

RESEARCH DEDICATED TO LIFE

LIH QUALITY MANUAL

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1 The Quality Manual

This manual is prepared for defining the LIH's interpretations of the ISO 9001:2015 standard, as well as to demonstrate how the institute complies with it. It is applicable for the activities covered by the ISO 9001 certification scope presented chapter 2.5.2.

2 LIH introduction

2.1. Overview / History

The Luxembourg Institute of Health (LIH) results from the merger of the biomedical research institute "Centre de Recherche Public de la Santé" (CRP-Santé) and the research infrastructure and biobanking service provider, Integrated BioBank of Luxembourg (IBBL). This merger is effective since the 1st January 2015 following the entry into force of the law on the organization of public research centers in Luxembourg (law of 3rd December 2014).

With its more than 360 collaborators from 36 countries, LIH is the largest public research institute in Luxembourg dedicated to biomedicine. Striving for excellence, its researchers, by conducting basic and translational research projects, aim to improve patients' lives, diagnosis, treatment, and implement personalized medicine.

The LIH is composed of three large thematic departments: oncology, infection & immunity and population health. Further information is available on the LIH website (www.lih.lu).

Besides, IBBL exists as an autonomous structure (with its own Quality Management System), which enables it to fully assume its specific role of research infrastructure and service provider.

2.2. Mission & Vision

LIH's slogan expresses its mission clearly and concisely: "Research dedicated to life".

LIH's **mission** is to impact on patients by performing and translating excellent biomedical research. Patient-centric and application-inspired research should become the distinguish characteristic of LIH in the Luxembourgish research landscape, advancing it further from its basic research efforts.

LIH **vision** is to put Luxembourg at the forefront of biomedical research and create a translational hub in the heart of Europe.

2.3. Strategic goals

The current economic, societal, scientific and technological context surrounding research leads LIH to produce evidence of its control over its activities in a highly competitive landscape. Following a deep analysis of its context reported on the 2018-2021 Strategic Plan, LIH has developed the following strategic objectives for the organization in order to reach its vision:

- To align LIH activity portfolio with the **strategic priorities of Luxembourgish research**. In cancer, this will be reflected in an increased engagement in the area of immune-oncology. In the inflammatory research field, activities will likely extent to the area of neuro-inflammation, creating stronger synergies between Luxembourgish institutes.
- To increase **inter-departmental and inter-institutional transversal collaboration** programs by connecting clinical with fundamental research work in so-called bed-to bench-to bed cycles. This will enable LIH to move closer to the patient and to contribute more directly to patients' unmet medical needs.

- To actively contribute to an **improved framework for translational, patient-oriented work** by promoting a closer alignment of IPR policies amongst Luxembourgish institutions, and by exploring new funding tools which could help the drive for tangible therapies and a more direct impact on patients. LIH will also actively participate in promoting the opportunities that a coordinated **move towards digital health** would hold for Luxembourg.
- To put emphasis on the **communication of its work to the Grand Public** in order to tangibly explain to Luxembourgers the value of fundamental patient-centered medical research, but also **to attract pupils and young students** more into the adventure of medical research professions.

To reflect how LIH is achieving its strategic goals, Key Performance Indicators (KPIs) have been defined and are listed in our Performance Contract. They are also reported internally in a Dashboard.

2.4. Interested parties

Due to their impact or potential impact on services /products, the relevant interested parties and their requirements must be identified.

The main interested parties of LIH are briefly presented below.

Funding bodies: The Luxemburgish Ministry of Higher Education and Research (MESR) is funding the LIH. LIH's obligations are described in the **four-year Performance Contract** established between the MESR and the LIH. The current one has been established in January 2018 and runs until December 2021. It describes the engagement using deliverables (KPIs) of the LIH in exchange to the payment of financial contributions. The National Research Fund (FNR) is also one of the main funder of LIH.

Research partners: LIH research projects in the fields of oncology, infection and immunity and population health are often performed in collaboration with national and international partners with the goals to share knowledge and speed up the transfer of knowledge into clinical applications for the benefit of patients.

Students: The Doctoral Training Unit provides to early-stage researchers specific courses to help them developing/improving competences to conduct high-level quality research activities. The Clinical and Epidemiological Investigation Center also provides health professionals with training and workshops to guarantee quality-assured clinical research involving patients and healthy individuals.

Patients & Healthy donors: The LIH works in close collaboration with the health care providers for the provision of biospecimens from patients and healthy donors. LIH commits itself to ensure the application of state-of-the-art ethical and quality standards related to its service and research activities.

Clients: The word "Client" is applied to customers, public or private organizations, to whom LIH ensures the provision of high-quality services, without sharing a common research or knowledge transfer goal. Clients are also internal like the final users of our processes.

General public: LIH is a public biomedical research organization which generates knowledge on disease mechanisms and contributes to the development of new diagnostics, preventive strategies, innovative therapies and clinical applications that impact the healthcare of Luxembourgish and European citizens. Especially, the field of personalized medicine cannot be successful without the awareness of the general public. Therefore, LIH ensures regular communication to the general public for a better understanding of LIH's research activities.

LIH staff: Employees contributes to the success of the institute in fulfilling its missions thanks to their expertise and engagement.

To ensure adequacy between service provided and interested parties' expectations, each unit included in the certification scope must list their own relevant interested parties and their requirements in the form Interested Parties (**QM-F-01**).

2.5. Organization

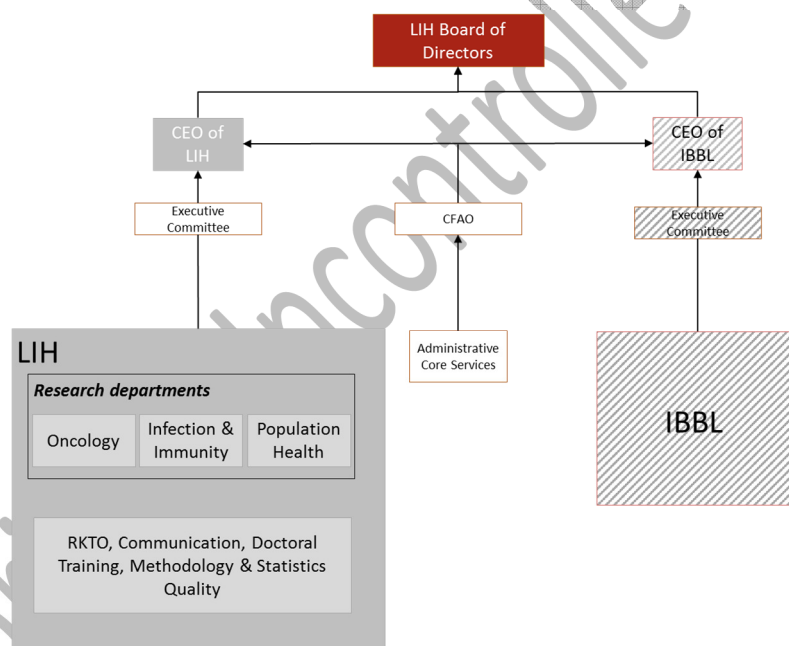
The three departments (Oncology, Infection & Immunity and Population Health) and the Methodology and Statistics unit included in the General Management department reflect the research focuses of the LIH. Each one is headed by a Director having an excellent track record and an internationally recognized scientific expertise in their field. The departments are further sub-divided into units and groups with specific research scopes, led by ambitious principal investigators / researchers. This organization guarantees an optimal training and supervision environment for early-stage researchers and students, essential for shaping their future career.

Numerous synergies were created between IBBL & LIH since the merger. Core administrative services were combined, which allowed to efficiently centralize recruitment and human resources management, accounting and procurement, as well as IT infrastructure and support.

2.5.1. Management structure

The overall management structure of the LIH is shown below:

Figure 1: Overall Management Structure



IBBL (shaded in the above figure) exists as an autonomous institute within the LIH and its QMS is excluded from this Quality Manual.

Besides, five governance structures have been put in place:

- The **Board of Directors** is nominated by the Government and is composed of nine external members of different professional backgrounds. Its mission is to oversee the activities at LIH. It is responsible for the general organization, for defining internal rules, for budget control, for framework contracts with partner organizations and for approving new strategies.
- The **Executive Committee of LIH**, composed of the Chief Executive Officer, the Chief Financial and Administrative Officer and the directors of the three research departments, is responsible for the implementation of the strategy approved by the Board of Directors and for day-to-day management of the institution. It guarantees the compliance with ethical principles, conventions and applicable laws.

- The **Collaborative Council** is a consultative body 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.
- Each research department has a **Scientific Advisory Board**. These boards are consultative bodies to the Board of Directors and comprise high-ranking external scientists. Their composition reflects the scientific area in which the departments are active. Their main tasks are to advise on the strategic and scientific orientations of the departments and to provide a scientific evaluation of the research units.
- The **Scientific steering committee** (SSC) establish the scientific priorities and research challenges to be pursued. This one is composed of 7 members, with representatives from all the LIH departments appointed by the CEO on the basis of their scientific expertise. The SSC meets twice a month to review/assess the project proposals and grants access to resources.

2.5.2. Organization chart and ISO 9001 certification Scope

The scope of the Quality Management System (relevant to our context, products and any interested parties) encompasses activities, locations, and people as represented in the following chart (red square).

The activities include, but are not limited to:

- Generate knowledge through research activities
- Develop skills of student, health professionals and scientific communities
- Provide routine and research services

Other LIH units are visible in the organizational chart and more details about it can be found on the LIH website.



2.5.3. Locations

The LIH Research Departments and the Administration and Research-Support Services within the ISO 9001 certification scope are located in three different locations, in Luxembourg City (2 sites) and in Esch-sur-Alzette (1 site).

House of Biohealth

Department of Infection and Immunity & Human Biomonitoring Research Unit
29, rue Henri Koch
L-4354 Esch-sur-Alzette
LUXEMBOURG

Luxembourg - Edison

Department of Population Health, Administration & Research-Support Services
1A-B, rue Thomas Edison
L-1445 Strassen,
LUXEMBOURG

Luxembourg - BAM

Department of Oncology
84, Val Fleuri
L-1526 Luxembourg,
LUXEMBOURG

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3 LIH Quality Management System (QMS)

3.1. Quality Approach

Our quality management system, complying with ISO 9001:2015 requirements, is a key tool supporting our ambition. It represents an important instrument that serves the continuous improvement of our internal functioning and thereby the quality of the services we perform for our partners.

Internally, this unifying project allows **improving operations**, to enhance the communication within and across units and to foster knowledge transfer. Externally, the appeal of the ISO 9001 certification is a significant benefit especially for industrial clients and research partners and **aim at increasing our private partnerships**.

3.2. Management and Leadership

The CEO of LIH, provides evidence of its leadership and commitment to the development and implementation of the QMS, to the benefit of Research, by engaging, directing and supporting persons to contribute to the effectiveness of the QMS and ensures that all other resources (infrastructure, knowledge, technology...) have been properly allocated.

Because, we are convinced that Quality can bring consistency in the management and conduct of our research activities, the participation of each collaborator of the Luxembourg Institute of Health during the performance of their duties is a crucial condition to the long-lasting functioning of such a system. This contributes to structure the organization, to the benefit of operational efficiency and to the achievement of our scientific mission.

The quality policy is communicated via this Quality Manual and the Quality Manager ensures that this one is properly understood and applied.

Through internal audits, measurement of key performance indicators, quality objectives and management reviews, the CEO monitors the QMS, its effectiveness and suitability with the LIH's strategy.

The assessment, by the Scientific Steering Committee, of the performance level and the follow up of the advances in LIH's scientific key research areas, allow LIH to identify and implement adequate measures in case of quality issues or identified rooms for improvement. Subsequently, information on our achievements is communicated and discussed during "city hall" meetings, and departmental or unit meetings.

3.3. Interested parties focus

Management demonstrates leadership and commitment with respect to the focus of the funding bodies, research partners, patients & Healthy donors, etc... by:

- Ensuring their requirements, including legal obligations, ethic and deontology, are determined, understood, and are met.
- Ensuring risks and opportunities that can affect our ability to supply output that meets the interested parties requirements with the aim of enhancing their confidence, fidelity and satisfaction.

3.4. Quality Policy

Through the quality policy, the Luxembourg Institute of Health is committed to comply with the ISO 9001:2015 norm and to seek continual improvement through a process of setting quality objectives, reviewing our systems, identifying corrective and preventive actions and implementing improvements.

LIH is committed to deliver loyal and constructive behavior with regard to its partnerships and at a corporate culture based upon professionalism, dedication and exemplarity.

The quality policy of our integrated quality management system (including quality, health, safety and environmental (QHSE) components), summarizes LIH's commitments for achieving its mission and vision, the strategic goals and key performance indicators:

Q

- Achieve Excellence in biomedical and translational research
- Become a transversal medical research institute at the cutting edge
- Provide high quality Education of young scientist through Training, Research and nurturing innovation

HS

- Guarantee the security of our collaborators, the preservation of their health and the safety of all their activities in compliance with the laws, regulations and industry standards in force.
- Develop the personnel's awareness of the risks raised by their activities and provide efficient training to help them to perform their tasks safely.

E

- Take preventive measures to minimize the effect of LIH activities on the environment

3.5. Quality document management

3.5.1. Management and dissemination tools

The QMS documentation is managed through the electronic records management system "Ennov Doc". It provides centralized access to the relevant quality documents of the organization, ensuring that only approved and current documents are accessible to staff.

All employees of LIH may contribute – alone or in targeted workgroups – to the system by writing, revising, reviewing or approving documents, according to their specific knowledge. Whereas, the QHSE Manager and the Quality Officer ensure consistency of the quality documentation and take care of disseminating the quality documents within the organization.

The Quality Manual is maintained by the QHSE Manager and approved by the CEO of LIH. Each update increments the version number of the document.

The Quality Manual may be provided to interested parties or other people/organizations after management approval¹.

3.5.2. Documented information structure and management

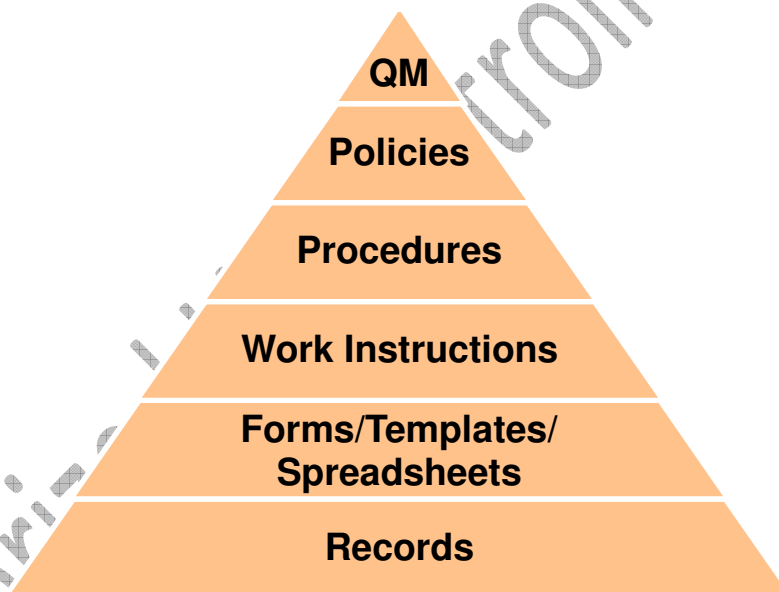


Figure 3: Quality Document Management (QM = Quality Manual)

Each document type contributes to a different objective in the description of the QMS:

Document Type	Objective
Quality Manual	Summarize the organizational structure of LIH, its quality policy and the processes building the quality system.
Policies	Communicate intentions and guidelines of management-relevant items
Procedures	Description of cross-sectional activities including responsibilities and resources

¹ The spread is not controlled, i.e. the recipients are not informed of updates.

Document Type	Objective
Work instructions	Description of workable / standardized practices for sharing know-how
Forms/Templates/spreadsheets	Tools to standardize traceability of process outcome (e.g. tests, reagent, results)
Records	Evidence of the execution of the processes and provision of products and services

The applied principles of document management cover:

- How to establish, review, approve, update, communicate and archive internal/external documents related to quality;
- The responsibilities and controls associated with the identification, storage, protection, accessibility, retention and disposal of records.
- The record management process of LIH is designed to prove the conformity of products and processes of the activities within the certification scope.

The key quality processes are defined in the procedures:

- Document Control ([QM-DC-001](#)) and Corporate Document Administration ([WI DC-901.02](#)), describing the document and records management processes,
- Management of non-conformances and CAPA ([QM-CI-001](#)), specifying the administration of nonconforming work, corrective/preventive actions and improvements.
- Guidelines for Measuring Customer Satisfaction ([QM-CI-003](#)) providing the best practice in gathering feedback from customers and any other interested parties in a proactive manner.
- Management of Internal Audits ([QM-CI-002](#)), covering the internal audit process.

3.6. Continuous improvement

The Plan-Do-Check-Act cycle is the foundation of LIH's approach for continuous improvement of the quality management system:

P

The process starts with the definition of the strategy, which declines in objectives and key performance indicators (KPI). The quality policy serves as guidelines to achieve these plans, which are materialized in the quality management documents, i.e. policies, procedures and protocols.

D

LIH staff implements the processes described in the QMS via the three core processes and thereby benefits from services provided by the operational & scientific support units and the administrative core units.

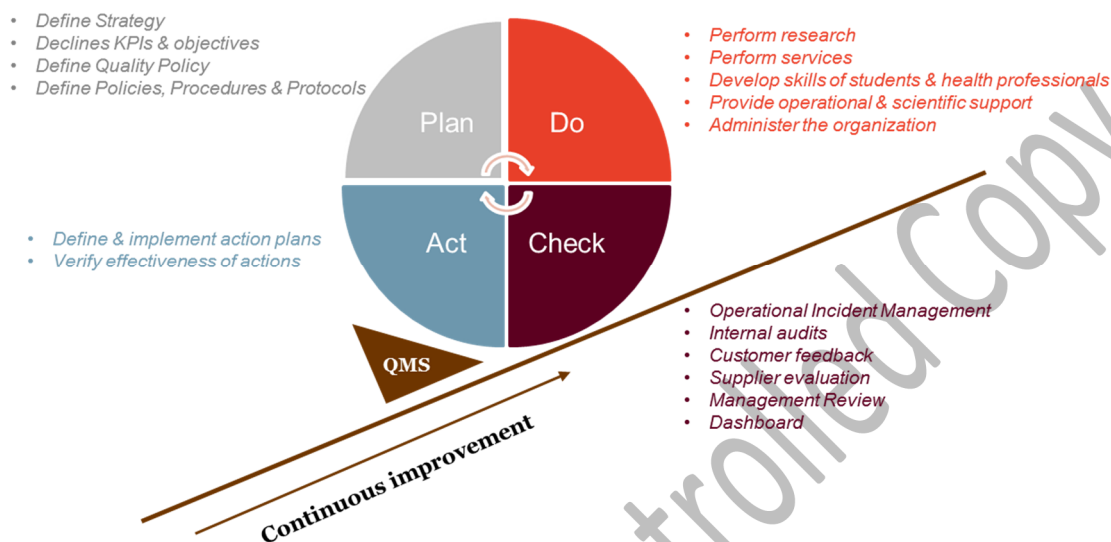
C

Monitoring of processes via the operational incident management, internal audits, customer feedback and supplier evaluations provide regular input of the performance of the processes to staff and management.

The Quarterly Dashboard summarizes progress of the organization with respect to KPIs and other appropriate metrics. The annual Management Review allows the overall synthesis of the achievements or weaknesses of the organization and the evaluation of effectiveness of the QMS.

A

Finally, based upon the monitoring results, management decisions are made and documented in actions plans, which cover corrective, preventive actions as well as improvements. Where relevant and feasible, the effectiveness of implemented improvements is verified.



4 Presentation of LIH's core processes

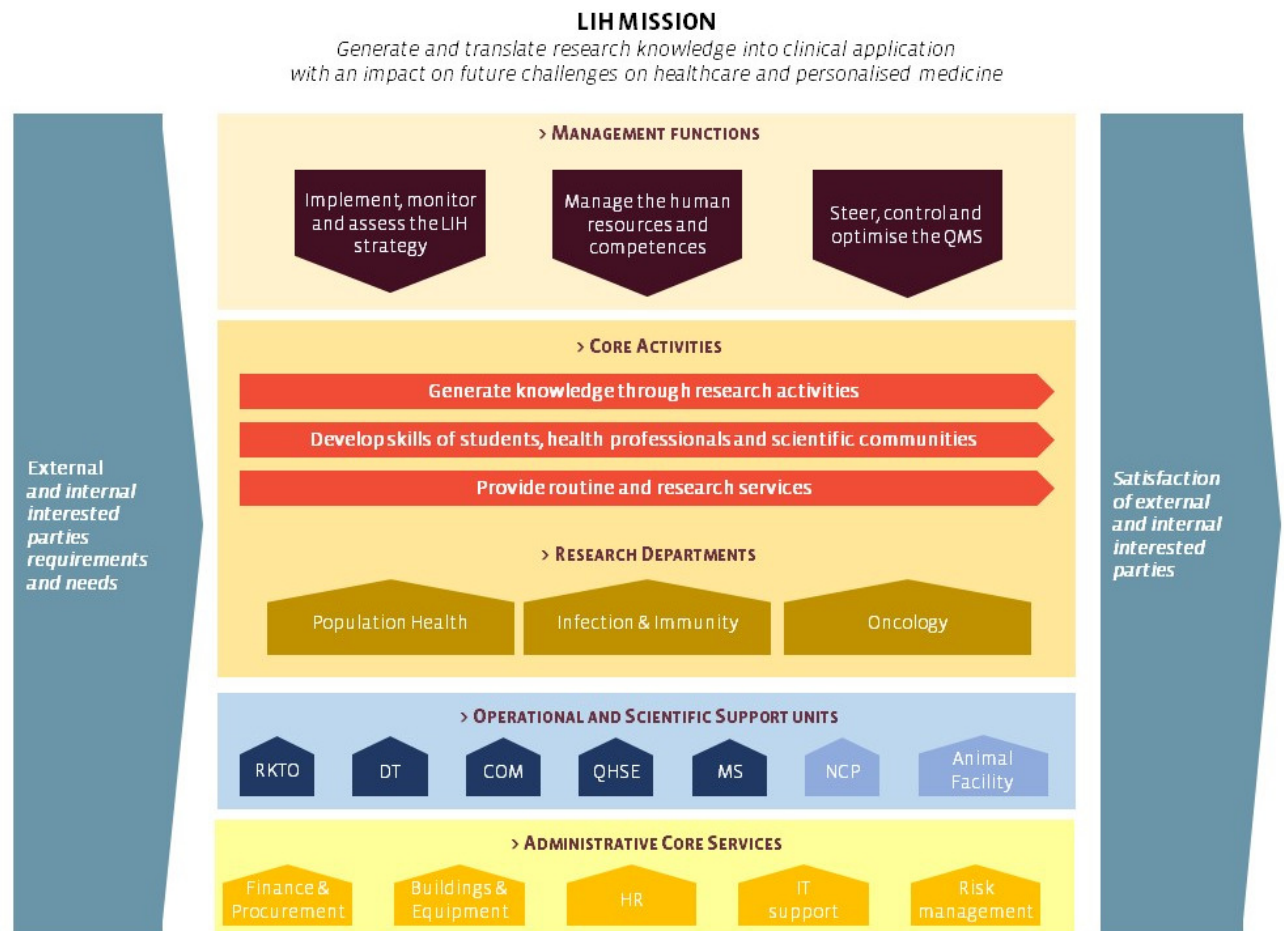
LIH has adopted the process approach.

By defining three key process-groups and by managing their inputs, activities, controls, outputs and interfaces; we ensure that system effectiveness is established and maintained.

4.1. LIH process map

The processes required for the efficient functioning of the quality management system are represented in the following process map, which contains the core processes, support and administrative processes as well as their interaction. This process map only covers the departments/units related to the current ISO 9001:2015 certification scope.

Figure 4: Process Map



Legend:

Operational and Scientific Support units: RKTO (Research Knowledge Transfer Office), DT (Doctoral Training), COM (Communication), QHSE (Quality, Health, Safety and Environment), MS (Methodology & Statistics), NCP (National Cytometry Platform).

Units in dark blue are part of the “General management” department, whereas units in light blue are part of Research departments.

4.2. Activity description by unit

4.2.1. Department of Population Health (DoPH)

The Department of Population Health is an interdisciplinary research centre focusing on epidemiology and public health research across a wide range of areas including cardio-metabolic conditions, sports medicine, human bio-monitoring, health economics and clinical investigations. The department is composed of six units: Sport Medicine Research Laboratory, Cardio-Vascular Research Unit, Health Economics and Evidence Synthesis Research Unit, the three others included in the ISO 9001 certification scope are listed below.

4.2.1.1. Epidemiology & Public Health Research Unit (EPHRU)

The EPHRU covers a wide range of research and service activities in the field of epidemiology and public health, diseases, which are prevalent in Luxembourg, Europe and worldwide, and the lifespan: from antenatal care, to the health of young people, adults and the elderly.

Specifically, EPHRU conducts:

- epidemiological studies in the general population;
- public health surveillance, particularly public health registries (e.g. cancer, injuries, nosocomial infections and perinatal);
- clinical, multidisciplinary epidemiological research, in collaboration with clinicians;
- public health consultancy activities such as health care and health system assessment.

Research themes cover diseases such as:

- cardio-metabolic disease, and their underlying risk factors: diabetes, hypertension, obesity, metabolic syndrome, lifestyle, nutrition, physical activity and psychosocial factors;
- cancer and more notably survival analysis compared with therapeutic models and procedures;
- neuro-degenerative diseases associated with ageing and cognitive decline;
- quality of life, general wellbeing and mental health research.

4.2.1.2. Clinical and Epidemiological Investigation Center (CIEC)

The role of LIH's Clinical and Epidemiological Investigation Centre (CIEC) is to promote and support local clinical research projects and to help researchers consolidating experimental findings through quality-assured clinical research involving patients and healthy individuals.

Acting as a national center coordinating clinical research activities involving clinicians in various medical fields, CIEC is a contact partner for pharmaceutical industries interested in conducting clinical trials in Luxembourg. CIEC stands for excellence in operational support in clinical research especially by undertaking to conduct all its studies in compliance with Good Clinical Practice (GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects).

Additionally, CIEC serves as a reference center for certified training in clinical research and development of clinical investigators in Luxembourg.

4.2.1.3. Human Biomonitoring Research Unit (HBRU)

The HBRU has strong expertise in analytical toxicology and development of biomarkers for the assessment of exposure to organic pollutants and for therapeutic drug monitoring.

Primary research goals are the development of biomarkers for the identification of human exposure to different occupational and environmental pollutants such as pesticides, polycyclic aromatic hydrocarbons and persistent organic pollutants. Furthermore, HBRU aims to expand the existing knowledge of the relationships between exposure to pollutants and subsequent biological/biochemical disorders.

The used analytical techniques are based on chromatography coupled with tandem mass spectrometry using blood, urine and hair samples as matrices. Methods developed include those for routine assessment of alcohol consumption as well as the exposure to cigarette smoke in active and passive smoking.

This expertise is currently applied within the scope of national and international epidemiological studies, but also provided as service offer to interested parties.

4.2.2. Department of Oncology (DONC)

The main mission of the Oncology Department is to achieve excellence through research that will have a strong impact on reducing the cancer burden within the Luxembourg population and beyond. Within prioritized areas, the aim is to develop excellence within basic, translational and clinical cancer research. This includes the implementation of a personalised medicine programme. The main activities of the department are focused on experimental cancer research with a strong translational research profile. Research activities, driven by NORLUX Neuro-Oncology Laboratory, Laboratory of Experimental Cancer Research and Genomics and Proteomics, focus on the cellular and molecular mechanisms of tumor progression using a wide range of state-of-the-art technologies, including genomic, transcriptomic and proteomic analyses, as well as in vitro and in vivo imaging modalities using state-of-the-art animal models for cancer research.

4.2.2.1. Animal Facilities

LIH is housing animal facilities especially for rodents that strictly follow the FELASA guidelines regarding the animal health status and are considered specific pathogen free (SPF) facilities. All operational aspects for the maintenance and experimentation on small laboratory animals follow national and EU regulations (EU Directive 2010/63/EU). The maintenance and wellbeing of the animals is taken care of by dedicated animal care assistants and the LIH Animal Welfare Structure (AWS) oversees all activities of the facility.

Although embedded in the DONC, these facilities are part of the scientific support services and consequently used by researchers of all LIH departments, if required.

4.2.3. Department of Infection & Immunity (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 divided in two units Allergology, Immunology, Inflammation Research Unit and Infectious Diseases Research Unit (detailed below).

The major focus of DII is on the analysis of complex mechanisms of infectious and inflammatory diseases. With a multi-disciplinary approach, the research strategy is based on the following elements: experimental discovery, bridging to clinical application and technology development.

4.2.3.1. Infection Diseases Research Unit (IDRU)

The Infectious Diseases research is specialized in fundamental and applied research topics concerning viral infections, virus-receptor interactions and vaccinology. The research activities have a major focus on HIV infection on the one hand and on Measles and Rubella as well as Influenza virus on the other hand.

The IDRU is composed of 4 different research groups:

- HIV Clinical and Translational Research Group*
- Molecular Signaling and Virus-Host Interaction*
- Clinical and Applied Virology
- Vaccinology and B cell Immunology,

of which groups marked with <*> are within the ISO 9001 certification scope.

HIV Clinical and Translational Research Group

The HIV Clinical and Translational Research (HIV-CTR) Group is interested in clinically oriented research in the field of resistance to antiviral therapy and transmission, as well as providing new translational knowledge on HIV cure and on HIV immunopathogenesis using humanized mouse models.

The Group is a partner in several European HIV and HCV networks, collaborates with life science and biotech companies, and has built up a network in emerging countries (mainly in Africa) to support knowledge and technology transfer.

HIV-CTR provides specialized technical support for the clinical follow-up of HIV and HCV-infected patients and is the first supplier of public health information for these infections in Luxembourg.

Molecular Signaling and Virus-Host Interaction

Altered cellular signaling and immune dysregulation are hallmarks of most auto-immune, inflammatory and chronic viral diseases. The expression, signaling and activity of chemokines and IFN are often altered in these pathologies but the molecular mechanisms and fine regulation at play are not completely understood. Most viruses have evolved strategies to hijack, bypass or lure these signal transducers and cellular effectors to favor their replication and/or to corrupt or evade immunity.

Therefore, our research interests revolve around two axes:

- Fundamental research aiming at gaining new insights into the complex structural and cellular mechanisms that lead to altered cellular signaling and cell transformation.
- Translational research aiming at developing novel tools and therapeutic approaches to interfere or modulate these processes and viral replication.

4.2.3.2. National Cytometry Platform

The National Cytometry Platform (NCP) is an open facility accessible to all scientists at LIH as well as external researchers. The NCP is a shared resource facility that is available to assist researchers with cytometry experimental design, data acquisition, cell sorting and data analysis. It is state of the art technological platform benefiting from the latest technology, and of the expertise of qualified staff in flow cytometry, mass cytometry and imaging flow cytometry.

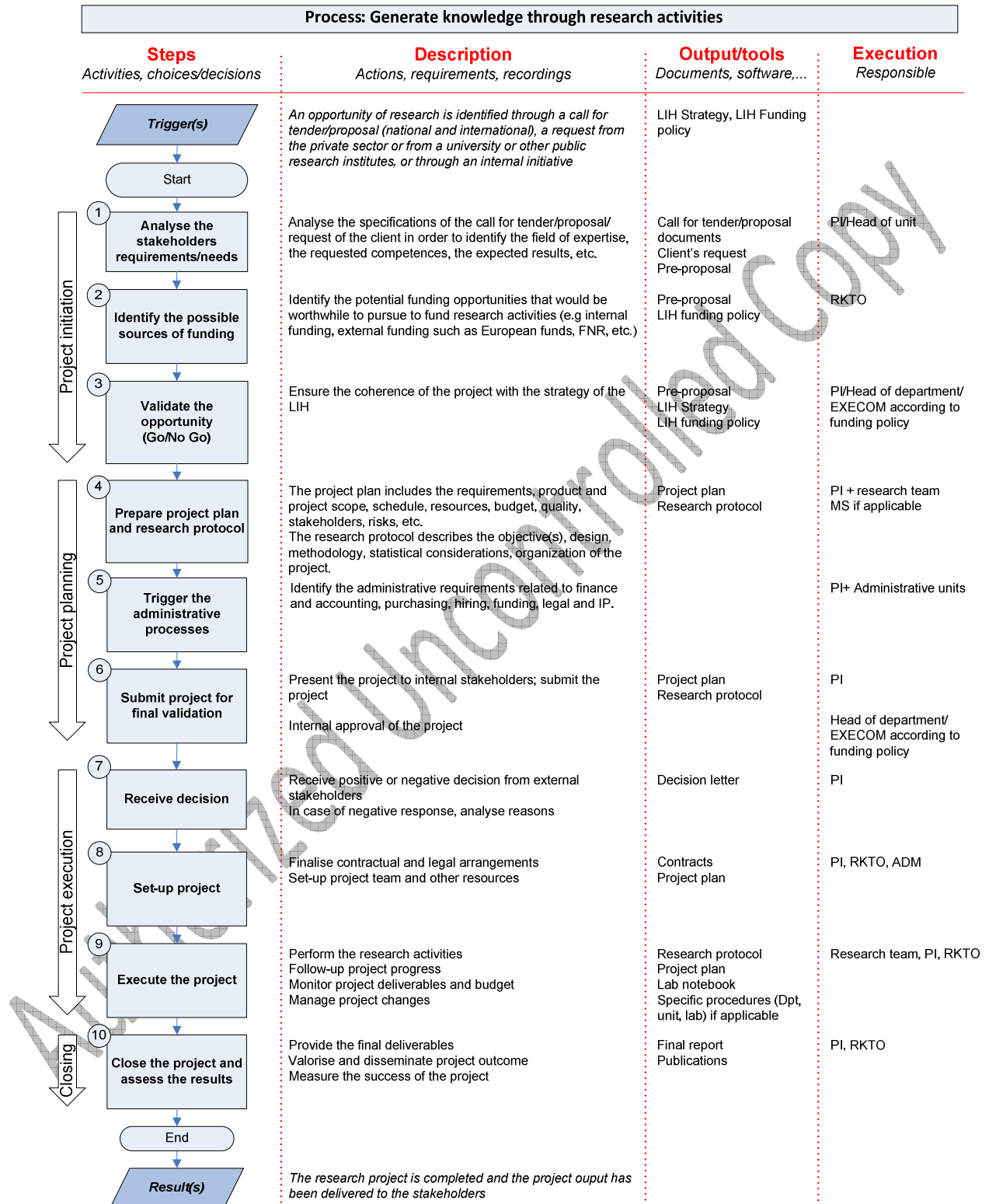
4.3. Core process description

The following illustrations describe the main workflows for each core process of the LIH. These workflows may be adapted depending on the specificities of each department or unit.

4.3.1. Generate knowledge through research activities

As described in the Grand-Ducal regulation dated December 29, 2014, the LIH's research activities have to create new knowledge related to disease mechanisms, epidemiology, and diagnostics to be translated into clinical applications for the benefit of patients.

Figure 5: Knowledge Generation Process



4.3.2. Develop skills of students, health professionals and scientific communities

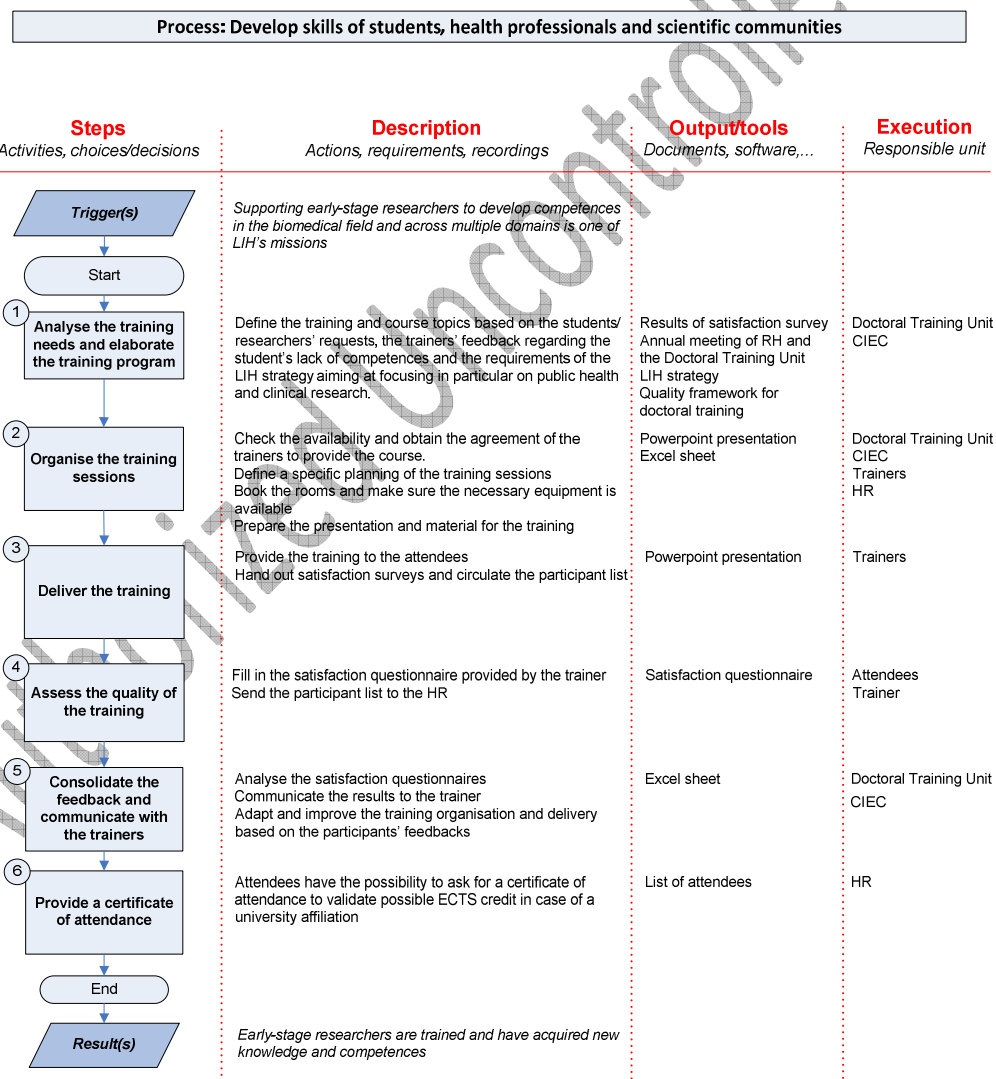
LIH is highly involved in the development of students and scientific and professional communities in the field of health.

This involvement is reflected, among others, by:

- Strengthening doctoral training in Luxembourg thanks to the implementation of the doctoral biomedical school within the Life Science Department of the University of Luxembourg,
- Exchange of expertise with foreign universities,
- Supervision of PhD students in biomedical research.

In addition, LIH researchers provide training and workshops for early-stage researchers to help them develop the skills they will need throughout their scientific careers (e.g. advice on drafting scientific presentation, writing a doctoral essay, advices to apply for scholarship, advices in the preparation and processing of statistical analyses...).

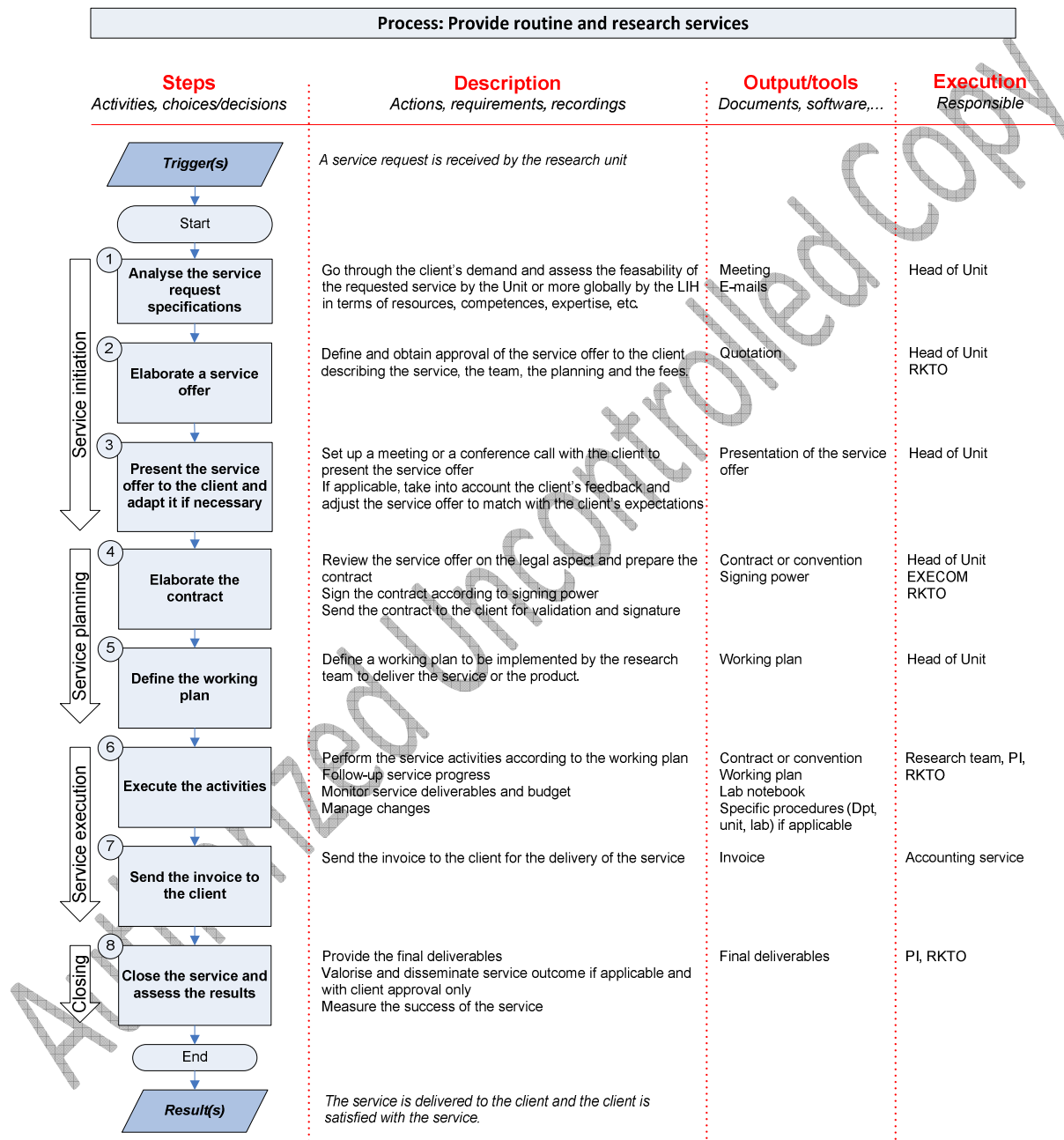
Figure 6: Skills Development process



4.3.3. Provide Services

For the account of specific clients, LIH research units perform studies, expertise and advice in the implementation of technology, new products, processes and services based on their oriented basic research and applied research.

Figure 7: Services Process



5 Operational & Scientific Support Processes

5.1. Research Knowledge Transfer Office (RKTO)

The Research Knowledge Transfer Office (RKTO) supports LIH's researchers to maximize the scientific, economic and societal applications of their research results, know-how and expertise while nurturing the excellence of their research projects.

Acting as facilitator for research grant capture, intellectual property management and knowledge transfer activities within LIH, RKTO contributes to lay the foundation for a sustainable entrepreneurial culture encouraging innovation within LIH, with the objective to act as a catalyst in the growth of biomedical RDI activities in Luxembourg.

Services provided:

- Identification and dissemination of research funding opportunities;
- Assistance in the preparation of high quality grant applications;
- Management and protection of the LIH intellectual property;
- Support for economic/societal value creation from project ideas & research results;
- Organization of information/training sessions promoting best practices in research grant capture, project management & intellectual property management and protection.

5.2. Methodology and Statistics (MS)

The Methodology and Statistics unit supports LIH research units and international pharmaceutical industry players by providing them with high quality methodological and statistical services.

The unit provides methodological support in statistical planning and analysis and data handling for various laboratories and research groups in the Luxembourg institute of Health and offers training in statistics and support in writing papers. In addition it provides consulting services for the pharmaceutical industry in Europe and the USA, attends the Data Safety Monitoring Board worldwide for randomized clinical trials, engages in collaborative research with various external partners for example the WHO and various universities, and gives external courses in statistics not only in the greater Luxembourg region but also worldwide.

Services provided:

- Planning of clinical, epidemiological and laboratory studies
- Support for grant applications and publications
- Data handling and statistical analysis
- Statistical education and training
- Consultancy for commercial organizations

5.3. Doctoral Training Unit

The training of doctoral candidates in a quality research and management environment is a key objective of the LIH.

The objectives of the unit are:

- Guarantee the best work and supervision conditions for PhD candidates
- Offer training courses tailored to the needs of the young researchers
- Promote career orientation and development
- Encourage social and scientific interactions between PhD candidates
- Serve as a contact point for questions related to doctoral training

On average about 50 PhD candidates, enrolled either at the University of Luxembourg or foreign universities, are carrying out research projects at LIH. Their work relates to the fields of application-targeted cellular, molecular or systems biology, biochemistry, epidemiology, statistics or bioinformatics.

The doctoral training unit, created in 2015, is in charge of overseeing and organizing all doctoral training-related activities. These responsibilities include the definition and implementation of a doctoral education framework in line with European best practices and specific guidelines of the Luxembourg National Research Fund (FNR).

5.4. Quality, Health, Safety & Environment (QHSE)

The mission of the QHSE unit is to implement a methodology to ensure that standards of reliability, transparency and efficiency are achieved throughout the institution's activities.

The role of the QHSE unit includes to:

- Conceive, maintain and actively contribute to an integrated quality management system in compliance with the strategic plan of LIH and those of the research departments
- Ensure that targeted third-party certifications and accreditations are achieved as applicable
- Act as “subject matter expert group” for all quality, health, safety and environmental questions within the organization.
- Provide training related to QHSE matters to continuously increase awareness and dynamics in this field
- Identify best practices and coordinate their transfer throughout the institution
- Implement and maintain processes that foster the continuous improvement of the QMS
- Foster the organizations’ knowledge related to (bio)safety and security measures to ensure LIH being a safe workplace for its employees and not adversely impacting the society / environment.
- Provide support and encourage responsible usage of resources to protect the environment.

6 Administrative core processes

6.1. Human Resources

Talent is key asset within LIH, therefore LIH adheres to the “HR excellence in Research” concept. The Human Resources department sets up an adequate framework for the management of the employees within the LIH, covering:

- The **recruitment** of staff
- The administration of the **compensation and benefits strategy**
- The **training and development** including preparing activities for newly hired workers, coordinating skills training and professional development opportunities that prepare employees for additional responsibilities within LIH and the appraisal management.
- The maintenance of **Job Descriptions** and Organizational Charts
- The **employee and Labor Relations** including activities such as reward events, identifying workplace issues, investigating employee complaints, ensuring HR compliance with employment laws and regulations, administering employee opinion surveys, defining policy development and performance management, including providing guidance to supervisors on how to conduct employee job performance appraisals

6.2. Finance

The Finance unit ensures that all financial aspects of the organization are efficiently managed in compliance with national and international as well as corporate rules. It is responsible for the planning, auditing, accounting and controlling of the LIH's finances.

6.3. Procurement

The Procurement unit ensures that LIH's demands, for the goods and services required to achieve its goals, are met. The department has a clear understanding of these demands and thorough knowledge of supplier markets that enables to negotiate proper contracts.

The purchasing process is centralized via an ERP system, to ensure an effective and efficient order process. Via the Supplier Management process, the unit provides the framework for monitoring the quality of purchased goods and the related suppliers.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what it is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not providing conforming products or services may be requested to conduct formal corrective action.

6.4. Building & Equipment

The Building & Equipment (BE) department is responsible for the operation and maintenance of the LIH's buildings and non-research specific equipment.

The BE department ensures that the facilities and the environmental conditions are suitable before the installation of the equipment. As required by the research units, monitoring and controlling of environmental conditions is performed.

LIH ensures in collaboration with the health & safety experts from QHSE and the operational units that the premises are conforming to the legal and security requirements and are appropriately arranged for different process steps. LIH controls access, maintains procedures for safety & hygiene, and performs environmental monitoring.

6.5. IT Support

The IT support team plans, operates and maintains LIH's information and communication technology infrastructure, enabling business users (researchers and administrative users) to carry out their roles efficiently, productively and securely.

Its role includes to:

- Develop and maintain an IT strategy that supports the LIH's business objectives and helps building a strong competitive advantage.
- Customizes software and other elements of the IT system to meet the needs of research departments and units.
- Develop and operate a network supporting effective communication and collaboration.
- Develop tools for collection, storage, management, securing and distributing data to users
- Protect the IT infrastructure and corporate data against attacks from viruses, cybercriminals and other threats, thus minimizing impact on critical business operations and services.
- Support LIH's employees to make the most effective use of IT resources.

6.6. Communication

The communication unit ensures that LIH's vision, missions, corporate identity, strategic plans and concrete projects are regularly and adequately communicated within the organization and externally to the interested parties including the general public. Examples are the annual report, press releases, intranet, conferences and events and the website: www.lih.lu.

6.7. Risk Management

The Risk & Compliance Officer works in close collaboration with the administrative core services, the QHSE unit and all operational & support services to ensure the planning, design, implementation and maintenance of risk management and compliance processes that are intended to manage risks to LIH, its employees, customers, reputation, assets and interests of stakeholders.

This process includes the identification of risks, their reporting (e.g. to department heads, Executive Committee, Board of Directors) to raise awareness and communicate responsibilities, the set-up of actions plans to avoid, reduce or transfer risks and the continuous follow-up of identified risks as well as the improvement of the system.

Risks and opportunities are managed according to the documents Risk Management Policy (POL CI-902.01) and Risk assessment procedure (PRO CI-901.01). Records associated to Risk Management are maintained in our GRC (Governance Risk and Compliance) application, Intalex.

7 Definitions & Terminology

BE	Building and Equipment
COM	Communication
CIEC	Clinical and Epidemiological Investigation Center
DT	Doctoral Training
ENNOV	Document management system
EPHRU	Epidemiology & Public Health Research Unit
ERP	Enterprise Resource Planning
EXECOM	Executive Committee (of LIH)
HBRU	Human Biomonitoring Research Unit
HR	Human Resources
IBBL	Integrated Biobank of Luxembourg
IPR	Intellectual Property Rights
IT	Information Technology
LIH	Luxembourg Institute of Health
MS	Methodology and Statistics
NCP	National Cytometry Platform
PI	Principal Investigator
QMS	Quality Management System
QHSE	Quality, Health, Security and Environment

RDI	Research Development and Innovation
RKTO	Research Knowledge Transfer Office

8 Recordkeeping and Archiving

Records cited in this document	Electronic: Responsible unit/Function	Paper: Responsible Unit/ function	Archiving place	Archiving duration	Confidential (yes/no)
Interested Parties (QM-F-01)	Unit in the scope of certification		Unit office	5 years	No

9 Revision History

Version	Effective date	Summary of change
01	18/01/2017	New document
02	24/05/2018	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.

*** End of document ***