

INFORMED CONSENT and AUTHORIZATION FORM TEMPLATE

Protocol Number: Protocol AST-FPB-003

Protocol Title: "A Multi-Center Study for the Collection of Surplus Surgical Tissues for Genomics, Proteomics and Biomarker Research (Fresh, Preserved, Blood)"

Principal Investigator: _____, MD

Site Address of Investigation: _____

24 hour Telephone #: _____

Sponsor: Asterand, Inc.

Purpose of Study

You are being asked to provide tissue and medical data for research use because you are about to have surgery that may involve removal of tissue. Whenever surgeons remove tissue during an operation, they send the tissue to a pathology laboratory to help them make an accurate diagnosis. Left-over tissue that is not needed is usually discarded. The purpose of this study is to collect tissue that would otherwise be discarded and place it with researchers. You may also be asked to provide blood samples for this study.

If you agree to participate in this study, your tissue, medical data, and blood sample (if applicable) will be placed with a for-profit biomedical research company named Asterand. The samples and medical data will be provided to researchers at non-profit research institutes and commercial companies. Your samples may be provided immediately for research use, or they may be stored indefinitely for use in future research. You must be at least 18 years of age and meet the criteria for participation in this study.

Research Use of Tissue and Medical Information

Researchers will be looking for biomarkers. Biomarkers are tiny molecules including those called protein, ribonucleic acid (RNA), and deoxyribonucleic acid (DNA). Some genes may affect your risk for certain diseases. Genes are made from DNA and are the basic "instruction book" for people. Everyone's genes are a little different. These differences explain some of the variations between people, like eye color, hair color, and blood types. They also partly explain why some people, but not others, get certain diseases. Information about these differences among people can help researchers discover new tools to diagnose and treat disease.

Your tissues may be stored in ways that allow the cells to grow and multiply. These multiplying cells may give rise to what is called a cell line. Cell lines can be used for multiple future studies, and these cells may be kept alive for many years.

Duration of Participation in Research

Your active participation in this study will end as soon as the samples are obtained. However, your passive participation in this study will last indefinitely because the samples you provide may be preserved for a long period of time.

Procedure for Acquiring Medical Information

Medical data and general facts about you will be collected for this study. Information such as age, gender, ethnic background and related medical data will be collected by your doctor and submitted to Asterand on study forms. Information such as diagnosis, medication history, treatments, response to treatments, follow-up data, and the source or condition of your cells and tissues may be collected. By

signing this consent form, you agree to allow access and transfer of your medical data for up to five (5) years after the date you sign this form.

Direct personal identifiers will never be sent to Asterand or its researchers. This includes your name, address, telephone number, social security number, medical record number, health insurance numbers, or any other unique identifier that could be used to identify you.

All samples and medical data will be given a code at the study site prior to transferring the samples to the sponsor or researcher. Additionally, all medical data will be given a second code by the sponsor of the study, prior to the transfer of the data to a researcher. The research staff at the collection site will be the only people able to unlink the code to your personal identifying information.

Study data and medical records may be reviewed, monitored or audited at the study site by the study sponsor, its agent, independent ethics committees, the institutional review board (IRB) or appropriate government agencies. Representatives from these groups may need to look at your medical records to ensure that the data on the study forms is correct or that the study was conducted properly. This type of review will take place at the study site where the medical records are stored.

By signing this consent form you agree to allow your genetic and clinical information to be released into one or more scientific databases. This will help advance medicine and medical research by allowing other researchers to use this information to help solve questions about disease and to compare results from many studies. These databases may be maintained by medical, academic, government, or private entities. If you agree, only your genetic information and some basic information about your medical history will be released into these databases. Since certain genetic information is unique to you, there is a small chance that someone could trace the information back to you. The risk of this occurring is presently very small, but may grow in the future as technology advances. Medical researchers who access your genetic and medical information have a professional obligation to protect your privacy and maintain your confidentiality.

Procedures

No additional surgical procedures are required to obtain tissue samples for this study since only left-over tissues will be used for this study. Neither Asterand nor the researchers influence or designate techniques for removal of tissues or collection of biomaterials.

You may also be asked to donate blood samples for research use. These samples may be collected with other required blood draws necessary for your treatment. The amount of blood collected for this study will not exceed three (3) tablespoons (equal to 45 mL). Blood will be drawn from a vein using a needle. A slide may be prepared for microscopic review. One to two (1-2) drops of blood may be taken by finger-stick to prepare the slide. All standard safety precautions will be followed.

Please indicate the type of sample you agree to donate for the purposes of this study by checking the appropriate boxes below:

- Surplus Surgical Tissue Sample**

- Blood Sample**

If you have any questions about the surgical or collection techniques used to remove your tissue or biomaterial samples, please direct these questions to your study doctor or surgeon. Your study doctor or surgeon will be able to inform you about what types of collection techniques will be used for the procedure, and if any experimental procedures will be used.

Risks

Providing tissue samples for this research study will not subject you to any additional medical risks other than those already present for your treatment. In the event that a blood sample is collected for this study, there are known risks associated with this procedure. These risks include bruising and/or swelling at the sampling site, minor discomfort, infection and/or inflammation of a vein, and in rare instances, fainting.

Privacy Risks

There is a small risk that someone not involved in the research study could find out about your research results or your participation in this study. All organizations participating in this study have taken reasonable steps to keep your research data confidential, to the extent permitted by law. However, absolute confidentiality can not be guaranteed. There may also be risks to participation that are unknown and unforeseeable.

Genetic Study Risks

This research will involve genetic studies and information. Although, procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you, there is a remote possibility that information from your participation in this study could adversely affect you or your family in some way if a genetic disorder were discovered.

Benefits

There are no direct benefits to you for taking part in this research study. However, data from this research study may benefit other patients with similar medical conditions in the future.

Findings

Neither you nor your study doctor will be given information obtained from the research conducted with your samples and data. However, if any new information regarding sample collection procedures is discovered which may affect your decision to participate in this study, you will be notified verbally and in writing in a timely manner.

Alternatives to Participation

This study is for research purposes only. Your alternative is to not participate in the study. If you do not participate, any extra tissue remaining after diagnosis will be discarded.

Costs

There will be no cost to you for participating in this study.

Compensation

You will not be paid for participating in this research study, unless such reimbursement is explicitly stated in this consent form.

The study doctor or institution will receive reasonable reimbursement for their services, equipment and supplies utilized during the study.

In the unlikely event that you become injured as a result of taking part in this study, no reimbursement, compensation, or free medical care is offered by Asterand, or the academic and commercial research institutions that receive the tissues and medical data for research.

Research studies may eventually lead to commercial products that are sold for profit in the future, such as tools or methods for diagnosing or treating diseases. If the results of any studies lead to the development of any commercial products, neither yourself nor your heirs will have any rights or interests in those products, including, but not limited to, ownership, right to assignment or licensing, or right to

production. Moreover, neither you nor your heirs will have a right to share in any profits related to such product.

Questions

Before signing this form, you should read and understand all of the information related to this study. You should ask questions about anything that you do not understand. The study staff will be available to answer all of your questions regarding the study.

If you have any questions about your participation or you experience a research related injury or illness, you should contact: _____ at _____.
If you have any questions about your rights as a research participant, you should contact: _____ at _____.

Voluntary Participation

Your participation in this study is strictly voluntary. Your decision to volunteer or withdraw from this research study will not affect or change the present or future health care or medical services you receive. Refusal to participate or a decision to withdraw will involve no penalty or loss of benefits to which you may otherwise be entitled.

Withdrawal from Study

You may withdraw from this study at any time. If you decide to withdraw, contact your study doctor. Per your request, Asterand will destroy any remaining tissue or biofluid samples that have not already been placed with a researcher (if possible) and no additional clinical data will be collected for follow-up purposes. Once samples are sent to a researcher, you will no longer be able to withdraw them. Your participation may also be withdrawn at any time, and for any reason, by your study doctor or the sponsor, without your consent. Examples of why this might occur include: Informed Consent issues, IRB issues, or discrepancies between samples and associated medical data.

Authorization to Use and Disclose Protected Health Information for Research

The Health Insurance Portability & Accountability Act (HIPAA) is a U.S. federal law designed to protect the privacy of your health information. During your participation in this research study, your private health information will be used and additional information about you may be discovered. Under US federal law, your study records cannot be used or disclosed by your study doctor for research purposes unless you sign this authorization.

Health data may come from your study records or from existing records kept by your doctor or other health care workers. Direct identifiable data like your name, address, medical record number, or social security number will never be sent to the sponsor (or the researchers) with your samples. However, the sponsor may monitor or audit this information at the study site for quality assurance purposes. If reports or articles are written about the study, you will not be identified by name in them.

The following protected health information will be used and disclosed for this study. This information may be shared with authorized users. Additionally, the sponsor may share the following information with researchers:

- Medical records and history pertaining to the research
- Laboratory test results
- Results of study related medical procedures
- Date of birth
- Dates of study related procedures
- Sample collection dates

Authorized users may include:

- The study doctor and staff responsible for sample and data collection for this study
- The sponsor and individuals working for the sponsor
- The Institutional Review Board
- The Food and Drug Administration (FDA) and other US governmental agencies
- Government agencies in other countries
- Monitors and auditors sent by the study sponsor to oversee the study conduct
- Labs working with the sponsor on this study

Once your health data has been shared with authorized users, it may no longer be protected by U.S. federal privacy laws.

This authorization has no expiration date. You have the right to revoke this authorization at any time by writing to your study doctor. If you do this, no new information will be collected from you. However, any information already collected in your study record may continue to be used. If study results are published you will never be identified by name.

Closing Statement and Signatures

I have read the above information in a language that I understand well. The content and meaning of this information has been explained to me and I have had all of my questions answered to my satisfaction. I will receive a copy of this signed informed consent and authorization form. I hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of my medical information.

Date Time Print Subject Name Subject Signature

Date Time Printed Name of Impartial Witness* Signature of Impartial Witness*

Date Time Printed Name of Investigator or Designee Obtaining Consent Signature of Investigator or Designee Obtaining Consent

Copy of consent form given to subject on (date) _____ by (initials) _____

** A witness signature is required if the subject is illiterate. The witness testifies that the subject appears to understand the study information and that the subject freely consented. The witness should not be a member of the study team. Subjects who do not speak English, may not sign this version of the Informed Consent and Authorization Form. An IRB-approved, translated ICAF must be used for non-English speaking subjects.*

This informed consent agreement complies with all requirements set forth by Title 21 Code of Federal Regulations Chapter I, Part 50.25, and is not intended to replace any informed consent or authorization/disclosure forms that are governed by Federal, State, or Local Laws requiring additional information. Moreover, nothing in this informed consent agreement is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted under the law.