

## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**Title:** COLLECTION OF BLOOD AND SURGICAL TISSUE: A MULTICENTER RESEARCH PROTOCOL

**Sponsor:**

**Investigator:**

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**Your Rights:** Subjects who participate in medical studies are entitled to certain rights. These rights include, but are not limited to the subject's right to be:

- Informed of the nature and purpose of the study;
- Given an explanation of the procedures to be followed in the medical study;
- Given a description of any discomforts and risks reasonably to be expected;
- Informed of medical treatment, available to the subject after the study, if complications should arise;
- Given an opportunity to ask questions concerning the study or the procedures involved;
- Given the opportunity to decide to consent or not to consent to a medical study.

**The Research:** You are invited to participate in a study that will collect blood samples and surgical material. Samples will be used for the development of diagnostic tests and other research and development purposes. Information about your medical and family history and available laboratory reports (blood studies and x-rays) will be collected.

If you decide to participate, a sample of your blood will be drawn. The study doctor or study staff will ask you questions about your health and lifestyle. You have the right to know what questions you will be asked before you make a decision about whether you want to participate.

**Use of the Samples:** The samples collected will be used for medical research purposes by **redacted**. The samples may be transferred, assigned or sold to participating private or public academic or government research institutions, or to commercial biotech, pharmaceutical and/or research organizations. This research may result in new or improved diagnostic and/or treatment products, services or devices. You will not benefit financially from this potential commercialization.

**Risks:** Drawing blood from your arm may cause pain, bruising, lightheadedness, and, on rare occasions, infection. There may be risks or side effects, which are unknown at this time.

**New Findings:** You will be told about any new information that might change your willingness to continue in this study.

**Benefits:** This is not a treatment study. You will not receive any direct benefit from participating in this study.

**Costs:** There will be no cost to you for participation in this study.

**Source of Funding:** Funding for this research study will be provided by **redacted**. The research may produce information or material that may be used for commercial purposes. If the research results in a commercial product(s), you will not personally benefit from this commercialization.

**Voluntary Participation/Withdrawal:** Your participation in this study is voluntary. You may decide to not participate in this study. If you do participate, you may freely withdraw from the study at any time. Your decision will not change your future medical care at this site. The study doctor or the sponsor without your consent may stop your participation in this study at any time.

**Questions:** If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction, contact:

Pathologist name and phone number \_\_\_\_\_

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**What Information Will Be Used or Disclosed?**

Your health information related to this study, including, but not limited to, blood and other tissue samples and related records may be used or disclosed 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:

**Who May Receive 1 Use the Information?**

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

\*You may not be allowed to see or copy certain information in your medical records collected in connection with your participation in this research study while the research is in progress. \*Your information may be redisclosed if the recipients described above are not required by law to protect the privacy of the information.

**Expiration:** Your authorization for the use and/or disclosure of your health information will expire upon completion of the research study and any related period of regulatory compliance.

**Confidentiality:** Information from this study will be given to the sponsor. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by the sponsor **redacted** or, Department of Health and Human Services (DHHS) agencies.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. Information about your identity will not be furnished to the researchers who receive your specimen and any data that may be published in scientific journals will not reveal the identity of the subjects.

**Consent:** Your signature indicates that you have read and you understand this consent form. You have discussed this study with the principal investigator and/or his study staff and you have decided to participate based on the information provided.

You understand that a signed and dated copy of this form will be given to you. You authorize the release of your medical records for research or regulatory purposes to the sponsor, Department of Health and Human Services agencies. By signing this consent form, you have not waived any of the legal rights, which you otherwise would have as a subject in a research study.

---

Subject Printed Name	Subject Signature	Date
Witness Printed Name	Witness Signature	Date
Printed Name of Person Conducting Informed Consent Discussion	Signature of Person Conducting Informed Consent Discussion	Date
Investigator's Signature (If different from above)		Date