PARTICIPANT INFORMATION SHEET

Dear Participant!

A. What are Biobanks?
A biobank (“bank of life”) 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 participant from whom the biospecimen were taken. One of the top priorities of biobanks is to protect the privacy and sanctity of the participant’s personal and medical information.

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

B. Aims of 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.

C. 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 coded, processed and stored at biobank along with informed consent, it is known as biospecimens.

D. Things to Think About
- The choice to let us use/keep blood or left over tissue or other biospecimens from your surgery for future research studies within and outside the country. Collected biospecimens will be stored in biobank until unutilised for research. No matter what you decide to do, it will not affect your medical care.
- The Manager of the Biobank of National Liver Disease Biobank would be the custodian of biospecimens, so collected.
- If, 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 given in writing to the biobank Manager.
- In the event of any part or whole of your sample has already been processed and analysed pursuant to your past consent, then these samples and the accompanying data cannot be withdrawn anymore.
- If related data is required for measurement of outcome then the same cannot be withdrawn. Further, if the specimen has been completely anonymised then consent for that particular cannot be withdrawn and also the biospecimen cannot be destroyed as it is no more identifiable.
- Accordingly, any remaining, unused samples will be destroyed and accompanying data will be deleted from the biobank’s systems.
- The institution where you are treated may give the health records, but it will not give your personal identifiable information.
- Your blood/tissue/other biospecimens will be used only for research (both for academic and commercial research) and will not be sold.
- NLDB reserves the right to carry out research at ILBS or any other place or may permit the research by other agency in India or abroad on such terms and conditions as it may decide.
- The research done with your biospecimen may help to develop new products/commercial products in the future. You will not be personally entitled to commercial gains and you will have no legal rights to any discovery or invention either directly or indirectly.
- However, community based donors are entitled to receive benefits accrued from the research conducted on the basis of their biospecimen. The benefits of the research would be returned to their
E. Where does biospecimen come from?
   i. Whenever a biopsy / surgery / diagnosis are performed or biospecimen is collected prospectively or biospecimen is donated voluntarily, the biospecimen that is removed or collected prospectively or donated voluntarily is examined under the microscope by a pathologist to determine the nature of the disease and assist with the diagnosis. Your biospecimen will always be used first to help make decisions about your medical care.
   ii. 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.
   iii. Your doctor has agreed to help collect samples for future research and many doctors across the country are helping in the same way. If you agree, the biospecimen will be saved for research.

F. How do researchers get the biospecimens?
   i. Researchers from various institutes and other organisations such as pharmaceutical and biotech companies, conduct research using cohort biospecimen.
   ii. They will contact the NLDB and request biospecimen for their studies. The NLDB reviews the way that these studies will be done, and decides if any of the biospecimen can be used. The NLDB will not share your identifying information to the researcher.

G. What type of research will be done with my biospecimen?
   Many different kinds of studies use blood/tissue/urine/faecal/swap/other biospecimens. Research is carried out to discover causes of disease and biomarkers, new ways of treatment, which includes new test and drug discovery.

H. Will I benefit from the research using my biospecimens?
   - It is hoped that the results of research on your and other patient’s biospecimen will provide information that will help people like you in future.
   - However, there will not be direct benefit to you because your biospecimen is not used immediately and research takes a long time.
   - The research that is done with your biospecimen is not designed specifically for you and research takes place on cohort of biospecimen. Though, you may not get any direct financial benefit but the benefits of research using biospecimens facilitates learning more about what causes diseases, how to prevent and treat them.

I. Why do you need information from my health records?
   In order to do research with your biospecimens, researchers may need to know your health related information. This helps researchers to answer questions about diseases. The information that will be given to the researcher includes your age, gender, race, diagnosis, treatments, and possibly some family history. This information is collected from your health records and sent to the NLDB but without your name or other identifying information.

J. How am I protected?
   The institutions from where you receive your treatment or have blood drawn etc. 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 this study 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 database electronically that is protected by two-layer security password on basis of group Level.
   
   We provide the access of data in four module levels:
   (i) Login Module, (ii) Security Module, (iii) Biobank Start-up Module and (iv) Biobank Module

   Authorisation of Access of data is divided in four groups Level:
   (i) Group Level, (ii) Module Level, (iii) Form access level and (iv) Form Option Access Level

   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 one person 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 supervision of CCTV monitoring.
K. Will I find out the results of the research using my biospecimens?
   Your doctor will give you the results of your diagnosis when results are known. These test results will be ready in a short time and will be used to make decisions about your care.
   You and your family will not be told of any new findings that come to light during the course of studies unless they are of significant prognostic importance. You have the option to choose if you wish to be informed about significant prognostic findings.

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<tr>
<th>I would like to be informed of findings with prognostic importance</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>I would like to be informed of results of genetic testing from the research studies performed</td>
<td>Yes</td>
<td>No</td>
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L. Potential Risk(s)
   You have already agreed to give biospecimen for your treatment as per standard medical procedure. There will be minimal risk for you, as only remnant surgical tissue/blood will be collected that is not needed for pathologic diagnosis. Thus, no additional risk/discomfort is associated in allowing NLDB to collect such biospecimen. Only slight discomfort may occur while collection of blood as it occurs in any other blood collection.

M. Sources of Funding
   Department of Biotechnology, Ministry of Science & Technology, Government of India

N. Duration of storage
   Collected biospecimens will be stored in biobank until useful for research.

O. Method of disposal
   Whenever your sample will not be useful for the research or you withdraw your consent then the biospecimens will be disposed off after the due approval of Biospecimen Release Board/Committee.

P. Conflict of Interest:
   There will be no conflict interest.

Q. Whom Do I Call if I Have Questions or Problems?
   If you have any questions regarding your rights as a participant in research, 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.
   Email: nlbd.ilbs@gmail.com, Ph.:+91-11-46300000. Ext.24813/24814, Website: www.nlbd.in
   A copy of this consent form will be given to you to keep
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:

<table>
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<tr>
<th>Name of the PI/Authorized Person</th>
<th>Name of the Hospital / Institute</th>
<th>Yes</th>
<th>No</th>
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2. I have read or have had read to me and understood the content of the Participant Information sheet and the Informed Consent. In addition, 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, 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. 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 academic and/or commercial 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 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):

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<thead>
<tr>
<th></th>
<th>Blood</th>
<th>Left over surgical tissue (tumor, other)/BAL/Sputum</th>
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<tr>
<td></td>
<td>Urine</td>
<td>Buccal Cells (oral rinse)</td>
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<td></td>
<td>Saliva</td>
<td>Skin punch biopsy</td>
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<td></td>
<td>Faecal</td>
<td>Other specimen____________________________________</td>
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Name of the Participant: (in block letters)

Signature / Thumb Impression of Participant

Date _________________________

Name of impartial Witness*: Signature of impartial Witness

*Impartial witness is required if the subject is unable to read the consent

To be completed by the authorized delegate explaining consent:

I, ______________________________ (name of authorized delegate) have informed the participant 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