study, you may be asked to provide any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you directly. We hope the information learned from this research study will provide more information about the features associated with inherited forms of GIST for individuals and families with this condition and allow clinicians to develop appropriate screening recommendations for at-risk individuals.

Other potential benefits of genetic testing include:

1) Testing information may relieve the anxiety and worry of not knowing your gene status. It may reduce feelings of uncertainty. For some people, simply knowing is better than not knowing.

2) This information may help explain the pattern of cancer in your family. If you have been diagnosed with cancer, testing may explain your own cancer history.

3) Your test results may give other family members information about their chance of having an alteration, of passing it on to children, and of developing cancer.

4) You may gain knowledge about your cancer risk. This information may help you and your doctors plan a program that includes monitoring for early signs of GIST or other cancers.

5) If an alteration has already been found in one of these genes in your family, learning that you do not have this alteration means you do not have an increased risk of GIST and related cancers because of your family history. If you have had cancer or a pre-cancerous condition, you would still have some increased risk based on your own history. If you have not had cancer, you would still have the general population risk of cancer, including any risk that may come from lifestyle and environmental factors.

6) You may learn about the chances that your children (or future children), and other relatives have to carry an altered gene.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Leaving the research study will not affect your medical care in any way.

If you choose not to participate, if you are not eligible to participate in additional aspects of the study, or if you withdraw from this research study at any time, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw from the study, we ask that you notify the investigators in writing.

I. WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company. The Dana-Farber Cancer Institute will receive no reimbursement for your participation in this study.

If you are eligible to participate in additional aspects of the research study and you elect to participate in these portions of the study, you will not be charged for the following:

- Genetic counseling
- Genetic testing
- Additional screening that may be recommended if you are found to carry an altered GIST gene.

You or your insurance company will be charged for other portions of your care during this research study that are considered standard care. You may be responsible for co-payments and deductibles that are standard for your insurance coverage. For example, if you have been diagnosed with a GIST, you would continue to have treatment as has been recommended by your oncologist. These services are not part of this research and you may have to pay for these yourself.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Dana-Farber Cancer Institute: (617) 632-3455
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

http://www.cancer.gov/clinicaltrials/learning/insurance-coverage

On rare occasions, laboratory research on human specimens results in discoveries that are the basis for new research products or diagnostic and therapeutic methods. It is not the policy of Dana-Farber Cancer Institute to compensate you for any future financial claim to your tissues for research and development for commercial and non-commercial purposes.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that may occur from taking part in this research study.

J. WHAT HAPPENS IF I AM INJURED OR SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

Providing your care does not mean that DF/HCC or the research Investigators are at fault, or that there was wrongdoing. There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research Investigator's name and phone number are listed in this consent form.

K. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS. The results of this research study may be published. You will not be identified in publications without your permission.

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include such groups as:

- The National Institutes of Health
- Federal research oversight agencies

Data Security

Information about your participation in this study will be stored in a secure computer. All files pertaining to this study will be kept in a locked office to which only study staff will have access. Access to the computer and to all other information stored on the computer is password protected. Test results and other sensitive personal information will never be stored in the same file as your name or other identifying information.

L. CERTIFICATE OF CONFIDENTIALITY

This research study is being conducted by Dana-Farber Cancer Institute. To help protect your privacy, Dana-Farber Cancer Institute has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS).

With this Certificate, Dana-Farber Cancer Institute cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative or other proceedings. Disclosure will be necessary, however, upon request of the Department of Health and Human Services for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family or even the research Investigator from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer, learns about your participation, and obtains your consent to receive research information, then Dana-Farber Cancer Institute may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

M. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the study staff as listed below:

Dana-Farber Cancer Institute

- Judy Garber, MD, MPH, Principal Investigator: 617-632-2282
- Kelly Branda, MS, CGC, Genetic Counselor: 617-632-5969
- Irene Rainville, MS, PhD, Genetic Counselor: 617-582-8537
- Helen Lim, MS, Lic Ac, Study Manager: 617-632-5247

- Lisa DiGianni, PhD, Project Manager: 617-632-5429

For questions about your rights as a research participant, please contact a representative of the Office for the Protection of Research Subjects at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

N. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research Investigators, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. **What protected health information about me will be used or shared with others during this research?**

   - Existing medical records
   - New health information created from study-related tests, procedures, visits, and/or questionnaires

2. **Why will protected information about me be used or shared with others?**

   The main reasons include the following:
   - To conduct and oversee the research described earlier in this form;
   - To ensure the research meets legal, institutional, and accreditation requirements;
   - To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
   - Other reasons may include for intervention, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care.

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research Investigators and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, and its subcontractors
- Other research Investigators and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research Investigators and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: Whom do I contact if I have questions about the research study?"
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your intervention or payment for your intervention, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

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DOCUMENTATION OF CONSENT

CONSENT TO PARTICIPATE

Consent of Subject: I_____ understand the purpose of this research and agree to participate and follow the procedures required. By signing this consent, I agree to the following points regarding this study:

(1) __**YES** __ **NO** (*please check one*) I agree to provide a blood or saliva specimen for research.

(2) __**YES** __ **NO** (*please check one*) I give permission for researchers to re-contact me to discuss further testing.

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time.

_____ _____

Signature of Subject Date

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date) at _____ (time.)

☐ A copy of this signed consent form was given to the subject or legally authorized representative, or, where the subject is a minor, the subject's parent or legal guardian.

For Adult Subjects

☐ The subject is an adult and provided consent to participate.

☐ The subject is an adult who lacks capacity to provide consent and his/her legally authorized representative:

- ☐ gave permission for the adult subject to participate
- ☐ did not give permission for the adult subject to participate

Signature of Individual obtaining consent: _____

Printed name of above: _____

Date: _____

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CONSENT FOR RELEASE OF MEDICAL RECORDS/PATHOLOGY SPECIMENS

Please fill out this form as completely as possibly and give as much information as you can about each cancer diagnosis or related medical condition.

Patient's Name_____ Patient's Date of Birth_____

Name of First Diagnosis, Age, Dates of Treatment	
Name of Hospital City, State	
Doctor/Surgeon's name(s)	

Name of Second Diagnosis, Age, Dates of Treatment	
Name of Hospital City, State	
Doctor/Surgeon's name(s)	

For the purposes of medical research, I give Judy Garber MD, Suzanne George MD, George Demetri MD, their Co-Investigators or their appointed representatives permission to review my medical records, operative notes, pathology reports, discharge summaries, and pathology specimens related to GIST or associated conditions.

Signature _____ Date _____

Relationship to Patient (self, parent, guardian) _____

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