STANFORD UNIVERSITY Research Consent Form

Protocol Director: Matt van de Rijn, MD, PhD

Protocol Title: Molecular Characterization of Leiomyosarcoma and GIST

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Matt van de Rijn. You may contact him now or later at 650-498-7154.

DESCRIPTION: You are invited to participate in a research study of biologic features of soft tissue tumors and how they relate to tumor development and growth. You were selected as a possible participant in this study because you have undergone biopsy or removal of some tissue.

If you decide to participate, If you decide to terminate your participation in this study, you should notify Dr. Matt van de Rijn at 650-498-7154.

This research study is expected to last ten years.

If you decide to participate, you will contribute a paraffin block from your surgical procedure to the study. You will need to request the hospital where your surgery was performed to send this block to Sharon Anderson who will deliver it to the laboratory of Dr. van de Rijn.

Your tissue will be maintained by Stanford University for such research purposes, as long as allowed by the law or until the Stanford University decides to discontinue your donated tissue sample or discontinue the Tissue Bank.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.
The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

RISKS AND BENEFITS: There are no physical risks beyond the usual risks associated with surgery because tissue is only being removed for clinical care and not for research.
While you will not directly benefit from this research we hope future patients will. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately 5 years, at the end of the study all identifying data will be destroyed.

PAYMENTS: You will not receive payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.** You have the right to refuse to answer particular questions.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

You are invited to participate in a research study of biologic features of soft tissue tumors and how they relate to tumor development and growth. You were selected as a possible participant in this study because you will be undergoing biopsy or removal of some tissue.

After the paraffin block of your tumor tissue has been received by Sharon Anderson, the tissue will be sent to Dr. van de Rijn's laboratory for analysis of specific genetic (DNA and RNA) and/or protein components that may be associated with the development, growth and spread of soft tissue tumors.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.
Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Matt van de Rijn at 650-498-7154.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, age, gender, site, outcome, blood and other tissue samples and related records in connection with this research study.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Dr. Matt van de Rijn
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2075 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a

medical or billing decision about you (e.g., if included in your official medical record).

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Matt van de Rijn. You may contact him now or later at 650-498-7154.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Matt van de Rijn at 650-498-7154.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, MC 5579, Palo Alto, CA 94304.

If you agree to participate in this research study, please proceed with the appropriate steps to have your tissues sent to Dr. Van De Rijn.