National
Liver
Disease
Biobank

Standard Operating Procedure

DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Participant Recruitment into a Biobank Program**

Document No. : **SOP: NLDB: B.1**

Version No. : **1.0**

Effective Date : **01/01/2025**

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Participant Recruitment into a Biobank Program

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:B.1	01/01/2025	7	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	**Review period**	**No. of copies**	**Approved by**	**Date**
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Participant Recruitment into a Biobank Program
Function	**Distribution**
To outline the procedures for participant recruitment into a biobank program in accordance with applicable ethical and regulatory requirements.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP provides detailed instructions for executing the participant recruitment process for the biobank program. SOPs are developed in accordance with national and international guidelines, conventions, and NLDB best practices.

RESPONSIBILITY:

This SOP applies to all qualified NLDB personnel and clinical staff at collection centres involved in participant recruitment and obtaining informed voluntary consent.

1.0 PURPOSE

The cost and value of a biobank is proportional to several factors including the participant accrual rate and the number, diversity and quality of the biospecimens banked in the program. Voluntary participation by patients is a central factor in the success of the biobanking program and also provides patients with opportunities to support research. To promote participation, biobank personnel and associated and collaborating clinical professionals at participating institutions should work to ensure that appropriate patients are recruited.

2.0 SCOPE

This SOP covers the overall processes for identifying, approaching and recruiting patients for the purpose of obtaining consent to participate in the ILBS biobank program. The SOP is relevant to biobank programs that collect biospecimens that are derived from standard medical procedures and that are not required for clinical diagnostic pathology requirements. These processes may be adopted as is, or modified as per NLDB at its collection sites to allow for the incorporation of site-specific details, conditions and requirements

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified NLDB personnel and clinical staff at the collection centres that are involved in recruiting patients and the acquisition of informed and voluntary consent.

Biobank supervisor: Developing an appropriate recruitment plan in conjunction with oncology physicians (surgeons/oncologists) at the hospital or their designate.

Clinical research coordinator (CRC)/biobank staff /appropriately trained consenting personnel: Obtaining and documenting informed consent and identifying patients for recruitment

4.0 MATERIALS, EQUIPMENT AND FORMS:

- Informed consent form.
- Participant recruitment log.

5.0 PROCEDURES

Informed consent is obtained either before or after a medical procedure (e.g. surgery) that yields a potentially available biospecimen through approved consent protocols. Patients may be invited to participate in a research study and donate biospecimens where this involves undergoing procedures specifically conducted to obtain a research biospecimen. In some cases this procedure involves minimal risk (e.g. phlebotomy or buccal swab) and inclusion in the consent form of permission to

obtain a blood sample. However, all other instances that may involve other levels of risk (e.g. obtaining an additional biopsy core during a standard core biopsy procedure that would not have otherwise been taken for diagnosis) fall outside the scope of this SOP and require consultation and approval from a BEC for the specific research protocol. Often this increased level of risk needs to be weighed against the value of a specific research question.

5.1 Inclusion criteria

To be suitable for participation in a biobank program that collects unused biospecimens after a medical procedure and diagnosis, the participant must meet the following general criteria:

- Must be able to give informed consent
- Must be scheduled to undergo a medical procedure such as surgery that yields a biospecimen as part of their treatment. Healthy or at risk individuals scheduled to undergo procedures other than surgery may participate (e.g. to donate tissues for normal controls) and support Liver disease research.

5.2 Other factors

- The determination of availability and appropriateness of a biospecimen or portion thereof for the biobank program will be made by an appropriate clinical professional (usually a pathologist). This determination must be made at the time of potential harvesting from a fresh specimen after a medical procedure and also at the time of potential harvesting from an archival pathology block at any time in the future.

5.3 Phases of consent process

The process of obtaining consent by ILBS biobank will be three phases or steps:

- Referral of potential patient (to secure permission to contact). As a research entity the ILBS biobank is not able to identify appropriate participants and is dependent on either relevant health professionals (typically a surgeon or their designate) introducing the program and making a referral (or self-referral by a knowledgeable patient). This will occur during the OPD visit, at the same time as the clinical diagnosis is established and the decision to proceed to medical/surgical interventions is reached. The introduction of the ILBS biobank program will be brief and will establish the permission of the patient to be contacted by the tissue bank program to discuss further. This introduction may also provide an opportunity to the patient to consider a positive action as part of reacting to the challenge of the diagnosis.
- Preliminary interview (to ascertain patient interest in the ILBS biobanking and preference for the format of provision of full information). This step may be in person or by telephone and will be used to describe the ILBS Tissue bank program in general terms, and most importantly to establish the preference of the patient for how to learn more about what is involved in participation (i.e. time and place to meet to discuss consent or medium to receive more information such as by email or mail).
- Informed Consent (interaction face to face or by phone to discuss in detail what is involved and to document the decision to decline or to provide informed consent by a signed consent form).

5.4 Pre and post procedure consent protocols

- **Pre-procedure consent protocol**. A significant number of patients may prefer this option. For many biobank programs, such as those led by surgical investigators, it is more efficient

and provides an opportunity to secure consent to obtain blood samples before and during procedures and to deploy specialized biospecimen handling protocols with patient consent. Disadvantages include the sometimes short pre-procedure consent period that can preclude consideration by the patient (e.g. patients requiring emergency surgery), high levels of stress experienced by some patients in the pre-procedure period, and the inefficiency for both patient and tumour biobank around taking time to discuss consent when the procedure that follows may not yield an appropriate biospecimen.

- **Post-procedure consent protocol**. A significant number of patients prefer this option. For many biobank programs, such as those led by pathologist investigators, it is more efficient and provides an opportunity to identify potential biospecimens before initiating the process of consent. Disadvantages include the need to deploy mechanisms to secure patient referral to consider consent and to track consent status and actions through the post procedure consent period.

  During the post-procedure consent period a biospecimen that has been collected will be held in temporary storage as an identifiable specimen before consent has been obtained. The identifiable biospecimen will be held in an agreed storage location and no research will be conducted until the consent status is known or the period has expired and the appropriate actions have been taken.

  The length of the consent period is 3 months. During the consent period the consent status (patient consented, patient declined, or no patient decision) of the biospecimen will be determined by the bank, and the appropriate action taken in response to each status category before the biospecimen is transferred to the custody of the ILBS biobank (i.e. accrued) and/or research is conducted on it.

5.5 Actions after expiry of the post procedure consent period.

If a patient meeting the inclusion criteria is referred to the ILBS Tissue bank program a post procedure consent protocol may be followed that culminates in the Informed Consent. The following limitations apply.

- The consent status must be determined during the relevant Post-procedure Consent Period
- The consent status will be either patient consented, patient declined, or no patient decision known.
- The appropriate action is taken in response to each consent status category and this should be determined. Where the patient's decisions are unknown, Anonymization and use of the sample may be done as approved by IRB.
- If the patient is approached as part of a pre-procedure/post procedure consent protocol and declines to participate in the Tumour Biobank Program: Purge all patient's information from the Recruitment Log; and Communicate the decline decision to relevant Biobank or clinical personnel so that data that may have been collected before the procedure are purged
- If the biospecimen is collected as part of a post-procedure consent protocol, and the consent period has elapsed and patient decision is not known, possible action is to anonymise the biospecimen and relevant data (or may be to purge as above) as determined in consultation with the IRB. Anonymization should occur as follows: Remove all patient identifying information from the Recruitment Log; Document that the expiry consent period has lapsed AND Communicate a patient decision unknown status to relevant Tumour

Biobank or clinical personnel so that data and biospecimens that have been collected are anonymised.

6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004; 144:229-34
- Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. Arch Intern Med. 2005; 165(1): 97-100.
- Patient Recruitment to Tumour Bank. OCRN Draft SOP: TB301.001 Feb. 2004.

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Standard Operating Procedure

DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Developing and revising consent form**

Document No. : **SOP: NLDB: B.2**

Version No. : **1.0**

Effective Date : **01/01/2025**

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Developing and revising consent form

Number	Effective date	Pages	Author	Authorized by
SOP:NLDB:B.2	01/01/2025	6	Mr. Satish Kumar	Dr. Chhagan Bihari
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1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Developing and revising consent form
Function	**Distribution**
To establish standardized procedures for the preparation, review, and revision of informed consent forms.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP defines the procedures for the development and revision of informed consent forms, including required content elements, Biobank Ethics Committee (BEC) approval, and review processes

RESPONSIBILITY:

This SOP applies to all NLDB clinical and research personnel involved in the development of informed consent forms. The Head of Department (HOD) and Biobank Technicians are responsible for the preparation, review, and revision of consent forms in accordance with applicable ethical guidelines.

1.0 PURPOSE

Obtaining voluntary consent of participants who have been informed about all the relevant aspects of the program is important for the ethical conduct. Participants consent to donate sample (surplus to the needs of the pathology department to biobank) and allow access to their clinical records for future research. The consent form should be developed and revised to comply with current national guidelines; local laws and have BEC approved consent protocols approval.

2.0 SCOPE

This SOP covers the procedures for developing and revising consent forms. The SOP covers basic elements of the consent form, BEC approval considerations and procedures for developing, reviewing and revising a consent form. These steps may be adopted as is, or modified by specific NLDB at its collection site to allow for the incorporation of site-specific details, conditions and requirements.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified NLDB personnel, clinical and research staffs at the collection centre that is involved in developing and revising consent forms. This may include the following personnel:
HOD & Biobank technicians: Developing, adapting and revising consent form in line with current ethical guidelines.

BEC: Reviewing and approving consent forms and keeping current with ethical guidelines.

4.0 MATERIALS, EQUIPMENT AND FORMS

- Informed consent form
- Current ethical guidelines

5.0 PROCEDURES

The primary purpose of the 'informed consent form' is to provide written confirmation that informed consent was obtained. It may also serve as a reference for discussion points that should be covered during the consent process.

5.1 Basic elements of the informed consent form guidelines

The consent form should contain:

5.1.1 Objectives of the biobank program. A statement as to the goals of the research for which the specimens will be used should be stated. The consent should cover expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

5.1.2 A description of any reasonably foreseeable risks or discomforts to the subject. Cover relevant risks such as those associated with giving blood that may include bruising, bleeding and infection at the site. Include risks associated with making information from health records available to NLDB but specify measures that will be taken to protect privacy and confidentiality.

5.1.3 A description of any benefits to the participant or to others that may reasonably be expected from the potential research. Outline that there are no direct benefits to participating in the program but that the new knowledge generated from the research may potentially lead to general benefits such as the development of new tests and therapies for liver diseases.

Individual data if generated will not be made available to the patient except in the rare case when the clinical usefulness of the data becomes medically significant, and this only after specific issues have been considered and measures have been undertaken.

5.1.4 A statement describing the extent to which confidentiality of records identifying the subject will be maintained. Provide assurance that reasonable measures will be taken to protect confidentiality of data and identity.

5.1.5 An explanation of whom to contact (such as a patient representative) for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event that the participant wishes to express a concern or complaint.

5.1.6 Specification that the patient will not receive any compensation for participation in the program. The patient will also have no share in any revenue generated from any tests, therapies or discoveries generated from research on the tissue or data.

5.1.7 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of treatment to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of medical care to which the subject is otherwise entitled.

5.1.8 Include direction and contact information indicating whom the participant can contact if they wish to revoke consent.

5.1.9 Mention policies and specific details that are pertinent to the release and sharing of samples. These may include whether samples will only be shared within academic institutions, or whether they are available more broadly. It may spell out conditions for sample release, including the need for each research project to have undergone BEC approval

5.1.10 An indication of the possibility that the patient could be contacted at a later date and the reasons for such contact, such as to obtain additional information or to provide general information about the research supported by the biobank, or to offer participation in a relevant research study. Contact for other purposes will only be done at the discretion of the BEC.

5.1.11

5.2 Revisions to the consent form

The person revising the informed consent form should be qualified by training to do so, and knowledgeable about the current ethical guidelines and laws. Revisions should be initiated when:

5.2.1 International, national, local or institutional ethical and safety guidelines or regulations change mandate the inclusion of specific elements not in the template or form currently in use.

5.2.2 There are amendments to the program or the BEC recommends change.

5.3 Legal and cultural language to be used in the consent form

5.3.1 Use language that will be easily understandable to the participant or the representative.

5.3.2 Do not use exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights.

5.3.3 Do not use language that releases or appears to release the NLDB, the PI, the research sponsor, the institution or its employees from liability for negligence.

5.3.4 Tailor consent form to address the situation in which the consent is being obtained (pre-procedure and post-procedure consent), demographic population of the participants (paediatric versus adult) and need for legally acceptable representative or impartial witness if relevant.

5.3.5 Use language that respects the culture, traditions and knowledge base of the cultural group being approached to participate in the biobank program.

5.4 BEC Approval of consent forms

5.4.1 Do not use any version of a consent form unless it has been reviewed and received approval from the BEC.

5.4.2 Whenever it is necessary to revise the consent form have the BEC approved revisions.

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Standard Operating Procedure

DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Requesting additional survey information**

Document No. : **SOP: NLDB: B.3**

Version No. : **1.0**

Effective Date : **01/01/2025**

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Requesting additional survey information

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:B.3	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
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1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Requesting additional survey information
Function	**Distribution**
To establish the process for requesting additional survey information.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP covers procedures for requesting additional information from participants or obtaining relevant data from medical records in an ethical manner within the biobank. It may be adapted by NLDB collection sites to incorporate site-specific conditions, requirements, and practices.

RESPONSIBILITY:

This SOP applies to all qualified NLDB clinical and research staff at collection centres involved in requesting additional survey information. The HOD Biobank determines the need for additional information and coordinates its collection, while the Biobank Ethics Committee (BEC) reviews and approves such requests.

1.0 PURPOSE

Participants consent to donate sample to biobank (that is surplus to the needs of the Pathology Department) and allow access to their clinical records for future research. The specifics of future research are often not known at the time of consent. Research is shifting towards molecular profiling and the ability to correlate this with longitudinal clinical data, demographic data, lifestyle factors, environmental and occupational exposure, patient medical history and clinical outcomes. Often, such information has not been collected at the time of specimen banking. Should it be deemed valuable to obtain this information, there should be procedures in place for this.

2.0 SCOPE

This SOP covers the procedures that should be in place within the biobank to request additional information from the participant or to ethically obtain this from participant medical records if possible. These steps may be adopted as is, or modified by NLDB at its collection sites to allow for the incorporation of site-specific details, conditions and requirements.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified NLDB personnel, clinical and research staff at the collection centre that are involved in requesting additional survey information. This may include the following personnel:

HOD Biobank: Determining that additional information would be of value and arranging to obtain it.

BEC: Reviewing and approving any requests that may be made to collect or access additional information.

4.0 MATERIALS, EQUIPMENT AND FORMS

- Informed consent form
- Current ethical guidelines
- Request for additional information

5.0 PROCEDURES

Biobank should strive to collect and store relevant clinical data associated with a specimen to maximize the use of biospecimen for current, future and longitudinal studies.

5.1 Maintenance of identifying and contact information

5.1.1 Maintain (only within the biobank) the ability to store identifying information and contact information for specimens as permitted under law and by patient consent to enable specimen use for longitudinal studies or outcome research.

5.1.2 Ensure that patient privacy is guarded and this information does not reach individuals not authorized to access it.

5.2 Procedures to request additional information

5.2.1 Establish local written procedures to facilitate the submission of a request for outcome data, additional clinical data or lifestyle and medical history.

5.2.2 Determine if this information can be accessed from patient records or if participant contact is required.

5.2.3 Contact the participant only if there is no alternative way to derive the information. The right to re-contact should be addressed in the original consent form.

5.2.4 It should have procedures to facilitate follow-up with the participants if needed.

5.2.5 Only have dedicated personnel that are specially trained to submit this request or contact participants.

5.2.6 Document clear rationale for collecting additional information and specify the value it will bring to the research.

5.2.7 All requests for additional survey information must be approved by the BEC approved consent protocols on a case-by-case basis.

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Standard Operating Procedure

DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Obtaining informed consent**

Document No. : **SOP: NLDB: B.4**

Version No. : **3.0**

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Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Obtaining informed consent

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3.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Obtaining informed consent
Function	**Distribution**
To define the procedures for obtaining informed consent.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP applies to the standardized execution of procedures and methods related to informed consent. SOPs are documented instructions based on national and international guidelines, as well as NLDB policies and best practices.

RESPONSIBILITY:

This SOP applies to all NLDB personnel and clinical staff at collection centres involved in obtaining informed and voluntary consent. The HOD is responsible for recruitment planning, while Biobank staffs are responsible for participant identification, obtaining consent, and proper documentation.

1.0 PURPOSE

Obtaining voluntary consent of participants who have been informed about all the relevant aspects of the program is vital for the ethical conduct of the biobank program. Participants consent to donate their tissue (typically material that has been determined to be excess to requirements for diagnosis and future care after a scheduled surgical treatment or medical procedure) and/or other biological specimens (e.g. blood sample) to the NLDB, allow access to their clinical records, acknowledge that they accept associated risks (e.g. risks of phlebotomy and/or loss of privacy) and give permission for these materials (specimens and data) to be used for broadly specified future research. Consent is usually accompanied by a commitment from the biobank that governance of the collection and storage and use of their materials will include review by an independent Biobank Ethical Committee approved consent protocols of the NLDB itself and of each research application to use the materials.

2.0 SCOPE

This SOP covers the procedures for obtaining and documenting informed and voluntary consent from a donor to participate in biobank program. It lists in step-by-step format, the appropriate tasks and procedures that must be followed at the step of obtaining consent. These steps may be adopted as is, or modified by NLDB at its collection sites to allow for the incorporation of site-specific details, conditions and requirements.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified NLDB personnel and clinical staff at the collection centres that are involved in the acquisition of informed and voluntary consent. This may include the following personnel:

HOD Biobank: Developing an appropriate recruitment plan in conjunction with physicians (surgeons/oncologists) at the centre/hospital or their designate.

Biobank staff/ appropriately trained consenting personnel: Obtaining and documenting informed consent and identifying patients for recruitment

4.0 MATERIALS, EQUIPMENT AND FORMS

- Informed consent form with information sheets.

5.0 PROCEDURES

The primary purpose of the informed consent form is to provide written confirmation that informed consent was obtained. It may also serve as a reference for discussion points that should be covered during the consent process. BEC approved information attached to the informed consent form also serves as an on-going reference for participants.

5.1 General informed consent guidelines

5.1.1 Prior to starting the consent process with a patient, review NLDB policy. This will provide a basis for ethical considerations that should govern the process. This provides the wider context of the processes within which the informed consent process occurs.

5.1.2 Keep in mind that the rights, safety and well-being of research participants are the most important consideration and should prevail over the interests and the goals of the biobank, science and society.

5.2 Obtaining written informed consent

The person obtaining informed consent should be qualified by training to do so, and be knowledgeable about the biobank program.

5.2.1 After receiving a referral through an appropriate mechanism and ascertaining/confirming the initial interest of the participant and/or appropriateness of the referral for the biobank, initiate the consent process.

5.2.2 Establish (e.g. through direct contact or by telephone) with the potential participant their initial interest and their choice for a meeting to inform them about the biobank program (e.g. time and meeting place). Note that the potential participant should be free to choose and may choose other mechanisms (e.g. to receive materials by email or mail and to discuss by telephone) but a face to face meeting is usually the optimal setting.

5.2.3 Ensure that the informed consent form with any additional BEC-approved information on the biobank program is a current BEC approved version and take a copy for the participant and the biobank to the meeting.

5.2.4 For the purpose of the consent discussion, meet the participant in a space that offers, if possible, a quiet and private environment.

5.2.5 Having another person (patient's family member or friend) at the consent meeting is acceptable and may help the patient relax, provide support, and facilitate the participant's information retention.

5.2.6 Initiate rapport with the patient and assess whether or not the patient is competent to consent to participate in the biobank program. Be sensitive to the possibility that recent diagnosis of a serious illness may be especially stressful and the patient may be in a state of reduced comprehension. The validity of consent obtained under these conditions should be questioned, if these circumstances exist, a second opportunity to meet at the participant's request may be offered and a decision and signature should be deferred.

5.2.7 Using the informed consent form as a guide, give the patient information (in clear language) about the following:

a. Objectives of the NLDB program, governance and intended users of the biobank

b. Confidentiality issues. Reinforce that the discussion is confidential. Provide assurance that confidentiality of data and identity will be protected. Describe in general lay terms processes and steps taken by the biobank to protect confidentiality.

c. Outline any procedures the patient may be invited to undergo to participate (e.g. phlebotomy) and procedures (e.g. surgery) that are part of clinical treatment that may offer an opportunity for participation.

d. Describe how the tissue sample, blood, other biological material, and data will be handled and stored.

e. Mention risks associated with giving blood that may include bruising, bleeding and infection at the site. Cover risks associated with making information from health records available to the biobank but specify measures (such as coding) that will be taken to protect privacy and confidentiality.

f. Outline that there are no direct benefits to participating in the program but that the new knowledge generated from the research may potentially lead to the development of new tests and therapies for diseases. Individual data if generated will not normally be made available to the patient.

g. Specify that the patient will not receive any compensation for participation in the program. The patient will also have no share in any revenue generated from any tests, therapies or discoveries generated from research on the tissue or data.

h. Clarify that participation is voluntary. The decision to decline to participate now or to withdraw from the program at any future date, will not affect the standard or type of care the patient will receive.

5.2.8 Allow the participant adequate time to read and assimilate the informed consent form. This may include reviewing the informed consent form at home. Encourage them to ask questions in return and answer the questions as honestly as possible. Identify contact information for the NLDB that should be included in the consent form so that the patient can obtain additional clarification or ask further questions.

5.2.9 If the patient agrees to participate in the biobank program, request that the patient sign and date one or more copies of the informed consent form as per institutional policy.

5.2.10 The individual obtaining the consent and/or the biobank representative should sign and date one or more copies of the informed consent form as per institutional policy.

5.2.11 Provide one copy of the completed informed consent form (along with attached BEC approved information) to the participant and retain one or more copies for the biobank program records or for other locations as required by institutional policy.

5.3 Alternate Situations for Obtaining Informed Consent

5.3.1 Consent using legally acceptable representative: If after assessing the patient's competence the patient is judged incapable of providing consent, the consent of a legally acceptable representative can be sought. Indicate on both copies of the informed consent form that the printed name, signature, and date were obtained from the legally accepted representative.

5.3.2 Impartial Witness: If the patient is unable to read, an impartial witness should be present during the entire informed discussion. Both the patient (if capable) and the impartial witness must sign and date one or more copies of the informed consent form. Indicate on both copies of the informed consent form that the printed name, signature, and date were obtained from the impartial witness.

By signing the informed consent form, an impartial witness attests that the information in the informed consent form and any other written information was accurately explained to, and apparently understood by, the patient or the patient's legally acceptable representative, and that informed consent was freely given by the patient or the legally acceptable representative.

5.3.3 Use of Interpreter: If the patient or the legally acceptable witness does not speak the language of the informed consent form, the consent discussion should take place in the patient's language using a qualified interpreter or family member if needed. Both the patient

(if capable) and the interpreter must sign and date one or more copies of the informed consent form. Indicate on both copies of the informed consent form that the printed name, signature, and date were obtained from the interpreter.

By signing the informed consent form, the interpreter attests that the information in the informed consent form and any other written information was accurately explained to, and apparently understood by, the patient or the patient's legally acceptable representative, and that informed consent was freely given by the patient or the legally acceptable representative.

5.4 Documenting informed consent

5.4.1 File the signed Informed Consent Form in the patient recruitment log. Include the following information:

a. Date when informed consent was obtained and who obtained the consent.

b. Whether a translator, legally acceptable representative or impartial witness was used.

5.4.2 Register consent status with the biobank's inventory database.

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DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Withdrawal of consent**

Document No. : **ILBS#NLDB: B.5**

Version No. : **1.0**

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Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Withdrawal of consent

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:B.5	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
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1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Withdrawal of consent
Function	**Distribution**
To define the procedure for informing participants of their right to withdraw consent at any time, without providing a reason.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP outlines the procedures to be followed when a participant withdraws consent, ensuring protection of participant rights. It may be adapted by NLDB collection sites to include site-specific and BEC-approved requirements, provided the intent of the SOP and participant protections are not compromised.

RESPONSIBILITY:

All qualified NLDB personnel and clinical staff at collection centres involved in receiving requests for withdrawal of consent and implementing follow-up actions. The Biobank Manager and treating physicians (or their designates) are responsible for receiving the request and forwarding it to the Biobank Principal Investigator (PI).

1.0 PURPOSE

Participation in the biobank program is voluntary. As part of the informed consent process, participants are informed that they can withdraw consent at any time and for any reason. For example, if patients have social, philosophical, religious or family concerns they may decide to withdraw consent.

2.0 SCOPE

The scope of this SOP is to outline the general procedures that should be undertaken to deal with the situation so as to uphold the rights of the participant when consent for the participant is withdrawn. These steps may be adopted as is, or modified by NLDB at its collection site to allow for the incorporation of site-specific details, conditions and BEC approved consent protocols requirements provided none of the changes alter the spirit of the SOP or result in a reduction of the protection of the rights of the participant.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified NLDB personnel and clinical staff at the collection centres that are involved in receiving the request for withdrawal of consent and to those involved in taking follow-up action. This may include the following personnel:

Biobank manager/ Physicians (Surgeons/Oncologists) at the centre/Hospital or their designates: Receiving request for withdrawal of consent forwards the request to the biobank PI.

HOD Biobank: Issues a directive to deem the samples un-bankable. Ensure that the materials and data have been processed. The PI may at their discretion delegate the authority to act on their behalf within this SOP.

Technician/Bioinformatician: Take follow-up action after consent is withdrawn to delete patient information (paper and electronic records), and discard samples as required.

4.0 MATERIALS, EQUIPMENT AND FORMS

- Withdraw consent request (written or oral).
- Confirmation documentation that sample has been removed from records.
- Inventory system and database.
- Unused samples from participant revoking consent.

5.0 PROCEDURES

The participant may withdraw consent at any time. Personnel at the NLDB should take appropriate steps to respect the will of the participant and ensure that the participant is able to withdraw without consequence.

5.1 Request to withdraw consent

5.1.1 A donor or an authorized third party may withdraw consent at any time.

5.1.2 The request to withdraw consent should be made in writing and addressed to responsible personnel at the NLDB.

5.1.3 Document the reason if voluntarily provided by the donor or authorized third party.

5.2 Follow-up action after receiving the request for withdrawal

5.2.1 After receiving the request for withdrawal of consent the personnel should re-assure the participant that there would be no consequences or negative impact on their normal course of treatment and care.

5.2.2 Notify the biobank PI or assigned delegate that the participant's consent has been withdrawn and the samples are deemed un-bankable.

5.2.3 Upon receipt of a withdrawal instruction, the biobank PI issues an instruction to withdraw to the relevant biobank personnel involved in both biospecimen and data aspects.

5.2.4 When required as per institutional policy documentation of withdrawal may be provided to the BEC and/or a certificate of destruction may be provided to the participant.

5.3 Follow-up action after receiving the "instruction to withdraw"

There are two scenarios to consider; the biospecimen and/or data have been collected by the biobank but a) not distributed for research or, b) all or a portion has been distributed for research.

5.3.1 Upon receipt of an "instruction to withdraw" the NLDB staff will determine whether scenario a) or b) applies.

5.3.2 Under both scenarios, ensure that unused tissue and other unprocessed biological samples from the participant that remain in the biobank are destroyed.

5.3.3 Under both scenarios, delete all personal identifying information. In scenario a) all electronic and physical records are deleted or destroyed. In scenario b) in accordance with institutional policy anonymised records and samples may be maintained. BECs may require that the original paper copy of the consent be maintained.

5.3.4 Do not collect any additional information about the individual from any source.

5.3.5 According to institutional policy samples such as embedded tissue blocks may need to be returned to the pathology department.

5.3.6 If required, store a log of all purged and discarded samples from withdrawn consent patients.

5.3.7 Should a backup of the inventory database/informatics system ever be restored, the PI should ensure that identifying records are not restored.

National
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Biobank

Standard Operating Procedure

DOCUMENT NAME: PARTICIPANT AND RECRUITMENT MANAGEMENT

DOCUMENT NO. : ILBS#NLDB:B

Document Name : **Notification of Significant and Relevant Findings**

Document No. : **SOP: NLDB:B.6**

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National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Participant and Recruitment Management

Notification of Significant and Relevant Findings

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SOP: NLDB:B.6	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
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1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Notification of Significant and Relevant Findings
Function	**Distribution**
To establish the procedure for communicating significant and relevant findings	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP covers the disclosure of significant research findings to biobank participants and may be adapted to site-specific, regulatory, and Biobank Ethics Committee (BEC)-approved requirements.

RESPONSIBILITY:

This SOP applies to biobank, clinical, and research staff involved in decisions regarding disclosure of research findings. The PI identifies significant findings, the BEC reviews and approves disclosure, and the HOD Biobank coordinates confidential and timely notification with the consulting physician.

1.0 PURPOSE

Biospecimens donated to the biobank are intended for research studies. In most cases the research findings have no immediate clinical relevance to individual participants. Very rarely the research may yield data that might be relevant to the participant's immediate treatment, outcome, wellbeing or future health or have impact on their family. There are many social, ethical, and clinical considerations attached to the decision to make disclosure of research findings directly to the patient.

2.0 SCOPE

This SOP covers the procedures for handling disclosure of significant and relevant research study findings to the biobank participant. These steps may be adopted as is, or modified by NLDB at its collection sites to allow for the incorporation of site-specific details, local laws and regulations, conditions and BEC approved consent protocols requirements.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified biobank personnel, clinical and research staff at the collection centres that are involved in decision making that might lead to disclosure of research findings. This may include the following personnel:

PI: Analyzing research data and determining if the data is significant and relevant.

BEC: Reviewing research data and determining if the data is significant or relevant. Deciding if and how the notification will occur.

HOD Biobank: Coordinating notification with the consulting physician in a sensitive, timely and confidential manner.

4.0 MATERIALS, EQUIPMENT AND FORMS

- Current ethical guidelines and relevant provincial legislation
- Research Findings

5.0 PROCEDURES

The primary goal of the biobank is to facilitate research that can advance the treatment of liver diseases. However, the biobank is responsible for ensuring that patients' rights are upheld and this may lead to involvement in return of significant information.

5.1 Plan for Dealing with Significant and Relevant Findings

If a potential and significant finding comes to light as a result of donating biospecimens to a biobank, the biobank should have a clear plan to engage with relevant parties to consider a number of issues relevant to the process of return of research data that will likely include BEC and clinicians.

5.2 Findings Review, Considerations and Consultation

Significant and relevant research findings should only be disclosed after careful consideration of the following:

a. Provincial laws and regulations

b. Whether or not individual results disclosure was covered by the consent process,
c. Confidence levels that the test/research results have been adequately validated and correctly interpreted,
d. The findings have significant implications for the participants health concerns and diagnosis,
e. A course of action or options to ameliorate or treat the participants health concerns are readily available,
f. The wellbeing of the participant should take precedence over the interests of science and society,
g. Whether contact with the participant is feasible.
h. In the event that the participant cannot be contacted, the effects of disclosure on family members who may be affected by the information (such as in the case of genetic or hereditary research),
i. Complete confidentiality is maintained and that results are not disclosed to insurance agencies or employers.
j. The availability of both pre and post-disclosure counselling.
k. The advice of the BEC that has been obtained.