Institute of Liver and Biliary Sciences (ILBS)
New Delhi

Proposal for starting

Fellowship in Biobanking Science

Program Name:-

Fellowship in Biobanking Science (FBS)

Institute of Liver and Biliary Sciences, Vasant Kunj, New Delhi is located in the national capital of India, is an apex medical institute in the country providing tertiary level health care in hepatic, pancreatic, biliary & liver transplant. The Institute serves a local population of 15 million and draws patients from all over the country and neighboring countries as well. The department of Clinical Nutrition at ILBS, first of its kind in an academic institute was established in 2012 as a central facility that provides comprehensive care to all patients belonging to the hepatic, pancreatic, biliary surgery, liver transplant and nephrology.

ILBS with the support of DBT has established "*National Liver Disease Biobank (NLDB)*", a facility for clinical and basic research in the field of HCV, Liver disease, Gallbladder and other diseases. It can house close to 5.4 million bio samples along with advanced analytical facility, including FACS, high resolution MS, NGS, and pathological analysis. Its aim to be a nodal center to the clinical and basic researchers to carry out their research from start to end under one roof along with human resource training. In order to deliver cutting edge services for collaborative liver disease research and academia-industry partnership in India, this facility has acquired a non-profitable business and financial model. It will help to seek answers regarding causes of diseases, treatment and genetic information.

As a part of its expansion plan of taking academic leadership in the field of Biobanking the department wants to establish the Fellowship and Certificate course in Biobanking Science.

Objective of the program:

1. To provide academic leadership in Biobank Sciences
2. To improve personalized treatment, patient care through high quality biosample
3. To provide basic research infrastructure and promote research in the field of Liver disease

A: Preamble

Multiplicities of liver diseases stand at the forefront of national health concerns. Notwithstanding the huge strides in the pharmacological advancements, biomarker discovery, therapeutic nutrition, personalized treatment is imperative in the management of these acute and chronic liver diseases. Biomedical research is rapidly progressing reflected by increasingly sophisticated methods demanding samples of high quality. Due to this rapid progress in different research areas the structured collection of high quality human biological samples and corresponding data gained more and more attention in the last decade.

Biobanks are defined as a systematic collection of human biomaterials and related data for scientific research. Biobanking is developing as a new branch of science which has a key role in biomedical research and precision medicine. It is very broad and diverse and includes sample collection, storage, research, education, funding, publishing, biobanking services, analytical services and others. Biobanks play an important role in the precision medicine, patient diagnosis and treatment, follow-up, and therapy monitoring and optimization. As per the timesmagazine published in 2009, Biobank is on the list of "**10 Ideas Changing the World Right Now**". Biobanks are the home of biospecimens where biosamples are collected and stored in organized way with their clinical, social and pathological information for research, new drug discoveries and drug development. Human Biospecimens stored at biobank are a precious and critical resource for the process of discovering new mechanisms causing disease or in determining its progression, resistance or response to treatment, and clinical outcome.

Biobanking is an integral part of medical research and treatment. Biobank research is increasingly recognized as an essential tool for exploring the origin of diseases and understanding the relationships between various health and disease determinants, such as genetics, lifestyle, environmental, and outcomes. The number of research project and patients treatment using biobank samples is constantly increasing. At the same time, requirements on quality of biobanking samples are increasing because of the growing spectrum of potential methods for different analysis and applications. The development of biobanking processes depends on a deeper understanding of biobanking procedure and data update.

Biobank science has developed in western countries but in India people are not aware about it. ILBS with support of DBT has established first National Liver Disease Biobank and plans to train students, scientist and doctors in this subject.

B: Facilities in the Institute of Liver and Biliary sciences

Faculty

1. Department of Hepatology including pediatric Hepatology&Clinical Nutrition
    - Number of faculty: 17

2. Department of HPB & Liver Transplant Surgery
    - Number of faculty: 9

3. Department of Biochemistry
    - Number of faculty: 1

4. Department of Pathology (including Microbiology, Virology,Lab & Transfusion Medicine)
    - Number of faculty: 6

5. Department of Medical Imaging & Interventional Radiology
    - Number of faculty: 4

6. Department Anesthesiology&Critical Care Medicine
    - Number of faculty: 10

7. Critical Care Medicine
    - Number of faculty: 2

8. Department of Nephrology
    - Number of faculty: 4

9. Department of Oncology
    - Number of faculty: 4

10. Department of Research
    - Number of faculty: 10

Investigative Facilities:

Hematology: Haemogram, Coagulation profile

Biochemistry: Liver function tests and Serum biochemistry, Bile studies, Hormonal assays

Microbiology: Gram & AFB staining, Cultures (bacterial, anaerobic & fungal), Immunological and Viral studies

Pathology: Cytology, Histopathology, Frozen section, Immunohistochemistry, Electron Microscopy

Radiology: X-rays, Ultrasound Doppler studies, CT- scan MRI, DEXA, DSA and Vascular Laboratory

Endoscopy: Upper & Lower G.I Endoscopy (diagnostic & therapeutic), ERCP, Capsule Endoscopy, EUS and ESWL

Operation Theatre: Arterial Blood Gas Analysis, Thromboelastograph, Intraoperative, Ultrasound with Doppler, Choledochoscopy, Perioperative Cholangiography

Research Department: RT-PCR, PCR, Gradient PCR, Culture facility, Luminex™, Seahorse XF Analyzers, Animal Facility, Live cell imaging Microscopes

Clinical Nutrition: Body composition analyzer (MF-BIA), Handgrip dynamometer, Harpenden's skin folds calipers

National Liver Disease Biobank: Cryostorage facility, advanced analytical facility, including FACS, high resolution MS, NGS, and pathological analysis

Curriculum, number of seats and eligibility criterion for courses in Biobanking

Place of training: NLDB, ILBS

Objective: The basic purpose of FBS in Biobank is to give in-depth knowledge and train students in the field of biobanking. The goal of this course is to share knowledge, experience and practical skills which will assist students to qualify for working in the multidisciplinary field of biobanking. The structured training programme would emphasize:

1. Teach in depth, the common principles of practical biobanking.
2. Put different types of biobanks in perspective and draw conclusions about the theoretical underpinnings that were operational.
3. To train students in the scientific basis of biobanking/biospecimen research in Standard Operating Procedure (SOP) development, implementation and in research exploitation of samples.
4. To train students in the advanced analytical facility, including FACS, high resolution MS, NGS, and pathological analysis
5. Logistical, practical and technical steps of biobanking, and evaluate their coherence and ad equation.
6. Compare different reports on biobank risk management and mitigation.
7. Develop Best Practices/ SOPs.
8. Development of desired technical expertise
9. Validate biobank protocols, training and technology transfers.
10. Biobank Quality Management Systems (QMS)
11. ELSI (ethical, legal and societal issues of biobanking)
12. Producing biobank cost analysis and recovery reports.
13. Understanding the research project based biosample and associated data collection.

Number of Seats:

FBS-2 seats per year

Eligibility:

FBS: MBBS/ MSc+ 2 years' experience (Life Science)/ MTech (life science)

Duration of Program:

FBS: 12 months

Fee of Program:

INR: 50,000

Existence of similar program elsewhere in country: No

USA/Europe: Yes

Process of selection of candidates:

- All India advertisement
- Objective based written test (100);
- Screening of application for compliance of basic qualification.
- Departmental assessment interview (Marks: 50): It will be a practical examination related to molecular techniques, Cryostorage, Basic computer, IHC, Grossing, tissue storage subject knowledge, communication skills
- In-waiting candidates: Candidates will be considered for the course in the following conditions:
    i. Selected candidate does not join the duties within one month of issuance of appointment letter
    ii. Candidates resign within one month of one's joining

Security Deposit: Selected candidates are required to deposit an amount of Rs. 20,000/- (Twenty Thousand only) at the time of joining. The deposit will be refunded without interest on completion of the training course or after completion of the internship whichever is later. If trainee leaves the training at any time before completion of the training, deposit will stand forfeited.

Teaching Plan

Class: The course is taught by an experienced team

Journal club: Presentation of biobank and advanced analytical facility published in molecular biology/biotechnology/other research journals

Review Seminar/Management issues: As per the academic schedule the students would make presentations regarding the assigned topic

Research projects: Students would prepare brief synopsis of one topic assigned by expert

D: ASSESSMENT SYSTEM

Graded Course Requirements (assignments, exams, presentations, participation):
Students will be evaluated based on a combination of attendance, course participation and short, descriptive analytic essay examination. A minimum of 80% attendance is required to successfully complete this course.

Format for assessment of communication skills, attitudes and behavior (Appendix V)

Assessment of knowledge
The knowledge will be informally tested on day to day basis in biobanking during academic sessions, and during interim viva-voce conducted during the training procedure.

Internal Assessment
The relevant knowledge should form part of routine assessment in the workplace i. e. does the student have an adequate knowledge base to support the decisions he/she makes? Theability to demonstrate appropriate knowledge will be assessed in the written examination. The candidates are required to maintain a logbook detailing academic activities performed. The overall internal assessment process is based on performance in donor consent, communication, and performance in academic programme, internal exam and logbook maintenance.

Theory paper (Total Marks: 100)

Paper I: 25 MARKS

- Basics of Biobanking
- Governance
- Ethics, Privacy and Security

Paper II: 25 MARKS

- Facility Design and Safety
- Quality Management and Process Improvement
- Informed Consent

Paper III: 25 MARKS

Biospecimen Collection and Processing

Biospecimen Storage and Distribution

Data Systems and Records Management

Paper IV: 25 MARKS Next Generation Sequencing (NGS) & Data Analysis

Chromatography & Mass Spectrometry

Histopathology techniques & Flow cytometry

Practical Examination (Total Marks: 100)

Components of Practical Examination

Component	**Marks**
Project	65
General viva	35

To be successful a candidate will be required to obtain at least 50% marks separately in theory and practical.

Examiners

There will be one internal and one external/two internal examiners. Examiners should have PhD/MD/ DNB (Pathology) and known in the field of Research/Biobanking.

APPENDIX – I, NEED FOR THE PROGRAM

Biobanks, as repositories for the storage of this biological material and its corresponding data, could become important tools and instruments in driving this change in the way health care is delivered. The number of biobanks around the world has increased dramatically, owing in part, to the need for researchers to have access to large numbers of samples for genomic research. The paradigm in medicine of “reactive approaches” centered on disease therapy is moving to a more personalized, prognostic, preventative, and contributing approach, focusing on the conservation of health Policies for enrolling participants, returning research results and obtaining samples and data can have a far reaching impact on the type of research that can be performed with each biobank. Research using biobank samples includes studies of the impact of environmental and other risk exposures on health, understanding genetic risks for common disease, identification of biomarkers in disease progression and prognosis, and implementation of personalized medicine projects. This research has been

instrumental in the progress of genetic and genomic research and translational medicine. National Liver Disease Biobank has equipped with unique cryostorage and analytical facilities. This course will provide a platform for Junior Scientists, Medical doctors about biobanking and analytical facilities to promote research and personalized medicine.

The extensive growth of biobanks requires training of highly qualified personnel in the field of biobanking and different disciplines linked to it. To meet this development this course provides knowledge and practical know-how about organization, management, infrastructure and emerging challenges in biobanking. The number of requests to use biological samples for medical research is constantly increasing over the last years. However, at the same time the requirements on quality of biobank samples (and data) will increase due to the growing spectrum of techniques and methods used for analysis and applications. For further development of biobanking processes the knowledge about prerequisites for such applications is of crucial importance to keep the quality of biobank resources up-to-date.

Appendix – II, Employment opportunity

The importance of Biobank in the field of medical research on various diseases cannot be over emphasized. There is a growing need of biobank expert as the inclination to open a biobank has increased in private and government hospitals in India to support the dramatic development by research in diseases prevention, prediction, diagnosis and treatment. Indian government has also started to provide initial funds to start biobanks for cancer, liver and rare diseases.
However, there is an acute shortage of trained manpower in the field of biobanking, this is chiefly related to paucity of dedicated centers and trained manpower. With the multidisciplinary training approach of NLDB at ILBS, this kind of training in biobank will equip the trainees to seek employment opportunities in the capacity of biobank technician /lab manager in hospitals, biobank, research centers at many government and non-government organizations

Appendix – III, syllabus

The selected candidate will receive training in major spheres of biobanking viz. operational, administrative & ethical aspects of biobanking by reading standard textbooks, monographs and peer reviewed journals as recommended in Appendix-IV. Candidate will be involved in basic operational processes viz. collection, storage, disbursement & dissemination, transport & shipping of biospecimens as well as collating & collecting data. The aim of the course is also to provide an opportunity to the

candidate to learn nuances of biobanking software, quality control of biospecimens and ethical issues related to biorepository.
A core syllabus is recommended but it does not purport to be either comprehensive or restrictive.

Basics of Biobanking
Provides an introductory overview of biobanking including key issues in establishing, maintaining and accessing a biobank.

Governance
introduces you to the concept of biobank governance and its importance to the everyday operations of a biobank.

Ethics, Privacy and Security
Discusses the importance of ensuring that biospecimens and personal health-related information are used ethically and optimally for research purposes.

Facility Design and Safety
Provides you with information on the fundamental physical components of a biobank facility. It also covers the importance of biobank facility design and security in maintaining a safe environment.

Quality Management and Process Improvement
Provides general information on the importance of quality management and process improvement for biobanks.

Informed Consent
Identifies and describes processes related to informed consent in the biobank setting.

Biospecimen Collection and Processing
Provides an overview of the types of biospecimens commonly collected and stored in a biobank and the procedures involved in biospecimen collection and processing.

Biospecimen Storage and Distribution
Provides an overview of proper biospecimen storage, retrieval and sample distribution procedures for a biobank.

Data Systems and Records Management
Provides an overview of the types of data systems and records management systems used for storing biospecimen data.

Next Generation Sequencing (NGS) & Data Analysis
Provides an introduction to Next Generation Sequencing (NGS) technology, platforms, data generation, and data analyses

Chromatography & Mass Spectrometry
Provides about mass spectrometry including ionization, analyzers, sample preparation Procedures, SDS-PAGE, Western Blot, MALDI-TOF Mass Spectrometry and different types of acquisitions, applications of mass spectrometry in determination of molecular mass of peptides and proteins, peptide mass finger printing, peptide sequencing, post translational modification and quantitative proteomics

Histopathology techniques & Flow cytometry
Histopathological techniques will Provides detail about histopathological techniques, grossing , samples preparation , H&E, special staining. Flowcytometry provides in-depth principles of Flow Cytometry, Principles and guidelines for experimental design, especially for multi-color Flow Cytometry & Data analysis

Appendix – IV, Recommended Reading

Course Materials (reading materials, textbooks, other course materials)
Course materials will consist of targeted journal articles, slide print-outs, and other digital and print media as determined by the individual lecturers.

Additional reading:

 2012 best practices for repositories collection, storage, retrieval, and distribution of biological materials for research international society for biological and environmental repositories. Bio-preserve Biobank. 2012 Apr;10(2):79-161. doi: 10.1089/bio.2012.1022. PMID: 24844904.

 Lehmann S, et al. Standard pre-analytical coding for biospecimens: review and implementation of the Sample PREanalytical Code (SPREC). Bio-preserve Biobank. 2012 Aug;10(4):366-74. doi: 10.1089/bio.2012.0012. PMID: 24849886.

 http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Chapters from various books
Official documents

Journals
Journal of Bio-preservation and Biobanking
Journal of Resources

Text books

Ethics, Law and Governance of Biobanking

Biobanking in the 21st Century

Next-generation Sequencing: Current Technologies and Applications

Mass spectrometry: Principle and application

Flow cytometry protocol

Appendix V,

Format for assessment of communication skills, attitudes and behavior

Attitude or behavioral pattern	Satisfactory	Cause of concern	Examples of cause of concern	Assessor
Communication skills (with patients & relatives)				
Communication skills (with staff)				
Communication skills (sensitivity to another's need)				
Reliability and punctuality				
Control of moods and emotions				
Personal presentation				
Social behavior				
Initiative				
Confidence				
Over or under assertive				
Departmental involvement				
Team work				
Personal organization				
Honesty and trustworthiness				
Enthusiasm				
Record keeping				

I confirm that causes of concern have been discussed with the resident/nurse/ doctors.
The outcome of this discussion was as follows.

Signature Name Date