

**Informed Consent Document for the ___ Repository Study
at Rush-Presbyterian-St. Luke's Medical Center**

Name of Repository Manager
Department
Phone Number
Name of Repository

A "repository" is a storage bank of medical information. You are invited to donate tissue/specimens/medical information about yourself for future research purposes. You are being invited to donate to this storage bank because _____. Your participation is entirely voluntary. Whether or not you participate will have no affect on your relationship with Rush-Presbyterian-St. Luke's Medical Center and/or your doctor.

PURPOSE

The purpose of this storage bank is to collect information and tissue about [variables of interest to the repository creators] for storage and future research.

EXPLANATION OF THE STORAGE BANK

The "repository" or storage bank will consist of [specify: computer database/freezer storage/locked file cabinet/etc.]. No one has access to the storage bank for research purposes except for the Repository Manager, whose name appears at the beginning of this consent document, and persons working directly under his/her supervision.

INFORMATION AND/OR TISSUE TO BE DEPOSITED IN STORAGE BANK

If you agree, the following medical information and/or tissue specimens will be added to the storage bank [list all medical information – e.g., demographics, clinical notes, measurements, lab values – under one heading and all tissue specimens – e.g., cells, blood, cartilage, muscle – under another heading.] The information/specimens will be stored [explain where for each group of variables will be stored and how security will be maintained]. We will collect this information by (collecting specimens from Pathology, while in surgery, from the medical record, etc.).

Since we do not yet know the exact questions that will be studied by scientists in the future, we cannot tell you what specific information they will be looking at or what that might mean to you.

If you change your mind and wish to withdraw your tissue/specimen/date at a later time, you may do so by contacting the Repository Manager at [local phone number] and no further use will be made of the _____ you donated.

PERSONS WHO WILL HAVE ACCESS TO THE INFORMATION

The information in the storage bank will be available only to scientists who have approval to do research studies.

Under rare circumstances, specific other persons may have access to the information in the storage bank. These specific persons might include representatives of the organization paying for the study, appropriate federal or state agencies (for example, the U.S. Food and Drug Administration), and the Rush Institutional Review Board.

If the results from any research study of your donated medical information are ever published for scientific purposes, your name and identity will remain confidential.

BENEFITS FOR YOU

You may not benefit from donating your _____ to this tissue bank. Some people feel it is important and valuable to contribute to research and the search for better medical understanding. The information gained from future studies may benefit other people in the future are the principal benefits of study participation.

POTENTIAL RISKS TO YOU

Confidentiality issues...

MEASURES TAKEN TO PROTECT YOU

A number of features of the storage bank will protect you and your medical information from unauthorized use.

1. Your medical information will be stored securely in [cite storage protection features – e.g., locked, encrypted, etc.].
2. The Repository Manager has been assigned to manage the storage bank and is the only person able to relate your medical information to your name or identity. Should the storage bank every be closed in the future, all identifying information about you will be removed so that it will never be possible to trace the information back to you.
3. The medical information you contribute to the storage bank will not be released to any insurance company, potential employer, government agent or agency, family member, or friend.
4. The Repository Manager will release medical information for research purposes to answer specific research questions, but only when each scientist has received approval from the Institutional Review Board (IRB) responsible for overseeing this repository. The IRB responsible for this repository is _____. Investigators will be not be given your name or the names of other persons who have provided information without your specific and separate consent.
5. When/if the results of future research are published or discussed in scientific conferences, no information will be included that might reveal your identity.

POSSIBLE COMMERCIAL PRODUCTS

[If it is possible that tissue specimens might be used to establish a commercially viable product, the possibility and example products should be described. The investigator should also go on to say that... “You will not participate in any profit that might be generated by research using the tissue specimen”].

COMPENSATION

You will not receive any payment for your contribution of medical information to this storage bank.

PERSONS TO CONTACT WITH QUESTIONS

If you have questions about participating in this research program, about the details of storage bank, or about the information in this consent document, please contact the Repository Manager [repeat name] at [repeat phone number].

If you have any questions about your rights as a research subject, please contact the Office of Research Affairs at (312) 942-5479.

Subject's signature

Date

Repository Manager/Individual obtaining consent

Date