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

(Medical Release Consent)

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)**.

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, and fax or mail it back to us. (The fax number and mailing address are provided at the end of this consent.) If the consent is mailed to us, we will send you a copy of the signed consent once it is received so that you can refer to it while you are involved in this research study.

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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 any of the GIST genes may be passed down from generation to generation in some families. Families who have a DNA change in any of the GIST 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.

The purpose of this study is to explore the inherited forms of GIST. We want to find out what genetic and other features are part of an inherited risk of GIST. We have some clues – some benign skin findings and sometimes other rare cancers have been reported – but we want to try to identify all of the features that may be present in individuals who have inherited risk of GIST.

We also want to identify factors that may contribute to an inherited tendency to develop GISTs. In particular, we want to explore the inherited changes in the genes that have already been associated with inherited forms of GIST. 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, if you at any time, decide to provide a specimen to see if you are eligible to participate in the study in its entirety, individuals who enroll 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

- Decide at any time to submit either a blood or saliva sample to obtain genetic analysis (if eligible) through this research study (Please refer to **Consent #1** on the website for more information.)
- 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 THIS PART OF RESEARCH STUDY?

SCREENING PROCESS

If you have been diagnosed with GIST you may be eligible to participate in all or part of FLAG. At this time, you have opted to participate only in the screening portion of the research study. The screening process includes:

1. Consent Form
Please read the consent form carefully and if you wish to, sign the form where indicated.

2. FLAG Questionnaire
Fill out the FLAG Questionnaire, which should take you at most 30 minutes to complete. The questionnaire asks for information on your personal and family cancer and health history. You may choose to skip any questions that you prefer not to answer. The information you provide will help to determine which parts of this study you are eligible for. If you do not meet the eligibility criteria, you will not be able to participate in all parts of this research study. If you prefer not to do the questionnaire, you will not be enrolled in the FLAG study.

3. Medical Records Documentation
We request that you give us permission to obtain and review your medical records and pathology specimens pertaining to your diagnosis of GIST, other cancers, or other non-cancerous conditions that may be linked with inherited forms of GIST. Permission to view your GIST and other cancer history is required in order that we can be accurate about these diagnoses. **NOTE:** You will need to complete page 12 of this consent to

authorize us to collect your medical records regarding GIST and other potentially related conditions, such as skin examinations and biopsies and other cancers.

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

You will only be asked to complete a questionnaire in this portion of the research study, which should take approximately 30 minutes of your time.

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 no physical risks to taking part in this research study. However, 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.

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.

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.

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 to not participate, or if you are not eligible to participate, or if you withdraw from this research study, 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.

I. WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you. If there are charges for medical records, these costs will be covered by research. The Dana-Farber Cancer Institute will receive no reimbursement for your participation in this study.

J. 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.

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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.

K. 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.

L. 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.

M. 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;

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- 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?"

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*) Allow researchers at Dana-Farber Cancer Institute to use my FLAG Questionnaire information for research purposes.

(2) __**YES** __ **NO** (*please check one*) Allow researchers at Dana-Farber Cancer Institute to collect information from my medical chart and my pathology specimens related to GIST for use in this research. (If yes, please complete the '*Consent for Release of Medical Records/Pathology Specimens'* on the final page of this consent.)

(3) __**YES** __ **NO** (*please check one*) Allow researchers to re-contact me to discuss which risk group I am determined to be eligible for.

(4) __**YES** __ **NO** (*please check one*) Allow researchers to re-contact me to discuss the possibility of enrolling other family members in this study.

(5) __**YES** __ **NO** (*please check one*) Allow researchers to re-contact me for other studies, which might be appropriate for my family or me.

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

Please sign and complete pages 10 and 12. A copy of this consent (<u>all 12 pages</u>) must be faxed or mailed back to Dana-Farber Cancer Institute.

Fax: (617) 632-3161
Attn: Helen S. Lim

Mailing Address: Dana-Farber Cancer Institute
44 Binney Street, SM 336
Boston, MA 02115
Attn: Helen S. Lim

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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

or

For Minor Subjects

☐ The parent or legally authorized representative gave permission for the minor to participate.

☐ The parent or legally authorized representative did not give permission for the minor 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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