Scripps Clinic informed consent statement for

Study Title: Scripps Clinic Bio-Repository

Collection and Storage of Human Biological Materials for Research Purposes

To be completed by person obtaining consent.

Specimen(s) to be collected:

☐ Tissue    ☐ Blood    ☐ Urine    ☐ Stool    ☐ Saliva
☐ Other (Specify): __________

This is a research study. Your study doctor will explain the research to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

Why is this study being done?

You are invited to participate in a long-term program to collect biological specimens (tissue, blood and other bodily fluids) for future research purposes. You are not being invited to participate in a specific study at this time, but the specimens collected could be used in multiple research studies in the future. The specimens may also be used by commercial companies for product development purposes.

The purpose of this study is to collect a variety of specimens from both healthy and sick volunteers and look for differences between the specimens. Differences between specimens may be related to the development of disease. Researchers will study the nature of disease with the goal of improving ways to prevent, diagnose and treat diseases. For example, tissues and bodily fluids (such as blood) are the source of DNA, RNA, and proteins. Scientists have found that changes in individual genes and/or proteins may cause, or be associated with, the development of disease.

Using the specimens, researchers at Scripps Clinic Medical Group (SCMG), Scripps Health and/or other collaborators designated and approved by the Bio-Repository Oversight Committee (like academic institutions and commercial companies) will apply modern scientific technologies in the areas of genetics, molecular biology, and immunology to study the nature of disease. The specimens may be stored in a way that allows the cells to grow and multiply. These multiplying cells may result in 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. Because the research will be conducted in the future, it is hard to know what kinds of research methods will be used and it is not possible identify all the ways in which the specimens will be used.
The goals of this research are to:

1. To provide a central collection bank to store tissue, blood and other body fluid specimens collected from patients with cancer and other diseases.
2. To release specimens from the bank to researchers to study relevant cellular, molecular and genetic properties of cancers and other diseases.

**How many people will take part in the study?**

We aim to enroll as many people as possible in order to maximize the sample size, thus allowing for a broader patient population to be obtained.

**What will happen if I take part in this research study?**

**Tissue Donation:**
If you agree to participate, we will preserve a small piece of your tissue that was taken out during your surgical procedure. After the pathologists (doctors who study tissue) have reviewed the tissue and have done all the necessary tests for your medical care, a small piece will be preserved for this bank. Extra tissue will not be removed during your surgical procedure; only the tissue that is required for your diagnosis and treatment will be taken out. There will be no medicines to take and no treatment given as part of this collection effort.

**Blood Donation:**
If you agree to donate blood, about 3 tablespoons (45mL) of blood will be drawn from a vein in your arm. If you have a special tube that stays in your vein (Hickman catheter or a port-a-cath), that device can be used to collect the blood. This sample of blood will be collected only for research purposes and is not a part of your regular medical care.

**Donation of other bodily fluids:**
In some cases, you may also be asked to donate a random urine, stool or a saliva sample. If you agree to donate a urine or stool sample, up to 4 tablespoons will be collected. If you agree to donate saliva, up to 2 tablespoons of saliva will be collected. To collect the saliva, you will be asked to spit into a special plastic cup or tube that is used to collect saliva. These samples will be collected only for research purposes and are not a part of your regular medical care.

**Collection of Clinical Data:**

It will be necessary for the purposes of the proposed research to conduct a review of your medical records to obtain information such as your age, weight, race and ethnicity, personal cancer history, and specific lab values. Access to your medical records from various medical facilities, including hospitals, clinics, doctor’s office and laboratories, may be required. Your name, address, and phone number will be stored in a database but will not be released to any researcher.

We request that you allow representatives of this program to continue to follow your health and continue to collect information from your medical records including information regarding your death or until such time you request to be excluded from this study.
Information that is gathered will be strictly limited to information directly relevant to the study of your specimens. These actions would be performed under the direction of Dr. Christopher Marsh and confidentiality would be maintained at all times.

**Review of Radiographic Films:**

Researchers may also wish to look at your radiographic films. Some examples of this include mammogram films, X-rays, CT scans, MRI scans and bone scans. Your original films may be sent to a researcher. Your name, address, phone number, and other identifying information will be taken off anything connected with your radiographic films before they are sent to any researcher.

**Storage of Materials:**

Your tissue, blood and other banked fluids will be stored in a secure, protected area belonging to and managed by the Scripps Clinic Bio-Repository. The specimens will only be available for research purposes to staff and/or collaborators (like academic institutions and commercial companies) designated and approved by the Bio-Repository Oversight Committee.

**How long will I be in the study?**

Your specimens will be collected once or multiple times (depending on your periodic clinic or lab visits/follow ups). After this, your participation will end. However, your specimens will be part of the SCMG & Scripps Health Bio-Repository until they are used up. This may take a number of years.

Due to unforeseen circumstances such as flood, fire, earthquake, tornado or electrical failure, your specimens may need to be destroyed. In this situation, you will not be notified that your specimens have been discarded.

**Can I stop being in the study?**

Yes. You can decide to stop at any time. If you decide to end your participation and you wish to have your specimens destroyed, you can at any time, send a written request to Dr. Christopher Marsh, who is managing the collection of specimens.

*The request must say if you want to temporarily or permanently stop the use of your specimens and if you would like to have your remaining specimens destroyed. You also have the option of allowing your specimens to stay in the Bio-Repository but with all personal identifiers permanently removed from your specimens.*

Any data that has been obtained from testing your biological specimens until that point will remain part of the research. If your specimens have already been sent to a researcher, it will not be possible to withdraw them. This is because of the methods used to protect your confidentiality and because your specimens may have already been used for research.
Notification of Research Findings:

The information about your specimens collected during the course of this collection effort is for research purposes only and not clinical care. You will not be informed about any results learned from any future research on your specimens.

Are there risks involved if I participate in the study?

Tissue Collection: There is no additional risk to you if you agree to donate tissue from a biopsy or surgical procedure. These procedures would be done whether or not you participate in this study. No extra tissue will be taken during your surgical procedure as part of this collection effort.

Blood Draws: There is a small complication risk involved with drawing blood for this study. Complications can include, but are not limited to, light-headedness or fainting, pain, bleeding and bruising at the needle site, skin or soft tissue infection at the needle site, injury to any nearby tissues (arteries, nerves, other veins, etc.).

To minimize these risks, your blood will be drawn by experienced technicians, the area will be cleaned before your blood is drawn, sterile supplies (needles, gauze, etc.) will be used and a band-aid will be applied after the sample is drawn. Whenever possible, blood for this research will be drawn when other blood is being drawn for regular tests your doctor has ordered.

Urine Collection: There is no physical risk in donating a urine sample.

Stool Collection: There is no physical risk in donating a stool sample.

Saliva Collection: There is no physical risk in donating a saliva sample.

Confidentiality: The greatest risk to you is the release of information from your health records. The chance that this information will be given to someone else is very small. However, every effort will be made to keep your medical information confidential.

Your name, address, phone number, and other identifying information will be taken off anything connected with your specimens before it is sent to a laboratory for this study. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the study team will not have access to results about any individual person, which will help to protect your confidentiality.
The files that contain any information linked to your name can only be accessed by a limited number of staff approved by the Bio-Repository Oversight Committee. Researchers using your tissue will not have access to this information.

However, there will be other facts about you that will be released such as age, gender and ethnicity (race) that could be used in an attempt to identify you, particularly if these are linked to the genetic information from your specimens. Information such as age, gender and ethnicity is important for researchers to know because it will help them learn if certain factors cause disease or if response to treatment is the same or different in men, women and children, differing age groups, in people of different ethnic backgrounds, or in people living under different environmental or behavioral conditions.

Because every person’s DNA is unique, there is a remote possibility that genetic information about you could be made known, like information about an inherited disorder, and it could affect your family. We will do our best to make sure this does not happen by following procedures to protect your confidentiality and your identity (described below).

This research follows the Genetic Information Nondiscrimination Act (GINA), a new federal law which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- This new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There also may be other privacy risks that we have not foreseen.

**Are there any risks to my community or group?**

Information on your ethnic and geographical background will be included with other information about you in the database. In future studies, researchers may find that certain genetic variations appear more often in people from your ethnic group than in people from other ethnic groups, and that these variations are more common in people with a certain disease. This may make some people look down on your ethnic group unfairly. Others may use the information to downplay differences between ethnic groups, to say that all people’s genes are about the same, so we do not need to respect the special concerns of different ethnic groups.

**Are there benefits to taking part in the study?**

This is a research study and it will not provide any direct health benefit to you. It is hoped that over time, information from the studies using these specimens will help researchers at Scripps Health and other collaborators approved by SCMG (like academic institutions and commercial companies) learn more about health and disease and how drugs and other treatments can be designed to help treat and prevent diseases.

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What other choices do I have if I do not take part in this study?

You are free to choose not to take part in this collection of human tissue, blood and other body fluids. Your decision to not participate will not change your medical care in any way.

Will my medical information be kept confidential?

We will do our best to make sure that the personal information in your medical record will be kept confidential. However, we cannot guarantee total confidentiality. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- the study doctor and his research associates
- the Scripps Institutional Review Board (IRB) or its designees
- the National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP), involved in keeping research safe for people

The value of the specimens in the Bio-Repository is related to the ability to link it with your clinical information, particularly results of treatment. Every effort will be made to keep your personal (name, address, etc.) information confidential. Your personal information will only be accessible by authorized staff of the Scripps Clinic Bio-Repository.

Certain clinical information (like age, gender, medical history and disease history) will be collected and may be sent to researchers with your specimens. Your personal information (name, address, etc.) will never be sent to a scientist using your specimens. Your specimens and clinical information will be marked with a code before it is sent to any researcher.

This clinical information and other information learned from testing on the specimens (like genetic information) may be entered into scientific databases. Many scientists may rely on the databases to compare research results and solve questions about diseases. The databases may be owned by non-profit or commercial companies.

What are the costs of taking part in this study?

There are no costs to you for taking part in this study.

The collection and storage of your specimens are being done for research purposes. You or your insurance company will not be billed for the preparation and shipment of these specimens or the testing that will be done with these specimens.
Will I be paid?
No, you will not be paid for taking part in this study.

Commercial Use of Human Biological Materials:

The specimens obtained will be used for research purposes and product development, and may be sold to research institutes or commercial companies as a “fee for service” in order to help recoup/offset the cost of the specimen collection, processing and storage. The specimens obtained from you along with other specimens may be used to develop one or more commercial products to be sold. There are no plans to share any profits with you from the sale of those products or the data obtained from the research using those specimens.

Re-contact in the Future:

In the future, researchers may wish to contact you about obtaining more information or more biological samples. If so, you will be contacted by a member of the research team from the Scripps Clinic Bio-Repository to request your permission.

Please read the statements below and make your choice. No matter what decision you make, it will not affect your care.

☐ I give my permission for researchers to contact me in the future about obtaining additional information or additional samples.

Subject’s Initials  ___________  Date  ___________

☐ I do not give permission for researchers to contact me in the future about obtaining additional information or additional samples.

Subject’s Initials  ___________  Date  ___________

If you agree now to be re-contacted, you can change your mind at any time. Please let Dr. Christopher Marsh know, and you will be removed from the contact list. Please contact Dr. Christopher Marsh as listed above if you wish to be removed from the list.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study.

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.
What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

For questions about the study or a research-related injury, contact the study doctor, Christopher Marsh, M.D., at (858) 554-4310.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the Scripps Office for the Protection of Research Subjects at (858) 678-6402.
Subject’s Consent

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject’s Signature ___________________________ Date (must be dated by the subject)

Subject’s Printed Name ___________________________

Signature of Person Obtaining Consent ___________________________ Date

Printed Name of Person Obtaining Consent ___________________________
Authorization to use your Private Health Information for Research

Name of Study:  Scripps Clinic Bio-Repository

Principal Investigator:  Christopher Marsh, MD, FACS

What is private health information?
Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- information provided by you directly to the Research Team,
- hospital records and reports; medical histories, and physicals;
- X-ray films and reports; operative reports; laboratory reports; treatment and test results; immunizations; allergy reports; prescriptions; consultations; clinic notes;

Who else will see my information?
In addition to the Principal Investigator, this information may be shared with:

- Members of the Research Team,
- Other researchers who have received institutional approval,
- Government agencies, such as the US Food and Drug Administration and agencies like it in other countries, or agencies of the Department of Health and Human Services, and
- Scripps committees that review research to help protect people who join research studies.

Once we have shared your information we cannot be sure that it will stay private. If you share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will Scripps Clinic Bio-Repository use and share my information?
Your information will be used and shared for up to 30 years after the date you sign this form.

What if I change my mind about sharing my research information?
If you decide not to share your information anymore:

- The research team can continue to use any of the private information that they already have.
- You will no longer be a part of the research study.
• You will still get the same medical care that you’ve always had at Scripps.
• You must write to the investigator and tell him that you no longer want to share your information. Write to the investigator at:

Christopher Marsh, MD
Center for Organ and Cell Transplantation
10666 N. Torrey Pines Road, 200N, La Jolla, CA 92037

If you agree to share your information you should sign this form below. You will be given a copy of this form to keep.

************************************************************************
I agree to share my information as described in this form
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_______________________________
Print your name

_______________________________ ______________________
Sign your name Date

If you have questions or concerns about your privacy and the use of your personal medical information, contact the investigator at the telephone number listed in the consent form.