



RESEARCH CONSENT FORM

NONTRANSPLANT TISSUE BANK (BioBank) Pre-Surgical

Project Title: NonTransplant Tissue Bank
Principal Investigator: Kenneth Shroyer, MD, PhD
Department: Anatomic Pathology

You are being asked to be a volunteer in a research study.

PURPOSE

The purpose this study is:

- The Nontransplant Tissue Bank (BioBank) is an effort of Stony Brook Medicine and Stony Brook Cancer Center in its commitment to research on cancer and other diseases.
- The purpose of this tissue bank is to store samples of blood, tissue, and body cavity fluid (i.e. pleural, peritoneal) in special freezers, so they can be made available in the future, to researchers in their study of cancer and other diseases.
- As you are about to undergo a medically indicated diagnostic or therapeutic procedure/surgery in the hospital, your surgeon is asking permission to store in the BioBank, a sample of your blood, tissue, and, if collected, body cavity fluid (i.e. pleural, peritoneal) that is taken during surgery.
- The BioBank is located in the Anatomic Pathology Laboratory at Stony Brook University Hospital.

PROCEDURES

If you decide to be in this study, your part will involve:

- Allow additional blood to be drawn (15 ml, or, about 3 teaspoons) at your pre-surgery tests, for a sample that will be stored in the BioBank for future research.
- Allow any leftover tissue, which remains after all necessary medical tests are done (specifically for your medical care), to be stored indefinitely in the BioBank for future research.
- Allow any leftover body cavity fluid (if collected), which remains after all the necessary medical tests are done (specifically for your medical care), to be stored indefinitely in the BioBank for future research.

- Allow your medical record to be linked (via a code) with your blood, tissue and body cavity fluid samples. Researchers will not be able to specifically identify you.
- The tissue and body cavity fluid specimens obtained during your procedure will be sent to Anatomic Pathology for routine diagnostic tests that are needed for your care. Priority will be given to making a pathological diagnosis. No samples will be saved for the BioBank if the entire specimen is needed for diagnostic work, even when you have signed this consent. The blood sample, which is not needed for diagnostic tests, will be sent to the BioBank.

In the future, the BioBank will provide de-identified data and samples for authorized research studies. The researchers must submit a proposal explaining the research that they wish to undertake and obtain approval from the BioBank Oversight Committee and the Committee on Research Involving Human Subjects (CORIHS) at Stony Brook University. None of your personal information will be attached to your samples.

RISKS/DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

- There are no foreseeable risks or discomforts associated with your participation in this study.
- Although the Tissue Bank uses coded identifiers that are kept in a secured computer database, there is always the possibility of a loss of confidentiality.

BENEFITS

- There is no benefit expected as a result of you being in this study.
- The results obtained from any research done on your tissue, body cavity fluid/blood will not affect your medical care, will not be placed in your medical record, nor made available to your doctor. It may help people with cancer or other diseases in the future.

PAYMENT TO YOU

- You will not be paid for your participation.
- Your tissue, blood, and body cavity fluid samples, will only be used for research and will not be sold.
- It is possible that future researchers may make financially valuable discoveries as a result of their work, and there is no plan to provide financial compensation to you.

CONFIDENTIALITY

Protecting Your Privacy in this Study:

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices).

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your tissue, blood and body cavity fluid samples for further research. You can do this at any time by writing to Dr. Kenneth Shroyer. If you contact us and let us know in writing, then any tissue, blood, and body cavity fluid that remains in the tissue bank will be destroyed and not be used in research. However, any samples already in use at that time will continue to be used by researchers. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

COSTS TO YOU

There will be no additional costs or charges to you or your insurance company for you to participate in this study.

ALTERNATIVES

Your alternative to being in this study is to simply not participate.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study you may contact the Division of Surgical Pathology, or Kenneth Shroyer, MD, PhD at 631-444-3000.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, (631) 632-9036, OR by e-mail, judymatuk@stonybrook.edu.

If you sign below, it means that you have read (or have been read to you) the information given in this consent form, and you would like volunteer in this study.

Subject Name (printed)

Signature of Subject

Date

Name of Person Obtaining Consent (printed)

Signature of Person Obtaining Consent

Date