Quality Manual

ISO 9001:2015
Quality Management System – Requirements

ISO 17025:2017
General requirements for the competence of testing and calibration laboratories

ISO 20387:2018
Biotechnology – Biobanking – General requirements for biobanking

CONTENTS

1 The Organization

1.1. Overview and Context

The Luxembourg Institute of Health (LIH) was founded in January 2015. Based upon the law of 3rd December 2014 on the organization of public research, it was created by fusion of the former CRP Santé and the Integrated BioBank of Luxembourg (IBBL). This law has been amended by the law of the 07th June 2023, which became effective on 01st July 2023. The most relevant change with impact on the quality management system is, that the IBBL is no longer an autonomous entity within the LIH, but has been fully integrated into the organizational structure of the institute.

RESEARCH DEDICATED TO LIFE

At the Luxembourg Institute of Health (LIH), we believe we have a collective obligation towards society to use knowledge and technology arising from outstanding research to have a direct and meaningful impact on people's health.

The Luxembourg Institute of Health (LIH) is a public biomedical research organization focused on precision health and invested in becoming a leading reference in Europe for the translation of scientific excellence into meaningful benefits for patients.

LIH places the patient at the heart of all its activities, driven by a collective obligation towards society to use knowledge and technology arising from research on patient-derived data to have a direct impact on people's health. Its dedicated teams of multidisciplinary researchers strive for excellence, generating relevant knowledge linked to immune related diseases and cancer.

The institute embraces collaborations, disruptive technology and process innovation as unique opportunities to improve the application of diagnostics and therapeutics with the long-term goal of preventing disease.

LIH aims to perform research that transcends the boundaries of classical disease definition. Its translational and transversal research strategy, combined with the increasing appreciation of the role of the immune system in determining disease, has led LIH to focus on two priority areas, with inflammation and immunity as the common thread:

Priority disease areas	Priority research topics
• Cancer • Immunological disorders	• Digital Health • Preventive Medicine • Clinical Research • Precision Health

The objective is to understand how distinct diseases are connected by shared immune-related mechanisms and to exploit this understanding towards the development of new diagnostics, innovative therapies and effective tools for personalized medicine, therefore putting the patient at the center of LIH's activities.

LIH strives for international research leadership, impact and innovation. Its research seeks to produce transformative and lasting solutions to make lives healthier, safer and more resilient by maintaining its excellence in interdisciplinary fundamental and translational research.

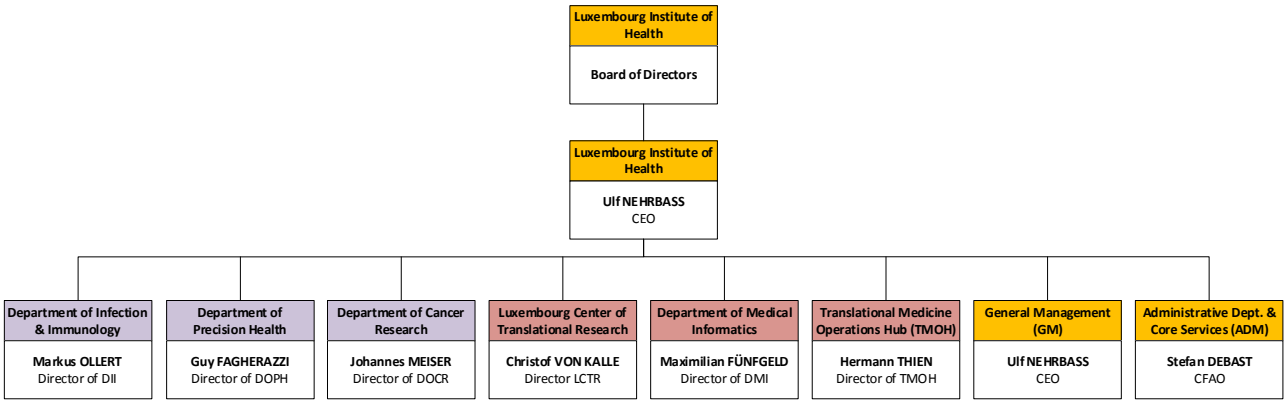
1.2. Mission & Vision

The mission of LIH is to leverage knowledge and technology arising from research on patient derived data, with the aim of having a direct and meaningful impact on people's health.

The vision of LIH is to become a leading European institute for precision medicine and precision health, transforming research excellence into tangible benefits for patients, with the long-term goal of preventing diseases.

1.3. Organizational Structure

The high-level organizational structure of the LIH is as follows:



The Board of Directors and the CEO are legally responsible for the activities of the whole LIH. Its current composition is presented on the LIH website: www.lih.lu

1.3.1. Research Departments

1.3.1.1. Department of Cancer Research (DOCR)

The vision of the department is to impact on patients' life by advancing the fight against cancer. Based on strong scientific track-records, we focus on priority research areas and provide research expertise covering the most common and/or malignant cancer types representing a health burden in Luxembourg. The department also represents a state-of-the-art training ground for next generation cancer researchers and acts as a reference point for cancer research in Luxembourg.

The main mission of the Department of Cancer Research is to advance the treatment options of cancer and reduce the cancer burden within the Luxembourg population and beyond. We do so through research excellence in priority areas covering the basic, translational and clinical research landscape to foster personalized medicine programs. Our activities focus on difficult to treat cancers and our teams have dedicated expertise in cancer immunology, the tumor microenvironment, tumor metabolism and neuro-oncology. We explore the cellular and molecular mechanisms of tumor progression using a wide range of state-of-the-art technologies, including multimodal omics technologies (genomics, metabolomics…), advanced immunoprofiling analyses, as well as *ex vivo* and *in vivo* imaging modalities leveraging patient data and innovative patient-derived models for cancer research.

1.3.1.2. Department of Infection and Immunology (DII)

The department aims to understand the complex mechanisms of infectious and inflammatory disease processes in order to enable new ways to diagnose, prevent or cure human diseases. Such a strategy requires the existence of a highly interdisciplinary research environment with intensive collaboration of basic and clinical immunologists, engineers, biochemists, computational and systems biologists, public health specialists and clinician scientists.

The DII defines itself as a clinical-translational research center at the crossroads of basic discovery, clinical application, and public health service.

As such, the major focus of DII is on the analysis of complex mechanisms of infectious and inflammatory disease processes. With a multi-disciplinary approach, the research strategy is based on the following elements: experimental discovery, bridging to clinical application and technology development. Major unsolved medical questions in the areas of inflammation (allergy, asthma, autoimmunity), cancer and infectious diseases (HIV) drive DII's current and future research agenda. The long-term objective of the DII is to develop into a center of complex immune system analysis in order to provide a better understanding of immune-mediated disease pathologies and infectious diseases.

1.3.1.3. Department of Precision Health (DOPH)

The Department of Precision Health (DOPH) is an interdisciplinary research center, focusing on epidemiological, clinical and public health research across a wide range of areas including digital health, lifestyle, human biomonitoring, health economics and sociodemographic inequalities in key diseases such cardio-metabolic conditions, neurodegenerative diseases, cancer, and COVID-19. By the evidence we generate, we aim at tackling the major causes of morbidity and mortality, improving quality of life and supporting clinical practice and public health bodies to advance the field of precision health.

By embracing novel digital technologies, Big Data and Artificial Intelligence approaches to analyze large datasets of patient-derived biological, clinical, environmental, and lifestyle information, we address major public health issues which are relevant to both Luxembourg and the international community. We carry out studies in epidemiology, clinical research or health economics and work on the impact on health of the exposome, lifestyle, socioeconomic inequalities – with a strong digital health dimension.

The department is also responsible for a range of public health projects such as disease registries or national surveys.

It relies on expertise from a number of disciplines (epidemiologists, data scientists, clinicians, methodologists, clinical trialists, translational researchers).

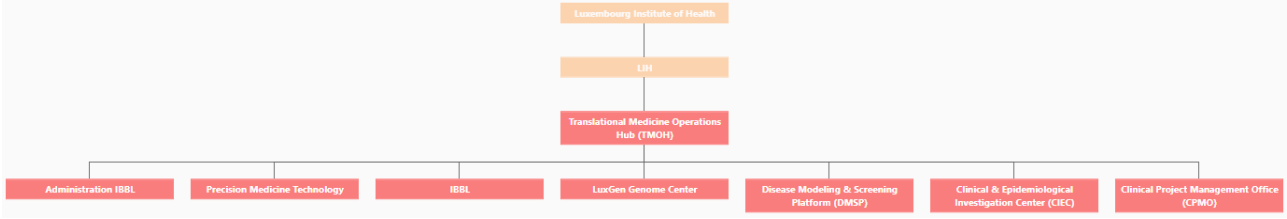
1.3.2. Luxembourg Centre for Translational Research (LCTR – Fuerschungsklinik) and Translational Medicine Operations Hub (TMOH)

1.3.2.1. Luxembourg Centre for Translational Research (LCTR – Fuerschungsklinik)

LCTR aims to foster bed-to-bench-to-bed collaborations within LIH, inter-institutionally across different stakeholders from research institutions and hospitals in Luxembourg and on the international level by collaborating within large consortia. In view of implementing translational programs across research topics, LCTR is supported by specific platforms and infrastructures from the Translational Medicine Operations Hub (TMOH), bridging between fundamental and clinical research and with Digital Medicine up into real-world healthcare. With the longstanding experience of the Luxembourgish National Centre for Excellence in Research on Parkinson's disease (NCER-PD) programme serving as a blueprint for translational bed-to-bench-to-bed cycles, LCTR is perfectly positioned to enhance and develop translational initiatives in biomedical research and beyond.

1.3.2.2. Translational Medicine Operations Hub (TMOH)

The TMOH offers the infrastructure to support translational medicine research. This is the overall organisational structure:



The TMOH ensures full research support from the operational planning of the study to its execution and closure via the collection, processing, storage and analysis of high-quality biological samples and structured

clinical data. It includes the operational units of the LIH (CPMO, CIEC, IBBL, Precision Medicine Technology) and its collaborative platforms (DMSP, and LuxGen) to integrate and optimize their accessibility, workflows and project/portfolio oversight.

TMOH provides the infrastructure to intra-institutional research, as well as transversal translational projects of "Research Luxembourg" and collaborations with external partners. These include publicly funded Research Projects like LITMUS, NCER-PD and CLINNOVA, as well as collaborations with industry partners. The central contact point of TMOH is the CPMO, which will guide researchers and their projects through the TMOH processes, as well as plan and track project execution.

As part of its mission, the TMOH hopes to improve patients' lives by providing Operational Excellence:

- Single Point of contact regarding Research Services for internal & external stakeholders
- Seamless workflow and high-quality project execution
- Consultation for projects regarding e.g. project design, operations, regulatory aspects
- Inbuilt collaboration (clear processes, interfaces, roles & responsibilities) and exchange of resources (technologies, SME)
- Transparent information/communication end-to-end (TMOH, LIH and beyond…)
- Continuous development – of methods, technology, science, quality, and processes, among others

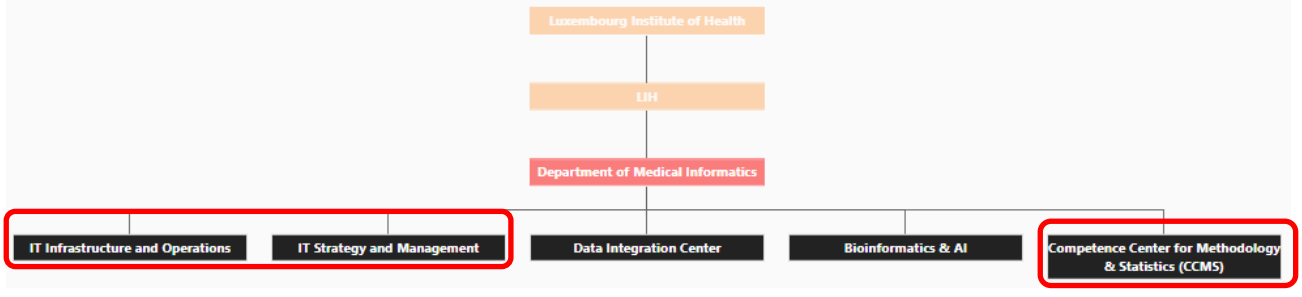
1.3.3. Department of Medical Informatics (DMI)

The Department of Medical Informatics' mission is to empower the institute's endeavors through comprehensive IT support, ensuring a robust infrastructure and secure environment for sensitive health data. The department is committed to efficiently managing systems and providing access to high computing resources for cutting-edge statistical and AI model development. It empowers the institute to achieve research excellence by providing expertise, secure data hosting systems, and advanced analytics tools. DMI facilitates multi-omics data analysis, statistics, machine learning, and scientific methodology, all while promoting FAIR data principles. Additionally, DMI is dedicated to advancing healthcare digitalization by exploring and designing innovative methods and applications.

The activities of the department are grouped in:

- IT support
- Research support
- Healthcare Digitization and Methodological Research

The units highlighted below, not performing solely research, are included in the LIH ISO 9001 certification scope.



1.3.4. Administrative Departments

Management and administrative processes are split across the following units as follows:

Department	Unit	Abbreviation
General Management	Business Development Office	BDO
	Data Protection Office	DPO
	Quality and Safety Management Office	QSMO
	Marketing & Communication	MARCOM
	Legal Office	LO
	Science Office	SO
Administrative Department & Core Services	Procurement	PRO
	Finance	FIN
	Human Resources	HR
	Buildings & Equipment	BE
	Reception	--

1.4. Locations

LIH staff executes their regular activities at the following locations/sites:

Address	Main Activities
1A-B, rue Thomas Edison L-1445 Strassen	• Head Quarter: General Management & Administrative Departments • Department of Precision Health • Parts of the Translational Medicine Operations Hub (TMOH)
6A, rue Nicolas Ernest Barblé L-1210 Luxembourg	• Department of Cancer Research • National Cytometry Platform (NCP)
6, rue Nicolas Ernest Barblé L-1210 Luxembourg	• Fuerschungsklinik Lëtzebuerg (Luxembourg Center of Translational Research (LCTR)) • Clinical and Epidemiological Investigation Center (CIEC) – Clinical Research Team • IBBL Satellite Lab
29, rue Henri Koch L-4354 Esch-sur-Alzette	• Department of Infection and Immunity • National Cytometry Platform (NCP) • Animal Facility
1, rue Louis Rech L-3555 Dudelange	• Integrated BioBank of Luxembourg (IBBL)
76, rue d'Eich L-1460 Luxembourg	• Human Motion, Orthopaedics, Sports Medicine & Digital Methods (HOSD)

1.5. Governance

The following governance bodies have been implemented to support the overall management of the institute:

Governance Body	Description
Board of Directors (BoD)	The composition and functioning of the BoD is defined by the Law of the 07th June 2023. It is composed of 11 members of different professional backgrounds, of which 9 are nominated by the Government. One default member is the head of the personnel delegation of LIH and one additional member is proposed by the Collaborative Council (CoCo, see below). Its mission includes, for example, the general organization, internal rules, budget control, framework contracts and approving new strategies.
Executive Committee (EXECOM)	The EXECOM is composed of the Chief Executive Officer (CEO), the Chief Financial and Administrative Officer (CFAO), the Directors of the Departments and the Deputy CEO. When needed, guests are invited for specific items. It is responsible for the development and implementation of the strategy and for day-to-day management of the institution in alignment with the BoD. It guarantees compliance with ethical principles, conventions and applicable laws.
Large Executive Committee (Large EXECOM)	The Large EXECOM is composed of the members of the EXECOM and the unit heads of the units belonging to "General Management" and "Administration". The role is on one hand to receive tasks from the EXECOM regarding the execution of strategic objectives and to report back the progress on these tasks. It also serves to exchange between the units and/or to escalate issues to the EXECOM.
Collaborative Council (CoCo)	The CoCo is a consultative body, stipulated by the law of the 3rd December 2014, composed of internal representatives of the research staff, the personal delegation and the research and innovation support personnel. It issues advisory opinions to the Board of Directors regarding research policy, development and innovation. It advises also on the content of the multiannual Performance Contracts concluded with the Government.
Scientific Steering Committee (SSC)	The SSC advises the CEO on strategic scientific aims and initiatives. It issues recommendations in the form of GO or NO-GO decisions for internally submitted research project proposals respectively grants. It is composed of the Deputy CEO, two representatives of each research department, one representative of LCTR and TMOH and two representatives of DMI.
Grand SSC (gSSC)	The Grand SSC is composed of the SSC plus additional outside members. It has the main task to provide the scientific strategic advices regarding the implementation of the strategy.
Translational Steering Committee (TSC)	The TSC is composed of representatives of Luxembourgish institutions involved in translational research such as the Hospitals, the LIH, the University of Luxembourg (incl. the Luxembourg Center of Systems Biology, LCSB), the Fuerschungsklinik Lëtzebuerg (Luxembourg Center of Translational Research. LCTR) as well as the Laboratoire National de Santé (LNS) and optionally patient associations. Its mission focusses on the steering of inter-institutional biomedical projects, which includes the review, selection, follow-up and termination of submitted projects as well as fostering synergies between projects and communication.
Grand TSC (gTSC)	The gTSC is composed of four international scientist and the CEO of LIH. Their mission is the assessment and support of the overall portfolio of inter-institutional translational projects.
Sample Access Committees (SAC)	Project-specific committees to govern access to biological material and associated data. In case, projects do not have their specific committee, the TSC acts as Sample Access Committee for them.
Biosafety Committee(s)	The Biosafety Committee(s) is (are) composed of subject matter experts regarding the handling of (hazardous) biological material and provides guidance on the internal rules regarding the identification and treatment biosafety risks within the institute.

Governance Body	Description
Animal Welfare Structure (AWS)	The AWS is the institutional ethics committee with respect to animal experimentation. Its role is to ensure that regulatory and ethical principles in the context of animal experimentation are promoted and followed with the overall objective to maintain laboratory animals' welfare.
Staff Delegation	The staff delegation is the legal representation of LIH personnel according to Luxembourg labor law. They are involved in processes and procedures according to their mandate, where by law or conventions defined.

2 Interested Parties

The analysis of the interested parties, i.e. of persons or organizations that can affect, be affected by, or perceive itself to be affected by a decision of activity of the institute, contributed to the definition of the scope and objective of LIH's integrated quality management system.

The table below enumerated the main interested parties.

Interested Party Category	Interested Parties (Explanations and Examples)	Requirements relevant to the quality of LIH's service provision
LIH	Research Departments	Fulfillment of vision and mission (see Section 1.2) Optimized inter-departmental collaboration and mutulization of internal resources for the support of transversal translational medicine (TTM) projects
Funding Bodies	Ministry of Higher Education and Research (MESR)	A multi-year performance contract (typically concluded for 4 years) contains the obligations of LIH; this includes the definition of key performance indicators as well as the mechanisms for measuring performance.
	Ministry of Health / Health Directorate (DISA)	Master Service Agreements between LIH and the DISA establish the context, work and deliverables for activities, where LIH supports the Ministry of Health in their mission in the field of public health.
	National and International Competitive Funding Bodies, e.g. those funding H2020, IMI, FNR, JNPD…	Project-specific agreements define the obligations of the LIH. They include deliverables and performance indicators as applicable as well as the mechanisms for measuring project performance.
	Humanitarian funders of research, e.g. Patient organizations, Rotary Club, individual donations…	Infrastructure and operations that demonstrate an innovative and/or effective contribution to biomedical research
Clients	Public or private organizations to whom LIH provides services, without sharing a common (research) goal	Flexibility, scientific and operational excellence paired with customer focus and embedded in a well-established QMS. This encompasses for example: • Responding to customers' needs and expectations and the ability to understand and forecast such needs • Providing samples, data and services in compliance with customers' needs and expectations • Assuring the quality of our services and support • Having competent and available and staff, able to provide information and advice on samples and services

Interested Party Category	Interested Parties (Explanations and Examples)	Requirements relevant to the quality of LIH's service provision
Research Partners	National and international partners for the establishment or management of translational research projects and/or sample collections with shared (research) goals, e.g. Team Luxembourg, Personalized Medicine Consortium, Luxembourg Clinical Researchers (from Hospitals and/or Public Institutions), Consortium partners, health professionals… Visiting Scientists	Multi-disciplinary researchers, who embrace collaboration and disruptive technologies. High quality research, expressed in setting-up and/or partnering in national and international research projects, successfully in receiving research funds and producing relevant research output (e.g. publications). Infrastructures which support clinical research such as the Clinical and Epidemiological Investigation Center (CIEC) or the Integrated BioBank of Luxembourg (IBBL). Effective project management for research and translational projects.
Biobank Users	LIH-internal researcher and external partners, looking for biobanking services	Availability of reliable, standardized, state-of-the-art biobanking infrastructure including: • Reception, storage and re-distribution of biological resources under controlled, optimal conditions • Provision of "fit-for-purpose" biological resources • Provision of (accredited) test and characterization data of biological material Contribution of IBBL to innovation by performing biospecimen research activities
Research Participants: Healthy Subjects & Patients and Patient Representatives	Research participants; healthy subjects or patients participating in clinical studies, clinical trials or cohorts Relevant patient representative organizations	Strict application of ethical, regulatory and quality standards in the scope of sample collection, transport, processing, storage and re-distribution as sign of respect and valorization of the donor's voluntary contribution to research. Involvement of patient representatives organizations in defining research scope and tools and in policies making, e.g. with so called Public & Patient Involvement (PPI) initiatives.
Governmental Bodies	CNPD – Commission Nationale pour la Protection des Données	Internal processes and provision of services to customers in line with national and international data protection and privacy rules
	CNER – Comité National d'Ethique de Recherche	Services in line with national and international ethical rules with respect to human biological resources
	ITM – Inspection du Travail et des Mines STM – Service de Santé au Travail Multisectoriel	Infrastructure and processes in line with rules and best practices with respect to operational health and safety at the workplace
	Ministry of Health and Social Security	Meaningful and high-quality contribution to activities focusing on public health, e.g. in sanitary crisis situations, by leveraging LIH's research capacities and by providing infrastructures and logistics for related biological materials and data management
	Ministry of Agriculture	Compliance with regulatory requirements regarding the execution of experimentation involving animals, including their welfare.
Proficiency Testing (PT) Partners & Participants	Biobanks and other laboratories processing and testing biological samples Consortia ISBER	Contribution to the overall improvement of comparability of biological resources by: • Providing a general, open proficiency testing program that serves the biobanking community to benchmark the performance of their processing and testing methods • Providing case-by-case, customized PT programs to support research objectives

Interested Party Category	Interested Parties (Explanations and Examples)	Requirements relevant to the quality of LIH's service provision
Suppliers	Supplier of equipment and consumables; Supplier of services; Subcontractors	Establishment of contractually based (long-term) relationships for supplying goods and services to LIH Acknowledgement of strategic suppliers as collaboration partners
General Public of Luxembourg and the "Grande Région"	Citizens of Luxembourg and the "Grande Région" are tax payers and thus indirectly contributing to the funding of LIH They are also potential participants in research projects, including the donation of biological material	Information in formats and words understandable by laymen about: • Personalized medicine and the role of the LIH in translational medical research at Luxembourg and abroad • LIH's contribution to achievements for the benefit of Luxembourg's population (e.g. new diagnostics, new prevention strategies, innovative therapies and clinical trials). • Information about possibilities how to support medical research Communication channels to LIH (e.g. via Twitter, Facebook, Website, meetings, press conferences)
Personnel	Staff of LIH	A working environment which • has defined roles and responsibilities • promotes the valorization of individual contributions to the objectives of the organization • provides motivating elements in compliance with labor laws and other related agreements • supports well-being and safe work practices to prevent work-related injury and ill health
Students	National and international students (at LIH)	An environment, e.g. via the Doctoral Training Unit, in which early-stage researchers are helped in developing/improving competences to conduct high-level quality research activities. Sharing of subject matter expert knowledge in internal training.
Neighbors	Co-tenants in premises, where LIH occupies spaces (e.g. LNS – Laboratoire National de Santé; LMVE – Laboratoire de Médicine Vétérinaire de l'Etat, LCTR – Luxembourg Center for Translational Research), Laboratoire de Biologie Moléculaire et Cellulaire du Cancer (LBMCC)	Collaborative relationships linked to the use of the same building and infrastructures

3 The Integrated Quality Management System

3.1. Integrated Quality Policy

The quality policy aims to build the framework for achieving LIH's mission and vision, the strategic activities and related quality objectives.

- The Board of Directors, the LIH Management and Staff commit to implement and maintain a working environment to constantly provide research and research service quality that meets the expectations of our researchers, partners, customers and other interested parties.
- The LIH Management lives this commitment by the implementation and maintenance of a risk-based and integrated Quality Management System and its certification/accreditation by external bodies. Ensuring compliance with the requirements of the certification and accreditation standards in the certification/accreditation scope and the applicable legal and statutory requirements is our aim. Changes in the organization are managed to preserve the consistency and integrity of the integrated QMS; this includes the commitment to apply an information security management system including the ALCOA principles for maintaining data integrity throughout the data life-cycle.
- LIH strives for continuous improvement of the organization and the optimization of its research services by careful planning of its activites with a focus on customer satisfaction, legal compliance and effectiveness & efficiency of its operations. Through regular monitoring and measuring of the performance level and the follow-up of technical and scientific advances in the areas of biomedical science, biobanking practices and information security, LIH is able to identify and implement adequate measures in case of quality problems or opportunities identified for improvement.
- LIH aims to design and maintain a secure working environment for its employees and people working at LIH premises in compliance with applicable laws and regulations. This includes to develop the people's awareness for occupational health & safety risks related to their activities and processes and training to address them and to ensure continual monitoring of the performance of OHS-related processes to seek opportunities for improvement.
- LIH staff members are committed to familiarize themselves with the provisions of the integrated QMS and to apply the defined procedures at their level of responsibility.
- LIH fosters communication of its mission, vision and objectives and the progress towards their achievement internally and externally.

3.2. Performance Measurement

3.2.1. Performance Contract

LIH and the Ministry of Higher Education and Research (MESR) conclude every 4 years a "Performance Contract", in which the mutual obligations are described. It contains a list of key performance indicators (KPI) for LIH to measure and to meet as well as the related mechanisms for reviewing performance.

These KPI are focusing on quantitative and qualitative elements regarding the research activities and the internal research services.

3.2.2. Process Performance

LIH utilizes different means to continuously determine the performance levels of its processes. Main elements are management and/or team meetings, quality control, internal and external audits, nonconformity management as well as the monitoring of customer feedback.

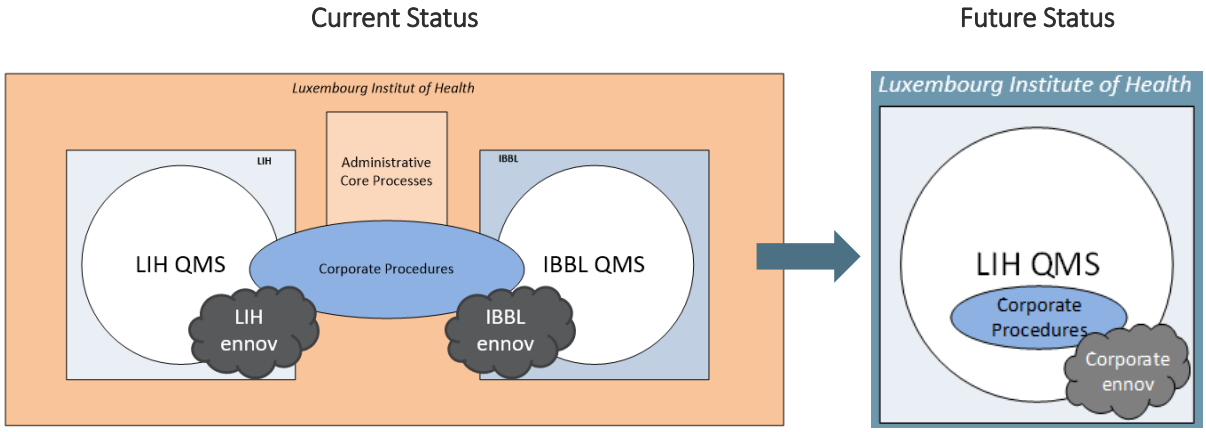
Additionally, where relevant, needed and possible to quantify process performance measurement, process owners define and monitor KPIs or Quality Indicators. These indicators may be monitored only, or may have fixed quality objectives to achieve. The performance review occurs at defined intervals or if needed and within the relevant leadership or team settings. At the latest, process performance review outcome is compiled during the regular management review.

3.3. Rationale of the integrated QMS

The overall responsibility for the design, implementation and maintenance of the integrated QMS of LIH lies with the Head of the Quality & Safety Management Office (QSMO), reporting to the CEO of LIH.

Different activities within the LIH require different levels of a (formalized) quality management system. Therefore, the institute decided to develop and maintain a quality management system according to the requirements of ISO 9001 as basis for the management and support processes of the institute. In order to safeguard the institute's assets, this general approach is complemented by addressing requirements of the ISO 27000 series regarding information security. The research service activities of the TMOH require in addition focused quality approaches to the different steps of the life cycle of biospecimen, especially by elimination of pre-analytical variations of samples and by providing reliable data. Therefore, related processes are submitted to additional quality requirements as expressed in sector-specific standards or regulations as ISO 17025, ISO 17043, ISO 20387 or GCP as examples.

The structure of the QMS has its roots in the independent development of two QMS at the former CRP Santé and the IBBL. Currently, the institute is in a transitions process to unique system, of which the current and the future status can be depicted as follows:



3.4. Scope of the Integrated Quality Management System

3.4.1. Main Applicable Regulations and Guidelines

The QMS for LIH has been conceived and is maintained by considering the requirements of the following laws, norms, guidelines and "Best Practices" (non-exhaustive list):

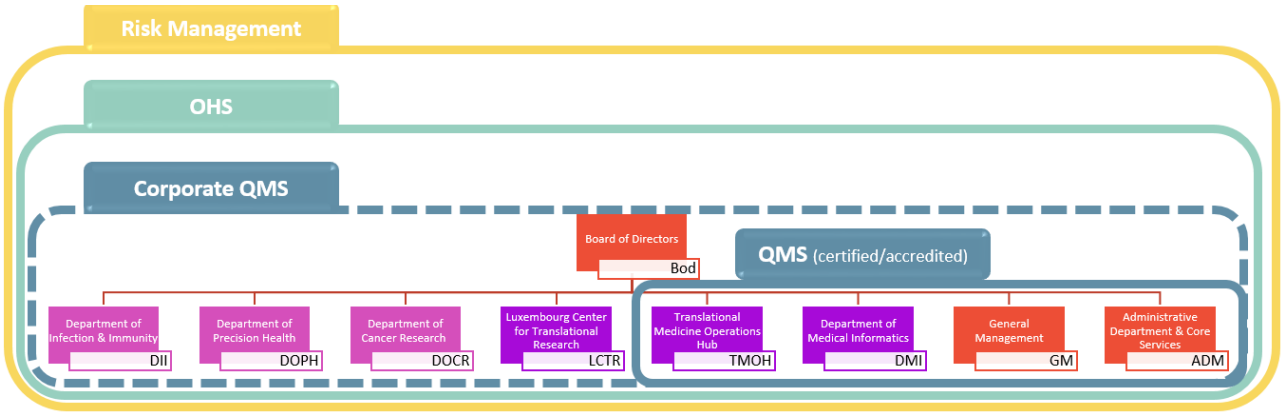
- Loi du 3 décembre 2014 – Organisation des centres de recherche publics
- Loi du 7 juin 2023 – portant modification de la loi du 3 décembre 2014 ayant pour objet l'organisation des centres de recherche publics
- EU 2016/679 Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) – GDPR
- ISO 9001:2015 Quality Management Systems – Requirements
- ISO 9001:2015 Amendment 1 (2024): Quality Management Systems – Requirements AMENDMENT 1: Climate action changes
- ISO 27001:2022 Information security, cybersecurity and privacy protection — Information security management systems —Requirements
- ISO 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 20387:2018 Biotechnology – Biobanking – General requirements for biobanking
- ISO 21899:2020 Biotechnology – Biobanking – General requirements for the validation and verification of processing methods for biological material in biobanks
- ISO 17043:2023 Conformity assessment – General requirements for proficiency testing providers

- ISO 31000: 2018 – Risk Management – Guidelines
- ISO 45001: 2018 – Occupational health and safety management systems – Requirements with guidance for use
- ISO 19011:2018 Guidelines for auditing management systems
- ISO 10012:2003 Measurement management systems – Requirements for measurement processes and measuring equipment
- Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
- Council of Europe, Recommendation Rec(2006)4 on Research on Biological Materials of Human Origin
- Good Clinical Laboratory Practice (GCLP) – World Health Organization (WHO), 2008
- ICH GCP – Guidelines for good clinical practice (ICH E6(R3)), Jan. 2025
- Clinical Trial Regulation on medicinal products for human use (Regulation (EU) No. 536/2014)
- Requirements for Certification of ECRIN Data Centres, with Explanation and Elaboration of Standards, Version 5.0, May 2023
- Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research – International Society for Biological and Environmental Repositories (ISBER), Forth Edition 2018
- NCI Best Practices for Biospecimen Resources – US National Cancer Institute, 2016
- OECD Best Practice Guideline for Biological Resource Centres – General Practices for all BRC's, 2007
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes
- Règlement Grand-Ducal du 11 janvier 2013 relatif à la protection des animaux utilisés à des fins scientifiques
- National Quality Framework for Doctoral Training – Fonds National de la Recherche Luxembourg (FNR), July 2019
- ALCOA(+) principles for data integrity (A: Attributable; L: Legible: C: Contemporaneous; O: Original; A: Accurate).
- Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 ("NIS 2 Directive")

3.4.2. ISO 9001 Certification and ISO 17025 Accreditation Scope

The integrated quality management system of LIH combines Quality Management System (QMS), Information Security (IS) and Occupational Health & Safety (OHS) requirements with an overarching Risk Management approach. LIH differentiates between management and support processes and core business processes, i.e. its research activities and the routine workloads of the research support processes provided by the Translational Medicines Operations Hub (TMOH).

The scope of the QMS submitted to formal ISO 9001 certification and ISO 17025 accreditation are as follows:



The present Quality Manual summarizes the QMS implemented for the certification, respective accreditation of LIH according to:

- **ISO EN DIN 9001:2015** Quality Management Systems – Requirements
- **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories

The core business/management processes in the ISO 9001 certification scope are:

- Research support services such as:
    - **collection/acquisition, handling, processing, testing, storage and distribution of biological material and associated data**
    - **complementary processes including project management, clinical research management, data management and statistics**
    - **related support and administrative processes.**

This scope is extended for the ISO 17025 accreditation scope to the following analytical methods:

- **M007:** Nucleic acid quantification by Spectrophotometry (in-house developed)
- **M005:** DNA quantification by Spectrofluorometry (in-house developed)
- **M008:** RNA Integrity Measurement (in-house developed)
- **M053:** 16S rRNA Gene Sequencing

The management system processes regarding Information Security and Occupational Health & Safety are not submitted to any formal certification.

3.5. Quality Documents Management

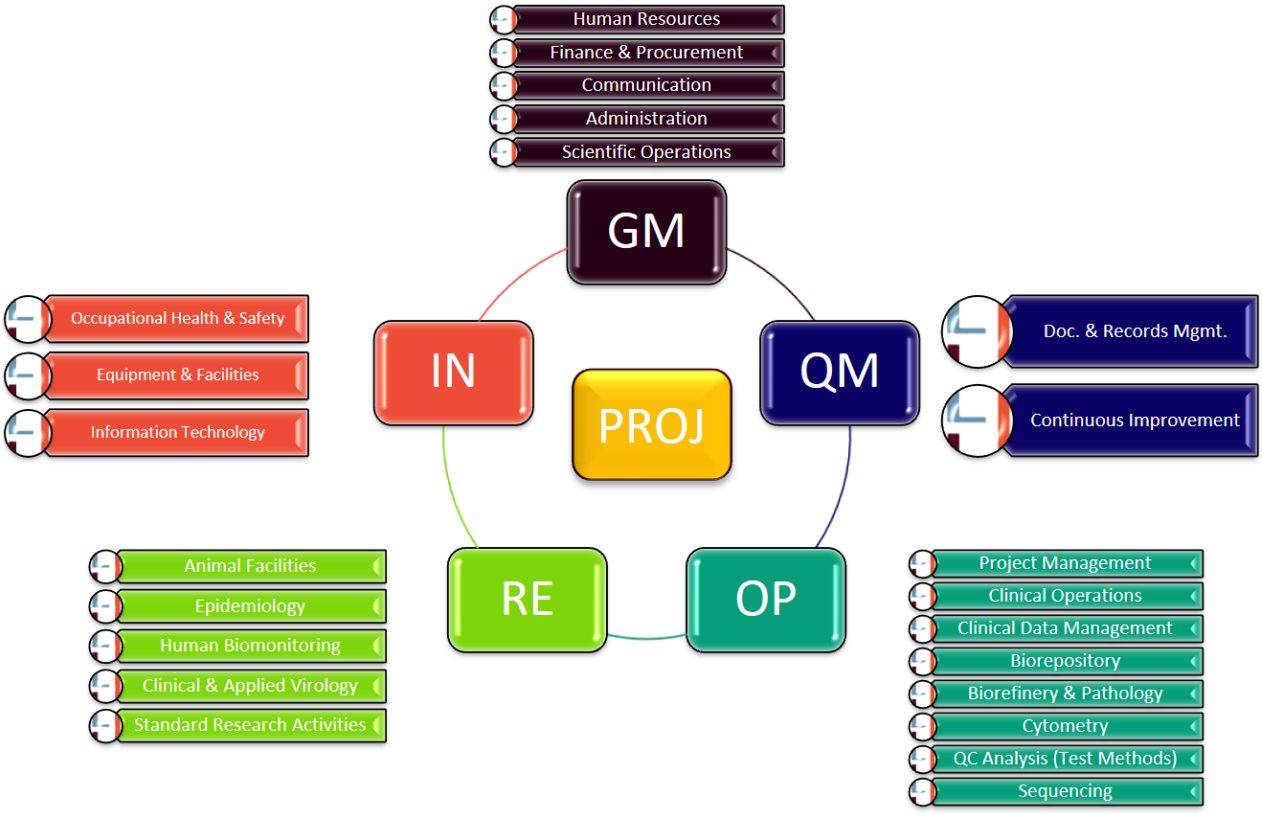
The QMS is planned and maintained via the current quality documents, which include:

Document Type	Objective
Quality Manual (QM)	Summary of the organization of the institute and the description of its integrated Quality Management System. LIH promotes the accessibility of the Quality Manual to its partners, clients and other interested parties by providing the current version on its website. The web-version is an authorized, but uncontrolled copy. Only the electronic version available on the website at its day of access is valid and current.
Policies (POL)	Intentions and directions of the organization, formally expressed by the management
External Documents	Regulatory texts, guidelines, publications…
Work Instructions (WI) **Assay Protocols (AP)**	Detailed instructions for the execution of standard tasks including corporate procedures (PRO) and work instructions (WI) (for administrative core services); Protocols for Test Methods (APs – IBBL only); Related annexes, forms, templates and spreadsheets for standardized record keeping
Project-specific Procedures	Detailed instructions for the execution of project-specific tasks with the associated annexes, forms, templates and spreadsheets Examples: Project-specific Standard Operating Procedures (PSOPs) and Project Specifications (PS)
Forms (F), assay sheets (AS), templates (T), spreadsheets (S) and annexes (A)	Documents, which are associated with their "parent documents" (i.e. procedures, work instructions, assay protocols or project-specific procedures) to facilitate the standardized recordkeeping
Guides (G)	Guidelines to describe specific tasks and not requiring the creation of any records
Records	All types of quality records, resulting from the execution of tasks covered by the documents above. Examples: completed forms, tables, lists, databases, reports, logbooks, job descriptions, control charts, analytical raw data…

The principles of document and record control and more details regarding legacy document types are summarized in WI DC-901 Quality Documents Management.

3.6. QMS Structure/Cartography

The documented QMS is structured in five chapters with related sub-chapters, constituting the five pillars on which the execution of LIH's research and research services are based:



The procedures defined in the QMS chapters "GM – General Management" and "IN – Infrastructure" are the backbone of the "**support and administrative processes**", while the **"(quality) management processes**" are covered in the QMS chapter "QM – Quality Management"; both process types are essential to fulfill the services to the customers. The "**service or operational processes**" are described in the QMS chapter "OP – Operations". The chapter "RE – Research" allows the management of procedures for "**research processes**", which usually are outside the formal ISO certification/accreditation scope. A supplementary layer of "project-specific procedures" (**PROJ**) ensures the fulfillment of customer-specific needs, where needed.

4 Core Processes

4.1. General Management

- Human Resources (HR)

  This sub-chapter covers the principles and provisions for the administration of human resources at LIH. LIH Management defines its human resources forecast in order to provide competent staff in sufficient number to execute the tasks within its mission. MESR defines FTE targets as a KPI in the Performance Contract. A formal recruitment process is applied to ensure transparency and equality regarding the selection of candidates.

  LIH ensures that management and staff are free from any undue internal and external commercial, financial or other pressures that may adversely affect the quality of their work. LIH adheres to stringent confidentiality rules in order to protect the privacy of employees, donors and partners, but also the intellectual property of LIH and its collaboration partners, where needed.

  Job Descriptions are used to define the job holders' responsibilities in relation to required skills, competencies and experience and hierarchical structures within LIH. LIH has processes in place, which ensure that hired staff is continuously trained in job-specific, regulatory, safety & health and quality matters. The performance appraisal process serves to determine the performance level of staff, identifying individual objectives and related development needs, and the effectiveness of training measures.

- Finance & Procurement (FP)

  The "FP" section of the QMS contains the processes for purchasing of goods & services and includes provisions for the selection and evaluation of suppliers and subcontractors. It covers also financial processes applied within the whole organization.

- Communication (COM)

  The communication sub-chapter of the QMS covers processes for the management of internal and external communication based upon the LIH Communication Guide and includes e.g. editorial processes and the management of press relations.

- Administration (ADM)

  Within the administration sub-chapter general administrative processes which include for example contract management, corporate governance and some compliance processes (via the legal office) and IP Management (via the Business Development Office).

- Scientific Operations (SO)

  The "SO" sub-chapter covers processes related to the management of research activities. It contains procedures regarding the implementation of the research strategy, processes to ensure research integrity and covers activities for the operational management of research projects.

4.2. Quality Management

- Document and Records Management (DC)

  This subchapter cover processes for the management of documented information at LIH.

  A document hierarchy has been established to manage quality documents and records within the institute. Naming and coding systems, including version numbering, ensure unique identification of each internal and external quality document.

  For internal quality documents, formalized review and approval processes are in place, related to the type of document. Controlled distribution and retraction of internal and external documents takes place and, where needed, access to obsolete versions is granted under controlled conditions. Listings of current documents and the documents themselves are easily accessible to the employees of LIH.

The principles for archiving documents are defined. Rules related to periodic revisions are specified as well as processes for annotations, corrections or deviations, when needed.

This chapter also contains corporate processes and procedures for ensuring compliance with current data protection regulations (e.g. personal data retention, personal data breach, data subjects' rights management).

- Continuous Improvement (CI)

  This subchapter contains the Quality Manual and different key processes aiming to identify and manage continuous improvement opportunities.

  This includes the corporate risk management processes, the management of nonconformities and customer complaints, the process for managing internal and external audits and the administration of related actions.

  It also covers performance monitoring activities such as the quality control of methods (e.g. in the biobank), measurement of customer satisfaction, the general management of KPIs and the execution of the process and/or management review(s).

4.3. Infrastructure

- Occupational Health and Safety (OHS)

  This subchapter covers the general provisions related to LIH's processes addressing occupational health and safety aspects.

  Therefore, LIH ensures that the premises conform to legal and security requirements and are appropriately arranged for different operational activities. LIH controls access, maintains procedures for occupational safety & hygiene (e.g. cleaning, decontamination & disinfection, waste management) and performs environmental monitoring. It includes emergency procedures in case of health & safety related incidents and accidents.

- Equipment & Facilities (EQ)

  The "EQ" chapter consists of processes for the management of laboratory and storage equipment.

  The laboratories (including the biobank) are furnished with the equipment, necessary for the correct performance of its services to researchers. A life cycle approach for equipment administration is applied to ensure that equipment is fit for purpose within the scope LIH's research services. This includes the execution of pre-defined risk-based qualifications or checks before an instrument is put into operation, a controlled phase of use as well as an organized retirement.

  Where metrological traceability is required, LIH has chosen to distribute responsibilities throughout the organization. Therefore, the responsibilities for the metrological function are described in job descriptions and procedures as applicable. Activities and requirements related to metrology (measurement processes and measuring equipment) are seamlessly integrated into the QMS, thus ensuring the establishment, documentation, maintenance and continuous improvement of the underlying measurement management system. Where required, related personnel at LIH has the adequate competence; alternatively activities are outsourced.

- Information Technology (IT)

  Here are summarized processes related to the information & communication technology (ICT) management. Processes addressing IT Project Management are included as well as activities called "IT support", which focus on the IT infrastructure (e.g. hardware, corporate software and information security) and the IT HelpDesk team. It also covers "Research Support" providing the necessary support in terms of system and expertise for the research activities of the LIH.

  Data management during the life-cycle of a research project (including biobank data) are increasingly performed using computerized systems. Therefore, the administration of these data must ensure data integrity throughout collection, processing storage and transmission e.g. by application of the ALCOA principles. In this context, LIH puts specific emphasis on data protection, including the privacy of subject's samples and data.

4.4. Operations

- Project Management (PM)

  This subchapter addresses project management of a (clinical) research project, such as lead, design, setup, initiation, operation and closure. It includes specific procedures for the structure and execution of IBBL's Proficiency Testing Services.

  In addition, provisions for sample and data access (such as governance, policies and procedures) are covered in this part of the QMS. This includes policies and procedures for sample and data distribution and destruction.

  The Clinical Project Management Office (CPMO) is the owner of related processes, in case TMOH units are involved in research projects and serves like a single-point-of-contact between internal and external stakeholders in terms of project coordination.

  For research projects without involvement of TMOH units, the Science Office acts as owner of related project management processes.

- Clinical Operations (CO)

  The "CO" subchapter of the QMS contains general principles for (human) specimen and data collection.

  The respect of legal and ethical principles for collecting biospecimens and related data is of utmost importance to ensure the rights, safety and well-being of the (human) subjects.

  Biospecimen science has demonstrated that the pre-analytical conditions of biological samples are relevant for the "fitness-for-purpose" of biospecimens and derived samples. In addition, the type and quality of associated data – sample and donor related – are important for providing useful and reliable input to biomedical research.

  Therefore this chapter focusses on the processes of clinical research operations (e.g. regulatory submissions, site and subject management, collection of biological material, monitoring).

- Clinical Data Management (DM)

  The "DM" sub-chapter addresses activities for controlled clinical data management and statistics within the clinical research projects. This starts with support for the study design, the creation of the study database, continues with site support and change management, and ends with the freezing of study databases and the release of major statistical output.

- Biorepository (REP)

  This subchapter defines the general principles for reception, storage, internal and external distribution as well as destruction of biological material by the "Biorepository" team of IBBL. The collection kit production and administration process is also included in this QMS section.

- Biorefinery & Pathology (REF)

  Here the general principles applied to "Sample Processing" performed at IBBL are covered.

  "Sample Processing" is defined as manual and/or automated manipulation of specimens or samples to produce derivatives.

  Sample Processing is a crucial step in the life cycle of biological samples. Therefore, IBBL maintains Work Instructions to describe risk-based specifications and requirements of Sample Processing Methods, validates critical methods, executes Sample Processing Methods under controlled environmental conditions, using suitable equipment and software, and adequately trained personnel, and ensures traceability of the Sample Processing steps by relevant records.

- Cytometry (CYT)

  The "CYT" chapter of the QMS covers the operational activities of the National Cytometry Platform (NCP). This platform provides state-of-the-art cytometry infrastructures for internal and external researchers. The related procedures cover the provided services: (i) use of the platform (instruments & software), (ii) training, (iii) consulting and (iv) execution of experimental work with or without subsequent data analysis.

- QC Analysis (Test Methods) (QC)

  The "Quality Control (QC) Assays" section of the QMS covers the processes related to sample testing performed at IBBL.

  "Sample Testing" is defined as manual and/or automated testing of specimens or samples to determine characteristics of specimens and samples. Output of a testing process is a result. Results can be quantitative or qualitative. Depending on needs, test results may be complemented with a statement of conformity.

  Sample Testing is an important step in the life cycle of biological samples, either for determining the "fitness-for-purpose" for any downstream use of the samples, or by annotating samples with relevant data.

  IBBL maintains Assay Protocols to describe risk-based specifications and requirements of Sample Testing Methods, validates important testing methods, executes Sample Testing under controlled environmental conditions, using suitable equipment and software, and adequately trained personnel, ensures traceability of the Sample Testing steps by relevant records, and communicates results to collaboration partners/clients only after formal approval and by official reporting means.

  The submission of selected analytical methods for accreditation according to ISO 17025 demonstrates LIH's commitment to reliable test and characterization data for biospecimens and samples.

- Sequencing (SEQ)

  This subchapter is dedicated to the procedures of the LUXGEN unit, regarding their standard sequencing activities.

4.5. Research

- Animal Facilities (AF)

  This subchapter covers the activities of the animal facilities, in which animal experimentations within research projects are performed. It covers the regulatory, ethical and operational aspects of the activities including the competence requirements and monitoring of staff involved in animal experimentations.

- Epidemiology (EPI)

  This part of the QMS is dedicated to epidemiological research activities. This includes the conception and execution of epidemiological research studies and the maintenance of health registries as a service (e.g. to the government).

- Human Biomonitoring (HB)

  This section of the QMS contains research procedures applied for human biomonitoring. It mainly focusses on sampling, analysis and use of related equipment to ensure the quality of the research results.

- Clinical & Applied Virology (CAV)

  This sub-chapter contains research procedures, which cover analytical activities in the scope of clinical and applied virology e.g. for measles or rubella virus.

- Standardized Research Activities (SRA)

  This part of the QMS is dedicated to standardized research activities, which have been identified to profit from the availability of written processes and procedures (e.g. best practice in cell culturing)

4.6. Projects

LIH distinguishes between the following project types with TMOH involvement:

- Research Projects
- Inter-institutional Translational Research Projects
- Fee-for-Service Projects (FFS)
- Internal/other Projects
- Short Projects

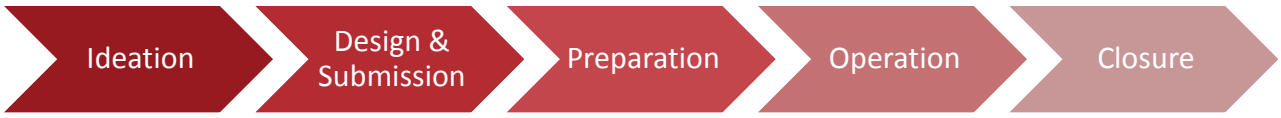
Depending on the type of project and the involvement of THMO units, project-specific procedures are being established.

Each research project, inter-institutional translational research project or FFS project involving biobanking activities by Biorefinery and/or Biorepository requires the establishment of a project-specific procedure.

5 Process Overviews

5.1. Research Project Life Cycle

This is the overall research project life cycle applied at LIH:



Phase	Input	Actions	Output
Ideation	Research idea of a researcher and/or funding opportunity	Formulate research idea; identify targeted funding source; prepare pre-budget; perform high-level risk assessment and mitigation plan; prepare "declaration of interest" (DOI); submit to SCC and/or TSC	Go / No Go decision by SCC and/or TSC
Design & Submission	DOI Go	Create the grant proposal according to the funder's requirements; submit the proposal to the funding body.	Funding awarded
Preparation	Funding awarded	Develop contract(s); develop and execute recruitment plan; organize purchasing (e.g. tender submission); finalize project budget; adapt facilities (if needed);	Signed contract(s)
Operation	Signed contract(s)	Perform research activities as per protocol, grant submission and contract(s); provide int. & ext. intermediate reports (e.g. scientific, financial); publish communications; identify IP options (e.g. patent vs. publication). Manage risks and opportunities as well as changes.	Grant-based activities done
Closure	Grant-based activities done	Prepare final report; ensuring closing of accounts, perform valorization & IP check	Final report Optional: Patent application; license or co-ownership agreement(s); communications; scientific publications

5.2. TMOH Project Life Cycle

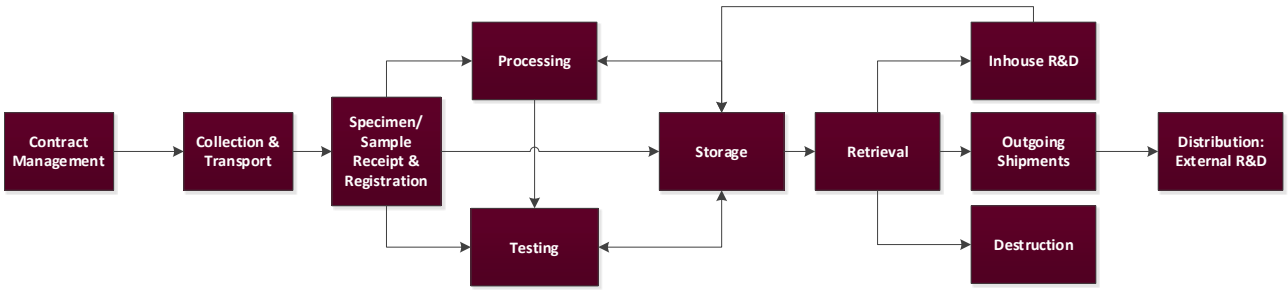
The following project life cycle overlaps with the above-mentioned research project life-cycle, in case TMOH units are involved in the research project. However, the main involvement of TMOH starts, once the funding has been awarded and it often ends, once the grant-based activities have been completed.

Phase	Input	Actions	Output
Lead	Formalized idea of a research or FFS project (e.g. via a "Declaration of interest", DOI)	Initial project filtering; PM allocation; Project exploration; Internal feasibility check; External feasibility check	SSC and/or TSC approval
Design	SSC and/or TSC approval	Stakeholder "round table"; Resources allocation; Project plan / Study protocol; Communication; Budget creation and validation; Submission; Legal approval	Contract(s)
Setup	Contracts	Kick-off meeting; Validation of methods and equipment; Data Management set-up; Definition of study procedures; Data integration and interoperability; Purchasing of consumables;	Checklist for set-up has been completed ⇒ "ready to go"
Initiation	"Ready to go"	Initiation meeting; site initiation; test run (optional)	Ready for "first patient first visit" (FPFV)
Operation	FPFV	Project-specific activities within the involved research, TMOH and support units (e.g. CPMO, CIEC, CCMS, DMI, IBBL, QM, MarCom) Oversight of project progress via CPMO.	"Last patient, last visit" (LPLV)
Closure	LPLV	CPMO: Financial reconciliation and report; end of study report; close-out meeting. Unit-specific closure activities according to the involvement in the project.	Primary research objectives achieved Secondary objectives can be pending.

In case of projects, which involve the creation of sample collections, closed projects may be transferred into a "storage phase", combined under a related umbrella project, in which the only remaining project activities consist of sample storage and distribution (see details in section 5.3).

5.3. Biobanking Process Overview

The following sub-processes describe the different process steps for a biobanking project.



Sub-process	Input	Actions	Output
Contract Management	Customer requirements Legal requirements IBBL/LIH standard procedures	Definition and documentation of the project scope (e.g. specifications, responsibilities, timelines, budget)	Project-related Contract(s) and related operational documents (e.g. WIs/APs, PSOPs)
Collection & Transport	Project-specific requirements (e.g. consenting, type of biospecimens, conditions of collection, transport…)	Collection & Transport of Biospecimens and Samples according to project specifications	Biospecimens & Samples collected and transported to IBBL
Biospecimen/Sample Receipt & Registration	Biospecimens/Samples collected and transported to IBBL	Verification of received biospecimens/samples and associated data against the project specifications; registration in the LIMS; verification of consent.	Received biospecimens/samples are registered and identified with unique identifier at IBBL; any discrepancies from specifications are documented
Processing	Received & Registered Biospecimens/Samples	Processing of samples according to project specifications	Samples as specified in the project scope are produced; related records are available; nonconformities are documented and followed-up
Testing	Received & Registered Biospecimens/Samples or Samples produced at IBBL (see "Processing")	Testing of samples according to project specifications	Characteristics/annotations of biospecimens/samples have been established according to project specifications; nonconformities are documented and followed-up
Storage	Received & Registered Biospecimens/Samples or Samples produced at IBBL (see "Processing") or Samples tested at IBBL (see "Testing")	Storage and registration of biospecimens/samples in defined storage locations following the project-specific requirements Management of sample movements maintaining integrity and traceability. Continuous control of environmental conditions related to storage.	Samples are physically stored in defined storage locations under controlled environmental conditions; sample information and sample location are recorded in the LIMS; sample movements are performed maintaining integrity and traceability of the samples; nonconformities are documented and followed-up
Retrieval	Internal or External Distribution Request for Samples and/or Data Stored Biospecimens/Samples	Preparation of sample picklist and picking of samples; Preparation of related data – both according to the provisions of the project scope and in accordance with the Distribution Request	Samples ready for shipment; Data ready for transfer
In-house R&D (outside the certification scope)	Samples retrieved from stock	Execution of Biospecimen Research projects	Evidence-based information about the impact of pre-analytical conditions on the "fitness-for-purpose" of samples

Sub-process	Input	Actions	Output
Outgoing Shipment	Samples ready for Shipment; Data ready for transfer	Packing and organization of shipment of samples according to project-specifications, the Distribution Request and legal requirements; Transfer of Data to the Recipient ensuring data privacy, data security and data integrity.	Samples are shipped to the Customer or a Third Party (according to project scope); receipt of samples has been confirmed; data are transferred to the Customer or a Third Party (according to the project scope); data are received in integrity and securely by the recipient, respecting data privacy requirements; Nonconformities are documented and followed-up.
Destruction	Client Request Withdrawal of consent Quality issue	Samples and data (when applicable) are safely destroyed	Destruction records
Distribution: External R&D	Samples are shipped to the Customer or a Third Party (according to project scope); receipt of samples has been confirmed	Customer or Third Party perform research using the provided biospecimens & samples	Research output such as publications, diagnostic or prognostics markers/tools, personalized medicine…

6 Abbreviations, Acronyms, Definitions

A	Annex
ADM	Administration
AF	Animal Facilities
ALCOA	A: Attributable; L: Legible; C: Contemporaneous; O: Original; A: Accurate
AP	Assay Protocol
AS	Assay Sheet
AWS	Animal Welfare Structure
BDO	Business Development Office
BIS	Business Information Solutions
BoD	Board of Directors
BRC	Biological Resource Centre
CAV	Clinical and Applied Virology
CCMS	Competence Center for Methodology and Statistics
CEO	Chief Executive Officer
CI	Continuous Improvement
CIEC	Clinical and Epidemiological Investigation Center
CNPD	Commission Nationale pour la Protection des Données
CNER	Comité National d'Ethique de Recherche
CO	Clinical Operations
CoCo	Collaborative Council
COM / MarCom	Communication / Marketing &Communication
CPMO	Clinical Project Management Office
CRP	Centre de Recherche Publique
CYT	Cytometry
DC	Document & Records Management
DIA	Data Integration and Analysis unit
DII	Department of Infection and Immunology
DM	Clinical Data Management
DMI	Department of Medical Informatics
DMSP	Disease Modelling & Screening Platform
DNA	Deoxyribonucleic acid
DOCR	Department of Cancer Research
DOPH	Department of Precision Health
DPO	Data Protection Office(r)
ECRIN	European Clinical Research Infrastructure Network
EPI	Epidemiology
EQ	Equipment & Facilities
EXECOM	Executive Committee
F	Form
FFS	Fee-for-Service
FNR	Fonds National de Recherche
FP	Finance & Procurement
FPFV	First patient, first visit
GCP/GCLP	Good Clinical (Laboratory) Practice
GDPR	General Data Protection Regulation
GM	General Management
HR	Human Resources
IBBL	Integrated BioBank of Luxembourg
ICH	International Conference on Harmonization
ICT	Information & Communication Technology
IEC	International Electrotechnical Commission
IN	Infrastructure
ISBER	International Society for Biological and Environmental Repositories
ISO	International Organization for Standardization
IT	Information Technology
ITM	Inspection du Travail et des Mines
KPI	Key Performance Indicators
LCTR	Luxemburg Clinical and Translational Research Centre (Fuerschungsklinik Lëtzebuerg)
LIH	Luxembourg Institute of Health
LMVE	Laboratoire de Médicine Vétérinaire de l'Etat
LNS	Laboratoire National de Santé
LO	Legal Office
LPLV	Last patient, last visit
LuxGen	Luxembourg Genome Sequencing Centre
MESR	Ministère de l'enseignement supérieur et de la recherche (Ministry of higher education and research) (Luxembourg)
NCI	National Cancer Institute (USA)
NCP	National Cytometry Platform
NF	Norme française (French norm)

OECD	Organization for Economic Co-operation and Development
OP	Operations
OHS	Operational Health & Safety
PM	Project Management
POL	Policy
PRO	Procedure
PROJ	Projects
PS	Project Specification
PSOP	Project-specific Standard Operating Procedure
PT	Proficiency Testing
RE	Research
QC	Quality Control; Quality Control Assays
QM	Quality Management, Quality Manual
QMS	Quality Management System
QSMO	Quality &Safety Management Office
R&D	Research & Development
REF	Biorefinery
REP	Biorepository
RNA	Ribonucleic acid
RPP	Research Pathology Platform
S	Spreadsheet
SAC	Sample Access Committee
SME	Subject Matter Experts
SO	Science Operations / Science Office
SOP	Standard Operating Procedure
SS	Study Summary
SSC	Scientific Steering Committee
STM	Service de Santé au Travail Multisectoriel
T	Template
TMOH	Translational Medicine Operations Hub
TTM	Transversal Translational Medicine
TSC	Translational Steering Committee
WHO	World Health Organization
WI	Work Instruction

7 Document Metadata

Document Information			
Document Code & Version:	QM CI.13	Application Date:	02/05/2025
Replaces:	QM QM.12		
Authorship & Approval	**Names**	**Functions**	**Approval Date(s)**
Author(s):	Sabine LEHMANN	Head of Quality & Safety Management	03/04/2025
Approver(s):	Stefan DEBAST, Maximilian FÜNFGELD, Frank GLOD, Hermann THIEN	Chief Financial and Administrative Officer, Director of Department of Medical Informatics, Deputy CEO, Director TMOH	23/04/2025, 22/04/2025, 04/04/2025, 04/04/2025
CEO, CFAO and/or CSO:	Ulf NEHRBASS	Chief Executive Officer	30/04/2025
QM Approver(s):	Alessandra ROSSATO	Senior Quality Officer	30/04/2025
Author of the first version of this document:		Sabine LEHMANN	

Changes Compared to Previous Version	Revision History
Update to cover the new organizational structure with the creation of Department of Medical Informatics (DMI) with inclusion of CCMS in it; creation of Luxembourg Center of Translational Research (LCTR); replacement of Transversal Translational Medicine (TTM) with LCTR and Translational Medicine Operations Hub (TMOH); inclusion of Precision Medicine Technology into the Operational Units of the LIH; Update of Governance section to include the Staff Delegation; Update of Interested parties section to include Ministry of Health/Health Directorate (DISA); inclusion of Patient representatives" in the Public & Patient Involvement (PPI); update of the section 3 including the word "integrated" in the title and addition of the "information security management system" and the reference to ISO 27000 series. Addition of the reference ISO 9001:2015 Amendment 1 (2024) on climate action changes and ISO 27001: 2022 on Information security, cybersecurity and privacy protection Information security management systems —Requirements; Directive (EU) 2022/2555 known as "NIS2 Directive"; Editorial updates, where necessary.	01 - 15/09/2014 - Legacy Document import., 02 - 09/06/2015 - Legacy Document import., 03 - 19/07/2016 - Legacy Document import., 04 - 17/10/2016 - Legacy Document import., 05 - 25/09/2017 - Regular update; update of members of Board of Directors; clarification of "Core Administrative Services" and their role in IBBL QMs; clarification of "Corporate Quality Documents" in the role of IBBL QMS., 06 - 19/01/2018 - Change of address after move; indication of voluntary interruption of accreditation due to move; addition of "neighbors" as interested parties after move., 07 - 28/06/2018 - Updates to cover ISO 9001:2015 requirements; removing certification for NF S96-900 and removing suspension of accreditation; update of some charts; editorial updates., 08 - 31/10/2019 - Update to ISO 17025:2017, Addition of ISO 20387 as reference, Update of PT schemes, Update of LIH overall org chart, Update of ISO 17025 accreditation scope (removal of 4 methods: M004, M006, M017, M046), Update of Document Hierarchy to add new document types (PS and G), Update of QMS structure drawing to highlight areas with (potentially) corporate procedures, addition of LIH as interested party, minor editorial updates across the whole document., 09 - 26/05/2020 - General review; editorial updates; Removal of details related to board of directors composition replaced byreference to website; Integration of LIH's mission and vision and embedding of IBBL's specific contributions to them; Editorial updates in the Quality Policy without changing the policy core; Update of the Interested Parties table, e.g. by focusing on TTM partners and by adding the Ministry of Health as explicit interested party in the view of LIH/IBBL roles in the COVID-19 pandemic contributions. , 10 - 25/02/2022 - General review to accommodate the organizational changes within LIH with an impact on IBBL, update the interested parties section, expand the rationale of the QMS in the scope of the overall LIH QMS, update the overviews of some Core Processes, update of Exhibit A and B to accommodate new unit names (e.g. CPMO instead of IBBL PM) and Exhibit F with new abbreviations; re-organization of the order of sections and deletion of the service offers section; editorial updates., 11 - 14/02/2023 - Combination of IBBL and LIH quality manuals into one document and re-organisation of sections within the document. Extension of the QMS structure / cartography by adding a chapter for "Research"; re-organisation of the QMS sub-chapters accordingly. New structuring of project life cycles: addition of the research project life cycle and the TMOH project life cycle besides an updated Biobanking process overview. Addition of a commitment to ALCOA principles for maintaining data integrity into the quality policy., 12 - 21/12/2023 - Addition of a specific paragraph concerning the amendment of the LIH founding law and its impact, and mention in the section related to the applicable regulations; Update of the information related to the Board of Directors and the Executive Committee; Addition of a description for the Large Executive Committee; Addition of the Ministry of Agriculture as Interested Parties; Deletion of SOP and PRO as type of quality documents; Update of the QMS cartography (addition of "Standard Research Activities" under the "Research" chapter); Minor editorial updates throughout the document; Use of the new layout for Quality documents.

7.1. Revision History – IBBL Quality Manual

Version	Effective Date	Author	Summary of changes
.01	15/SEP/2014	Sabine LEHMANN	New document
.02	09/JUN/2015	Sabine LEHMANN	Changes related to the merger with CRP-Santé (e.g. "The organization", "Management Structure"); update of section "Service offers"; update of section "Quality Manual" to integrate requirements for ISO 17025 accreditation; update of "Process Overview" flowchart; update of "Interested Parties" section to include the 'General Public of Luxembourg' and the 'Grand Region'; two Exhibits added (C, D); renumbering of all Exhibits; minor editorial changes throughout the whole document.

Version	Effective Date	Author	Summary of changes
.03	19/JUL/2016	Sabine LEHMANN	Revision of section "Service Offers" to align it with the updated marketing strategy of IBBL; section "Management Structure": update of board members; section "Quality Manual": inclusion of methods for extension of the accreditation scope; section "Document Hierarchy": inclusion of "Corporate Documents"; update of the "Mission & Vision" section; minor editorial changes throughout the whole document.
.04	17/OCT/2016	Sabine LEHMANN	Clarification of certification & accreditation scope; addition of the law of 3rd December 2014 as reference; elucidation on the roles & responsibilities of technical management and quality manager; clarification of terminology used in Annex D.
>.04	See document metadata table above; field "revision history"		

7.2. Revision History – LIH Quality Manual

Version	Effective Date	Author	Summary of changes
.01	18-Jan-2017	Sabine LEHMANN	New document
.02	24-May-2018	Laurent PREVOTAT	Update in order to be compliant with ISO 9001:2015. Moreover, Mission/Vision and strategic goals have been modified according to the new performance contract. The Quality Policy has also been revised. Update of some information regarding certified units. Exclusion of Genomic unit and inclusion of the National Cytometry Platform.
.03	17-Aug-2020	Laurent PREVOTAT	Adaptation of the Quality Policy, update of the organizational chart, removal of the Process Flowcharts.

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