RESEARCH CONSENT FORM

NON-TRANSPLANT TISSUE BANK (Biobank)
Adult Surgical Form

Project Title: Non-Transplant Tissue Bank
Principal Investigator: Kenneth Shroyer, MD, PhD
Department: Pathology

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

PURPOSE
The purpose this study is:

- The Non-Transplant Tissue Bank (Biobank) is a joint effort of Stony Brook Medicine and the Stony Brook Cancer Center in a commitment to research cancer and other diseases. The Biobank is located in Stony Brook University Hospital.
- The purpose of this Biobank is to store samples of blood, tissue and body cavity fluid (i.e., fluid from your chest or abdomen) in special freezers so they can be made available in the future to researchers for their study of cancer and other diseases.
- Either you are about to undergo, or you have recently undergone, 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 tissue and, if collected, blood taken before surgery and body cavity fluid taken during surgery.

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

- Allow additional blood to be drawn (15 ml or about one tablespoon) at your pre-surgery testing that will be stored indefinitely in the Biobank for future unspecified 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 unspecified 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 unspecified 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 clinical 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. Researchers must submit a proposal explaining the research that they wish to undertake and obtain approval from the Biobank Review 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.

If future studies will be obtaining information about your health and genetic information, there is a requirement to comply with a policy known as the Genomic Data Sharing Policy, which comes from the federal National Institutes of Health. Researchers can do studies that are more informative when they share with each other the data or information they get from studying human genetic data. After we assign a code (which means we remove all direct identifiers, like your name) to your medical information and to the information we obtain from your tissue samples, we will send that information to one of the National Institutes of Health databases or repositories. There, it will be used in future research along with similar information from other research participants. We will not know what types of health-related research will be done with the data that are sent there. Stony Brook will keep the master list that links your code number to your identifying information and only certain Stony Brook research staff members will ever have access to this master list.

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.
- There are no physical risks to you by having your information and tissues donated and stored for use in future research studies. However, there may be the risk of a breach of confidentiality affecting you and your relatives as a result of having your information stored in a repository. For example, there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.
- While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in a database back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is not known how likely your identity could become re-connected with your genetic and health information, but we believe this possibility is very small.

BENEFITS

- There is no benefit to you expected as a result of you being in this study.
- There is no direct benefit to you by allowing your genetic information from this study to be placed for storage in a repository at the National Institutes of Health. However, allowing researchers to study your genetic information in the future may lead to a better understanding of how genes affect health. This may help other people in the future.
- 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. However, 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:

- As explained above, approved investigators who perform research on your tissue may be required to send information they obtain about your health and your genes to one of the federal National Institutes of Health databases or repositories, so it can be used in future

research along with similar information from other research participants. Preserving the confidentiality of your information is very important to us, and we will do so by removing any information that can identify you (like your name), and instead, assign a code to your medical information and the information we obtain from your tissue samples before we send that information to one of the National Institutes of Health databases or repositories. Stony Brook will keep the master list that links your code number to your identifying information and only certain Stony Brook research staff members will have access to this master list.

- 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, the sponsor of the study (and those who work for them), Stony Brook University's Committee on Research Involving Human Subjects (CORIHS), applicable Institutional officials, and certain federal offices including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA).
- 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 Stony Brook 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 simply not to 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 Principal Investigator, Dr. Kenneth Shroyer, 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 the Stony Brook University Research Subject Advocate, Ms. Lu-Ann Kozlowski, BSN, RN, (631) 632-9036, OR by e-mail: lu-ann.kozlowski@stonybrook.edu
- You can visit Stony Brook University's Community Outreach webpage at http://www.stonybrook.edu/research/orc/community.shtml for information about being in research studies and read frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

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

Please place patient specimen barcode label here

If the patient is unable to provide consent, a Legally Authorized Representative (LAR) may consent for them.

_____
Printed Name of LAR Signature of LAR Date

LAR's relationship to this patient: _____