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Standard Operating Procedure

**DOCUMENT NAME: PRIVACY,
SECURITY & ETHICS**

DOCUMENT NO. : ILBS#NLDB:K

Privacy, Security & Ethics***Ethical Issues***

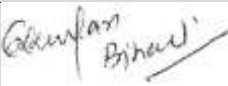
Document Name : Ethical Issues
Document No. : ILBS#NLDB: K.1
Version No. : 1.0
Effective Date : 01/01/2025

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Document Name: SOP "Ethical Issues"				
Document No ILBS#NLDB:K.1	Approved & Issued by:		Dr. Chhagan Bihari HOD, Biobank	Issue Date: 01/01/2025
Rev. No.: 1.0				

Privacy, Security & Ethics

Ethical Issues

Number	Effective date	Pages	Author	Authorized by
SOP: NLDB:K.1	01/01/2025	7	Mr. Satish Kumar	Dr. Chhagan Bihari
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1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

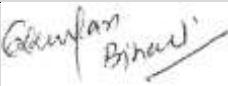
Location	Subject
Biobank Reception area Almira	Ethical Issues
Function	Distribution
To give information about: Ethical Issues	<ul style="list-style-type: none"> ➤ HOD ➤ Biobank Reception area ➤ Master files

SCOPE AND APPLICATION:

As part of the informed consent process, participants are informed of their right to withdraw consent at any time without providing a reason. This includes withdrawal due to personal, social, philosophical, religious, or family concerns.

RESPONSIBILITY:

This policy applies to NLDB and all personnel involved in any aspect of the biobank program.

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Ethical Issues

1.0 INTRODUCTION

Human biological specimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetics insights, scientists have greatly increased their use and demand for properly prepared and clinically annotated tissue samples that yield valuable insights into the mechanisms and pathways of human disease. Research on human tissue samples has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of human biological material (HBM) in basic and translational research in general. These guidelines have been applied to dealing with issues related to collection, study, storage, transfer and disposal of tissue specimens and associated patient data. In view that HBMs are becoming a valuable and irreplaceable resource and society's interest in the advancement of medical knowledge, this policy is intended to foster a consistent and coherent ethical framework that should govern specimen use.

2.0 PURPOSE

The NLDB is committed to promoting and educating for adherence to high ethical standards and practices in the collection and storage of human tissue and annotating data for research purposes. This policy is intended to outline general principles that can be used in most situations to ensure that the interests of the patient are safeguarded.

3.0 SCOPE

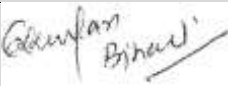
This policy applies to major ethical considerations that arise in the conduct of tissue banking and/or research. The issues concern custodianship, risk, confidentiality, consent and quality of research.

4.0 RESPONSIBILITY

This policy applies to NLDB and to personnel involved in all aspects of the biobank program.

5.0 POLICIES

The use of HBM and accompanying data is critical for medical research. The public and program participants should have confidence that biobank and researcher will use and handle such material according to recognized ethical standards. It is important to ensure that collections of HBMs are used ethically and optimally for the research to benefit health and knowledge. The interests of the

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participants should always take precedence over the interests of research, science and society. The following principles in areas requiring ethical consideration should guide the ILBS biobank in collecting, maintaining and managing the resource it controls:

➤ **Ethics Review**

The following principles should guide the NLDB in the process of obtaining consent.

- To ensure that the interests of the patient are safeguarded, processes such as consent, collection, storage and proposed research should be reviewed and approved by an appropriately constituted Research Ethics Board (REB).
- The standard of “minimal risk” should be considered in the review process. Then physical risks in donating tissue samples for research may be minimal, but the risk that information from research on the sample and annotated data could harm the privacy and confidentiality of the participant should be considered.
- Biospecimen and annotation data collection should be conducted under REB approved collection protocols. Typically this will involve obtaining informed consent directly from participants. Participants should be informed and understand what the tissue sample is to be used for. In some circumstances an REB may provide a “waiver of consent” on behalf of the participants.

➤ **Confidentiality**

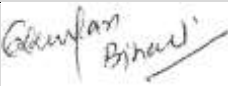
- Personal and medical information and research results relating to the participant and tissue sample should always be treated as confidential. The participant should be made aware of the type of personal and medical information that will be used by researchers, and what safeguards will be in place to protect their confidentiality and anonymity.

➤ **Economic Factors**

- Economic factors may provide motivation for participants to provide tissue samples but this could compromise the quality and safety of the collection. Subjects should not be offered or receive any financial compensation for participation in the program. Participants may be reimbursed for costs involved in participation. Human biological material (HBM) collected from participants should be treated as gifts.
- HBMs should not give rise to financial gain. The NLDB should not sell (for a profit) samples of HBMs that they have collected. A reasonable payment from users of the biobank to recover costs of obtaining, managing, maintaining, processing and handling the biobank collection is however acceptable.

➤ **Custodianship of tissue data**

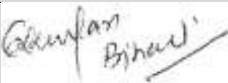
- Custodians should bear responsibility for the samples and data in their collection so that biobank will be able to safeguard the interests of the participants.

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- Custodians of the tissue samples should bear responsibility for keeping proper records of all uses that have been made of the materials, whether by themselves or others. If transfer of material occurs, appropriate material transfer procedures should be followed and documented.
- Custodians of “Existing Collections” should ensure that they make optimal use of the resource they control and seek the advice of the established Ethical committee through periodic (e.g. annual) review.
- **Commercialization and Intellectual Property Issues**
- The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is very dependent on commercial involvement. Access by the commercial sector to HBMs within the biobank should be facilitated if consistent with the goals of the biobanks. However, no one commercial enterprise should be given exclusive rights of access to the collection. Patients should be informed in the consent process, that samples or their products may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialize research might help alleviate ethical concerns that participants are not aware of intended uses of their tissue.
- Intellectual property (IP) rights arising from research using human samples may be sold or licensed in the same way as other IP rights. Before allowing access to samples by either academic or commercial sector researchers, the biobank or “custodian” of the HBMs and data should make clear (by contractual agreement) its Policies on ownership of IP.
- **Genetic Testing**
- The ability to study samples stored in NLDB and to generate information about genetic disease and susceptibility to disease has raised concerns over risk to participants associated with discrimination and stigmatization of individuals. Privacy of research results should never be breached, as the consequences for the participant are likely to be social, economic and psychological.
- Only those bio samples will be released for genetic testing, for which the relevant informed consent has been obtained and with approval of ethics committee.
- Much genetic information generated as results from research is of unknown or uncertain predictive value. Results should never be disclosed to the patient or added to medical records unless consent is obtained through an Ethical committee approved protocol. If consent is sought, then appropriate counselling will be available. During this counselling, participants should be advised of the potential risks and implications of genetic information.

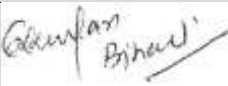
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6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Declaration of Helsinki. <http://www.wma.net/en/30publications/10policies/b3/index.html>
- International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. <http://www.ich.org/products/guidelines.html>
- Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations.
<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clin-pract-prat/reg/1024-eng.php>.
- Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010. <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>.
- USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. <http://www.fda.gov/oc/gcp/default.htm> or <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
- Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. <http://www.hhs.gov/ohrp/policy/ictips.html>
- 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
- Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>
- National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999. <http://bioethics.georgetown.edu/nbac/hbm.pdf>
- Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505. *Ownership and Use of Tissue Specimens for Research - Acce*

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Privacy and Security

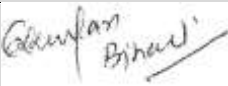
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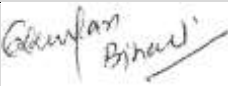
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To give information about: participants are informed to ensure that the privacy of the patient is safeguarded.	<ul style="list-style-type: none"> ➤ HOD ➤ Biobank Reception area ➤ Master files

SCOPE AND APPLICATION:

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.

RESPONSIBILITY:

This policy applies to all personnel involved in the biobank program who have access to patient information, biospecimens, and research data.

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Privacy and Security

1.0 INTRODUCTION

The value of the human biological material (HBM) for research purposes is greatly enhanced by accompanying personal or clinical data related to the individual providing the sample. Personnel should treat any information about the individual, however derived, as confidential. Rules protecting the privacy of personal information collected for research purposes are outlined in national research ethics guidelines.

To comply with the guidelines on privacy and confidentiality, participants will be informed about how information about them will be used. Biobank should have each participant's explicit consent to obtain, store and use information about them. (cf. Informed Consent). Participants should also be made aware of what safeguards are in place to protect their confidentiality.

2.0 PURPOSE

The NLDB is committed to compliance with national guidelines and laws safeguarding the privacy and confidentiality of participants that have provided personal and clinical data and tissue samples to the ILBS Tissue bank. The purpose of this Policy is to outline general principles to ensure that the privacy of the patient is safeguarded.

3.0 SCOPE

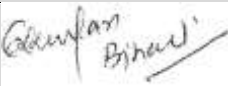
This policy applies to privacy and confidentiality considerations that arise in the conduct of biobanking and research in ILBS or through ILBS. The issues concern storage, transmission, retention and sharing of participant information in a manner compliant with legislative and ethical requirements.

4.0 RESPONSIBILITY

This policy applies to the personnel involved in all aspects of the biobank program that have access to patient information, samples and research results.

5.0 POLICIES

The use of HBMs and accompanying data is critical for medical research. The public and participants should have confidence that biobanks and researchers will use and handle such material with confidentiality. It is important to ensure that sensitive information is used ethically and optimally for the research to benefit health and knowledge. Safeguarding the privacy of the participants will be of

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primary importance. The following set of policies or principles should guide the biobank in collecting, maintaining and managing the confidential information it controls:

➤ **Accountability for Personal Information.**

- Accountability of biobank for compliance to the privacy policy and applicable legislation rests with each member's biobank or biobank manager for day-to-day collection and processing of personal information. The name of the designated official, accountable for overseeing compliance to these principles, will be a matter of public record.
- As the custodian of personal information in its possession, including information that may be transferred to a third party, the biobank will use contractual means (such as an MTA-Material Transfer Agreement) and ethical approval to ensure a comparable level of protection while the information is being used by the third party.

➤ **Identifying Purposes for the Collection of Personal Information**

Medical information relating to the participants and tissue samples should always be treated as confidential. The participant will be made aware of the type of personal and medical information that will be used by researchers at the time of informed consent.

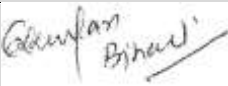
➤ **Consent for the collection use and disclosure of Personal Information**

- Consent is required for the collection of personal information and the subsequent use and disclosure of this information. The biobank should seek consent for the use or disclosure of the information at the time of HBM collection.
- In keeping with the concept of 'informed consent', the biobanks will make an effort to ensure that the participants are advised of the overall purposes for which their information will be used. Participants will be confident that biobanks will follow the guidance of Ethical committee for reviewing and approving access to their material.
- Information will not be used for purposes that have not been specifically identified in the consent process without seeking the guidance of the Ethical committee of record.

➤ **Limiting Collection**

Biobank will not collect personal information indiscriminately. Both the amount and the type of information will be limited to that which is necessary for the purposes identified by the collecting biobank in the consent process.

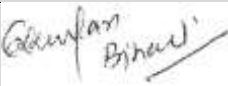
➤ **Limiting Use, Disclosure, and Retention of Personal Information**

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- The biobank should control the release of information to researchers by evaluating each request for scientific merit and compliance with approved ethical standards.
- Researchers using the biobank can only use HBMs or disclose information in accordance with the terms and conditions outlined in a Material Transfer Agreement (MTA).
- **The biobank will implement procedure (approved by an BEC) with respect to the retention of personal information**
 - For cases of withheld consent, all case related tissue and data held (electronically or on paper) by the local biobank will be removed or destroyed.
 - For cases of revoked consent, all case related tissue and data will be destroyed. Guidance of the involved Ethical committee will be used in the management of case related tissue and data accrued, that cannot be destroyed as it may already be engaged within a research protocol. In some cases, such material may be used as anonymous donor/tissue with limited and relevant clinical characteristics (that are required for ongoing study) and with Ethical committee approval.
- **Accuracy of Personal Information**
To minimize the possibility that inappropriate or insufficient information may be used to make decisions or conclusions about the research undertaken, and data will be accurate, complete and up-to-date.
- **Ensuring safeguards for Personal Information and HBMs**
 - The security safeguards should protect HBMs and personal information against loss or theft as well as unauthorized access, disclosure, copying, use or modification. ILBS Biobank will protect personal information and HBMs regardless of the format in which it is stored.
 - Security safeguards appropriate to the sensitivity of the personal and clinical information will be protected this information.
 - Methods of ensuring security of HBMs and associated information will include the following methods:
 - i. Physical measures such as locking biobank filing cabinets, freezers, fridges and restricting access to offices and laboratories.
 - ii. Organizational measures, such as limiting access on a 'need-to-know' basis.
 - iii. Technological measures, such as using passwords, firewalls, and encryption.
 - iv. Encoding procedures such as de-identification or de-personalization of source data.
 - v. Routine back-up of data and information stored electronically.
- **Openness about biobank Policies and Practices**

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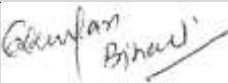
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- NLDB will be open about its policies and practices with respect to management of personal information. Participants will be able to acquire information about policies and practices without unreasonable effort and this information will be made available in a form that is generally understandable.
 - NLDB will make information about policies and practices available in a variety of ways. This may include brochures available at its place of business or at promotional events and online access to policies, forms and selected educational material.
 - **Individual Access to Own Personal Information**
 - Personal information includes data that has been collected (including lifestyle and clinical data) but not data created by research.
 - Exceptions to individual access will be controlled by the ethical committee and may be warranted if the information contains references to other individuals, is prohibitively costly to provide, is not traceable or cannot be disclosed for legal, security or commercial proprietary reasons.
 - If valuable medical information becomes available from research on biobank samples, the decision to contact the patients or their families to offer benefits of that research will be guided by the Ethical committee approval record and best clinical practice.
 - **Complaints**
- Biobanks will put procedures into place to receive and respond to complaints or inquiries about its policies and practices relating to the handling of personal information. The procedure will be easily accessible and simple to use.

6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Declaration of Helsinki. <http://www.wma.net/en/30publications/10policies/b3/index.html>
- Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010. <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>.
- Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. <http://www.hhs.gov/ohrp/policy/ictips.html>
- Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>
- Canadian Federal Personal Information Protection and Electronic Documents Act. <http://lawslois.justice.gc.ca/eng/acts/P-8.6/index.html>
- Ontario's Personal Health Information Protection Act

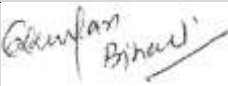
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http://www.elaws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

- Alberta's Freedom of Information Protection of Privacy Act <http://www.oipc.ab.ca>
- Alberta's Health Information Act.
http://www.assembly.ab.ca/HIARReview/Health_Information_Act.pdf
- British Columbia's Freedom of Information Protection Act.
[http://www.oipc.bc.ca/legislation/FOI-ACT%20\(2004\).pdf](http://www.oipc.bc.ca/legislation/FOI-ACT%20(2004).pdf)
- Manitoba's Freedom of Information and Protection of Privacy Act (FIPPA) and Personal Health Information Act (PHIA) <http://www.ombudsman.mb.ca/access.htm>
- Quebec's Act respecting access to documents held by public bodies and the protection of Personal information. http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/A_2_1/A2_1_A.html
- American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility. 2003. J. Clin. Oncol. 21(12):2397-2406.

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