

INFORMATION AND CONSENT FORM
To Participate in a Registry Study
for Parents/Guardians or Adult Participants

Study Title: Life Raft Group GIST Registry Protocol
Study #: LRG2013PR112
Sponsor: Life Raft Group, Inc.
Study Doctor: Peter Knox
The Life Raft Group
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WHAT IS THIS REGISTRY STUDY ABOUT?

An organization called the Life Raft Group (LRG) wants to find out more about a cancer called Gastrointestinal Stromal Tumors (GIST) as well as other cancers that may or may not be related to GIST. To collect this information, LRG has created a research registry.

A registry is a place where medical information, family history and other related information from patients is collected and stored for medical research. The purpose of the Life Raft Group GIST registry is to collect and store medical information and other information from individuals with the same disease or other cancers that share commonalities such as molecular targets, treatments, or other factors. Information from patients in this registry will be used for medical research to better understand GIST and these other diseases. Scientists studying GIST and these other diseases need more accurate, real-world information to understand how these diseases affect people.

People with GIST and other related or unrelated diseases are being asked if they would like to participate in the Life Raft Group registry. The Life Raft Group GIST registry is also linked to a tissue bank, which is a place that stores tumor tissue, blood or other samples from patients. You may also be asked to provide samples to the tissue bank. You would need to read and sign a separate consent form about the tissue bank. **You do not have to take part in any other Life Raft Group activities, including the tissue bank and online forums, to take part in this registry.**

If you have any questions about or do not understand something in this form, you should ask the investigator or his/her study staff. You should also discuss this study with anyone you choose in order to better understand this study and your options.

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a parent or guardian or legally authorized representative who might sign this form on behalf of the person in the study.

WHO IS PAYING FOR THIS STUDY?

The Life Raft Group, the sponsor of the study, is paying for this study.

WILL BEING IN THIS STUDY HELP ME?

Being in this study will not directly benefit you. Information from this study might help researchers understand GIST and other cancers better and that may help others in the future.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

This is not a treatment study. Expenses related to your condition and its therapies, doctor charges, other office visits, or other tests are **not** paid by the registry. ***You or your medical insurance provider will be responsible for all costs associated with your regular medical treatment.***

HOW LONG WILL I BE IN THE REGISTRY?

If you decide to be in this study and the investigator says you can be in the study, your participation will last as long as the registry is active or until you decide to withdraw from the study.

WHAT WILL HAPPEN DURING THIS STUDY?

While you are in the study, you are expected to:

- Provide initial demographic information, such as your name, date of birth, gender, date of diagnosis and other similar information.
- Provide details about your treatment history.
- Provide regular updates including results of scans, current treatment (such as drug name and dose) and information related to recurrence or progression of your disease.
- Provide information to the registry on an ongoing basis (generally whenever you have a new scan performed).
- Tell the investigator or study staff if you want to stop being in the study at any time.
- Your family members or a caregiver may provide updates if you are not available.

Do I need to come in for study visits?

- No, this is not a treatment study. You will be asked questions about your treatment, but no in-person visit is necessary. All information will be collected via phone interviews, via email, questionnaires or via internet updates.

The Life Raft Group maintains an electronic mailing list community (a listserv) that members are eligible to participate in. Members of this private listserv may discuss medical histories. This registry will not record information discussed by registry participants in this listserv or other social media (such as Facebook). Study staff may, however, contact you for a more formal update if staff notices a relevant posting (the posting may trigger a call or email from the study staff to confirm and authorize recording of the relevant information).

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

You will not change your regular medical care for this study. This study should not involve any physical risk to you. There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the investigator or study staff if you would like to know more about how your information will be protected while you are in this study.

WILL I RECEIVE PAYMENT?

No; participants will not receive any payment for study participation.

DO I HAVE TO BE IN THIS REGISTRY?

Your participation in the registry is voluntary. The care you receive from your regular doctor will not be affected in any way, whether or not you decide to be in the registry. If you want to stop being in the registry, tell the investigator or study staff. If you decide to withdraw from the registry, the investigator or staff may ask you some questions about being in the registry. The investigator or the sponsor can remove you from the registry at any time, even if you want to stay in the registry. You can still take part in other LRG activities even if you choose to leave this registry.

For adults considering whether to be in the study:

What if I work with the study center or sponsor? What if I am a family member of someone who works with the study center or sponsor?

Study center/sponsor employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

For parents/guardians who are considering whether to allow their child to be in the study:

What if I work with the study center or sponsor? What if I am a family member of someone who works with the study center or sponsor?

Study center/sponsor employees and their family members do not have to let their children be in this study. No one should influence or pressure you to let your child be in this study. An employee's or his/her family member's decision to allow a child to be in this study, or to have the child leave the study early, will not affect the employee's job or job benefits.

WHO CAN I TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

Do not contact the Life Raft Group with emergency situations. Registry updates of your medical condition can wait.

You can ask questions about the study at any time. You can call the investigator or study staff at any time if you have any concerns or complaints. You should call them at the phone number listed on page 1 of this form if you have questions about the study procedures or other questions. The study staff cannot answer questions about the reasons or validity of your medical treatment. This type of question should be referred to your regular doctor(s).

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the investigator or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.

Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.

Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS REGISTRY?

This section explains who will use and share your private health information if you agree to be in this study. If you do not sign this form, you cannot be in the study.

During the study, the investigator and the study staff will use, collect, and share health information about you (your "records"). Your records may include any information about you that you provide, such as your name, address, phone number, and medical information.

The registry aims to share detailed medical and other information with researchers, while still protecting your privacy. This is done by hiding the

name, address and other “identifying” information from the researchers. We call this information “de-identified” because it has been removed of all personal identifiers. Your personal information (such as your name, address, or other information that identifies you or your family) will be labeled with a code number and stored in a secure place and protected with a password. Only authorized people who work in the registry will know the code and be able to identify you if needed.

The de-identified data collected and compiled by the registry belongs to the GIST community. The Life Raft Group is the guardian of the information contained within the registry.

If a researcher wants to access your name or other identifying information, the study staff will ask your permission first. Otherwise, your name and identifying information will only be used or shared when required by law. Your records may be used and shared with these people in the following situations:

- The sponsor, The Life Raft Group, and people who work with or for the sponsor will use your records to review the study and to check the results of the study.
- If there is a federal audit of the study, some government workers, such as employees of the U.S. Food and Drug Administration (FDA), will be able to see your information.
- You release your information to other people not involved in the study.
- You agree in writing to the release of your information to other people.
- The investigator or study staff suspects things they must report under federal, state, or local law, including child or elder abuse, certain communicable diseases, or a possible threat to you or others. There may be other things the investigator or study staff must report under law.

You do not have a guarantee of absolute privacy because of the need to share your information. After the investigator shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people

who do not have to protect the privacy of your records. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes.

The investigator, the study staff, or LRG may use some facts about your being in this study in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.

You have the right to see and copy your records related to this research.

You can cancel this authorization to use and share your records at any time. If you want to cancel your authorization, you must write a letter to the investigator. If you cancel your authorization, you will not be able to continue in the study.

Even if you cancel your authorization and leave the study early, the investigator and study staff will still be able to use and share your records that they have already collected as described above.

This authorization to use and share your records expires in 50 years.

You will receive a signed copy of this form.

Signature of Participant (if adult)
or Parent/Guardian
or Legally Authorized Representative

Date

CONSENT

I have read this form, and I have been able to ask questions about this registry. The investigator or study staff has talked with me about this registry. They have answered all my questions. I voluntarily agree to be in this registry.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

Name of Participant (Print)

Date of Birth

Signature of Participant (If an Adult)

Date

If participant does not have the legal capacity to consent to their participation:

I certify that under state law I am the parent/guardian or legally authorized representative of the participant named above and that I am authorized to sign this consent to his/her participation in the research study described above. I am also authorized to allow the use and sharing of the participant's study-related records as described above.

Name of Parent/Guardian
or Legally Authorized Representative (Print)

Relationship to Participant

Signature of Parent/Guardian
or Legally Authorized Representative

Date

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I attest that the participant and/or parent/guardian or legally authorized representative named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study or allow his/her child to be in this study.

Name of Person Explaining Consent (Print)

Signature of Person Explaining Consent

Date

WITNESS STATEMENT

As an impartial third party, I witnessed the entire consent discussion and the signature of the participant (or, if applicable, the participant's legally authorized representative) on this form.

Name of Witness (Print)

Signature of Witness

Date