INFORMED CONSENT

PART I: INFORMATION SHEET

Introduction

What are Biobanks?

A biobank is a place that stores blood and other human samples donated by patients or healthy donors for research in cancer or other diseases. These biospecimen are commonly annotated with information about the donating participant. One of the top priorities of biobanks is to protect the privacy and sanctity of the participant's personal and medical information.

What are biospecimen?

Biospecimens are materials such as urine, faecal, blood, tissue, cells, DNA, RNA, and protein taken from the human body. These samples are coded, processed and stored at biobank along with informed consent.

What is purpose of the research?

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

Procedures and Protocols

Where does biospecimen come from?

Whenever a biopsy/ surgery/ diagnosis are performed or biospecimen is collected prospectively or biospecimen is donated voluntarily, that biospecimen is examined under the microscope by a pathologist to determine the nature of the disease and assist with the diagnosis. 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.

How do researchers get the biospecimens?

Researchers from various institutes, pharmaceutical and biotech companies, contacts NLDB and request biospecimen for their studies. NLDB reviews the way these studies will be done, and decides if any of the biospecimen can be used. NLDB does not share identifying information to the researcher.

What type of research will be done with my biospecimen?

Multiple studies use blood/ tissue/ urine/ faecal/ swap/ other biospecimens and research is carried out to discover causes of disease, biomarkers, new ways of treatment, which includes new test and drug discovery.

Why do you need information from my health records?

In order to do research with biospecimens, researchers need to know health related information. This helps researchers to know about diseases. The information that may be given to the researcher includes age, gender, race, diagnosis, treatments, and possibly some family history. After consent, this information is collected from your health records but without name or other identifying information.

Protection and Confidentiality

The institutions from where you receive your treatment or have blood drawn will protect your records so that all your personal information will be kept private/ anonymised, unless otherwise required by law. All information and biospecimen obtained for research will be assigned a secure code that will not use your name and any other identifying information. We protect your personal information/ biospecimen details in secured digital database that is protected by two-layer security and password on basis of group level.

We provide the access to data in four module levels:
(i) Login; (ii) Security; (iii) Biobank Start-up and; (iv) Biobank

Authorisation of access to data is divided in four group levels:
(i) Group; (ii) Module; (iii) Form Access and; (iv) Form Option Access

All Biospecimen details and personal information kept in 1-D/2-D barcode format. Your name, address, phone number and other identifying information will not be associated with your biospecimen 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 participant which will help to protect your privacy. Further, the hard copy of your information will be kept in separate room protected with lock and under the surveillance of CCTV.

Voluntary Participation

Participation is voluntary. You are being asked to donate biological waste/ left over tissue/ other biological materials for future research. If you agree, biospecimen will be collected, processed and stored along with relevant clinical information. It will help to seek answers for causes of diseases, treatment and information

Benefits

The research done with your biospecimen is not designed specifically for you and research takes place on cohort of biospecimen. The research done with your biospecimen may help to develop new products/ commercial products in future but you will not be personally entitled for commercial gains and you will have no legal rights to any discovery or invention either directly or indirectly. You may not get any direct benefit because your biospecimen is not used immediately and research takes a long time, but the benefits of research using your biospecimen may help to know more about what causes diseases, how to prevent and treat them and will provide information that will help people in future.

Risks

You have already agreed to give biospecimen for your treatment as per standard medical procedure. There will be minimal risk for you, as only leftover biospecimen will be collected that is not needed for pathologic diagnosis. Thus, no additional risk or discomfort is associated allowing NLDB to collect such biospecimen. Only slight discomfort may occur while collection of blood as it occurs in any other blood collection.

Right to Refuse or Withdraw

You have complete rights to refuse to participate and to withdraw your consent for allowing use/ storage of the samples and health information without any penalty, loss of benefits to which you are entitled. In that case withdrawal of your consent for your samples is to be given in writing to the biobank manager.

Note: In the event of any or whole part of your sample has already been processed or analysed, pursuant to your past consent, then these samples and the accompanying data cannot be withdrawn anymore.

Method of disposal

Whenever your sample will not be useful for the research or you withdraw your consent then the biospecimen will be disposed off after the due approval of Biospecimen Release Board and accordingly, any remaining, unused samples will be destroyed and accompanying data will be deleted from the biobank's systems.

Duration of storage

Collected biospecimens will be stored in biobank until useful for research.

Important information

- Your choice, no matter what you decide to do, will not affect your medical care.
- The Manager of National Liver Disease Biobank would be the custodian of biospecimens, so collected.
- If related data is required for measurement of outcome and if the biospecimen has been completely anonymised then consent for that particular biospecimen cannot be withdrawn and also the biospecimen cannot be destroyed as it is no more identifiable.
- Your biospecimen may be used for research within and outside the country (both for academic and commercial research) and will not be sold and NLDB reserves the right to permit the research by other agency in India or abroad on such terms and conditions as it may decide.

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

You and your family will not be told of any new findings that come to light during the studies unless they are of significant prognostic importance. You have option to choose if you wish to be informed about findings.

I would like to be informed of findings with prognostic importance		Yes		No
I would like to be informed of results of genetic testing from the research studies performed		Yes		No

Who to Contact?

If you have any questions regarding your rights as a participant, concerns about the study, or if you feel under pressure to enroll or to continue/ discontinue/ withdraw your participation, you may contact at any time.

Name: Dr. Birendra Kumar Yadav Designation: Manager Email: biobank.ilbs@gmail.com
Phone: +91 11 46 300 000; Extension: 24813/ 24814 Website: www.nldb.in

A copy of this informed consent will be given to you to keep, if you requires.

PART II: CERTIFICATE OF CONSENT

I have read or have had read to me and understood the content of the participant information sheet and the informed consent and I consent voluntarily to participate as a participant in this research and I confirm that,

1. 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.
2. I had the opportunity to discuss the study operation with my medical practitioner. All my questions have been answered satisfactorily and I received a copy of information and consent form.
3. I had enough time to decide whether I want to participate in the study or not.
4. I understand that I am entitled to withdraw my consent whenever I want (in writing) without stating any reasons and without any disadvantages. 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 the academic and/or commercial research purposes. The study may lead to development of new laboratory tests and medications, which may 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 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 necessary treatments will be as per institutional policies.
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. Since research studies take long time, these would not have any effect on my treatment. I understand that I shall not be entitled to know the research results obtained from my samples or to claim any resulting revenues, except of prognostic results, as per my wish.
10. 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 party.
11. I agree to donate the following human biospecimens (put initials to all that apply, in block letters):

Name of Participant: …….. Signature of participant: …….
Date:

Name of impartial witness: ……. Signature of witness: ……
Date:

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

	Blood		Left over surgical tissue (tumour, other)/BAL/Sputum
	Urine		Buccal Cells (oral rinse)
	Saliva		Skin punch biopsy
	Faecal		Other specimen _____(specify)

I confirm that the participant was given an opportunity to ask questions and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual hasn't been coerced into giving consent, and consent has been given freely and voluntarily

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Name & signature of the person taking consent Name of the Hospital / Institute
Date: