NATIONAL LIVER DISEASE BIOBANK

PATIENT INFORMATION SHEET

Dear Patient!

What are Biobanks?

A biobank ("bank of life") is a place that stores blood and other human tissue samples donated by patients or healthy donors for research in cancer or other serious diseases. These biospecimens are commonly annotated with information about the patient/donor from whom the biospecimen was taken, including data about their medical conditions and background. However, one of the top priorities of biobanks is to protect the privacy and sanctity of the donor's personal and medical information.

Participation in this endeavor is voluntary. You are being asked to donate urine, blood and/or surgical tissues and or other biological materials for future research. If you agree with this, blood/tissue/other biospecimens will be collected, processed and stored along with relevant clinical information in biobank. These stored biospecimens are used in research in India and abroad for various studies to learn more about diseases. It will help to seek answers regarding causes of diseases, treatment, and genetic information.

What are Biospecimens?

Biospecimens are materials such as urine, faecal, blood, tissue, cells, DNA, RNA, and protein taken from the human body. When these samples are properly processed and stored at biobank along with a written consent it is known as biospecimens.

Things to Think About

The choice to let us use/ keep the left over blood/tissue/other biospecimens from your surgery for future research studies within and outside the country for an unlimited amount of time is up to you. No matter what you decide to do, it will not affect your medical care.

If, however you change your mind in future and you wish to withdraw your consent for storage of the samples and health information and wish that they can be destroyed, you may do so at anytime without penalty, loss of benefits to which you are entitled. The withdrawal of your consent for your samples to be used in future research has to be performed by writing to the biobank Investigator/ Manager. If (part of) your sample has already been processed and analysed conform with your past consent, then these samples and the accompanying data cannot be withdrawn anymore. However, any remaining, unused samples will be destroyed and accompanying data will be deleted from the biobank's systems.

In the future, other researchers may need to know more about your health. The institution where you are treated may give them reports about your health, but it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Your blood/tissue/other biosamples will be used only for research and will not be sold. The research done with your blood/tissue/other biosamples may help to develop new products/commercial products in the future. You will not be personally entitled to commercial gains which are made from the study of the donated tissues and you will have no legal rights to any discovery or invention that either directly or indirectly results from the use of the biospecimens, and informatics.

Where does tissue come from?

Whenever a biopsy (or surgery) is performed, the tissue that is removed is examined under the microscope by a trained doctor to determine the nature of the disease and assist with the diagnosis. Your tissue will always be used first to help make decisions about your medical care. After all tests have been done, there is usually some left over tissue. Sometimes, this tissue is not kept because it is not needed for the patient's care. Instead, a patient can choose to have the tissue kept for future research. People who are trained to handle tissue and protect the donor's rights make sure that the highest standards are followed. Your doctor has agreed to help collect tissue from many patients. Many doctors across the country are helping in the same way. If you agree, only left over tissue will be saved for research. Your doctor will first use whatever tissue is needed for your care.

Why do people do research with biosamples?

Research with blood/tissue/other biosamples can help to find out more about what causes certain diseases, how to prevent them, and how to treat them. Research using tissue can also answer other health questions.

How do researchers get the biosamples?

Researchers from universities, hospitals, and other health organizations, including commercial organisations such as pharmaceutical and biotech companies, conduct research using tissue. They contact the NLDB and request samples for their studies. The NLDB reviews the way that these studies will be done, and decides if any of the samples can be used. The NLDB gets the biosamples and health information about you from your hospital, and sends the tissue samples and some information about you to the researcher. The NLDB will not send your name, address, phone number, social security number, or any other identifying information to the researcher.

What type of research will be done with my biosample?

Many different kinds of studies use blood/tissue/urine/faecal/swap/other biospecimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs.

Some research looks at diseases that are passed on in families (called genetic research). Research done with your blood/tissue/other biosamples may look for genetic causes and signs of disease. Even if your blood/tissue is used for this kind of research, the results will not be put in your health records.

Will I benefit from the research using my biosamples?

It is hoped that the results of research on your blood/tissue/other biosamples and blood/tissues/other biosamples from other patients will provide information that will help other patients in the future. However, there will be no direct benefit to you because your blood/tissue/other biosamples may not be used for some time after you donate it and because research can take a long time. The research that may be done with your blood/tissue/other biosamples is not designed specifically to help you. The benefits of research using blood/tissue/other biosamples include learning more about what causes diseases, how to prevent them, and how to treat them.

Will I find out the results of the research using my biosamples?

Your doctor will give you the results of your biopsy when results are known. These test results will be ready in a short time and will be used to make decisions about your care. Though research

involves the test results of many different people, your biopsy result involves only you.

You will not receive the results of research done with your blood/tissue/other biosamples. This is because research can take a long time and uses blood/tissue/other biosamples from many people before results are known. Results from research using your blood/tissue/other biosamples may not be ready for many years and will not affect your care right now, but it may be helpful to people like you in the future.

Why do you need information from my health records?

In order to do research with your biosamples. Researchers may need to know your personal and health records information. This helps researchers to answer questions about diseases. The information that will be given to the researcher includes your age, sex, race, diagnosis, treatments, and possibly some family history. This information is collected by your hospital from your health record and sent to the NLDB but without your name or other identifying information.

Risk(s)

There will be minimal risk for you, as only remnant surgical tissue will be collected that is not needed for pathologic diagnosis but has to be removed as treatment. No additional tissue will be removed for the sole purpose of this study hence no reimbursement will be given.

Risks associated with blood and other biosamples

There is no potential risk but slight discomfort or bruising may occur while collection of blood as it occurs in any other blood collection.

How am I protected?

The institution from where you receive your treatment from/ have blood drawn from/ etc will protect your records so that your name, address, and phone number will be kept private, unless otherwise required by law. All information and samples obtained for this study will be assigned a secure code that will not use your name and any other identifying information. The code will be stored in secured database and safeguarded by biobanking staff who will sign Confidentiality Disclosure Agreement.

The NLDB is in charge of making sure that information about you is kept private. The NLDB will take careful steps to prevent misuse of records. Your name, address, phone number and other identifying information will not be associated with your blood/ tissue/biosamples when it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

Whom Do I Call if I Have Questions or Problems?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enrol or to continue/discontinue/withdraw to participate in this study, you may contact or ask more questions about the study at any time, Please contact Dr. Birendra Kumar Yadav, Biobank Manager. nldb.ilbs@gmail.com /Ph.:+91-11-46300000. Ext.24813/24814

A copy of this consent form will be given to you to keep.

PATIENT INFORMATION SHEET

1. I confirm that the nature, purpose, and possible side effects of the project have been explained to me, clearly and in detail, by the physician or another member of the project team:

.....	.....	**Yes**	**No**
Name of the **Medical Practitioner** (print)	Name of the **Hospital / Institute** (print)		

2. I have read or have had read to me and understood the content of the Patient Information sheet and the Informed Consent imprinted below. In addition, I had the opportunity to discuss the study operation with my Medical Practitioner. All my questions have been answered satisfactory. ☐ ☐
3. I had enough time to decide whether I want to participate in the study or not, and I give a free consent to participating in the study as described in the Information sheet. ☐ ☐
4. I understand that I am entitled to withdraw my consent whenever I want (in writing) without stating any reasons and without any disadvantageous consequences. If I withdraw my consent, my samples will be destroyed and my data will be deleted from the study file. ☐ ☐
5. I understand that although the project will foster the advancement of medical knowledge and improve future treatments of human diseases, I will not experience any direct benefits by participating in this study. I have been assured that all tests shall serve only the research purposes. The study may lead to development of new laboratory tests and medications, which will be sold in the future. ☐ ☐
6. I understand that I will not receive any money for providing my biospecimens and that I will not be able to claim compensation, royalties or any other financial advantages or profits, which are potentially based on scientific results gained from research with my biospecimens. ☐ ☐
7. I understand that if I will be injured or get sick as a result of participating in this study, my standard state/voluntary insurance will be billed for any necessary treatments. No other payment is available from the study sponsor or my doctor. ☐ ☐
8. I have been assured that, in the event research results are published, neither my medical history nor my identity will be disclosed. The study protocols are kept in anonymous form. I agree to allow my data to be digitally saved and analyzed in applications for statistical purposes. For quality assurance purposes I agree that only authorized persons, who are also subject to medical confidentiality, may view my data for inspection and control. Furthermore, the applicable legal statutes pertaining to data privacy apply. ☐ ☐
9. I understand that the content of the study is confidential and that I am not allowed to pass on any information to any other party except personnel involved in this study. ☐ ☐
10. Since this is a preliminary study and the results from the study do not have any effect on my type of treatment, I will not be informed of the results of the test. I understand that I shall not be entitled to know the research results obtained from my samples or to claim any resulting revenues. ☐ ☐
11. I received a copy of, read, and understand the information and consent form for study participants. ☐ ☐
12. I agree to the transfer of my biospecimens to the sponsor of this study, and understand that they could also be used by the third parties. ☐ ☐
13. I agree to donate the following human biospecimens (put initials to all that apply): ☐ ☐

____	Blood	____	Surplus surgical tissue (tumor, other)
____	Urine	____	Buccal Cells (oral rinse)
____	Saliva	____	Skin punch biopsy
____	Sputum	____	Other specimen _____(specify)
____	BAL	____	I will not donate any human biospecimens at this time
.....			.....

Name of the **Patient** (print in block letters)	
Signature / Thumb Impression of Patient Date _____	
Name of impartial Witness* Date _____ *Impartial witness is required if the subject is unable to read the consent	Signature of impartial Witness

_____
_____

To be completed by the authorized delegate explaining consent*:*

I, _____ (name of authorized delegate) have informed the patient named above of the purpose, nature, duration, and risks of the study, and confirm that he/she has given consent to participate in the study

....

Date (day/month/year) Signature of the authorized delegate