INFORMED CONSENT FORM TEMPLATE

Title: Study in Collection of Specimens including Leftover/Surplus Surgical Tissues, Blood, Urine, Stool, Saliva and other materials for Genomics, Proteomics and Biomarker Research
Protocol: BCI Informed Consent Form Template

Principal Investigator: [*INSERT NAME OF PRINCIPAL INVESTIGATOR***]**
Site of Investigation: [*INSERT DONOR INSTITUE NAME AND ADDRESS]***]**

24 hour Telephone #: [*INSERT DONOR INSTITUE EMERGENCY PHONE NUMBER***]**

Sponsor: Biochain Institute, Inc.

1.0 Scopes of Study

1.1 Purpose of Study

You are being requested to donate Leftover/Surplus Surgical tissue, other materials, and medical data for research use because you are about to have a surgical procedure 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. Extra tissue, or Leftover/Surplus Surgical tissue herein, that is not needed is usually discarded. The purpose of this study is to collect tissue that would otherwise be discarded and arrange for its placement with researchers to help find new ways to identify and treat diseases. Your consent to donate tissue will not require you to have any additional surgery other than that required for your medical care or treatment. You may also be asked to donate Blood samples, Urine, Stool, Saliva and other materials for this study.

If you agree to participate in this study, your tissue, medical data, and Blood sample, Urine, Stool, Saliva and other materials (if applicable) will be placed with a for-profit biomedical research company named Biochain. The samples and medical data will be provided to researchers at non-profit research institutes and commercial companies. Your samples and medical data may be provided immediately for research use, or may be stored indefinitely for use in future research.

1.2 Research Use of Tissue and Medical Information

Researchers will be looking for biomarkers. This may lead to discovery of new ways to diagnose and treat diseases. Biomarkers are tiny molecules including those called protein, ribonucleic acid (RNA), and deoxyribonucleic acid (DNA). Some genes may affect your risk for certain diseases. 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. 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 such as cancer, diabetes, asthma, and depression. Information about these differences among people can help researchers understand how to best use drugs to 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. Some tissue and biofluid samples may be sent out fresh on the same day of collection to a researcher who is actively working on a project.

1.3 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 donate may be preserved for a long period of time.

1.4 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 Biochain on study forms. Information such as diagnosis, 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.

1.5 Procedures for Collecting Samples

Surgical tissue will be placed with a pathologist for final diagnosis of disease and any Leftover/Surplus Surgical tissue remaining will be collected experimentally, otherwise it would be discarded if you do not participate in this study. No additional surgical procedures are required to obtain tissue samples for this study since only leftover/surplus surgical tissue will be collected. Neither Biochain nor the researchers influence or designate techniques for removal of tissues or collection of biomaterials.

You may also be asked to donate Blood samples, Urine, Stool, Saliva and other materials for research use. These samples may be collected with other required blood draws necessary for your medical treatment. The amount of blood collected for this study will not exceed 100 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. There will be no or very minor discomforts in collection of Urine, Stool, and Saliva.

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

☐ **Leftover/Surplus Surgical Tissue Sample** ☐**Blood Sample** ☐**Urine Sample**

☐**Other Materials (Print):** ☐**Stool Sample** ☐**Saliva Sample**

_____ _____ _____

Signature of Study Patient Date Time

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 and/or surgeon. Your study doctor and/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.

This study and informed consent form have been reviewed and approved by an Independent Ethics Committee or Institutional Review Board.

2.0 Risks

The donation of tissue for this research study will not subject you to any additional medical risks other than those already inherent in the ordinary course of 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.

There is no risk to collect Urine, Stool, and Saliva samples.

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. **[***INSERT DONOR INSTITUTE NAME***]** and all organizations participating in this study have taken reasonable steps to keep your research data confidential, to the extent permitted by law. However, if you inform others about your participation, your confidentiality could be affected.

3.0 Benefits

There is no direct benefit 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. Neither you nor **[**INSERT INSTITUTE NAME**]** will be provided information obtained from the research conducted with your donated tissue.

4.0 Alternatives to Participation

The alternative to taking part in this study is to have your specimen handled according to the current standard of practice. This means that the tissue will be placed with a pathologist for final diagnosis of disease and any Leftover/Surplus Surgical tissue remaining will be discarded.

5.0 Confidentiality and Privacy Act

Personal identifiers will never be sent to Biochain 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.

To further protect your identity, medical data sent to Biochain will be coded at least twice prior to placement with researchers. At the study site, your medical data will be assigned an initial code prior to sending the information to Biochain. A second code will be assigned to your data at Biochain prior to placement with researchers. Only **[***INSERT DONOR INSTITUTE NAME***]** will possess the “key” to unlink the code to your personal identifying information.

The results of the study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Study data and medical records may be reviewed or audited at the study site by the study sponsor, its agent, independent ethical review 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.

6.0 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 Biochain, 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.

7.0. Questions and Contact
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 answer questions regarding this study.

If you have any questions about your donation or if you experience a research related injury or illness, you should contact:

[INSERT PRINCIPAL INVESTIGATOR'S NAME**]**
[24 HOUR TELEPHONE NUMBER**]**

If I have any questions about your rights as a research participant, you should contact:

[*INSERT IRB CONTACT, PATIENT RIGHTS ADVOCATE, INSTITUTIONAL CONTACT and/or BIOETHICIST***]**
[*INSERT PHONE NUMBER***]**

8.0. Voluntary Participation
Your participation in this study is strictly voluntary. Your decision to volunteer for this research study will not affect or change the present or future health care or medical services you receive. Refusal to participate in this study will not involve penalty or loss of benefits to which you may otherwise be entitled.

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

10.0. Withdrawal from Study
You may withdraw from this study at any time. If you decide to withdraw, contact your study doctor. Your withdrawal will not affect or change the present or future health care or medical services that you may receive, nor will it result in any penalty or loss of benefits to which you are otherwise entitled. Per your request, Biochain 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, it will not be possible to withdraw them because of the measures taken to protect your privacy and because the sample may have already been used for experiments.

Alternatively, your participation may be withdrawn at any time, and for any reason, at the discretion of 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.

11.0. Compliance with Laws and Authority
The informed consent agreement herein is not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective. Nothing in this agreement is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

12.0 Consent to Participate in this Study
My signature below indicates that I have read, or had read to me, in a language understandable to me, the above information contained in this consent form. The content and meaning of this information has been fully explained to me. I have had the time and opportunity to ask questions about the study and this form, and all of my questions have been answered. I have read all pages of this consent form including the risk and benefit sections. By signing this form,

I certify that all information I have given, including my medical history, is true and accurate to the best of my knowledge. I am not giving up any of my legal rights by signing this form. I will be given a signed copy of this informed consent form.

_____ _____ _____

Signature of Study Patient Printed Name of Study Patient Date Time

_____ _____ _____

Signature of Legally Authorized Representative Date Time

_____ _____

Printed Name of Legally Authorized Representative Relationship to Patient

_____

Signature of Witness Printed Name of Witness Date Time

_____

Signature of Investigator/Designee Obtaining Consent Date Time

_____

Printed Name of Investigator/Designee Obtaining Consent Institute Name

Governing Regulation, Guidelines and Guidance:

This informed consent agreement complies with all requirements set forth by Title 21 Code of Federal Regulations Chapter I, Part 50.25, Elements of informed consent, FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Content of this informed consent agreement complies with all requirements set forth by Guidelines for Writing Informed Consent Document, the Office of Human Subjects Research (OHSR), National Institutes of Health (NIH). U.S. Department of Health and Human Services (DHHS).

Leftover/Surplus Surgical Tissues, Blood, Urine, Stool, Saliva and other materials may be collected by following Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable, OMB Control No. 0910-0582, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Biologic Evaluation and Research, and Office of Blood Research and Review

[Informed Consent Form for Fetal Tissue]

Donor Information for Informed Consent

Donation of Blood and/or Aborted Pregancy Tissue for Medical Research, Education, or Treatment

The blood from pregnant women and tissue that has been aborted has been used for research to treat and find a cure for various diseases such as cancer, diabetes, and some neurological diseases.

The blood and/or pregnacy tissue can be donated after an abortion. Before you give your consent, read each of the following statements and initial the line to the right. We will be happy to answer any questions you have.

I have already decided to have an abortion and signed a consent form for it before I was shown this consent _____

I agree to give my blood and/or tissue from the abortion as a gift to be used for research, education, or treatment _____

I understand I have no control over who will get the donated blood and/or tissue or what it will be used for _____

I have not been told the name of any person who might get my donation _____

I understand there will be no changes to how or when my abortion is done in order to get my blood or the tissue _____

I understand I will not be paid _____

I understand that I don't have to give my blood or pregnancy tissue, and this will not affect my current and future care at _____Hospital _____

Sinature _____ Date: _____
Witness_____ Date: _____

Patient's Name: _____DOB: _____
Date: _____

___ Aborted tissue was donated
___ Consent for the abortion was obtained prior to requsting or obtaining consent for the tissue donation
___ No substantive alterations in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the tissue