You are being asked to allow your child to be a volunteer in a research study

PURPOSE
The purpose of this study is:

- The Non-Transplant Tissue Bank (BioBank) is an effort of Stony Brook Medicine and Stony Brook Cancer Center in their commitment to research on cancer and other diseases.
- The purpose of this tissue bank is to store samples of tissue, blood 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.
- Your child is about to undergo a medically indicated diagnostic or therapeutic procedure/surgery in the hospital and your child’s surgeon is asking permission to store in the BioBank, a sample of your child’s 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 allow your child to be in this study, his/her part will involve:

- Allow additional blood to be drawn (15 ml, or, about 3 teaspoons) when your child has his/her 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 child’s medical care), to be stored indefinitely in the BioBank for future research.
- Allow any leftover body cavity fluid, which remains after all the necessary medical tests are done (specifically for your child’s medical care), to be stored indefinitely in the BioBank for future research.
• Allow your child’s medical record to be linked (via a code) with your child’s blood, tissue and body cavity fluid samples. Researchers will not be able to specifically identify your child.

• The tissue and body cavity fluid specimens obtained during your child’s procedure will be sent to Anatomic Pathology for routine diagnostic tests that are needed for your child’s 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 child’s personal information will be attached to your child’s samples.

RISKS/DISCOMFORTS
The following risks/discomforts may occur as a result of your child being in this study:

• There are no foreseeable risks or discomforts associated with your child’s 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 your child being in this study.

• The results obtained from any research done on your child’s tissue will not affect your child’s medical care, will not be placed in your child’s medical record, nor made available to your child’s doctor. It may help people with cancer or other disease in the future.

PAYMENT TO YOU/YOUR CHILD
• Your child will not be paid for his/her participation.

• Your child’s 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 your child.

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

We want to make sure that this study is being done correctly and that your child's rights and welfare are being protected. For this reason, we will share the data we get from your child 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 your child is in this study we will get data about his/her health from his/her medical record. We will also get health data from the results of the tests your child will have done in this study. Your child has a right to privacy but the data we get about his/her 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 child's health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your child's rights and safety are protected. Not all of these people are required by law to protect your child's 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 child's blood, tissue and body cavity fluid samples for further research at any time. You can do this by writing to Dr. Kenneth Shroyer. If you do this, then any samples that remain in the BioBank will be destroyed and not used in research. However, any de-identified samples already in use at the time will continue to be used by researchers.

When you sign the consent form at the end, it means three things:

- That you have read this section.
- That you will allow the use and reporting of your child's 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 your child or your insurance company for your child to participate in this study.

**ALTERNATIVES**

Your alternative to allowing your child to be in this study is to simply not give permission for his/her participation.

**YOUR CHILD’S RIGHTS AS A RESEARCH SUBJECT**

- Your child’s participation in this study is voluntary. You do not have to have your child in this study if you don’t want him or her to be.
You have the right to change your mind and withdraw your child from the study at any time without giving any reason, and without penalty.

- Any new information that may make you change your mind about your child 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 or your child's legal rights by signing this consent form

**QUESTIONS ABOUT THE STUDY OR YOUR CHILD’S RIGHTS AS A RESEARCH SUBJECT**

- If you have any questions, concerns, or complaints about the study you may contact the Department of Pathology or the Principal Investigator, Dr. Kenneth Shroyer, at 631-444-3000.
- If you have any questions about your child’s 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, judy.matuk@stonybrook.edu.

You can visit Stony Brook University’s Community Outreach webpage at [http://www.stonybrook.edu/research/orc/community.shtml](http://www.stonybrook.edu/research/orc/community.shtml) for information about being in research studies and read frequently asked questions. You can also ask questions or leave comments about how you feel about being a research subject in this study.

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 to have your child to be a volunteer in this study.

__________________________
Minor Subject’s Name (Printed)

__________________________
Parent/Legal Guardian Name (Printed)

______________________________  _____________
Parent/Legal Guardian Signature  Date

______________________________
Name of Person Obtaining Consent (Printed)

______________________________  _____________
Signature of Person Obtaining Consent  Date
Child aged 7 to 11 years old: confirm that assent discussion has occurred and that child agreement was obtained

Child aged 12 to 17 years old: confirm that signed assent has been obtained and sent to the Tissue Bank (BioBank) along with this form