# TBANK: PROTOCOL FOR COLLECTING, BANKING AND DISTRIBUTING HUMAN TISSUE SAMPLES

***NOTE:*** *When we say “you” in this consent, we mean “you or your child.”*

# What is the purpose of the biorepository?

You are being asked to donate your tissue samples and health information to the St. Jude Biorepository because you are a patient, parent, relative or legal guardian of a patient, or a healthy volunteer. Once you understand the purpose of the biorepository, risks and benefits of donating samples and health information, and you agree to participate, you will be asked to sign this consent form and we will give you a copy.

A biorepository is a laboratory that collects, stores and provides human tissue samples and health information for current and future research. Gathering and storing samples and health information in a biorepository provides important resources for researchers so they may learn more about diseases and conditions and develop new diagnostic tests, and new treatments for many kinds of diseases.

Samples and information that are banked are used for a wide range of research including the study of genetic diseases. Your specimens may undergo whole genome sequencing. A genome is made of DNA and contains the complete set of genetic instructions. Genetic diseases may be inherited, for example, sickle cell anemia, cystic fibrosis and epilepsy. Cancer is commonly a genetic disease, and may be caused by inherited genetic changes, and genetic changes that occur in cells after birth.

Samples may also be used to create “cell lines”. Cell lines are created by growing cells from samples into more cells either in the laboratory, or in other species such as mice. Human samples grown in other species are called “xenografts.” Cell lines and xenografts made from donated samples will also be stored in the St. Jude Biorepository and research laboratories and used for research.

It is important that you know the following:

* + The choice to donate your samples and health information is up to you and will not affect your treatment.
  + You may decline to donate samples for research.
  + You may stop us from using your samples and or health information for research at any time. You can request that your tissue samples be removed from the Biorepository and destroyed. However, we cannot retrieve samples and information that has already been given to researchers or used in research studies.

If you have questions or concerns before or after agreeing to donate to the Biorepository, you can contact Dr. Charles Mullighan, the Medical Director of the Biorepository (901-595-3387 or charles.mullighan@stjude.org) or Matthew Lear, the Technical Director (901-595-2528 or matthew.lear@stjude.org).

NIH/NCI has developed a useful brochure (in English and Spanish) about tissue research, which can be found at: <http://www.cancer.gov/clinicaltrials/resources/providingtissue/>

If you have questions about your rights as a research participant, you can contact the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644. (Toll-free 1-866-583-3472).

# What will be done?

Left over material from your biopsy, surgery, spinal tap, blood draw or other medical care will be collected at any time now or in the future and stored in the St. Jude Biorepository. Extra amounts of blood or other body fluid, or tissue samples may also be collected during routine medical procedures. In these cases, about 2-6 teaspoons of extra blood or bone marrow or an extra ½ teaspoon of cerebrospinal fluid (fluid surrounding brain and spinal cord) will be drawn.

For individuals who are not patients, we may collect a blood sample or a sample from your cheek using a swab. We may collect about 2 tablespoons of blood, depending on your age and weight.

We will collect basic health information from you and your medical records. More detailed information

will be collected when needed for research. Examples of information that will be used for research include your medical history and physical exams, health status, results of laboratory tests, medical procedures, x-rays, scans, treatments and medications.

# How will samples and health information be stored?

Your donated samples and basic health information will be stored in the St. Jude Biorepository until the samples are used up or until you ask for them to be removed from the Biorepository. Health information will be used indefinitely, unless you ask us to stop using it for research.

Your identity will be removed from the samples and they will be labeled with a unique code. The Biorepository will maintain a link between the code and your identity. Codes and any private health information will be kept in a password protected database that is protected by a firewall. Only authorized Biorepository staff will have access to the database. Samples will be kept in locked freezers and only authorized Biorepository staff will have access to the freezers.

# How will samples and health information be shared?

Requests to use your samples and health information for research are reviewed and approved by a committee of scientists who review the research to make sure it is good science.

Most research will not require knowing who you are. However, there are cases that your identity is needed to conduct research. When your identity is necessary, researchers must also obtain approval from the St. Jude Institutional Review Board (IRB). The IRB is a regulatory board that reviews, monitors, and approves all research studies involving humans. The IRB follows state and federal laws as well as ethical codes to make sure your rights and welfare are protected.

Research data and samples are shared with other researchers at St. Jude and elsewhere. This sharing allows for more research and important research findings. You will not be notified every time your samples and information are used for research. If researchers require additional information or testing from you, you will first be contacted by Biorepository staff or your primary physician to ask if a researcher can contact you. If you agree, the Biorepository will provide the researcher your contact information. If you do not agree, you will not be contacted by the researcher.

Research data obtained from tumor and normal specimens, such as genetic data, are often shared with the research community using various databases, including those maintained by St. Jude, the federal government, and international collaborative databases. This is to advance scientific discovery, and to satisfy requirements of organizations that fund research, and journals that publish the results of research. There are two types of databases used for sharing research data. One is a public, unrestricted access database and the other is a controlled access database. Each is described below.

***Unrestricted access databases:*** The information from research studies using your samples, genetic information and health information may be freely available in a public, unrestricted database that anyone can use. A public database could include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. Summary-level information about all participants included in a dataset, including you, but not genetic data for each individual, may be shared. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in the dataset, or how often certain gene changes are seen across participants from many studies. However, the risk of anyone identifying you with this information is very low. This public information will not be labeled with your name or other information that could be used to easily identify you.

***Controlled access databases*:** Your individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database must agree not to attempt to identify you. Examples are the St Jude Cloud which is run by St Jude, the database of Genotypes and Phenotypes which run by the Federal Government and the European Genome-Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples

to study genetic changes in pediatric diseases.

# Will I be given research results or findings?

You will not be given individual research results. Most researchers will not know your identity. By law, research results cannot be reported to you or your physicians. However, we may contact you to provide counseling and offer clinical testing if researchers discover something that could affect you or your family’s health. You can refuse this information unless the information concerns a minor child, is related to a disease that is serious, and could possibly be prevented or treated before the child turns

18. If you are not contacted, this does not mean that you do not have any genetic variants (changes) that might be related to a disease or condition.

# Is there a risk of harm associated with donating samples and health information for research?

Donating samples poses little or no physical risk beyond the risks of the procedure itself. The risks of a blood draw include brief stinging pain, bruising, and slight bleeding at the needle site. Rarely, the needle stick site may become infected. Some people may feel faint. The risks of biopsy or other procedures, such as lumbar puncture (spinal tap) will be discussed separately with you.

The primary risk from donating samples and health information for research is the accidental release of or unauthorized access to, your private information. This could result in embarrassment, loss of employment, discrimination or criminal charges. In the unlikely case that your genetic information is taken and linked back to you, it could be used in ways that cause you or your family distress. Also, some genetic results can help predict future health problems that may affect you and your relatives.

This may be information that if told to you, could cause you and your family distress or psychological harm.

# Are there benefits from donating samples and information to the Biorepository?

Donating samples to the St. Jude Biorepository will likely not benefit you directly. What we learn from current and future research studies using donated samples and information may help people in the future.

# How will privacy and confidentiality be protected?

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI (protected health information) may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude Internet website: [www.stjude.org](http://www.stjude.org/).

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

The Biorepository has received a Certificate of Confidentiality from the federal government. The Certificate of Confidentiality protects release of your personal medical information or samples even if a court orders St. Jude to release them. You can still give permission for personal information to be released. The Certificate of Confidentiality does not protect release of information in certain circumstances. These include clinical or research data that are placed in the medical record for the purposes of clinical research and clinical care. In addition, researchers and study staff are required by law to report suspected child abuse, and neglect, or harm to self or others. Tennessee state law requires researchers to report every case of certain contagious diseases they find. These diseases all spread easily between people, and if you are found to have one of the diseases named in the law, you will be told, so you can be given treatment to help control the spread of the infection.

Results of future research may be published or discussed in conferences. Your name, medical record number, and similar identifying information will not be included unless you agree.

The Biorepository has many years of experience in preventing unauthorized access to information.

Your privacy and the confidentiality of your information are very important to us and we will take significant efforts to protect them. Additionally, wherever possible, the information will be released without information that may personally identify you, such as your name, address and date of birth. Personally identifiable information is rarely released for research purposes, and must be required in order for scientifically justified research to be performed, and must have the approval of the St Jude Institutional Review Board.

# What are the costs and will I be paid for my donation?

There are no costs to you for donating your samples and information to the Biorepository. You will not be paid for donating your samples or health information. If new product, drug or medical test is developed using your sample or information, it may be sold for profit. If this happens, you will not share in that profit.

St. Jude may sell your samples and health information to commercial companies that conduct research or develop new drugs, devices, tests. You will not receive any payment from the sale of your samples and information. Samples or information that are sold will not include identifying information.

# Permission to Use Your Data/Information: Authorization/HIPAA

If you sign this document, you give permission to the St. Jude Biorepository to use or disclose (release) your health information as described in this document. With approval of the St Jude Institutional Review Board, the health information associated with you and your tissue samples that the Biorepository may use or disclose (release) for research purposes includes information related to your medical history, diagnosis, laboratory test results, x-rays, scans, medical procedures, diagnostic testing results treatments and medications. The health information may be used by and/or disclosed (released) to researchers and their staff at St. Jude Children’s Research Hospital as well as researchers around the world and commercial companies.

The choice to donate your samples and health information is up to you and will not affect your treatment in any way. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this Authorization, but if you do not, you cannot donate samples and information to the St. Jude Biorepository. You may change your mind and revoke (take back) this Authorization at any time, and request that your tissue samples be removed from the Biorepository and destroyed. Even if you revoke this Authorization, health information already provided to researchers cannot be retrieved. To revoke this Authorization, you must write to:

HIPAA Privacy Officer

St. Jude Children's Research Hospital 262 Danny Thomas Place, Mail Stop 280 Memphis, TN 38105

This Authorization does not have an expiration date.

# PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):

I have read this document, or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to donate to the St. Jude Biorepository.

AM/PM

Parent/Legal Guardian Signature Date Time (circle one)

# ASSENT DISCUSSION (Required for participants 7-13 years old)

* The Biorepository was explained to the minor participant in age-appropriate terms and the minor verbally agreed to donate samples and information to the Biorepository.
* Minor declined to allow their samples and health information be donated to the Biorepository. The minor declined for the following reason(s):
* An assent discussion was not initiated with the minor for the following reason(s):
  + Minor is under 7 years of age.
  + Minor is incapacitated.
  + Minor refused to take part in the discussion.
  + Other

**PARTICIPANT STATEMENT (14-17 years old and Adult Participants 18 years and older):** I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to donate samples and information to the Biorepository.

AM/PM

Participant Signature Date Time (circle one)

**RESEARCHER/DESIGNEE STATEMENT:** I have explained the Biorepository to the participant and his/her parent(s) or legal guardian(s). The participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

AM/PM

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| --- | --- | --- | --- | --- | --- |
| Research/Designee Signature |  |  | Date | Time | (circle on) |
| Print Name |  |  |  |  |  |
| Interpreter (if needed) |  |  | Date | AM/PM  Time | (circle one) |

PLEASE FAX CONSENT FORM TO PROTOCOL OFFICE #6265