

**N a t i o n a l**  
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# Standard Operating Procedure

**DOCUMENT NAME: RECORDS AND  
DOCUMENTATION MANAGEMENT**

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***DOCUMENT NO. : ILBS#NLDB:C***

**RECORDS AND DOCUMENTATION MANAGEMENT****Information access control**

**Document Name : Information access control**

**Document No. : ILBS#NLDB: C.1**

**Version No. : 1.0**

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

**Address**

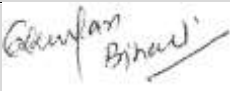
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National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 2 of 7
Document Name: SOP "Information access control"			
Document No ILBS#NLDB:C.1	Approved & Issued by:		Dr. Chhagan Bihari HOD Biobank
Rev. No.:1.0			Issue Date:01/01/2025

**RECORDS AND DOCUMENTATION MANAGEMENT****Information access control**

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:C.1	01/01/2025	6	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

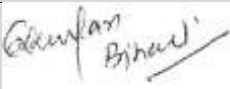
Location	Subject
Biobank Reception area Almira	Information access control
Function	Distribution
To establish requirements for secure, accurate, and traceable electronic data sharing	<ul style="list-style-type: none"> <li>➤ HOD</li> <li>➤ Biobank Reception area</li> <li>➤ Master files</li> </ul>

**SCOPE AND APPLICATION:**

This SOP outlines general elements and features that should be in place to ensure that access to participant and sample information is controlled so as to limit access to authorized personnel only.

**RESPONSIBILITY:**

This SOP applies to authorized NLDB personnel responsible for database management and protection of sample and participant information. The IT Manager ensures implementation and monitoring of data security measures, while the HOD Biobank defines and controls access to information.

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 3 of 7
Document Name: SOP "Information access control"			
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Rev. No.:1.0			

# RECORDS AND DOCUMENTATION MANAGEMENT

## Information access control

### 1.0 PURPOSE

NLDB is intended to manage the safekeeping of clinical and sample data in its custody. It is accountable for limiting disclosure of information, maintaining privacy of the participants and safeguarding the integrity of the information.

### 2.0 SCOPE

This SOP outlines general elements and features that should be in place to ensure that access to participant and sample information is controlled so as to limit access to authorized personnel only.

### 3.0 ROLES AND RESPONSIBILITIES

This SOP applies to NLDB employees that are responsible for the database system and the safekeeping of sample and participant related information.

**IT manager:** Implements and audits security policies adopted by the biobank. Uses best practices for computer hardware and software security.

**HOD Biobank :** Implementing and defining procedures to control access to information

### 4.0 PROCEDURES

The facility should employ processes to limit access to sensitive and valuable information held by the biobank.

#### 4.1 Data access – limit access to “need-to-know” basis

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

**4.1.1** Technicians, administration, and IT staff are involved in entering, preparing, auditing, accessing and releasing data stored within the biobank. Define roles so as to limit access.

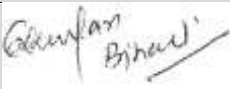
**4.1.2** Where appropriate, necessary confidentiality agreements have been signed.

**4.1.3** Audit all permissions as part of a regular data access check-up recommended every 6 months or whenever major changes to data access systems are made.

#### 4.2 Data access – release of data for research

**4.2.1** Selected and de-identified information on a particular participant or sample should be extracted from the database (at the biobank) in a report form and sent to the researchers electronically or by hard copy.

**4.2.2** All released data must have a release code (also known as biobank reference number or biobank identifier) that permits the biobank to link the data to the sample and to trace their origins. At no time should any release code contain any data that can be interpreted to identify the donor (e.g. birth date, cancer registration number, etc.).

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## RECORDS AND DOCUMENTATION MANAGEMENT

### Information access control

**4.2.3** The release code used for data and samples is a public identifier. Depending on the circumstances, the biobank may decide to make the release code different from the code used within the biobank, and unique for each case used for each study release or the same for each study receiving the same materials. The former strategy means that researchers cannot cross reference cases and data to conduct secondary research without involvement of the biobank where this might compromise individual identities or the scope of the original consent. The latter strategy means that research results can be shared more effectively and the value of the research data amplified.

**4.2.4** Log and record data release. Specify:

- a. Date Released.
- b. Name of researcher and institution released to, and
- c. Study released for.
- d. Individual reference numbers associated with the release.
- e. At least two biobank individual should sign with thumb impression, and maintain the record

### 4.3 Other electronic data access issues

**4.3.1** Where possible biobank should ensure sensitive information is fully contained within and protected by the institution network.

**4.3.2** Audit, monitor and document access to information by logging events when information is accessed or released.

**4.3.3** Report deviations

**4.3.4** Investigate deviations to determine cause and source.

**4.3.5** Take corrective action to avoid future occurrence.

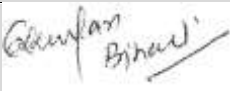
**4.3.6** Use of "strong" passwords.

**4.3.7** Do not share passwords with anyone.

**4.3.8** Do not write passwords down

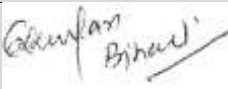
**4.3.9** If an account or password is suspected to have been compromised, report the incident to your IT staff and change all passwords.

**4.3.10** Application developers must ensure that their programs contain the following security precautions.

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Rev. No.:1.0			

**RECORDS AND DOCUMENTATION MANAGEMENT****Information access control****5.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

- Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).  
[http://www.isber.org/Search/search.asp?zoom\\_query=best+practices+for+repositor](http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositor)

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 6 of 7
Document Name: SOP "Information access control"			
Document No ILBS#NLDB:C.1	Approved & Issued by:		Dr. Chhagan Bihari HOD Biobank
Rev. No.:1.0			Issue Date:01/01/2025



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# Standard Operating Procedure

**DOCUMENT NAME: RECORDS AND  
DOCUMENTATION MANAGEMENT**

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**DOCUMENT NO. : ILBS#NLDB:C**

**RECORDS AND DOCUMENTATION MANAGEMENT****Database back up**

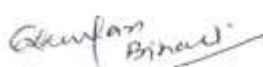
**Document Name : Database back up**  
**Document No. : ILBS#NLDB:C.2**  
**Version No. : 1.0**  
**Effective Date : 01/01/2025**

**Address**

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 Website: [www.nldb.in](http://www.nldb.in), [www.ilbs.in](http://www.ilbs.in),

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 2 of 6
Document Name: SOP "Database back up"			
Document No ILBS#NLDB:C.2	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank
Rev. No.: 1.0			

## RECORDS AND DOCUMENTATION MANAGEMENT

### Database back up

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:C.2	01/01/2025	6	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

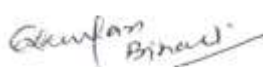
Location	Subject
➤ Biobank Reception area Almira	Database back up
Function	Distribution
To give information about: general elements and features that should be in place in order to share data electronically.	<ul style="list-style-type: none"> <li>➤ HOD</li> <li>➤ Biobank Reception area</li> <li>➤ Master files</li> </ul>

#### SCOPE AND APPLICATION:

This SOP defines the requirements for secure electronic data backup and sharing within the biobank.

#### RESPONSIBILITY:

This policy applies to NLDB personnel responsible for database management and the secure handling and protection of sample and participant-related information.

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 3 of 6
Document Name: SOP "Database back up"			
Document No ILBS#NLDB:C.2 Rev. No.: 1.0	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank
			Issue Date: 01/01/2025

## RECORDS AND DOCUMENTATION MANAGEMENT

### Database back up

#### 1.0 PURPOSE

NLDB is intended to manage the safekeeping of clinical data and other sample associated data in their custody. NLDB will have policies regarding security safeguards to protect data and personal information stored in its database against failure, loss and damage. Failure may occur due to user error (modifying or destroying the data on its own or through a user choice), media failure (failure of equipment such hard drive) or a catastrophic event such as a fire, flood, power outage, virus, or deliberate hacking. The backup process must ensure the database can be completely and accurately recovered. The aim is to limit data loss to no more than one day.

#### 2.0 SCOPE

This SOP outlines general elements and features that should be in place to ensure that information stored in a database can be recovered accurately, completely and in a timely manner.

#### 3.0 ROLES AND RESPONSIBILITIES

The policy will apply to personnel from NLDB that are responsible for the data base system and the safekeeping of sample and participant related information.

#### 4.0 MATERIALS, EQUIPMENT AND FORMS

- Database backup system
- Removable backup media
- Offsite storage location

#### 5.0 PROCEDURES

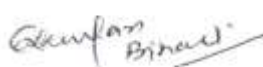
The NLDB facility will employ backup systems to protect the data stored on the database from damage and loss. In the case of user error, media failure or catastrophic events, the system should ideally be able to recover the information to or near the point before failure occurred. There should also be confidence that the information is complete and free of corruption.

##### 5.1 Database backup – General description of process

- IT staff at the biobank will implement and monitor regular backups.
- Send regular backup copies to offsite storage in case of fire, flood, earthquake or other “Acts of God” which may destroy on-site archives.
- Test data recovery at specific intervals as specified in the backup/recovery plan and record results. Test both individual records and full database recovery. Be sure to test offsite archival sets as well.

##### 5.2 Database backup – Routine process

- Backup system will be automated and will not require daily user intervention.

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Rev. No.: 1.0				

## RECORDS AND DOCUMENTATION MANAGEMENT

### Database back up

- Perform validation to ensure the nightly backup completed successfully. Investigate any failed backups and resolve with the highest priority.

#### 5.3 Database backup – Frequency

- Will be backed up nightly
- Weekly Offsite Storage

#### 5.4 Database backup – Recovery plan

#### 5.5 Hard Copy maintenance:

The sample and clinical data procurement and release related documents like: Performa, forms, consent forms, and biobank master register, release data, will be maintained in the biobank software as well as in the form of hard copies in the locker

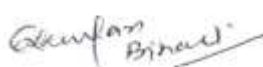
#### 5.6 Database backup – Audit and validation of recovered data

Will perform tests for full database recovery as well as individual record retrieval, monthly.

### 6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).

[http://www.isber.org/Search/search.asp?zoom\\_query=best+practices+for+repositor](http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositor)

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 5 of 6
Document Name: SOP “Database back up”			
Document No ILBS#NLDB:C.2	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank
Rev. No.: 1.0			Issue Date: 01/01/2025

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# Standard Operating Procedure

**DOCUMENT NAME: RECORDS AND  
DOCUMENTATION MANAGEMENT**

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**DOCUMENT NO. : ILBS#NLDB:C**

**RECORDS AND DOCUMENTATION MANAGEMENT****Data transmission**

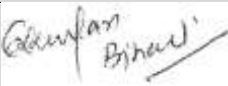
**Document Name : Data transmission**  
**Document No. : ILBS#NLDB:C.3**  
**Version No. : 1.0**  
**Effective Date : 01/01/2025**

**Address**

National Liver Disease Biobank,  
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Telephone: +91-11-46300000; extension: 24816, 24813.  
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National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 2 of 5	
Document Name: SOP "Data transmission"				
Document No ILBS#NLDB:C.3	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
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## RECORDS AND DOCUMENTATION MANAGEMENT

### Data transmission

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:C.3	01/01/2025	5	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

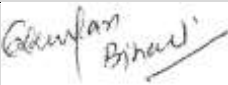
Location	Subject
Biobank Reception area Almira	Data transmission
Function	Distribution
To provide guidance on the key elements required for secure electronic data sharing.	<ul style="list-style-type: none"> <li>➤ HOD</li> <li>➤ Biobank Reception area</li> <li>➤ Master files</li> </ul>

#### SCOPE AND APPLICATION:

This SOP outlines general elements and features that should be in place in order to share data electronically.

#### RESPONSIBILITY:

This SOP applies to NLDB personnel involved in database management and electronic data transmission. The HOD Biobank ensures BEC-approved de-identified data export; the IT Manager manages and monitors the export process, while the Technician verifies data integrity and de-identification prior to transmission.

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 3 of 5	
Document Name: SOP "Data transmission"				
Document No ILBS#NLDB:C.3	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

# RECORDS AND DOCUMENTATION MANAGEMENT

## Data transmission

### 1.0 PURPOSE

When data transmission is required, it is important to ensure that no data is lost or modified, and that participant's privacy is protected.

### 2.0 SCOPE

This SOP outlines general elements and features that should be in place in order to share data electronically.

### 3.0 ROLES AND RESPONSIBILITIES

The SOP applies to personnel from NLDB that are responsible for the database system and for the transmission of data stored on the system.

**HOD Biobank:** Provides guidance to IT on scheduling of export. Ensures export of de-identified data to NLDB is approved by BEC.

**IT manager:** Establishes and schedules data export process, monitors submission status, reviews process logs for errors.

**Technician:** Validate data integrity and ensure that data is de-identified.

### 4.0 MATERIALS, EQUIPMENT AND FORMS

- Internet connection
- Electronic transfer protocol
- Access to the NLDB Application

### 5.0 PROCEDURES

The facility should employ fundamental systems to ensure that data transmitted to collaborated hospitals is complete, free of corruption and protected from interception. At no time should personal identifiers be included in the export file.

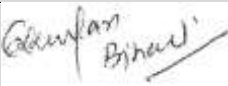
#### 5.1 Data transmission – general description process

##### 5.1.1 Using BIMS:

- a. Using the built in tools generate the CSV export file.
- b. Validate the file, ensuring that data integrity is maintained and that all participants are de-identified.
- c. Send CSV file to requesting hospital as per established electronic transfer protocol.
- d. Ensure confirmation of data submission.

#### 5.2 Data transmission – frequency

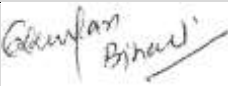
**5.2.1** Generate and submit a data file as required:(NLDB recommends monthly) Biobank may submit more or less frequently depending on the rate of new sample accrual and sample use for research.

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 4 of 5	
Document Name: SOP "Data transmission"				
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Rev. No.: 1.0				

**RECORDS AND DOCUMENTATION MANAGEMENT****Data transmission****5.3 Data transmission – audit and validation**

**5.3.1** NLDB tracks all submissions to the national catalogue. Attributes include:

- a. Date/time of submission
- b. Biobank ID and province
- c. Submission number
- d. Version
- e. Status (record error, invalid file, success)

National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 5 of 5	
Document Name: SOP "Data transmission"				
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# Standard Operating Procedure

**DOCUMENT NAME: RECORDS AND  
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***DOCUMENT NO. : ILBS#NLDB:C***

**RECORDS AND DOCUMENTATION MANAGEMENT****Clinical annotation**


**Document Name : Clinical annotation**  
**Document No. : ILBS#NLDB:C.4**  
**Version No. : 1.0**  
**Effective Date : 01/01/2025**

**Address**

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National Liver Disease Biobank, Institute of Liver & Biliary Sciences: D -1, Vasant Kunj, New Delhi-110070, India.			Page 2 of 6	
Document Name: SOP "Clinical annotation"				
Document No ILBS#NLDB:C.4	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
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## RECORDS AND DOCUMENTATION MANAGEMENT

### Clinical annotation

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:C.4	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

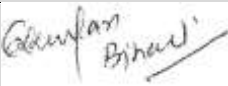
Location	Subject
Biobank Reception area Almira	Clinical Annotation
Function	Distribution
To give information about: Standardized and complete data capture provides the best hope for analysing.	<ul style="list-style-type: none"> <li>➤ HOD</li> <li>➤ Biobank Reception area</li> <li>➤ Master files</li> </ul>

#### SCOPE AND APPLICATION:

This SOP covers the procedures to ensure that consistent and high quality data is associated with samples in the biobank. These steps may be adopted as is, or modified by NLDB at its collection site to allow for the incorporation of site-specific details, local laws and regulations, conditions and BEC requirements.

#### RESPONSIBILITY:

**Technician:** Conducts and assists with quality assurance procedures; Records and documents outcomes.

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Document Name: SOP "Clinical annotation"				
Document No ILBS#NLDB:C.4	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

# RECORDS AND DOCUMENTATION MANAGEMENT

## Clinical annotation

### 1.0 PURPOSE

Bio samples donated to the NLDB is intended for research studies. The success of translational research, and ultimately personalized medicine, depends on the ability to forge a connection between phenotypic clinical data and molecular measurements on samples. The efficient integration of clinical data with scientific results has become critical in determining populations of patients that may best benefit from a new drug or therapy. Standardized and complete data capture provides the best hope for analysing large data sets, over many institutions, and will allow comparisons with other similar or collaborative studies.

### 2.0 SCOPE

This SOP covers the procedures to ensure that consistent and high quality data is associated with samples in the biobank. These steps may be adopted as is, or modified by NLDB at its collection site to allow for the incorporation of site-specific details, local laws and regulations, conditions and BEC requirements.

### 3.0 ROLES AND RESPONSIBILITIES

The SOP applies to all qualified NLDB personnel, clinical and research staff at the collection centres and biobanks that are involved in clinical annotation of samples.

**HOD Biobank:** Determining the range of clinical data that will be collected for a sample.

**BEC:** Reviewing and deciding if sensitive clinical data should be collected.

**IT manager & Technician:** Collecting and managing clinical data.

### 4.0 MATERIALS, EQUIPMENT AND FORMS

- Health records, Pathology Reports
- Patient Questionnaires
- Inventory and specimen database

### 5.0 PROCEDURES

The primary goal of NLDB is to facilitate research. Extensive and consistent annotations of the specimens are crucial to the overall value of the bio-banked samples in research studies.

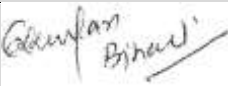
#### 5.1 Determining the clinical data set

**5.1.1** Define the minimum clinical data to be collected for all biospecimens. Note that this set may be subject to change over time, and may depend on the particular research study.

**5.1.2** Use harmonized terminology or common data elements to describe data being collected to facilitate data sharing and universal understanding

#### 5.2 Collecting and management of clinical data

**5.2.1** Data collection should strive to conform to requirements stipulated by regulatory agencies and/or by internationally recognized standards.

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## RECORDS AND DOCUMENTATION MANAGEMENT

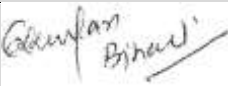
### Clinical annotation

- 5.2.2 Track researchers' requests for specific data to guide the extent of collection of data in the future.
- 5.2.3 Only collect data if adequate consent procedures are in place.
- 5.2.4 Have a method of validating data collected so as to ensure accuracy.
- 5.2.5 In linking and annotating samples comply with privacy regulations.
- 5.2.6 Maintain identifying and contact information as permitted under privacy law to enable the specimen to be useful for longitudinal studies.
- 5.2.7 Attempt to collect outcome data with tracking of treatment and patient outcomes.
- 5.2.8 Use only trained personnel to collect, enters, transfer and validate clinical data.

### 5.3 Specific clinical annotation

The following data about specimen and participant represents examples of the type of data that is valuable to collect.

- 5.3.1 Demographic data
  - Contact information (when approved by the consent)
  - Date & Place of birth
  - Race/Ethnicity
  - Physician
- 5.3.2 Lifestyle Factors
- 5.3.3 Family History
- 5.3.4 Epidemiological risk factors
  - Alcohol/Smoking Data
  - Environmental and occupational exposure
- 5.3.5 Patient's medical history
- 5.3.6 Patient's cancer history, including family history
- 5.3.7 Pathology data
  - Diagnosis data
  - Histology
  - Site, Stage, grade, size
- 5.3.8 Pertinent diagnostic studies (Biomarkers like PSA etc.)
- 5.3.9 Information on initial staging procedure
- 5.3.10 Treatment data
  - Type (chemotherapy, Radiation, Other)
  - Dose

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**RECORDS AND DOCUMENTATION MANAGEMENT****Clinical annotation**

➤ Therapeutic agent name

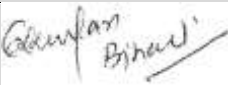
**5.3.11** Response to Treatment

**5.3.12** Surgery Data

➤ Type of Surgery

➤ Margin status

**5.3.13** Follow-up data/Outcome data:Vital status

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**N a t i o n a l**  
**L i v e r**  
**D i s e a s e**  
**B i o b a n k**



# Standard Operating Procedure

**DOCUMENT NAME: RECORDS AND  
DOCUMENTATION MANAGEMENT**

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***DOCUMENT NO. : ILBS#NLDB:C***

**RECORDS AND DOCUMENTATION MANAGEMENT****Document maintenance**

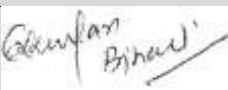
**Document Name : Document maintenance**  
**Document No. : ILBS#NLDB:C.5**  
**Version No. : 1.0**  
**Effective Date : 01/01/2025**

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## RECORDS AND DOCUMENTATION MANAGEMENT

### Document maintenance

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:C.5	01/01/2025	6	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

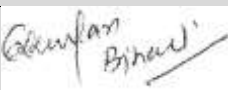
Location	Subject
Biobank Reception area Almira	Document maintenance
Function	Distribution
To give information about: Processes for maintenance of all written (notebooks), original paper records, and true copies such as photocopies, microfiche or microfilm as well as electronic records.	<ul style="list-style-type: none"> <li>➤ HOD</li> <li>➤ Biobank Reception area</li> <li>➤ Master files</li> </ul>

#### SCOPE AND APPLICATION:

This SOP covers the management and maintenance of all biobank records, including paper-based documents (e.g., notebooks, original records, copies) and electronic records.

#### RESPONSIBILITY:

This SOP applies to NLDB personnel involved in document control. The Head of Biobank ensures proper record maintenance, while technicians document specimen processing and related activities.

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# RECORDS AND DOCUMENTATION MANAGEMENT

## Document maintenance

### 1.0 PURPOSE

The NLDB is committed to high standards for quality assurance and operational practices in the collection and storage of human tissue for research purposes. Systems should be in place to document all activities of the biobank.

### 2.0 SCOPE

This SOP covers processes for maintenance of all written (notebooks), original paper records, and true copies such as photocopies, microfiche or microfilm as well as electronic records.

### 3.0 ROLES AND RESPONSIBILITIES

This SOP applies to NLDB personnel involved in generating, maintaining and managing records and documents within the biobank program. Roles and responsibilities may vary at specific sites.

**HOD Biobank:** Ensures adequate documentation and maintenance of records.

**Technician:** Documents all processing of specimens; Documents clinical activities pertaining to participation in the biobank.

**IT manager:** Audits records, maintains updated computer records.

### 4.0 MATERIALS, EQUIPMENT AND FORMS

- BIMS
- Office storage / filing materials.

### 5.0 PROCEDURES

Maintaining well-organized, complete and accurate documentation of all biobanking activities is vital to the operation of a successful biobank. Timely collection and filing of all required documents also assists in the efficient management of biobanking activities.

#### 5.1 General principles for the management of study files

**5.1.1** Create a logical, organized filing system that allows for rapid location and retrieval of program documents. Ensure that any electronic system is searchable.

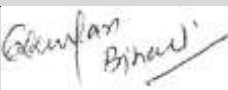
**5.1.2** Store essential hard copy documents in a binder or file box in a secure location.

**5.1.3** Protect the confidentiality of all participant records (e.g., recruitment logs, Informed Consent Forms) and store in a secure location.

**5.1.4** Create a separate reference binder to store documents, SOPs, Policies, published papers etc.

**5.1.5** Ensure only the most recent SOP versions are easily accessible to the relevant personnel to avoid confusion with previous versions.

**5.1.6** Routinely update all documents to reflect current information and status. Archive all documents relating to consented participants as required by the BEC and / or scientific need.

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## RECORDS AND DOCUMENTATION MANAGEMENT

### Document maintenance

#### 5.2 Participant file creation and maintenance

- 5.2.1 Ensure that all personnel are trained in the use of the filing system.
- 5.2.2 Open a participant file soon after patient recruitment.
- 5.2.3 File new documents on an on-going basis.
- 5.2.4 Prior to making any modifications, deleting or destroying any documents, obtain approval from someone in a supervisory role at the biobank. Document all changes and actions performed on the document.

#### 5.3 Document standardization (common terms and data elements)

- 5.3.1 Maintain records, policies and procedures in a standardized format. Ensure that the standardization is homogeneous throughout all documentation.
- 5.3.2 To promote the use of common terms and formats, implement the use of drop down menus and document templates where possible.
- 5.3.3 Generate, circulate and make accessible all lists of definitions and commonly used terms Update as relevant.

#### 5.4 Document standardization (signatures)

- 5.4.1 Use full legal names for signatures.
- 5.4.2 Use ink for all signatures.
- 5.4.3 Each person signing the form should date signatures.

#### 5.5 Document standardization (recording date and time)

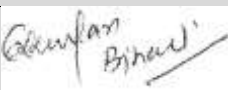
- 5.5.1 Record time based on a twenty-four hour clock. Time is recorded by four digits. The first two digits represent the hour, the following two digits represent minutes.
- 5.5.2 Record dates using a consistent format throughout all documentation.

#### 5.6 Document storage

- 5.6.1 It is recommended to store documents so as to protect them from loss or damage such as environmental damage (e.g. moisture, fire) or misadventure.

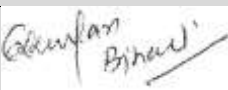
#### 5.7 Document destruction procedure

- 5.7.1 Paper documents with sensitive information requiring destruction will be passed through a paper shredder before disposal in the general garbage.
- 5.7.2 Electronic documents should be permanently deleted and non-retrievable.

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**RECORDS AND DOCUMENTATION MANAGEMENT****Document maintenance****6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

- Medical Research Council, Ethics Series. Good Research Practice  
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415>

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