

Stanford University IRB Guidance On Data and Tissue Repositories

Databases, registries (data banks), and repositories (tissue banks) all involve the collection and storage of information and/or biological specimens over time. Some are created and maintained primarily for diagnostic or clinical purposes. Others are created specifically for research. Many serve more than one purpose.

In any case, databases, registries (data banks), and repositories (tissue banks) constitute a vast resource that researchers can draw upon to address questions extending far beyond those envisioned when they were first created.

Research use of these resources is governed by both the federal human subject protection regulations (Common Rule and DHHS regulations) at 45 CFR 46 and the federal privacy rule regulations (HIPAA) at 45 CFR 160 & 164. Specific requirements depend upon how and why the information or specimens in the resource are collected, stored, used, and shared.

As a general rule, however, the research use or disclosure of individually identifiable private information or individually identifiable human specimens at Stanford University or its affiliates (i.e., SHC, LPCH, VAPAHCS), by their employees or agents, or from their databases, repositories, data banks, tissue banks, or registries require the review, approval, and oversight of Stanford's IRB. Investigators whose activities may be subject to human subject protection or privacy rule requirements should submit the appropriate materials to the IRB for an official determination.

A. Definitions

The terms *database*, *registry*, *data bank*, *repository*, and *tissue bank* are often used imprecisely, and sometimes interchangeably. The following definitions are not universally accepted, but are provided solely to clarify usage in this information sheet.

Database. A database is collection of information elements (i.e., data) arranged for ease and speed of search and retrieval. Most databases are now maintained electronically, but the term can also be applied to paper record systems.

Examples of databases include the following:

- A set of observations (i.e., data) resulting from a research study
- An electronic file of a medical provider's patients
- A collection of diagnosis, treatment, and follow-up information for a hospital's oncology patients
- A file of outcomes information compiled for quality assurance activities
- A list of potential research subjects

Registry. A registry or “data bank” is a collection of information elements or databases whose organizers:

- Receive information from multiple sources
- Maintain the information over time
- Control access to and use of the information by multiple individuals and/or for multiple purposes, which may evolve over time

Registries often contain codes that link information and specimens to their donor’s identify. Examples of a few well-known registries and data banks include:

- Centers for Disease Control & Prevention (CDC) State Cancer Registries
- Familial Gastrointestinal Cancer Registry
- National Registry of Myocardial Infarction (NRMI)
- National Registry of Veterans with Amyotrophic Lateral Sclerosis
- The National Library of Medicine Hazardous Substances Data Bank (HSDB)
- The National Practitioner Data Bank
- The US Census 2000 Data Bank

Repository. A repository or “tissue bank” is a collection of biological specimens whose organizers:

- Receive specimens from multiple sources
- Maintain the specimens over time
- Control access to and use of specimens by multiple individuals and/or for multiple purposes, which may evolve over time

Repositories usually include demographic and/or medical information about the individuals from whom the specimens were obtained. Repositories often maintain codes that link the information and specimens to their donor’s identify. Examples of a few well-known repositories include:

- The National Human Radiobiology Tissue Repository
- The National Institute of General Medical Sciences (NIGMS) Human Genetic Cell Repository
- The National Institute on Aging Cell Repository
- The National Marrow Donor Program (NMDP) Research and Outcomes Repositories
- The National Surgical Adjuvant Breast & Bowel Project (NSABP) Data and Tissue Banks

Registries, data banks, and tissue banks are all considered “repositories” for regulatory purposes. Any reference in this guidance to *repositories* applies equally to *data banks*, *tissue banks*, and *registries*.

B. Non-Research Databases and Repositories

Databases and repositories are often created and maintained for purposes that are totally unrelated to research. Such purposes may include diagnosis, treatment, billing, marketing, quality control, and public health surveillance, to name just a few of the many possibilities.

For example, providers often create databases for treatment or payment purposes. Institutions often create databases for quality assurance and quality improvement purposes. Disease-specific registries are often mandated by State law or regulation for public health purposes.

In spite of the fact that these databases and repositories are created for non-research purposes by persons who have no intention of using them for research, they may contain information that is of great interest to researchers.

IRB Oversight

The creation (or operation) of non-research databases or repositories does not involve human subject research and does not require IRB oversight.

However, **IRB oversight is required for use in research** of identifiable private information or identifiable human specimens from non-research databases and repositories (including data/tissue banks and registries).

When research involves identifiable private information or identifiable human specimens from non-research databases or repositories, each research use must receive prospective IRB review and approval and continuing IRB oversight, unless the research satisfies the criteria for exemption stipulated under HHS regulations at 45 CFR 46.101(b).

Examples of activities that involve the research use of information or specimens from non-research databases or repositories (and thus require IRB review, approval, and oversight on a project-by-project basis) include:

- Use in a project to identify cancer markers of identifiable human tissue samples that were originally collected and stored solely for diagnostic purposes
- Use of a medical provider's patient database to identify and recruit potential research subjects
- Use of quality assurance data containing identifiable private information for an activity designed to develop or contribute to generalizable knowledge

Researchers who wish to use information or specimens from a non-research database or repository (including data/tissue banks and registries) should submit an application for IRB review and receive IRB approval before initiating the research. Where available, the application should include any available information about the circumstances under which the information or specimens were originally collected.

Investigators who believe their research may be exempt from the human subject regulations should include a request for exemption #4 with the IRB application.

Informed Consent

Obtaining informed consent for the research use of information or specimens from non-research databases and repositories is usually problematic. Because research use was not anticipated at the time of collection, research informed consent has not usually been obtained from the individuals who provided the information or specimens. Standard treatment and surgical consents rarely meet the regulatory requirements for research informed consent.

Where it is possible to do so, IRBs may require researchers to obtain the informed consent of subjects for research involving information or specimens contained in non-research databases or repositories.

IRBs may also require that provider's obtain the permission of potential subjects before releasing contact information from non-research databases or repositories to researchers for recruitment purposes.

However, informed consent is not always required in these situations. The IRB can, and where justified does, waive (or alter) the usual informed consent requirements if it finds and documents, per HHS regulations at 45 CFR 46.116(d), that:

- The research involves no more than minimal risk to the subjects
 - The waiver (or alteration) will not adversely affect subjects' rights and welfare
 - The research could not practicably be carried out without the waiver
- and*
- Where appropriate, the subjects will be provided with additional pertinent information after participation. *(This last criterion rarely applies to research involving information or specimens from databases or repositories.)*

Investigators who believe that criteria (i), (ii), and (iii) above apply to their research should include a request for waiver of informed consent with their IRB application.

Privacy Protections

Under the HIPAA privacy rule, protected health information (PHI, i.e., identifiable health information) in non-research databases and repositories (including data/tissue banks and registries) held in the portions of Stanford and its affiliates covered by HIPAA may not be used or disclosed for research except as allowed in Stanford's *HIPAA: Research and Patient Privacy Policy* (or the VA HIPAA's policies if at VAPAHCS). Their requirements are summarized below.

The PHI may not be used or disclosed for research unless:

- Written authorization for use and disclosure of PHI in research has been obtained from the patient-subject
- or*

- The IRB approves and documents a formal waiver of the authorization requirement
or
- The holder of the PHI receives and documents the HIPAA required representations from the investigator and determines that the research involves only one or more of the following:
 - Decedents' information
 - De-identified information
 - Limited data sets
 - Review preparatory research.

Because research use was not anticipated at the time of collection, authorization for research has not usually been obtained from the individuals who provided the information or specimens to the non-research database or repository. In such circumstances, an alternative mechanism for accessing the relevant PHI is required.

Waiver of Authorization. The most flexible mechanism for obtaining PHI without authorization is through a waiver, which the IRB may approve if it finds and documents, per HHS regulations at 45 CFR 164.512(i)(2)(ii) that:

- (1) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on at least the following:
 - An adequate plan to protect the identifiers from improper use and disclosure; *and*
 - An adequate plan to destroy the identifiers at the earliest possible opportunity unless there is a research or a health justification for retaining them (or retention is required by law); *and*
 - Adequate written assurances that the PHI will not be reused or disclosed to another person or entity (except as required by law, for authorized oversight of the research, etc.).
- (2) The research could not practicably be conducted without the alteration or waiver.
- (3) The research could not practicably be conducted without access to and use of the PHI

Investigators who believe that criteria (i), (ii), and (iii) above apply to their research should submit a request for waiver of authorization on the IRB application.

Alternatives to Authorization Waivers. Mechanisms are available for research use and disclosure of (i) decedents' information, (ii) de-identified information, (iii) limited data sets, and (iv) reviews preparatory research without prior authorization of the patient-subject.

From a practical standpoint, the most useful of these alternatives to a waiver of authorization are those for (i) research that only involves decedents' information, and (ii) research that only involves de-identified information.

Investigators whose research solely involves information about deceased individuals should submit the HIPAA required representations on the Stanford or VA HIPAA form to the holder of the PHI (i.e., SHC, LPCH, VAPAHCS, Stanford investigator in School of

Medicine). Because the human subject regulations do not apply to deceased individuals, an IRB application is not required.

Investigators whose research solely involves de-identified information should indicate that at the appropriate section of the IRB application, whether for exempt, expedited or regular IRB review.

Investigators who believe that their research involves only limited data sets or reviews preparatory to research may propose use of these mechanisms, but they are of limited value to most researchers.

C. Research Databases

Obviously, many databases are created and maintained specifically for research purposes. Examples include:

- A list of names, diagnosis, and contact information developed and maintained to identify prospective research subjects
- A collection of medical information intended for use in future cooperative research studies

Other research databases are created and maintained to serve dual or multiple purposes. Examples include:

- A collection of patients' diagnosis, treatment, and follow-up information intended for and used to conduct (i) internal quality assurance programs and (ii) generalizable studies on the effectiveness of particular treatment interventions.
- A compilation of patient information that was originally created and used for billing purposes but is now also routinely used to identify prospective research subjects.

IRB Oversight

When the intended purpose of a database containing identifiable private information includes research (*even in part* as in the two examples immediately above), collecting, storing, sharing, and using the information are all considered human subject research activities and all require oversight by the IRB.

Research databases containing identifiable private information are routinely used at for the purposes and in the manner specifically described in the IRB-approved protocol and informed consent document under which the information was collected.

However, investigators wishing to use database information for research that *differs* in any way from that described in an applicable protocol approved by the IRB must submit a new or amended protocol for IRB review before initiating the new project.

Sometimes, researchers wish to preserve or expand a research database so it can be used not for a specifically defined new project, but by multiple researchers and/or for multiple purposes, which may evolve over time.

In such cases, one alternative is to submit a new or modified application for IRB review each time a new or revised project is defined. However, a more flexible and efficient alternative is to define and operate the database as a repository, which will be discussed in Section D below.

Informed Consent

The written informed consent of subjects is usually required for collecting, storing, sharing, or using identifiable private information to be used in or from a database whose purposes include research.

Because research use is specifically anticipated at the time of collection, research informed consent can usually be obtained from the individuals who provide the information. However, the IRB can, and occasionally does, waive the usual informed consent requirements under the same criteria described in the discussion of informed consent in Section B, above.

As recognized in the above discussion of IRB oversight, research databases containing identifiable private information are routinely used for the purposes and in the manner specifically described in the IRB-approved consent document under which the information was collected.

However, investigators wishing to use database information for research that *differs* in any way from that described in an applicable informed consent document approved by the IRB must submit a new or amended consent document for IRB review before initiating the new project.

As discussed above, researchers sometimes wish to preserve or expand a research database so it can be used not for a specifically defined new project, but by multiple researchers and/or for multiple purposes, which may evolve over time.

Again, one alternative is to submit a new or modified application for IRB review each time a new or revised project or is defined. However, a more flexible and efficient alternative is to define and operate the database as a repository, which will be discussed in Section D below.

Privacy Protections

An authorization from patient-subjects for the research use or disclosure of PHI is usually required for collecting, storing, accessing, using, or disclosing PHI to be used in or from a database whose purposes include research.

Because research use is specifically anticipated at the time of collection, research authorization can usually be obtained from the individuals who provide the information. However, the IRB can, and occasionally does, waive the usual authorization requirements under the same criteria described in the discussion of privacy protections in Section B, above.

Researcher wishing to use or disclose information in research databases may also be permitted to exercise the other alternatives to authorization (review of decedents' information, de-identified information, limited data sets, or review preparatory to research) under the conditions described in Section B.

Research databases containing PHI are routinely used and/or disclosed at for the purposes and in the manner specifically described in the research authorization under which the information was collected.

However, investigators wishing to use or disclose PHI for research that *differs* in any way from that described in the applicable research authorization must obtain approval from the IRB, in addition to any human subject (i.e., IRB) approval that may be required.

As discussed above, researchers sometimes wish to preserve or expand a research database so it can be used not for a specifically defined new project, but by multiple researchers and/or for multiple purposes, which may evolve over time.

Again, one alternative is to submit new privacy rule materials to the IRB for each new or revised project. However, a more flexible and efficient alternative is to define and operate the database as a repository, which will be discussed in Section D below.

D. Research Repositories

As indicated in Section A, a repository is a collection of information elements, databases, and/or biological specimens whose organizers:

- Receive data and/or specimens from multiple sources
- Maintain the data/specimens over time
- Control access to and use of the information/specimens by multiple individuals and/or or multiple purposes, which may evolve over time

Data and/or tissue banks and registries are considered repositories for regulatory purposes. Any reference in this information sheet to *repositories* applies equally to *data/tissue banks and registries*.

When the intended purpose of a repository containing identifiable private information and/or identifiable human specimens includes research (even in part), collecting, storing, sharing, and using the information and/or specimens are all considered human subject research activities and all require oversight by the IRB. Informed consent is usually required as well.

Similarly, an HIPAA authorization from patient-subjects for the research use or disclosure of protected health information (PHI) is usually required for collecting, storing, accessing, using, or disclosing PHI to be used in or from a repository whose purposes include research.

An example of a combined consent and authorization form for a pathology tissue repository is enclosed as exhibit 1.

Why Create or Use a Research Repository?

The advantage to investigators of creating, maintaining, and/or using a research repository lies in the prospective intent of the repository's organizers to control access to and use of information and/or specimens by **multiple** investigators and/or for **multiple** research projects, most of which are not (and cannot) be specifically identified and described when the repository is created.

Given this focus on multiple, yet-to-be-identified investigators and research projects, a repository's operating procedures must include detailed mechanisms for controlling the collection, storage, use, and sharing of its information and specimens.

Investigators who collect information and/or specimens to be entered into the repository (i.e., collecting investigators) must agree in writing to specific conditions stipulated by the IRB exercising oversight of the repository (i.e., the Repository IRB). Likewise, investigators receiving information and/or specimens from the repository (i.e., recipient investigators) must also agree in writing to specific conditions required by the repository's IRB. Operators of the repository must implement physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens that the Repository IRB finds sufficient to ensure the protection of subjects' privacy and the confidentiality of subjects' information.

When these subject protection mechanisms are sufficiently well-defined and implemented, and especially when these mechanisms ensure that subjects' information and/or specimens cannot be identified by recipient investigators, the IRB can confidently approve relatively broad parameters for sharing the information and/or specimens with research investigators (i.e., recipient investigators).

These comprehensive subject protection mechanisms permit new collecting investigators, new research projects, and new recipient investigators to be added to the repository's activities without protracted IRB review, as long as they fall within the parameters previously approved by the IRB. Depending upon how the approved parameters are defined, such new activities may require only expedited review by the IRB. In limited circumstances, they may simply require timely notification of the IRB.

Developing & Maintaining a Research Repository

Under a repository protocol, the IRB can approve relatively broad parameters for collecting, storing, sharing, and using the repository's information and/or specimens in research.

If developed properly, the repository protocol incorporates a series of research protections that permit multiple uses of repository information and/or specimens by multiple investigators and/or for multiple research projects with minimal additional review by the IRB.

A repository protocol may be submitted to the IRB to:

- Define the operating parameters for establishing and maintaining a research repository.
- or*
- Convert an existing research database, non-research database, or non-research repository into a research repository.

Researchers who wish to develop or maintain a repository (including data/tissue banks and registries) should submit an application for IRB review and receive IRB approval before initiating any repository-related activity.

In addition to the usual information contained in a human research protocol and an IRB application, the IRB expects that protocols for establishing and operating a research repository will include at least the following specific information:

- The specific conditions under which data/specimens may be accepted into the repository, including submission to the repository of a copy of each subject's signed authorization and signed consent document,
- A detailed description of the physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens to ensure the protection of subjects' privacy and the confidentiality of subjects' data/specimens,
- The specific conditions under which data and/or specimens may be shared with or released to research investigators,
- An separate authorization and separate consent document or a combined authorization and consent (see exhibit #1 for an example of a pathology tissue repository combined form) that includes, in addition to the usual elements of consent, a clear description of each of the following:
 - The general concept and purpose of repositories
 - The name and purpose of the specific repository for which consent is being solicited
 - As specifically as possible, the types of research that the repository will support
 - The repository's physical and procedural mechanisms for protecting subjects' privacy and the confidentiality of data/specimens
 - The conditions and requirements under which repository information or materials will be shared with recipient-investigators
 - Specific risks related to a breach of confidentiality related to the information being collected
 - Where human genetic research is anticipated, information about the consequences of DNA typing (e.g., regarding possible paternity determinations) and related confidentiality risks.

Using Research Repositories

The use and disclosure of information/specimens from a research repository are determined by (i) the IRB responsible for the review, approval, and oversight of the

repository; and (ii) the IRB responsible for research at the site where the information/specimens are used.

Stanford's IRB is responsible for any research repository maintained at Stanford or its affiliates, including their employees or agents (e.g., Stanford faculty).

Information/specimens from these repositories may be accessed, used, shared, or disclosed in accordance with the IRB-approved repository protocol and informed consent document, authorization, and any additional approval conditions stipulated by the IRB. Once provided to recipient-investigators outside Stanford and its affiliates, use and disclosure of the information/specimens must also comply with any additional requirements of the recipient institution and its IRB.

Repositories Outside Stanford and its Affiliates

When information/specimens are received in Stanford and its affiliates' facilities or employees or agents, their use and disclosure must comply with any conditions stipulated by the sending institution's IRB. Stanford's policies and procedures for the protection of human subjects and the use and disclosure of protected health information must also be observed.

It is up to Stanford's IRB, not the investigator, to determine the human subject protection and privacy rule protections required for any research utilizing information/specimens from repositories outside Stanford and its affiliates. Investigators should consult the IRB before initiating any research involving information and/or specimens obtained from outside repositories (including outside data banks, tissue banks, and registries).

Where recipient-investigators have signed agreements prohibiting their access to identifying codes or linkers, the IRB may determine that the research does not involve human subjects or is exempt from human subject requirements, and/or does not involve protected health information.

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Exhibit #1
Exemplary Consent Document for Pathology Tissue Bank

**STANFORD TISSUE BANK CONSENT FORM:
DONATING TISSUE FOR MEDICAL RESEARCH**

Please check one of the following:

You are an adult subject in this study.

You are the parent or guardian granting consent for a minor in this study.

Print minor's name here: _____

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

* * * * *

Are you participating in any other research studies? yes no

* * * * *

PURPOSE OF RESEARCH. You are invited to donate your tissue and blood to the Stanford Tissue Bank with some of your health information (both current and possibly future), in order that they may be used in future medical or health related research, e.g., studies of cancer and other diseases. Stanford researchers hope to obtain advances in medical and health research by studying your tissue. You were selected as a possible subject in this study because you are having a surgical procedure at the Stanford University Medical Center, and your doctor has determined that you may be eligible to donate tissue for medical research.

Your decision whether or not to participate will not prejudice you or your medical care and your surgical procedure. If you decide to participate, you are **free to withdraw** your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care.

HOW TO PARTICIPATE IN THE STUDY. Research using tissues is an important way to try to understand human health and medical conditions, and to learn how to

protect health and prevent, treat or cure conditions such as cancer. You have been given this consent form because you are having a surgical procedure, and your doctor has determined that you may be eligible to donate tissue for medical research.

During your surgery, some tissue may be removed from your body. This may be the main reason for your surgery, or the tissue may be removed for diagnostic or preventative reasons. After the surgery and all the tests have been done, some of the removed tissue may be left over. This tissue would normally be discarded because it is not needed for your medical care. Instead, you may choose to donate this tissue for medical and health research to the Stanford Tissue Bank. If you choose to donate your tissue, a very small amount of blood (less than 1 tablespoon) may also be collected and saved for research. Additionally, as explained more fully later in this consent form, some of your current and possibly future health information may be associated and stored with these samples at the Stanford Tissue Bank.

In the future, a researcher may wish to conduct research that requires human tissue such as yours. That researcher would then ask the Tissue Bank for a tissue sample and yours might be provided for the research. The tissue will be used primarily by researchers at Stanford University. However, there may also be collaborative efforts with other universities, the government, and private companies.

Your tissue will be maintained by Stanford University for such research purposes, as long as allowed by the law or until the Stanford University decides to discontinue your donated tissue sample or discontinue the Tissue Bank.

USE IN COMMERCIAL DEVELOPMENT OF PRODUCTS. Any tissue you donate which is used in research may result in new products, tests, or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the researchers, Stanford University and/or others (e.g., private companies). However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES. There are negligible medical risks to you. If blood is drawn, there may be slight discomfort, or bruising from the needle stick site in your arm. To minimize risk, the blood sample (less than 1 tablespoon) will be collected at the same time blood is drawn for laboratory tests performed as part of your routine medical care.

While every effort will be made to protect your identity and health information, there is a small risk of loss of privacy. Confidentiality of your health information is discussed below in more detail.

POTENTIAL BENEFITS. Neither you nor your doctor will receive the results of research done with your tissue (unless that is an explicit part of the future research). Research using your donated tissue may lead to discoveries that help others in the future.

However, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

YOUR RIGHTS AS A RESEARCH SUBJECT. You should not feel obligated to agree to participate. Your participation in this study is entirely voluntary. Your alternative to participating in this study is not to participate.

You should feel free to ask questions as they occur to you. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, now or in the future, it will not affect your ability to receive medical care at Stanford University Medical Center, and you will not lose any benefits to which you would otherwise be entitled.

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. To withdraw from this study, contact Dr. Jonathan R. Pollack, Director of the Stanford Tissue Bank, at 650-736-1987.

CONFIDENTIALITY AND AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES.

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The goal of this study is to obtain donations of tissue and blood to the Stanford Tissue Bank for use in future medical and health research projects, e.g., to learn more about cancer and other diseases. In order to understand the significance of the research done on your tissue, researchers may need to know some things about you, for example, your gender, age and your health history. The relevant information from your medical records will be

associated and stored with your tissue sample at the Stanford Tissue Bank and may be updated from your medical record from time-to-time. Your health information and tissue will be stored under a unique code (i.e., not with your name, address or telephone number). Information about the code will be kept in a secure location and access to it and your identity limited as described below.

Will the Stanford Tissue Bank take any precautions before releasing my health information and tissue to others for future researcher studies?

The Stanford Tissue Bank will follow all legal requirements before releasing your health information and tissue to others for research in the future. For example, currently for most such research, the law requires that the Stanford University Administrative Panel on Human Subjects evaluate the benefits of the research against any risks and protections to you, including any risk to your confidentiality. If the Panel is satisfied, the researcher would be required to submit the Panel's decision to the Stanford Tissue Bank, in order to obtain release of your health information and tissue for research.

In future research studies, will my identity be disclosed with my health information to other researchers and other individuals by the Stanford Tissue Bank without my permission at the time?

Under current law, any future research study that wishes to use your health information, with any direct or indirect identifiers, generally requires another, separate authorization form signed by you at that time. There are some limited exceptions from that requirement. Under the main exception, the independent review process described above by the Stanford University Administrative Panel on Human Subjects is required to ensure that the use or disclosure of your medical information without your authorization poses only minimal risk to your privacy. Both now and in the future, release of identifying information would occur only to the extent and under the conditions specified by law.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to donate tissue for the Stanford Tissue Bank. Signing the form is not a condition for receiving any medical care.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue use of your tissue and any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your protected health information in this study, you must write to: Jonathan Pollack, M.D., Ph.D., Director, Stanford Tissue Bank, Stanford, CA 94305-5176.

What Personal Information Will Be Used or Disclosed?

As described above, your health information may be gathered and stored in association with your donated tissue under this research study, including, but not limited to, information in your medical records and information derived from your blood and other tissue samples and related records. To the extent that the results of future research studies are presented at scientific or medical meetings or published in scientific journals, your identity will not be disclosed.

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:

- The Protocol Director, Jonathan Pollack, M.D, Ph.D.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.
- The Stanford Tissue Bank staff.

Who May Receive / Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Regulatory agencies responsible for overseeing this type of research such as the Office for Human Research Protections or the Food and

Drug Administration, both in the U.S. Department of Health and Human Services.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your protected health information will expire on December 31, 2505.

_____	OR	_____
Signature of Subject		Signature of Legally Authorized Representative and Description of Representative's Authority to Act for Subject
Date _____		

FINANCIAL CONSIDERATIONS. You will not be paid to participate in this research study, and you will not be responsible for any costs associated with this study. You do not waive any liability rights (e.g., for personal injury) by signing this form.

CONTACT INFORMATION

- If you have any questions about this **research study**, its procedures, risks and benefits, you should ask the Protocol Director, Dr. Jonathan Pollack. You may contact him/her at 650-736-1987. If you have any additional questions later, Dr. Pollack will be happy to answer them.
- If you think you have experienced a **research-related injury** call Dr. Jonathan Pollack at 650-736-1987.
- If you are not satisfied with the manner in which this study is being conducted or if you have any questions concerning your rights as a research study subject, you may contact the Administrative Panel on Human Subjects in Medical Research at (650) 723-5244, or write the Administrative Panel on Human Subjects in Medical Research, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO

PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature of Subject

Date

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date