



RESEARCH PERMISSION FORM

NON-TRANSPLANT TISSUE BANK (Biobank)

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

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 cancer and other diseases. The Biobank is located in the Anatomic Pathology Laboratories at Stony Brook University Hospital.
- The purpose of this Biobank is to store samples of tissue, blood 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 in their study of cancer and other diseases.
- Your child is about to undergo, or has recently undergone, a medically indicated diagnostic or therapeutic procedure/surgery in the hospital. In either case your child's surgeon is asking permission to store in the Biobank, a sample of your child's tissue and, if collected, blood taken before surgery and body cavity fluid that is taken during surgery.

PROCEDURES

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

- Allow additional blood to be drawn (15 ml or about one tablespoon) when your child has their pre-surgery tests, for a sample that will be stored in the Biobank for future unspecified 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 unspecified research.
- Allow any leftover body cavity fluid (if collected), 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 unspecified 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. 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 child's personal information will be attached to these 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

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

BENEFITS

- There is no benefit to your child expected as a result of your child being in this study.
- There is no direct benefit to your child by allowing their 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 child's 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 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. However, 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 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:

- As explained above we are required to send information we obtain about your child's health and 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 child's information is very important to us, and we will do so

by removing any information that can identify your child (like their name), and instead, assign a code to your child's medical information and the information we obtain from their 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 child's code number to their identifying information and only certain Stony Brook research staff members will ever have access to this master list.

- 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, 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).
- While your child is in this study we will get data about his/her health from their medical record. We will also get health data from the results of the clinical tests done for your child's care. Your child has a right to privacy but the data we get about their health in this study can be shared with the people referenced above (the study team, Stony Brook CORIHS, applicable institutional officials, and federal offices such as the OHRP and FDA).
- 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 their 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 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.
- Visit Stony Brook University's Community Outreach page, <http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research> for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your child's 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 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 Biobank along with this form