RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Collection of Consented Remnant Specimens for Research

PROTOCOL NO.: 14001
WIRB® Protocol #20180798

SPONSOR: SeraTrials, LLC, a BioIVT Company

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Name
Phone Number (24-hour number)

INTRODUCTION

A person who takes part in a research study is called a "research subject". The use of "you" in this consent form refers to you as the research subject. The study investigator will be called Dr. [Investigator Name], "doctor" or "study doctor" throughout this consent form. SeraTrials is the sponsor of this research and will be referred to as the "sponsor" or "SeraTrials" throughout this consent form.

SUMMARY

You are being asked to participate in a research study because you meet the study criteria for participation. Before you decide to be part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent. This consent form provides information about the research study. You will be asked to read this consent form and the study staff will review the consent form with you and answer any questions you may have. If you decide to participate in the study, you will be asked to sign and date this consent form. You will be given a copy of this signed and dated consent form.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- Participation in this study is voluntary.
- Portions of medical data you provide may become part of the research record. If that happens, your medical information may be looked at and/or copied by the sponsor of this study and government agencies such as the United States (US) Food and Drug Administration (FDA) or other groups associated with the study.

PURPOSE OF THE STUDY
The purpose of this study is to collect surgical remnants (excess tissue removed during your surgery you are undergoing that would typically be discarded) for use in future scientific and medical research. In some cases whole blood and a sample of urine may also be collected. The fluids collected for this study may be referred to as, "samples" or "specimens" throughout the rest of this consent form. Human specimens are in great demand by researchers seeking information that will lead to improved disease prevention, diagnosis, and management.

This study may aid in the development and improvement of new diagnostic test kits, devices, biomarker discovery and clinical/medical research on particular diseases and illnesses. Your samples may be stored and used for future research purposes and may be transferred to partners such as universities, pharmaceuticals and biologics companies and research labs for industrial/commercial use. They might also perform genetic tests that look at the cells that make up your specimens (for example, DNA, RNA, markers of disease, markers of risk for disease), and look for certain features or traits of people (for example, age, gender, body weight, family history of certain medical conditions).

Background and Purpose of this Research Study
Dr. [Investigator Name] is working with SeraTrials. SeraTrials is a biotechnology company that obtains biological samples from people who meet certain criteria to be used in research. The samples are used by researchers in academic, pharmaceutical and medical device laboratories.

PROCEDURES
Your participation in this study will be for one (1) visit. Information about your personal and medical history will be collected after you have provided consent. Study staff will inform you that one or more specimen samples will be collected during the visit. Make sure to initial next to the specimen you have agreed to provide below:

_____ **Surgical Remnants:** You must be already undergoing elective cosmetic surgery (breast enhancement or reduction, facial contouring and rejuvenation, body contouring, etc.). You may be asked to allow study staff to provide the excess tissue removed during your surgery that would typically be discarded, to the sponsor.

_____ **Blood Draw:** You may be asked to allow study staff to collect a blood sample of up to 50 mL [equal to about 3.5 tablespoons].

_____ **Urine:** You may be asked to provide a urine sample. A cup will be given to you for collection at the doctor's office.

Your samples and personal /medical history information will be de-identified and given a unique study code number. All study records are kept confidential and paper files are kept in locked cabinets only accessible by study staff. Study files on computers are encrypted and password protected.

Samples may be stored and used for up to 10 years from the date of collection. If samples are not completely used within this 10 year period, samples will be destroyed.

The Sponsor and the study doctor might follow-up with you to confirm information in the research record or to inquire about your health and well-being. The Sponsor might contact you by phone, or more likely, the study doctor will talk with you and review your medical records at a regularly scheduled office visit. These procedures are done periodically to ensure the health information linked to your specimens is up to date.

RISKS AND DISCOMFORTS

Blood Draw: The sample blood drawing procedure may cause pain, bruising, infection, accidental arterial puncture, clotting of the vein at the site where the needle is inserted, and/or a fainting spell. The finger stick/prick blood draw may cause some soreness and bruising at the site of puncture and rarely infection.

Loss of Confidentiality: We take steps to protect your data from a breach of confidentiality. Absolute secrecy cannot be guaranteed. Since DNA (the chemical that makes up genes) information is unique to you, in the future a link between your DNA and your identity may be possible. However, researchers who are provided with specimens to perform genetic research have agreed to make no attempts to identify you.

There are no known risk/safety information associated with providing surgical remnants that would typically be discarded and urine, for research.

There may be risks that are unknown.

RESEARCH RESULTS

The researchers do not plan to provide you with the results of any of the studies done on your samples, because other research may be necessary before these results are meaningful. Results of the research will not be applicable to any individual subjects in the study. **It is important that you do not participate in this study for the purpose of evaluating your health status.**

BENEFITS

If you agree to participate in this study, there will be no direct medical benefit to you. We hope any information learned from using your specimens and clinical information will help advance current and future research into the cause and treatment of medical conditions and disorders.

COMMERCIAL USES
Any specimens you provide that are used in research may result in new products, tests, or discoveries. In some instances, these developments may have commercial value. There are no plans for you to share in any financial benefits from these products, tests, or discoveries.

COSTS
There will be no cost to you for participating in the study. You are responsible for the costs outside of this research.

PAYMENT FOR PARTICIPATION
You will not be paid for participating in this study.

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your demographic and medical information. For example:

- Demographic information such as age, gender, race and ethnicity.
- Date of surgery and/or sample collection.
- Sometimes past and present medical history such as medications, health condition and surgical history may be requested.

Who may use and give out information about you?
Information about your health may be used and given to research partners by the study doctor and staff.

Who might get this information?
The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor

Your information may be given to:

- Universities, pharmaceutical and biologics companies research labs.
- United States (US) Food and Drug Administration (FDA).
- Governmental and regulatory authorities.
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board (WIRB).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done according to federal and international standards

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. You have to request to be withdrawn.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

CONFIDENTIALITY OF INFORMATION COLLECTED FOR RESEARCH PURPOSES
We will take steps to keep your personal information private, but we cannot guarantee total confidentiality. All identifiable information about you will be replaced with an alphanumeric code. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored in a locked cabinet or electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information. We will not release information about you to others not listed above, unless required or permitted by law. Your research specimens, data and records may be kept by the Sponsor or other researchers indefinitely.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, seek medical attention at a suitable facility immediately. Inform your study doctor regarding your hospitalization. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, SeraTrials is paying the study doctor for the costs associated with the conduct of study activities.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you
- if you are unable to keep your scheduled appointments
- if the study is cancelled prior to completion

QUESTIONS
Contact Dr. [Investigator Name] at [phone number] (24 hours), [address] for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study procedures, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers. If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to participating in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of the Subject Date

_____
Printed Name of Person Conducting the
Informed Consent Discussion (printed)

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date