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UNIVERSITÉ DU LUXEMBOURG

Research Ethics

Guidelines

Disclaimer

This document is published by the research ethics committees of the University of Luxembourg, and has been compiled based on EU and national legislation, as well as international research ethics guidelines to raise awareness in the research community of the host institution. The members of the research ethics committees cannot be held personally responsible for the content of the present document.

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Executive Summary

Aware of its obligation to comply with the highest standards of research integrity and in line with the institutional, national and international legal requirements, the University of Luxembourg (UL) has the **mission** to strengthen and maintain a strong ethical culture supporting good scientific practice (GSP) in research.

UL has therefore established the Ethics Review Panel and the Animal Experimentation Ethics **Committee**, which take preventive, detective and corrective **measures** to ensure that any individual involved in conducting research at or for UL adheres to GSP.

To raise awareness of the core values underlining *"responsible institutional behaviour"* and responsible conduct of research, UL **disseminates** the present Research Ethics Guidelines as guidance to everybody involved in conducting research at or for UL.

Every research activity can entail possible ethical risks to the involved parties, for which assessment needs to be undertaken. The ultimate **reason** to effectively apply the present guidelines to research is to protect all parties involved and aim for a *"minimal-risk standard"*. Any research at UL, including human participants, human biological material, personal data, animals and/or potentially harmful changes to the environment, therefore, requires ethics approval by the Ethics Review Panel and/or the Animal Experimentation Ethics Committee.

UL will take allegations of misconduct in research very seriously, for example cases of researchers abusing their research freedom or putting at risk or injuring constitutionally protected legal interests of others. The Ethics Committees will conduct comprehensive assessments of such cases, and if the suspicion of alleged scientific misconduct is substantiated, refer them to an independent national commission (Luxembourg Agency for Research Integrity; LARI) for further enquiry and investigation. The present guidelines describe the responsibilities of the involved parties and the procedures of the Ethics Committees in cases of suspected or alleged research misconduct.

RESEARCH ETHICS AT THE UNIVERSITY OF LUXEMBOURG

1.1 INTRODUCTION

The goal of the present guidelines is to provide overall guidance in research ethics, and to make recommendations on how to safeguard good scientific practice (GSP) by following guidelines and self-control mechanisms. These essential preventive countermeasures to research misconduct affect many different research areas. Any research study involving human participants, human biological material, personal data, animals and/or potentially harmful changes to the environment requires ethics approval ***before*** any relevant activity takes place. Also, the University of Luxembourg (UL) takes it very seriously in case a researcher is abusing his/her research freedom. With these goals, UL advocates the highest standards of ethics in research. All individuals involved in conducting research at or for UL - whether as staff (principal investigators, researchers and research assistants), junior researchers (doctoral candidates), students (graduate, undergraduate), or visitors (including contractors on campus) - shall ensure that research complies with all applicable laws (Chapter 1.5) and institutional procedures (*Internal Rules of Procedure* and *Code of Conduct*), regardless of the location of the research.

🕮 Read more:

Internal Rules of Procedure (UL, 2015)
Code of Conduct (UL, 2016)

1.2 ETHICS REVIEW PANEL

According to Article 26 of the Luxembourgish Law of August 12, 2003 on the creation of the University of Luxembourg, the University Council has established the Ethics Review Panel to address ethical issues related to the scientific role of UL as a community of people involved in planning, executing and publishing research.

1.2.1 Terms of Reference and Remit

Aware of its obligation to comply with international standards to independently verify ethical aspects of research, and in line with the *Policy on Ethics in Research* (🕮 Read more, Appendix 7.1.1), UL has established the Ethics Review Panel (ERP) (Art. II.4.2 bis 101, *Internal Rules of Procedure*). The ERP exercises appropriate administrative overview to ensure that UL provides the infrastructure and the organisational prerequisites for safeguarding good scientific practice. Firstly, the ERP ensures that the institution's policies and procedures for protecting the fundamental rights (including legal rights) of human participants, as well as protecting the environment, are effectively applied to research. Secondly, the ERP must take proper precautions to deal with cases of research misconduct so that UL can meet the expectations of research at the highest international standards. Consequently, the ERP has two remits:

(1) **Ethics Reviews of Research Proposals (and Publications)**

The ERP provides ethics reviews of research proposals (and publications) involving human participants, human biological material, personal data, and/or potentially harmful changes to the environment [1]. In this respect, the ERP acts as an advisory body to the Vice-President for Research for any research conducted at or for UL *before* the work, for which ethics approval is sought, is undertaken.

(2) **Cases of Suspected or Alleged Misconduct in Research**

The ERP addresses any cases of suspected or alleged misconduct in research, in which there is an individual involved in conducting research at or for UL. Within this remit, the ERP conducts an assessment of suspected or alleged misconduct in research involving staff (principal investigators, researchers and research assistants), junior researchers (doctoral candidates), students (graduate, undergraduate), and/or visitors (including contractors on campus) at or for UL, and, advises the UL President on the outcome of the assessment, and notifies the Luxembourg Agency for Research Integrity (LARI). In cases where the suspicion of scientific misconduct is substantiated through the assessment, the case is referred to LARI for further enquiry and investigation.

🕮 Read more:

Policy on Ethics in Research (UL, 2012)

1.2.2 Members

The ERP consists of at least 5 members: the Chair, 3 members representing the different Faculties and 1 member representing the Interdisciplinary Centres of UL (Art. II.4.2 bis 102, *Internal Rules of Procedure*). Administrative support is provided by the University to the ERP, for taking minutes of meetings, administrative checks of applications, organisation of ERP meetings and general administrative tasks. The UL President is invited as a permanent guest in the ERP (*ex officio*).

Official appointment: ERP members, the ERP Chair, and the ERP Deputy Chair are confirmed by the Rectorate and appointed by the UL President. A letter confirming the appointment is sent to the Human Resources Department.

The regulations and selection/election procedures for ERP members are described in Appendix 7.2.

1.2.3 Meetings

The ERP meets monthly, with the exception of the month of August. The dates of the meetings are determined, announced and published twice a year on the UL intranet, at least 1 month in advance of the first meeting of a series.

The meetings of the ERP are not open to the public. Nevertheless, experts in the field can be consulted or invited by the ERP for specific agenda items of a particular meeting. These experts can be external or internal to UL.

1 At the University of Luxembourg, changes to the environment include biological agents which belong maximally to risk group 2.

A quorum of 75 percent must be present in the meetings for the ERP to be able to take decisions. In the case of 5 ERP members in total, a quorum of 3 out of 5 ERP members must be present in the ERP meetings to be able to take decisions.

The ERP Chair ensures adherence to the agenda and compliance with the regulations. Minutes of each meeting and the written feedback are prepared by the administrative support to the ERP and signed by the Chair after approval by the Committee. The letters containing the decision and the required modifications, if any, as agreed by the ERP, are prepared by the administrative support to the ERP and signed by the Chair.

All members, the administrative support and any invited experts will respect confidentiality regarding the minutes and all matters discussed in the ERP.

Additional meetings can be called by the Chair upon request of ERP members, the University Council, or the Rectorate, as needed. These meetings are announced and the relevant documentation distributed at least one week before the meeting. In exceptionally urgent cases, *i.e.* when organizing a meeting in time is not feasible, the review process of ethics applications can be undertaken in writing.

🕮 Read more:

ERP Meeting Dates

1.2.4 Reporting

The ERP provides an annual summary report of its activities in both remits to the University Council and the Rectorate, without compromising confidentiality.

More information can be obtained from:

ERP Secretary

1.3 Animal Experimentation Ethics Committee

1.3.1 Terms of Reference and Remits

The Animal Experimentation Ethics Committee (AEEC) is responsible for ensuring on behalf of UL that all care and use of animals for research and teaching purposes is conducted in compliance with the Grand-Ducal Regulation of January 11, 2013 on the protection of animals used in scientific research (Art. II.4.2-ter.101, *Internal Rules of Procedure*). The role of the AEEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of ***Replacement, Reduction and Refinement*** [2].

The AEEC is required to:

- approve guidelines and procedures for the care of animals that are bred, held and used for research or teaching purposes on behalf of UL;
- monitor the acquisition, transportation, production, housing, care, use and fate of animals used at UL;

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2 **Replace** the use of animals with alternative techniques, or avoid the use of animals altogether.
Reduce the number of animals used to a minimum, to obtain information from fewer animals or more information from the same number of animals.
Refine the way experiments are carried out, to make sure animals suffer as little as possible.

- recommend to UL any measures needed to ensure that the standards of the legislation are maintained;
- examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals for scientific purposes;
- approve only those studies, for which animals are essential, justified, and which conform to the requirements of the Grand-Ducal Regulation, taking into consideration factors including ethics, the impact on the animal(s) and the anticipated scientific or educational value;
- withdraw approval for any project, which is discovered to be non-compliant with the Grand-Ducal Regulation;
- examine and comment on all plans and policies of UL, that may affect the welfare of animals used for scientific purposes;
- maintain a record of proposals and projects;
- comply with the reporting requirements of UL, and the legislation in compliance with the Grand-Ducal Regulation;
- perform all other duties required by the legislation.

1.3.2 Members

The AEEC consists of at least 4 members from the following categories:

- *Category A* - person with qualifications in veterinary science and with experience relevant to the activities of the institution;
- *Category B* - suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities;
- *Category C* - person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes;
- *Daily Care* - person responsible for the daily care of animals kept for use in teaching and research activities;
- Additional members with skills and background as is deemed necessary to ensure the effective functioning of the Committee.

Official appointment and re-appointments: Before appointment, all members of the AEEC shall acknowledge in writing their acceptance of the terms of reference of the AEEC and UL's requirements for confidentiality.

The regulations and selection/election procedures for AEEC members are described in Appendix 7.3.

1.3.3 Meetings

The AEEC shall meet as frequently as necessary but at least every 3 months.

Minutes of AEEC meetings will be taken by an appointed Secretary that records decisions and other aspects of the AEEC operations. The AEEC may invite people with specific expertise to attend the meeting, to provide advice as required. Researchers may be also invited to discuss issues relating to their work.

1.3.4 Reporting

The AEEC provides an annual summary report on its activities to the University Council and the Rectorate.

More information can be obtained from:

AEEC Secretary

1.4 INTERNAL AND EXTERNAL COMMITTEES

1.4.1 Internal Committees

Biosafety Committee

The Biosafety Committee's role is to ensure the coordination of biosafety policies and measures at the level of UL, as well as to review and approve the risk assessment of new or modified activities involving biological agents.

The Biosafety Committee is composed of laboratory safety coordinators and the biosafety officer. Laboratory safety coordinators are responsible for all safety-related issues inside each laboratory; while biosafety officers implement the biosafety procedures at the different BSL1&2 laboratories, contribute to the organisation of waste management and decontamination, and participate in the preparation of new requests for permission to handle genetically modified organisms to be submitted to the Ministry of Health. Other participants may be included on a regular or *ad hoc* basis, depending upon the needs of the committee.

The Biosafety Committee should seek advice from different internal and external specialists (*e.g.* with expertise in animal care, medical issues), and may at times require assistance from independent experts in various associated fields, local authorities and national regulatory bodies.

The Biosafety Committee meets at least quarterly, but can convene more frequently according to the circumstances (*e.g.* implementation of a new biosafety programme, launch of new activities, preparation of a move into new facilities, occurrence of an accident, changes in regulations). Issues treated by the committee are addressed and recorded formally.

More information can be obtained from:

Biosafety Officers
Security and Safety Officers (SIL)

📖 Read more:

Biological emergency procedures (UL, 2010)
Biosafety practices (UL, 2010)

Ethics Advisory Committee

The Ethics Advisory Committee (EAC) has a two-fold role:

- to investigate and advise on ethical issues involved in the activities of the UL community upon request of the University Council or the Rectorate;
- to address complaints, *e.g.* by conducting enquiries and investigations into suspected or alleged discrimination or harassment of its Faculty, staff, students and visitors (including contractors on campus) and, depending on the outcome, to advise the UL President on possible actions.

Cases of discrimination or harassment with respect to *"gender, sexual orientation, origin, nationality, family status, disability or age"*, as well as *"religious and political beliefs"* are treated insofar as they harm the ethical and moral values of the UL community.

More information can be obtained from:

EAC Secretary

Gender Mainstreaming Committee

The Gender Mainstreaming Committee (GMC) (Art. II.4.2, *Internal Rules of Procedure*) has the purpose of engaging in missions to gender issues such as:

- to promote and raise awareness of gender issues in the different Faculties, Interdisciplinary Centres and Administration of UL;
- to encourage the promotion and coordination of gender activities in the areas of teaching and research;
- to advise and help establish human resources policies taking into account issues of gender;
- to ensure the recruitment of staff to respect the balance between all genres;
- to develop organisational and infrastructure devices to improve the reconciliation between work and private life, particularly with regard to the care of children and other dependents;
- to raise awareness of issues of abuse of power, harassment or sexual harassment;
- to consult or advise the committee on request of disputes, EAC (and the Ombudsperson [3]) of UL on gender issues.

The role of the GMC is to bring rules and procedures on gender issues to the UL President's attention, to improve university life of staff and students of UL.

More information can be obtained from:

Gender Mainstreaming Committee

Internal Audit

The Internal Audit provides a service to all levels of UL's management. UL considers the Internal Audit as an independent and objective assurance and consulting activity designed to add value and to improve UL's operations.

The objectives of the Internal Audit are to assist members of UL by providing them with analyses, appraisals, recommendations, counsel and information concerning the activities reviewed and by promoting effective control, sound business practices and quality assurance.

The work of the Internal Audit includes:

(1) **Internal Audit Interventions**

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3 The **Ombudsperson** (*Internal Rules of Procedure,* Section 3, Art. II.4.301) listens to all UL members (Art. II.4.302), offers advice about the institute's policies and procedures and helps to promote ethical conduct and values. Further, (s)he is the first person to address for voicing one's concrete suspicion of misconduct. The OP works informally, must act in a strictly objective manner, and has the duty to observe confidentiality.

The Internal Audit operates as an objective and independent appraisal function, examining and evaluating the adequacy and effectiveness of UL's internal control systems and procedures. Furthermore the Internal Audit contributes through an ongoing quality assurance of the evolving operations and processes to the continuous development of UL. The scope of the internal auditing is defined within the audit plan which is discussed with the management beforehand.

(2) **External Audits**

The Internal Audit is coordinating and accompanying the audit intervention or review in order to ensure a proper course of action.

More information can be obtained from:

Internal Audit

Litigation Commission

The Litigation Commission is in charge of assessing the admissibility and the merits of claims and disputes which do not fall in the remit of the ERP and the EAC.

The Litigation Commission

- is consulted on all decisions of objections taken against students;
- shall be retained if the person appeals the decision of a disciplinary sanction imposed by the UL President against a student;
- designates one of its members to issue opinions in conjunction with the commission of specialists, if challenged by a temporary basis;
- can take part of an appeal from a user of UL library against a sanction taken against him/her.

More information can be obtained from:

Litigation Commission

Staff Delegation

The general mission of the Staff Delegation is to protect and defend the interests of UL staff related to work conditions, job security and status of staff. More in particular, this includes the following activities:

- to give its opinion and put forward proposals on any issue related to the improvement of working conditions, terms and conditions of employment and social rights of the employees;
- to present individual or collective complaints to the employer;
- to prevent and help resolve any individual or collective disagreements that may arise between the employer and the employees;
- to refer, where the aforementioned disagreements are not resolved, to the Labour Inspectorate any complaint or observation relating to the application of the legal, regulatory, administrative and contractual provisions relating to working conditions and protection of the staff;
- to give its opinion on the drafting or amendment of the operating regulations of the organisation, closely monitor the implementation of such rules and propose amendments on which management must take a decision;
- to promote the integration of disabled and handicapped persons, and endeavour to create jobs appropriate to their physical and intellectual capacity;

- to participate in the management of the institution's welfare activities;
- to protect staff against sexual harassment at work. If necessary, the employer is proposed any action to prevent such act;
- to give its opinion prior to the creation, modification and cancellation of a complementary pension scheme;
- to participate in safety and health at work, environmental protection, and in the prevention of work accidents and occupational illnesses. This is especially supported by the safety delegate;
- to contribute to equal treatment between female and male staff in terms of access to employment, vocational training and career advancement, and in terms of pay and working conditions, especially through the Gender Mainstreaming Committee;
- to propose modifications to internal by-laws (*Internal Rules of Procedure*).

More information can be obtained from:

Staff Delegation

Disability Office

The Disability Office is concerned with disability issues, to consider the special needs of students with disabilities and chronical health issues in all areas of UL. These include: architectural, accessibility related, and user aspects of teaching, learning, and research, including psychosocial counselling and advice on questions of reasonable accommodations (*e.g.* for tests and exams) and mobility.

More information can be obtained from:

Disability Office

1.4.2 External Committees

National Commission for Data Protection

The National Commission for Data Protection (Commission Nationale pour la Protection des Données, CNPD) is an independent authority created through the Luxembourgish law of August 2, 2002 on the protection of individuals with regard to the processing of personal data. It verifies the legality of the processing of personal data and ensures the respect of personal freedom and fundamental rights with regard to data protection and privacy. Its mission also extends to ensuring the respect of the amended Act of May 30, 2005 regarding the specific rules for the protection of privacy in the sector of electronic communications. The CNPD reacts by means of a judicial remedy to complainants who file any breach of rights and obligations.

More information can be obtained from:

National Commission for Data Protection (CNPD)

National Research Ethics Committee

The main role of the National Research Ethics Committee (CNER) is to protect the rights of participants in research studies, such as clinical trials involving experimental drugs, therapies, or medical devices. Its role is, therefore, bound to the fields of research, which involve human participants. A clinical trial which involves any medical intervention, as described above, may take place only after approval from the CNER and from the Ministry of Health (Art. 25, Luxembourgish Law of August 28, 1998).

National Consultative Ethics Committee for Life Sciences and Health

In Luxembourg, ethical concerns in research in the fields of biology, medicine and health are addressed by the National Consultative Ethics Committee for Life Sciences and Health (CNE), either on its own initiative or at the request of the Government, and the respective European Directives.

Luxembourg Agency for Research Integrity (LARI)

The Luxembourg Agency for Research Integrity (LARI) is a non-profit organization addressing cases of alleged scientific misconduct by establishing a National Commission for Research Integrity (CRI). The CRI's mission is to ensure an independent enquiry and investigation in cases of suspected scientific misconduct. The constitutent members of LARI are: The Luxembourg National Research Fund (FNR), The University of Luxembourg (UL), The Luxembourg Institute of Science and Technology (LIST), The Luxembourg Institute of Health (LIH), and the Luxembourg Institute of Socio-Economic Research (LISER).

More information can be obtained from:

National Commission for Data Protection (CNPD)
National Research Ethics Committee (CNER)
National Consultative Ethics Committee for Life Sciences and Health (CNE)

1.5 LEGAL AND POLICY FRAMEWORK

The framework of academic research at UL is defined by institutional policies (as listed below in the Table), as well as national and European legislation (Appendix 7.1).

Document	***Content***
Code of Conduct	Principles, values, standards, or rules of behaviour for UL
Internal Rules of Procedure	Rules relating to the operational aspects at UL, covering the role of the Council, Committees and all subsidiary bodies
Policy on Ethics in Research	Principles to apply to all research work carried out at or for UL
Safety Procedures	Explicit policies to limit the risk of work-related accidents, sickness and disability (*e.g.* Standard Operating Procedures, SOPs)

While focusing on the research itself, it is sometimes difficult for researchers to retain an overview of the different types of legal regulations and requirements that affect their research. When UL researchers conduct research in a country other than Luxembourg, procedures normally followed in the particular country may differ from those applicable in Luxembourg. The following table summarises the legislation that might affect research activities at or for UL:

Grand-Ducal Regulation

Minimum requirements for the workplace (transposing EU Directive 1990/679)	November 4, 1994
Frequency of medical examinations in occupational medicine	June 17, 1997
Protection of workers against the risks related to biological agents at work	June 8, 1999
Contained use of genetically modified organisms (transposing EU Directive 1998/81)	October 17, 2002
Clinical trials in human medicines (transposing EU Directive 2001/20/CE)	May 30, 2005
Protection of workers from risks related to exposure to laser radiation (transposing EU Directive 2006/25)	July 26, 2010
Protection of animals used in scientific research (transposing EU Directive 2010/63/UE)	January 11, 2013

Luxembourgish Law

Execution of EU Directives	August 9, 1971
Establishment of hospitals	August 28, 1998
Copyright (transposing EU Directive 2001/84)	April 18, 2001
Protection of personal data (transposing EU Directive 1995/46/CE)	August 2, 2002
Creation of the University of Luxembourg	August 12, 2003
Patents (transposing EU Directive 1998/44/CE)	April 25, 2008

EU Regulation

Registration, evaluation, authorisation and restriction of chemicals (REACH)	1907/2006
Classification labelling packaging (CLP) of chemicals	1272/2008
Horizon 2020 - the framework programme for research and innovation	1291/2013
Clinical trials (repealing EU Directive 2001/20/EC)	536/2014
General data protection regulation (repealing EU Directive 95/46/EC)	2016/679
Processing of personal data	45/2001

EU Directive [4]

Generation and contained use of genetically modified organisms	2001/18/EC
Generation and contained use of genetically modified micro-organisms	2009/41/EG
Protection of biotechnological inventions	1998/44/EC
Good clinical practice in the conduct of clinical trials of medicines for human use	2005/28/EC
Waste framework	2008/98/EC
Protection of animals used for scientific purposes	2010/63/EU

EU Decision

Specific programme implementing Horizon 2020	2013/743/EU

The *Policy on Ethics in Research* (Appendix 7.1.1) outlines the principles that apply to all research work carried out at or for UL. It should be read in conjunction with the present guidelines which deliver the specifications of ethics in research at UL. In order to provide a framework for researchers to deal with the ethical aspects of their research, a range of topics that might arise during planning and conducting a project is covered in the present Research Ethics Guidelines.

4 EU Directives are translated into national law. As they can be even more strict than EU Directives, Grand-Ducal Regulations and Luxembourgish Laws have priority in the host country. For example, the EU Directive 2009/41/EG is not applied in Germany, because of a stricter national law.

Chapter 2 defines the general ethical core values and principles of good scientific practice (2.1) in order to ensure research integrity and quality. As many different research areas are addressed, the present ethics guidelines are broad and have been formulated so as to comply with internationally accepted guidelines for good scientific practice. They are not, however, meant to be exhaustive for all research areas. Detailed information and relevant documents are in place in many (discipline specific) research areas at UL. Deviations of good scientific practice leading to research misconduct (2.2) are summarised in the same chapter and underline the importance of following good scientific practice guidelines (2.3).

Chapter 3 explores the phases of risk assessment and risk minimisation in the design of ethical research implicating human participants, human biological material, personal data, animals, researchers, and/or potentially harmful changes to the environment, as well as dual-use research of concern during dissemination of scientific knowledge. The ethical considerations in research implicating the listed parties are addressed in detail.

Chapter 4 focuses on the ethical considerations of the Ethics Review Panel and the Animal Experimentation Ethics Committee for the reviews of research proposals (and publications). Any research involving human participants, human biological material, personal data, animals and/or potentially harmful changes to the environment; which is prepared, conducted, or published by or with support of its Faculty, staff, junior researchers, students, or visitors; must be reviewed by the ERP and/or AEEC.

UL will take allegations of misconduct in research very seriously and respond appropriately if such misconduct has indeed taken place. Chapter 5 outlines the institutional procedures on suspected or alleged misconduct in research, and addresses the situation of the involved parties before official complaint as well as resulting from research misconduct.

Chapter 6 provides the readers with an up-to-date list of internal as well as external contacts, with whom they can get in touch when needed.

Chapter 7 is devoted to additional informations which might be useful when performing research, *e.g.* types of legal acts, types of national and international agreements, as well as guidance on how to publish.

2 RESEARCH INTEGRITY AND QUALITY

In the following chapter, we define the general ethical core values and principles of good scientific practice that are important to ensure research integrity and quality. Deviations of good scientific practice leading to research misconduct are summarised afterwards and underline the importance of following good scientific practice guidelines.

2.1 GENERAL ETHICAL CORE VALUES AND PRINCIPLES OF GOOD SCIENTIFIC PRACTICE

Any research should be designed, undertaken, published and reviewed in a way that ensures scientific integrity and quality. To successfully promote and maintain these core values, the following fundamental principles of good scientific practice (GSP) have been set by the European Science Foundation and should be understood and applied to all research work carried out at or for UL:

* ***Honesty*** in respect of own actions as well as of other researchers
* ***Duty of Care*** for humans, animals, the environment or the objects studied
* ***Reliability*** in performing research planning, execution, self-discipline and quality control
* ***Confidentiality*** to ensure respect towards study participants through data privacy
* ***Trust(worthiness)*** towards the public, research community and funding bodies
* ***Objectivity*** through facts capable of proof and transparency in handling of data
* ***Impartiality and Independence*** to avoid conflict of interest
* ***Fairness*** in acknowledging the contribution of predecessors, competitors and colleagues
* ***Openness and Accessibility*** through fair and full, open and honest communication
* ***Responsibility*** towards all professional and social parties, for future science generations

The commitment of researchers to adhere to these principles of GSP defines scientific integrity as these are prerequisites for the credibility and acceptance of research and science.

🕮 Read more:

The European charter for researchers (European Commission)
Singapore statement on research integrity
The European code of conduct for research integrity (ESF)
Fostering research integrity in Europe (ESF)
Integrity in scientific research (Swiss Academies of Arts and Sciences)
Scientific integrity (ISBN 978-1555813185), Bibliolab

2.2 RESEARCH MISCONDUCT

The following types of irresponsible conduct of research can be distinguished:

- Severe Misconduct
- Deviation of Accepted Practice
- Retaliation against any Person
- Conspiracy

- Encouraging Misconduct by Exerting Pressure

Research misconduct does not include **honest error** or honest differences in opinions, interpretations or judgments of data.

A **finding of research misconduct** (Gewin *et al.*, 2012) requires that:

- the misconduct is committed intentionally, knowingly, or recklessly;
- there is convincing evidence.

Research misconduct can vary from the less to the most severe forms through the degree of impact: sloppy work, questionable practice and severe misconduct. The illustrated examples in the following paragraphs should raise awareness of the different forms of research misconduct in the research community.

🕮 Read more:

Best practices for ensuring scientific integrity and preventing misconduct (OECD, 2007)
Do pressures to publish increase scientists' bias? (PLOS ONE)
Pathological publishing (The European Journal of Psychology applied to legal context)
Misconduct policies, academic culture and career stage, not gender or pressures to publish, affect scientific integrity (PlosOne)
Only human: scientists, systems, and suspect statistics (Opticon1826)
Research: Uncovering misconduct (Nature)
Negative results are disappearing from most disciplines and countries (Springerlink)
Investigating the effect of academic procrastination on the frequency and variety of academic misconduct (taylor & francis online)
Risk factors for fraud and academic misconduct in the social sciences (academia.eu)
Why the impact factor of journals should not be used for evaluating research (BMJ)

2.2.1 Severe Misconduct

Severe misconduct is defined as fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results from research activities.

Fabrication means making up data or results, and recording or reporting them.

Falsification means manipulating research data, materials, equipment, or processes, or selectively changing or omitting undesirable results so that data is not accurately represented in the research record. Data can be distorted through bias or lack of objectivity by

- "*cherry picking*", when a researcher selects only segments of evidence that appear to be in favour of his/her own hypotheses and ignores the ones refuting them;
- "*p-hacking*" or "*data fishing*", measuring increased number of samples until any statistical significance shows up, and
- "*HARKing*", hypothesising only after the results are known (*post-hoc*) while pretending that these hypotheses were formulated *a-priori*. This should not be confused with the inductive research approach. The inductive approach (or inductive reasoning) is an accepted research strategy, which starts with observations, followed by theories or hypotheses that are proposed towards the end of the research process as a result of these observations .

🕮 Read more:

Forensic tools in biomedical science (ORI)
The art of detecting data and image manipulation (Elsevier)
Forensic software traces tweaks to images (Nature)
Screening tool for unreliable data (Wiley)
Data mining techniques in fraud detection (Rekha Bhowmik)
Detecting fraud at journals (The Scientist)
Calculating the probability of random sampling for continuous variables in submitted or published randomised controlled trials (Wiley)
Are these data real? Statistical methods for the detection of data fabrication in clinical trials (BMJ)
Faking science: a true story of academic fraud (Diederik Stapel)
How many scientists fabricate and falsify research? (PlosOne)

Plagiarism is regarded as a non-legal but ethical offense, which needs its own set of elements and is defined as *"the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts"* (Federal Office of Science and Technology Policy, 1999). The perpetrator committing plagiarism is *"thereby gaining (him-/herself) the rewards earned by others"* (Bruce Railsback, University of Georgia). The objects of plagiarism can include *"words, ideas, findings, writings, graphic representations, computer programs, diagrams, graphs, illustrations, information, lectures, printed material, electronic material, or any other original work created by someone else"* [5] (Higher Education Academy, UK).

Plagiarism is among the most frequently reported ethics issues and accounts for 42% of all types of misconduct cases reported to Elsevier Journals publishing staff in 2012. Errami and Garner reported that *"up to 200,000 of 17,000,000 articles in Medline database (1.2%) may be duplicates, or plagiarised"* (Fig. 2, Errami *et al.*, 2008).

As a legal offense however, the **violation of intellectual property rights** includes *"artistic and literary works"* (such as publications, books, art paintings) which are owned by their creators and are protected by copyright-related rights and databases, covered by the Luxembourgish Law of April 18, 2001. Also inventions deriving from research are protected by the Patent Law of April 25, 2008 (Art. VI.1.101, *Internal Rules of Procedure*).

More information can be obtained from:

Legal Affairs

🕮 Read more:

Guiding principles for the valorisation of research results and intellectual property rights (UL)
Valorisation and intellectual property rights (UL)
How to file a patent in Luxembourg: an applicant's guide (Ministry of Economy and Foreign Trade)
10 pragmatic recommendations for a better integration of IP in your business (LuxInnovation)
A tale of two citations (Nature)

5 The use of freely available sample letters (such as cover letters) is not considered as plagiarism. However, it is still advisable to adapt the text to the situation rather than literally copying these letters.

Deception can occur in proposing, carrying out, or reporting results (*e.g.* abstracts, posters, papers, presentations, conference papers) from research activities. A typical example for unethical research is the Tuskegee study that investigated the effects of untreated syphilis in the 1930s in Alabama. Study participants were not informed about the fact that they had syphilis and the purpose of the study. They were given a lumbar puncture, which was misleadingly described as a *"special free treatment"*.

When reporting results from research activities, **claiming and offering undeserved authorship** as well as denying authorship (also in case the person leaves the workplace) are unacceptable, and should be categorically excluded:

Authorship Forms	***Definition***
Ghost or phantom authorship	To leave out authors who should be included
"Honorary" authorship [6]	To include authors who did not contribute significantly
Paper doping, authorship clubs / cartels	To add guest author(s) to increase chances of publishing
Group authorship	To name a group as sole author without giving individual names

Unreasonably obstructing or delaying a publication, as well as including a researcher's name to a publication against his/her wishes are also part of false and deceptive forms of authorship. Please find the ethical responsibilities for authorship and inventorship in Appendix 7.5.

Senior scientists should strictly refrain from the **exploitation of young scientists** (including students), especially the wrongful appropriation of their scientific contribution without the appropriate acknowledgement of authorship or co-authorship. Any psychological, social or economic **pressure** should not be exerted on any involved researchers (Chapter 2.2.4).

In general, the publication policy known as the **Ingelfinger rule** states that journals only consider manuscripts in which the substance has not been submitted or reported elsewhere (Angell *et al.*, 1991). Scientists should avoid **duplicate** submission or publication**,** where manuscripts describing essentially the same research are published in more than one journal or primary publication (including translations), unless it is permitted by both journals and stated in the secondary publication. **Salami slicing**, or creating several publications from the same research (*"least publishable unit"*), should also be avoided as it is manipulative towards the publication system.

🕮 Read more:

International Committee of Medical Journal Editors (ICMJE)
How to handle authorship disputes: a guide for new researchers (COPE)
Authorship in scientific publications (Swiss Academies of Arts and Sciences)
Best practice guidelines on publication ethics (Wiley)
Authorship and responsibilities (Online lecture, Elsevier)
Simultaneous submission/multiple, duplicate publication (FactSheet from Elsevier)

[6] Also known as courtesy authorship, default authorship, gift authorship or guest authorship.

Salami slicing (FactSheet from Elsevier)
Incidence of data duplications in a randomly selected pool of Life Science publications (Sci Eng Ethics)
The Ingelfinger Rule Revisited (NEJM)

2.2.2 Deviation from Accepted Practice

Deliberate, dangerous or negligent deviations from accepted practice (GSP standards) in carrying out research are regarded as research misconduct. Firstly, this includes failure to follow agreed protocols, if this failure results in

i) unreasonable risk or harm to humans, animals and/or the environment, and/or

ii) infringements of quality and integrity of research data.

Examples of deviations from accepted practice can include:

- insufficient understanding of accepted practices;
- setting up methods which are not in line with the study aim;
- failure to follow the investigation plan;
- errors of experimental (*e.g.* inaccuracy in the execution of methods), analytical (*e.g.* improper use of statistics, conclusions not in line with data collected) or computational nature;
- participant's consent form designed to attract in a manipulative way;
- personal data not preserved according to ethical standards;
- misusing animals for research purposes;
- leaving important changes to the environment.

🕮 Read more:

International Statistical Institute's code of ethics (ISI Council)
Statistics making an impact (The Royal Statistical Society)
Uses and misuses of statistics (K C Chakrabarty)
Why most published research findings are false (PloS)
The rules of the game called psychological science (SagePub)
Improving research reproducibility (Ahajournals)
Assessing the integrity of clinical data (Springer)

Secondly, deviation from accepted practice can occur through facilitating misconduct in research by collusion in, or concealment of, such actions by others.

Conflicts of interest (COI) can arise in situations at work when an employee's personal interests overlap with professional interests and, therefore, create a bias in professional judgement and objectivity. Combining ICMJE with their own criteria, Friedman and Richter found that between 16.6% and 32.6% of manuscripts had one or more author(s) with a COI, and found a strong association with positive reported findings (Friedman *et al.*, 2004). In 1997 only 16% of over 1300 scientific journals had established COI policies, and less than 1% of the articles published in these journals contained any COI disclosures (Krimsky *et al.*, 2001).

Type of COI	***Involvement***	***Examples***
Intangible conflicts	Academic activities and scholarship	Fairness in teaching evaluation, preferences of research proposals, rivalry with colleagues, conflicts of commitment

Tangible conflicts	Direct financial benefits	Employment, equity interests, grants, or patents
	Indirect financial benefits	Honoraria, consulting fees, mutual fund ownership, or expert testimony

Intangible conflicts of interest involve scholarly or academic, professional, or social concerns; while tangible conflicts of interest can be quantified or measured. As such, the latest usually involve a financial connection or arrangement between two or more parties involved in the research.

The correct way to handle any potential COI is through transparency and disclosure. As an example, while publishing any disclosure of potential COI needs to be given by the authors in the **cover letter** to the journal editor. The editor, reviewer and authors should:

- Not misrepresent credentials or publication record;
- Not be closely related to each other (*e.g.* family, partner, close friend);
- Not have had a professional relationship (*e.g.* student-supervisor, scientific collaboration);
- Not have common economic interests (*e.g.* through the joint management of a company);
- Not be direct scientific competitors (unfairly holding up a rival's publication);
- Not have been involved in the evaluation of each other's institutions or running projects.

More information can be obtained from:

Legal Affairs

🕮 Read more:

Conflicts of interest (Columbia University)
Scientific peer review of research grant applications and development contract projects (NIH)
Financial relationships and interests in research involving human subjects
The effect of a COI disclosure form using closed questions on the number of positive COI declared (PeerJ)
Factsheet: Conflict of interest (Elsevier)
Conflict of interest policies in science and medical journals (Sci. Eng. Ethics)
Research ethics for scientists: A companion for students (ISBN 978-0-470-74564-9, BiblioLab)
Health industry practices that create conflicts of interest: a policy proposal for academic medical centers (JAMA)
Relationship Between Conflicts of Interest and Research Results (J Gen Intern Med.)
Conflict of interest policies in science and medical journals: editorial practices and author disclosures (Sci Eng Ethics)

2.2.3 Conspiracy

Conspiracy is defined as a secret plan by an individual to apply unlawful or harmful practices.

Sabotage includes damaging, destroying or manipulating experimental arrangements, equipment, documents, hardware, software, chemicals or other materials required by another person to carry out a research activity. When Heather Ames joined the research group at the University of Michigan, she turned out to become a victim of sabotage. The post-doc Vipul Bhrigu destroyed his colleague's experiments by poisoning her cell culture media with alcohol to get ahead (Maher *et al.*, 2010).

🕮 Read more:

Sabotage (Nature)
Research fraud factsheet (Elsevier)
The Swedish Research Council's definition of *"scientific misconduct"* (Springer)

In the peer review process, the identity of reviewers is often kept anonymous from the authors. This results in a **lack of transparency** with regards to evaluative information about research proposals, and published articles. A handful of researchers have exploited loop-holes in the peer review system to ensure that they would review their own papers, or obstruct the review of their competitors' papers. Delaying reviews on purpose, or passing on scientific results which have been acquired in confidence, is regarded as research misconduct. Please find the ethical responsibilities of peer reviewers in Appendix 7.7.

🕮 Read more:

Committee on Publication Ethics (COPE)
Peer review policy (Nature Publishing Group)
The peer review scam (Nature)
On being a scientist: A guide to responsible conduct in research (ISBN 978-0309119702, BiblioLab)
Opening peer review: the democracy of science (Journal of Negative Results in BioMedicine)
Keeping the minutes of science (Velterop JJM, ELVIRA 2)
An index to quantify an individual's scientific research output (PNAS)
Research Integrity: Sabotage! (Nature)

2.2.4 Encouraging Misconduct by Exerting Pressure

Scientists and institutions are exposed to enormous pressure to *"publish or perish"*. Under all circumstances however, good scientific practice guidelines must be followed. No pressure should be put on researchers to produce *"good"* or *"nice and round"* stories containing substantial publication bias in terms of positive findings or appealing novel concepts. Sometimes, and inadvertently, situations may arise where not only the community but also the superior and/or supervisor contributes to creating an environment, in which pressure is exerted to confirm or reject predefined outcomes at all costs. At UL, any kind of such behaviour is regarded as research misconduct.

2.2.5 Retaliation against any Person

Misconduct also includes retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct in research and who has not acted in bad faith. However, if any allegation is found to be unsubstantiated, and has been frivolously or maliciously made, this may result in disciplinary action being taken against the member of staff who made the allegation (Chapter 5.4.3).

🕮 Read more:

OECD
The journal's role in scientific misconduct (ORI)
Scientists behaving badly (Nature)
Why growing retractions are (mostly) a good sign (Fanelli D)
A comprehensive survey of retracted articles from the scholarly literature (PloS)
Ethical authorship and the Ingelfinger Rule in the Digital Age
Measuring scientific misconduct - lessons from criminology (MDPI)

Scientific misconduct in Europe: a confusing situation (scienceonthenet)
Coping with scientific misconduct (BMJ)

2.3 MANDATORY OBSERVATION OF GOOD SCIENTIFIC PRACTICE GUIDELINES

2.3.1 Particular Responsibilities of the University of Luxembourg

The measures taken by UL to ensure that their researchers adhere to GSP, can be divided by their nature into preventive, detective and corrective measures.

Preventive Measures

Infrastructure and Organisation

As it is essential that institutions provide the infrastructure and the organisational prerequisites for safeguarding GSP (Art. II.4.2-bis 101, *Internal Rules of Procedures*), UL has formulated the *"Policy on UL Ethics in Research"* (Appendix 7.1.1), and has established the Ethics Review Panel and other positions (*e.g.* safety officers) to ensure the safety of human participants and researchers in research, as well as to disseminate GSP. These guidelines and procedures should be followed by all individuals, *i.e.* staff (principal investigators, researchers and research assistants), junior researchers (doctoral candidates), students (graduate, undergraduate), and visitors (including contractors on campus) involved in conducting research at or for UL.

GSP Training

UL has the responsibility to convey to all individuals involved in conducting research at or for UL the basic rules and values of responsible conduct of research in all its steps, according to national and international regulations and guidelines. To raise awareness of GSP and aim for sensitisation, the ERP organises the Induction Days, and disseminates information during trainings, in written form, e.g. the present Research Ethics Guidelines.

The GSP training aims at strengthening the ethical culture and *"responsible institutional behaviour"* within UL. GSP guidelines are taught to all students, PhD candidates and junior researchers, preferably at the beginning of a degree course when introducing the basics of scientific work.

All researchers are expected to attend an ethics training, for example the course on *"Good Scientific Practice"* which is taught at UL on a regular basis.

More information can be obtained from:

www.scientificintegrity.de

📖 Read more:

Tie funding to research integrity (Nature)
Scientists (of the world) behave! (Wiley-VCH)
The impact of ethics programmes and ethical culture on misconduct in public service organisations (Emerald Insight)

Detective and Corrective Measures

Cases of Suspected or Alleged Misconduct in Research

To carry out its responsibility in research, UL must take proper precautions in the legal framework to respond to cases of suspected or alleged misconduct in research so that UL can meet the expectations placed on it, and to control and prevent the misuse of facilities and funds.

UL's procedures include the provision *i)* to have a recognized committee in place (*i.e.* the Ethics Review Panel) who undertakes an assessment, and *ii)* to refer cases to an independent body (Luxembourg Agency for Research Integrity; LARI) to undertake an enquiry and investigate cases of suspected or alleged misconduct in research.

Insurance

Research, such as clinical trials involving drugs, can lead to drug-induced suffering through *Adverse Drug Reactions* or *Suspected Unexpected Serious Adverse Reaction* [7]. Such adverse reactions may include hearing loss, allergic reactions to medication applied (*e.g.* streptomycin), or quadriceps muscle contracture resulting from intramuscular injection of chloramphenicol. UL recognizes its obligation to individuals (researchers as well as human participants) who may suffer unintended, adverse consequences as result of participation in a research study performed at or for UL, and guarantees treatment and compensation costs for any damage inadvertently caused.

More information can be obtained from:

Assistant of the Director of Administration

2.3.2 Particular Responsibilities of Superiors and/or Supervisors

Preventive Measures

Superiors and/or supervisors should create an atmosphere of trust and honesty, discuss issues openly, and define clear guidelines (regarding *e.g.* lab books, server space for original data, Chapter 3). They should act as role models in order to practice, encourage and teach GSP.

It is the responsibility of the superiors and/or supervisors to ensure, that

i) their team members attend the ethics trainings;

ii) they are particularly made aware of research area-specific ethics topics; and

iii) research projects under their supervision are conducted on a day-to-day basis applying the principles of GSP, and in compliance with rules and regulations as mentioned in Chapter 1.

Detective and Corrective Measures

Superiors and/or supervisors have the duty

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7 An **adverse drug reaction** is *"an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product."*
A **suspected unexpected serious adverse reaction** is an adverse reaction that is both unexpected and also meets the definition of a serious adverse reaction.

i) to act in cases of suspected or alleged misconduct in research;
ii) to review allegations with competence, impartiality and independence; and
iii) to forward such cases to the responsible committee(s).

2.3.3 Particular Responsibilities of the Individual Researcher

All parties involved in a research project are accountable for their actions within the project. Individual researchers are **accountable** towards society, colleagues and/or project partners, their research area, their collaborators, their employers and/or research institution and other places where the research is taking place, and, to the funding body sponsoring the research. This includes respecting human participants, animals, the environment, and the research community.

Being an author not only comes with credit but also with **key responsibilities** to report only real and unfabricated data within a reasonable time frame. When presenting the results, researchers have to be aware of the results they have produced. Thus, conclusions have to be in line with the data collected and the limits of their reliability and applicability have to be explicated.

Researchers must adhere to the ethics policies of UL, of research funding bodies and publishers, and need to reflect on a regular basis as to whether they adhere to sound principles of good scientific practice.

🕮 Read more:

Seven reasons to care about integrity (Science Europe)
Research integrity guidelines (FNR)
Dissecting doctoral advising: a comparison of students' experiences across disciplines (Taylor & Francis Group)

3 GUIDELINES FOR GOOD SCIENTIFIC PRACTICE

The following chapter explores the phases of risk assessment and risk minimisation in the design of ethical research implicating human participants, human biological material, personal data, animals, researchers, and/or potentially harmful changes to the environment, as well as dual-use research of concern during dissemination of scientific knowledge. The ethical considerations in research implicating the listed parties are addressed in detail in the following.

3.1 RESEARCH AREA-SPECIFIC ETHICAL REQUIREMENTS

When designing a research project, the principal investigator (PI) needs to validate - in addition to questions of scientific validity - whether his/her project design complies not only with **legal requirements** (Chapter 1.5) but also **ethical requirements**. This includes an appropriate level of risk-use assessment with regards to the fundamental rights including legal rights of the society, participants, the community they represent and researchers as well as animals involved.

Depending on the research environment, many **ethics guidelines** and details on the circumstances specific to the **different research areas** have been published, *e.g.* from professional societies, that are useful in the planning of research. Some examples are listed below:

Research Area	***Professional Association***
Life Sciences	Life Science Research (World Health Organisation) Declaration of Helsinki (World Medical Association, 1964) Universal Declaration on Bioethics and Human Rights (UNESCO) Convention on Human Rights and Biomedicine (Council of Europe) Biomedicine Convention
Physics and Engineering	American Physical Society National Academy of Engineering National Society of Professional Engineers Center for Engineering Ethics and Society The American Society of Mechanical Engineers Royal Academy of Engineering
Humanities and Social Sciences	American Psychological Association British Psychological Society Deutsche Gesellschaft fur Psychologie International Sociological Association American Anthropological Association

It is challenging to maintain research integrity standards within **cross-boundary research collaborations** as involved institutions might have different views on research culture, training methods as well as on the publication of research results. Therefore, before research is initiated, it is important to delineate the rights, obligations, expectations, and roles played by all parties involved in the study (*e.g.* authors and journals).

Agreements should be taken in compliance with laws, policies and regulations (Chapter 1.5) and ratified by all collaboration partners (Montreal statement). Publication clauses, for example, that restrict the investigator

(non-disclosure agreements, confidentiality agreements) are problematic from an ethical point of view, because they make it difficult to openly access research results. This may cause for relevant results (*e.g.* for specific patient groups) to be published late or not at all, and may, therefore, delay or prevent future research on this topic. A list of different types of national and international agreements, compiled by the Legal Affairs Office, can be found in Appendix 7.4.

More information can be obtained from:

Legal Affairs

🕮 Read more:

Global Science Forum (OECD)
Montreal statement on research integrity in cross-boundary research collaborations (3rd World Conference on Research Integrity)

3.2 Risk Assessment and Minimisation

"A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

(U.S. Department of Health & Human Services)

Managing risk and uncertainty is essential to the success of research projects. Research studies can entail possible ethical risks to the environment and/or the fundamental rights of study participants, for which an assessment needs to be undertaken. The research project must entail minimal risk and burden to the society, participants, the community they represent, and researchers as well as animals involved. Under all circumstances, any risks should be balanced against the anticipated benefits of the research study (proportionality) and a *"minimal-risk standard"* must be respected. Possible risks to any parties involved in research are listed in the following table.

Ethical Considerations	***Examples of Possible Risks***
Human participants	Potential physical or psychological harm
Human biological material	Circumstances of collection
Personal data	Circumstances of collection, disclosure of personal data, re-use of personal data, loss of confidentiality
Animals	Misuse of animals, potential harm
Researcher [8]	Accidents with lasers, physical damage, chemicals, biological agents
Environment	Temporary or permanent changes to the environment
Dissemination of scientific knowledge	Dual-use research of concern, authorship disputes, peer review process

The PI needs to assess the risks and benefits of implicating humans or animals in research, and reflect on any **measures** that need to be put in place to mitigate possible ethical risks. Each research project implicating

8 This includes all individuals involved in conducting research at or for UL: Staff, junior researchers, students, visitors or any other third party.

potential risks must be reviewed and approved by an Ethics Commission in accordance with all applicable laws (Chapter 1.5), *before* the work for which ethics approval is sought is undertaken.

🕮 Read more:

Code of practice for research (UKRIO)
Recommended checklist for researchers (UKRIO)

3.2.1 Human Participants

Any researcher should consider and be aware of the active or passive involvement of human participants in their study (National Science Foundation), *i.e.* individuals from whom the researcher intends to obtain:

- *Data through interaction,*
  Interaction includes communication (*e.g.* written as *per* questionnaires) or interpersonal contact between researcher and participant (*e.g.* face-to-face as *per* interview).

- *Data through intervention*,
  Intervention includes both (1) physical procedures by which data are gathered and (2) manipulations of the participant or the participant's environment, that are performed for research purposes.

The potential risks for human participants involved in a study are summarised in the following table:

Potential Risk	***Description***
Physical harm	Exposure to pain, discomfort, or injury from invasive procedures
Psychological harm	Anxiety, distress and/or any other kind of psychological harm
Deception	Intentionally misleading, withholding information about the nature of experiments
Invasion of privacy	Intrusion of subjects' private space
Breach of confidentiality	Misuse of information that has been given voluntarily by a study participant
Social and economic harm	Actions that may result in embarrassment, guilt, stress, loss of employment, or criminal prosecution

The **protection of the fundamental rights** including legal rights of study participants must be the highest priority during planning and execution of research studies. These rights include respect, autonomy, safety, health, well-being, privacy, confidentiality, and dignity.

Fundamental Right	***Examples of Possible Risks***
Respect	Human biological material treated as means
Safety	Unsafe environment during study
Health	Physical harm Psychological harm (emotional, behavioral) Deception
Well-being	Potential stress or fatigue through collection of data
Privacy and Confidentiality	Infringement of participant's *"private space"*
Autonomy and Dignity	Moral or financial obligation to participate in study

Due to potential risks in the use of *"any form of capture, processing and dissemination of sounds and images that identify individuals"*, it must be clear which **inclusion and exclusion criteria** will be used for the

recruitment of participants prior to data collection. After choosing the appropriate research method, a researcher needs to determine whether (s)he needs to acquire permissions (*e.g.* safety procedures, patent rights, legal regulations concerning research with humans or animals) to apply the chosen method. Data can be either collected **directly** (*e.g.* questionnaires, forms, interviews) or **indirectly** from a person, which means that data are used for further processing or secondary use [9] (*e.g.* data collected from medical patient records) (Art. 4(2), amended Luxembourgish Law of August 2, 2002).

Examples in which appropriate measures are taken to protect the fundamental rights of the human participants are listed:

Fundamental Right	***Appropriate Measures Taken***
Well-being	The researcher has the duty to ensure that study participants do not leave the data collection session (*e.g.* experimental session, interview) in a worse condition than before the study, *i.e.* mentally sound and physically fit.
Autonomy	In rare cases, the number of study participants may not be sufficiently high and researchers may, therefore, volunteer for **self-experimentation**. However, to ensure objectivity in a research project, self-experimentation is not recommended.

🕮 Read more:

National Science Foundation (NSF)
Common rule for the protection of human subjects (NSF)
ALL European Academies (ALLEA)
Ethics of self-experimentation (COPE)

Vulnerable Groups and Children

Particular consideration must be given in case the research study involves vulnerable populations. Vulnerability can result from limited or complete lack of autonomy and/or freedom, social discrimination, stigma, dependency as well as increased physical or psychological susceptibility towards the study circumstances:

- *Vulnerability derives from participation in research due to possible undue consequences,*
  the economic situation of the participant can potentially affect the autonomy to give informed consent and dignity to participate in a research study.
- *Vulnerability can be increased due to study circumstances,*
  Individuals can participate under certain conditions only, *e.g.* patients.

Vulnerable populations include pregnant women, neonates, children and adolescents, individuals with cognitive impairment and/or mental disorders, people with anxiety disorders or other mental disorders, mentally-deficient persons, members of social minorities, the elderly, and detained persons.

9 Further processing for secondary use of data must be authorised by the CNPD (Chapter 4.1.2).

Before engaging in research with vulnerable populations, it should first be clearly established that similar results could not be obtained or derived from non-vulnerable populations (*principle of subsidiarity*) (European Commission).

Assessment of potential harm includes the type of intervention, magnitude, probability, timing, equity, as well as **unexpected findings**. Specific ethical consideration for vulnerable groups and children is also needed with regards to the Information Sheet as well as the Informed Consent (Participants' Information and Consent), as these groups might not be able to give informed consent. Therefore, a legal representative or guardian must be available.

To reduce the number of vulnerable groups in a study to a minimum,

i) any specific characteristics of the **recruitment method** must be outlined,
eligibility, inclusion and exclusion criteria, and characteristics of the source population (*e.g.* cases and control groups) must be justified,

ii) the objective sampling as well as the detailed consideration of the necessary sample size and effect size should be performed using power analysis, where appropriate (Art. 8, Helsinki Declaration).

As vulnerable groups might be more sensitive to different conditions during the study (*e.g.* destabilisation), the duration and intensity of the study must not be exhausting. This can be solved by *e.g.* including regular breaks, performing interviews in the presence of psychological support. The location in which the study takes place must be appropriate to the study, and must not add any risks nor any infringement to the fundamental rights of the participants.

🕮 Read more:

Ethics for researchers (European Commission)
The World Medical Association Declaration Of Helsinki (June 1964, as amended by the 64th WMA)
Opinion 2/2009 on the protection of children's personal data (Data Protection Working Party)
Working document 1/2008 on the protection of children's personal data (Data Protection Working Party)
Guidelines for the ethical conduct of medical research involving children (Archives of Disease in Childhood)
A Child's Legal Rights - Gillick competency and Fraser guidelines (NSPCC)
Ombudscommittee for Children's Rights (ORK)
Ethics and Research with Children (ISBN 0-335-21650-1, Bibliolab)

3.2.2 Human Biological Material

Studies in which the researcher obtains pathological or diagnostic specimens from human participants, or establishes cell-lines from human biological material[10], must be subjected to a risk assessment and risk minimisation in compliance with the Grand-Ducal Regulation on clinical trials in human medicines of May 30, 2005 and the Luxembourgish Law on hospital establishments of August 28, 1998 as well as the *"Good Clinical Practice"* guidelines, an international quality standard that is provided by the *International Conference on Harmonisation.*

[10] Human biological material includes body fluids, tissues, organs, biopsies, as well as biological waste.

Pathological or diagnostic specimens can be obtained directly from participants, or indirectly *via* so-called *"population biobanks"* or other repositories. In the first case, the **collection** process of human biological material may involve **potential harm or risks** for participants and researchers (Art. 8, Helsinki Declaration). The collection of human biological material could imply potential stress or fatigue in human participants. The duration and intensity of tests must, therefore, not be exhausting. The amount of human biological material extracted must not harm the study participant. An example in which appropriate measures are taken is listed:

Risk Assessment	***Appropriate Measures Taken***
Repetitive blood sampling. Risk of infection at sampling site.	Blood draws up to 350 mL /day doses do not represent a significant risk according to published evidence. Blood draw occurs only in specialised facility after appropriate cleaning and performed by professional personnel.

Researchers performing the extraction should be trained and qualified to perform the data collection. Data collection should take place in a specialised facility, that deals with the potential risks that might occur during data collection.

In the second case, i.e. human biological material is extracted at another institution than UL, the **source** institution needs to provide the ethical approval of the respective Ethics committee (in addition to the Ethics Review Panel) (Chapter 4.1.2).

Further, the extent to which collected biological material can be linked to the identity of its donor is decisive during risk assessment as research can be potentially harmful to groups associated with the donor. Patients have the right to know whether their medical records and biological specimens which have been collected for other purposes (*e.g.* for clinical care), may be used for future epidemiological research. Further consent of the patients is not needed, unless the research for which these data are used poses more than minimal risk.

Under the present category, already established cell-lines (commercially available) are considered to entail only low risk as they are well characterized and the researchers are provided with the safety information sheet.

🕮 Read more:

HeLa Cells: A new chapter in an enduring story (NIH)
AABB technical manual (Chapter 4)
Transfusion Therapy, Clinical Principles and Practice (Paul D. Mintz MD, AABB Press)
Transfusion Medicine: Self-Assessment and Review (ISBN 978-1563951664)

Participants' Information and Consent

1. *Conditions for a valid consent*

All studies involving human participants from whom personal data or biological samples are collected, stored, processed, analysed and/or reported on, require **informed consent** to be obtained from the individuals taking part in the research study (Art. 25-32, Helsinki Declaration).

An informed consent is based on the principle of **autonomy** and is defined as *"the decision, which must be written, dated and signed, to take part in a (study), taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent*

or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation." (FP7, EU).

"Chapter I Art. 2. (c): "the data subject's consent": any freely given specific and informed indication of his wishes by which the data subject or his legal, judicial or statuary representative signifies his agreement to personal data relating to him being processed." (Act of July 27, 2007)

When personal data are involved in any research projects, legal requirements (August 2, 2002) foresee that consent must be given by the study participant **freely, specific and informed** for the research purpose. With the new Data Protection Regulation[11] of 27 April 2016 that will become applicable from 25 May 2018 in the Grand-Duchy, the consent of the person concerned must always be free, specific and informed, as defined above. It should also be unique and the result of an expression of will by which the person concerned agrees, by a statement or a **clear affirmative act**, that data relating to the person being collected, processed and stored (Art. 4 and 7, EU Regulation 2016/679). This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement, or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent[12].

In case of collection or processing of **sensitive data** (Chapter 3.2.3) within the meaning of Article 6 of the aforementioned law (August 2, 2002), the law requires that consent must be express, that is to say explicit. Express consent covers all situations where it is offered to a person to accept or reject a particular use or disclosure of personal information and to actively respond to the question, whether orally or in writing. For example, in case study participants provide **biological material and personal data** as part of the study, consent must be given for both parts as well as for data storage (European Forum for Good Clinical Practice, EFGCP).

If appropriate, the consent form should contain information for cases in which there may be **unexpected (*i.e.* incidental) findings** in health-relevant data, *i.e.* if the research reveals physical, mental or otherwise unusual information the participant is not aware of. The consent form should provide the option for participants to indicate whether they want to be informed and if so, whether they wish to be referred to a professional trained in the specific area of concern (*e.g.* mediator, general practitioner) to discuss further action (confidentiality overruled by health at risk consideration).

2. *Modalities of a valid informed consent*

Generally, explicit or express consent is given in writing and attested by a handwritten signature, to guard proof if challenged. The use of the oral form of the informed consent in research projects is considered as a valid option but must be justified as it presents evidence concerns. This could involve *e.g.* participants who are uncomfortable when reading and writing. In any case, the researcher must record the statement of a consent, and the clear answer of the participants indicating willingness to participate in the specified study.

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11 For more information, please read Article 7 of the Data Protection Regulation: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN.

12 Preamble paragraph 32 of the European Regulation mentioned called GDPR (General Data Protection Regulation).

The different variations of consent are listed in the following table.

Type of Consent	***Definition***	***Potential Risks***	***Recommendation***
General Consent	biological material and/or personal data are re-used for further research projects only defined in the future	it is highly problematic to protect the rights of a human participants for research projects only defined in the future	Not recommended. Only specifc consent is valid
Group Consent	the approval of the study participants as a group is considered	the explicit expression of will from the individual might be overlooked	Not recommended. Only individual consent is valid
Opt-in Consent	the study participant's approval is absolutely mandatory		
Opt-out Consent	a clear rejection is not required and consent is thus granted	the explicit expression of will from the individual might be overlooked	Not recommended. It is the expression of right of opposition not the expression of data subject consent

In case there are substantial **amendments** to the research study, participants need to be informed and asked again for their consent. In clinical studies, a substantial amendment is defined as *"a modification to the protocol which is likely to have an impact on the safety of the trial subjects or to change the interpretation of the scientific documents in support of the conduct of the trial, or if they are otherwise significant"* (CNER).

The ERP recommends the following:

- Personal data and personally identifiable information should be collected at the minimum level necessary in any research project (principle of proportionalty).
- Study participants must be given clear information
    - to understand the research purpose,
    - to give *individually* the *explicit* consent to the processing of their personal data for the research project,
    - to evaluate the related implications and possible consequences by their consent, and
    - to decide freely to necessarily withdraw from their consent anytime.

Taking into consideration research area-specific requirements, deviations from these recommendations are possible after careful consideration by the Ethics Review Panel of all risks for the involved participants (Chapter 4.1.2). The ERP may decide to consult the lawyer in charge of personal data protection in the UL Legal Department.

More information can be obtained from:

Personal Data Protection Lawyer

A clearly written **information sheet** describing the nature and significance of the study, and explicitly stating any potential implications benefits and risks is attached to the informed consent form.

Participants' information sheet and informed consent should include a description of all of the following:

✓ Nature and purpose(s) of the research;

✓ Research methods (incl. recruitment) and procedures (incl. expected duration);

- ✓ Potential risks (*e.g.* potential discomfort) and anticipated benefits to the participant or to others;
- ✓ Right to ask questions, to refuse to participate in the study or to withdraw consent [13] at any time without any consequences;
- ✓ Compensation for participation [14];
- ✓ Conflict of interest (Chapter 2.2.2);
- ✓ Liability for injury (Chapter 2.3.1);
- ✓ Identity of the main researcher of the study (whom to contact, institutional affiliations);
- ✓ Permission to conduct the research at the intended location;
- ✓ Information on data management (access, use, storage, level of protection); and
- ✓ Sources of funding.

As it is prohibited to give human individuals incentive payments to encourage participation in a research study through promise of financial gain, volunteers can only be **reimbursed** or receive a **compensation** for their participation in the study. Any economical considerations should not be a reason to participate in a study (*e.g.* participation of developing countries).

Kind of Measure	***Definition***
Reimbursement	Payment of expenses incurred through involvement in a research study, *e.g.* travel costs
Compensation payments	Reward for the time and effort of involvement in the study (for adult participants)
Appreciation payments	Small tokens given after study completion

Study participants are given a full and careful explanation of their involvement in the research project; they need to understand whether the study involves a "treatment" or rather a "trial"; they, therefore, need to sign the informed consent before taking part **voluntarily** in the research. In order to prevent misunderstandings (e.g. therapeutic misconception), both the information sheet and the consent form need to be comprehensive and should therefore be written in lay language (Fig. 3). As they are handed out to volunteers before they take a decision on participation, both documents should be phrased in a way so as not to manipulate the outcome of the decision. Every participant should be provided with a **private copy** of the information sheet and the consent form. To ensure that the potential risks are understood by study participants, researchers need to organise briefing and debriefing sessions.

🕮 Read more:

Opinion 15/2011 on the definition of consent (Data Protection Working Party)
Guidance for informed consent (European Commission)
Substantial amendments (Comité National d'Ethique de Recherche, CNER)
Informed consent in genomics and genetics research (Annual Review of Genomics and Human Genetics, 2010)

13 If an individual withdraws his/her consent, all data will be erased. The *"point of no return"* to withdraw from a study corresponds to the time point of identification key list destruction and should be made explicitly clear to the study participants. In case of death of a data subject, a family member or next of kin must be asked for consent to continue processing of the study participant's data.

14 Study participants may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study. All payments, reimbursements and medical services provided to research subjects must have been approved by the ERP.

The procedure for the ethical review of protocols for clinical research projects in Europe (EFGCP)
Checklist for the informed consent form (Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.)
Evaluating the consent preferences of UK research volunteers for genetic and clinical studies (PLOS ONE)
The Nuremberg code (U.S. Department of Health & Human Services)

Examples and template for the Information Sheet and the Consent Form:

ERP Intranet (UL)
Swiss Ethics
Research Integrity Board (Arizona University)

Vulnerable Groups and Children

If a study involves vulnerable participants or children (minors, individuals under the age of 18) who cannot sign the consent, informed consent of parents [15] or the **authorised/legal representative** must be obtained prior to any research activity. The principle stating that *"the interests of the patient always prevail over those of science and society"* must be followed at all times (Art. 5, Helsinki Declaration).

"Article 25: When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorised representative." (Helsinki Declaration)

It is a legal duty to listen to children (Art. 12, UN Convention of the Rights of Children) and, therefore, the investigator must also obtain an **assent** from a child who is able to give assent. Hence, information sheets must be in accordance to the age of the involved children, as age is the key factor in children's competence to consent to a research study (Hein *et al.*, 2015).

Age group	***Recommendations***
Children (under 5 years)	Information should be predominantly pictorial Formal consent is required from parents
Pre-adolescents (under 16 years)	Child's assent must be considered (*e.g.* Gillick competency test [16]) Information sheet should explain briefly and in simple terms the background and aim of the study, as well as an explanation that the children's parents will be asked for consent
Adolescents, "mature minors" [17] *(16 – 18 years)*	Written informed consent is required from adolescents and parents [18]

Information sheets should indicate how the study will affect the child at home, his/her school education (*e.g.* classroom research assignments) or other activities. Also, the appropriate **length of time** for consideration

15 Formal consent is generally needed from one parent only, as there are sometimes cases in which the second parent is not *"reasonably available"* (Nelson *et al.*, 2013).
16 The **Gillick competency test** is widely used in England, Wales and Northern Ireland.
17 The **Mature Minor Rule** enables the researcher to ask questions to the minor in order to determine whether or not he/she has the maturity to provide his/her own consent for participation.
18 Exceptional are cases in which sensitive topics, such as sexual health, contraception, and adolescent behavioural studies are involved and there is a duty to preserve the adolescent's confidentiality.

should be given to parents and children to give their consent or assent. The investigator should be attentive to subtle verbal or/and non-verbal signs of refusal, such as *"child is tired"* or *"child is not feeling well"*.

At all times, a **dissent** (refusal to grant, withdrawal of consent or assent) from a child must be respected, even if the parent's formal consent remains. However, as the legal guardian has responsibility to safeguard the child, it is the legal guardian's wish to know whether there is an unexpected finding of the minor which overrules.

Any **compensation** measures for the participation in the study should be in proportion with the child's age in order to avoid bias (Modi *et al.*, 2014; Funnell *et al.*, 2012).

🕮 Read more:

A child's legal rights - Gillick competency and Fraser guidelines (NSPCC)
Why is it hard to make progress in assessing children's decision-making competence? (BMC Medical Ethics)
Obtaining Consent from Both Parents for Pediatric Research: What Does "Reasonably Available" Mean? (Pediatrics)
Guidance on clinical research involving infants, children and young people: an update for researchers and research ethics committees (Arch Dis Child)
Quantitative valuation placed by children and teenagers on participation in two hypothetical research scenarios (J Med Ethics)

3.2.3 Personal Data

3.2.3.1 Definitions

Any information derived from private, professional or public life that has been acquired in a research project and relates, directly or indirectly, to an identified or identifiable *"data subject"* [19] can be defined as ***"personal data"***. According to Article 2 (e) of the amended Luxembourgish Law of August 2, 2002, the factors that could identify the individual relate *"to its physical, physiological, mental, economic, cultural, or social identity"*. The definition of *"personal data"* is very broad and comprises every document, record, pathological or diagnostic specimen that relates to an individual.

In addition, one can distinguish ***"sensitive data"*** (Art. 6 and 7, amended Luxembourgish Law of August 2, 2002) as any information relating to an individual's race or ethnicity, political opinions, religions or beliefs, trade-union membership, health and sexual life (incl. genetic data).

"Article 2 (r): "Processing of personal data" means any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction." (modified Luxembourgish Law of August 2, 2002)

19 The *"data subject"* defines a natural person whose personal data is processed.

3.2.3.2 Principles for Data Collection and Data Processing

10 Commandments of Data Protection

Data protection relates to the protection of data integrity as well as to the respect towards confidentiality of personal data given by study participants. In order to protect the data subjects' privacy and personal data, those who process personal data concerning other people must comply with the amended Law of August 2, 2002 and to the following **10 Commandments of data protection** (partly overlap with the principles of the Caldicott Committee, UK):

- ***Legitimacy*** in processing personal data, in compliance with legal requirements
- ***Purpose*** [20] for which personal data is processed, must be justified
- ***Necessity*** *"Need to have, not nice to have"* ***and proportionality*** of personal data for the specified purpose
- ***Accuracy of data*** needs to be ensured
- ***Fairness*** in the collection, record, communication and use of personal data
- ***Security and confidentiality*** in the processing and storage of personal data
- ***Transparency*** in the processing of operations performed on your personal data
- ***Stringent protection*** for particularly sensitive data
- ***Surveillance*** *via* audio, video, and/or data of identifiable people is strictly limited by law
- ***Personal data for advertising or marketing purposes*** need special consent

🕮 Read more:

Introduction to Data Protection (CNPD)
10 Commandments of Data Protection (CNPD)

In principle, it is absolutely prohibited to process any sensitive data, including genetic [21] or judicial [22] data. Exceptions are regulated by legitimacy conditions for sensitive data (Art. 6 (2) and 6 (3), amended Law of August 2, 2002), in which

i) human participants give their explicit consent to the data processing (Art. 6 (2) a),
ii) the processing of data is necessary in the public interest for historical, statistical or scientific reasons (Art. 6 (2) g),
iii) the processing of data is necessary for the purpose of preventive medicine, medical diagnosis or the provision of care or treatment (Art. 6 (3) e), or
iv) the research project has been approved under the legislation applicable to biomedical research (Art. 7 (2)).

The processing (including also storage) of sensitive data must be explicitly authorized by the CNPD (Article 6 (3) c and d, amended Law of August 2, 2002).

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20 **Purpose limitation** means that personal data must not be further processed in a way incompatible with the specified, explicit and legitimate purposes for which such data was collected.
21 Processing of genetic data must be explicitly authorised by the CNPD (Chapter 4.1.2).
22 Judicial data includes data relating to infringements, criminal convictions and safety measures.

To prevent study participants from being identifiable, either directly or through combining identifiers linked to these participants, personal data should preferably be collected anonymously (privacy by design[23]), or should be **anonymised or at least pseudonymised** at a later stage.

Pseudonymisation means the "*processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject before the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that personal data are not attributed to an identified or identifiable natural person*". (General Data Protection Regulation (GDPR) of 27 April 2016)

Pseudonymisation is a technique that allows the removal of an association between the information – in our case, a research result – and the study participant by replacing one attribute in a record by another. According to the International Organisation for Standardisation (ISO), pseudonymisation can be performed with or without the possibility of re-identifying the donor of the data (reversible or irreversible pseudonymisation, ISO 25237:2008). As it is typically a unique attribute that is replaced, study participants are still likely to be identified indirectly, even after an irreversible pseudonymisation.

The EU ***"Article 29"*** Data Protection Working Party has pointed out that the collection of few demographic data is sufficient to identify a person: *"It must be clear that 'identification' not only means the possibility of retrieving a person's name and/or address, but also includes potential identifiability by singling out, linkability and inference [24]"* (Opinion 0829/14/EN). In this sense, *"pseudonymisation reduces the linkability of a dataset with the original identity of a data subject; as such, it is a useful security measure but not a method of anonymisation."*

With regard to the processing of personal data, the Working Party set up by the EU Data Protection Directive 95/46/EC [25] has published anonymisation procedures with respect to the participant's or donor's privacy and prevention of identification of human participants. **Anonymisation** is the *"process by which personally identifiable information (PII) is irreversibly altered in such a way that a PII principal can no longer be identified directly or indirectly, either by the PII controller alone or in collaboration with any other party"* (ISO 29100:2011). In either way, whether anonymisation occurs through randomisation or generalisation, a **trusted third party** (TTP) [26] can be recruited to act as the independent intermediary that receives raw (non-coded) data and transforms it *via* an algorithm into coded [27] data. The **concordance** or **key list** should be stored separately to the related research data, and/or stay with the TTP. A written contract between the controller [28] (UL as an entity) and the processor [29] (researcher and/or TTP) is mandatory, as the processor

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23 **Privacy by Design** describes data protection and privacy compliance which is designed into the systems holding information right from the start (and not afterwards).

24 **Singling out** means to distinguish by uniqueness, linkability means to link records by means of correlation analysis, and inference means to deduce with significant probability.

25 The **Data Protection Directive** harmonises national laws which require high-quality data management practices on the part of the *"data controllers"* and the guarantees of a series of rights for individuals.

26 The thrusted third party and the Data Protection Officer should not be the same person.

27 A code represents a unique number permitting the researcher's use of data without identifying the data subject.

28 The natural or legal person who determines the means and purposes of the data processing.

29 The natural or legal person, public authority, agency or any other body which processes personal data on behalf of the data controller.

should only act on instructions from the controller and the obligations related to security of processing of the controller will also be incumbent on the processor (Art. 22 (3), Luxembourgish Law of August 2, 2002).

With regards to studies involving collected personal data, a **risk assessment** of the security of processing is recommended - that means, in particular accidental and unlawful destruction, loss, alteration, unauthorized disclosure or access to personal data transmitted including the breach of confidentiality from any involved parties. The recommended measures have to mitigate any risks of breach of privacy. Depending on the risk of the breach of privacy, as well as the state of the art and the costs associated with their implementation, these measures must include *i)* the protection, as well as the safe processing and storage of personal data, and *ii)* securing access to and use of personal data[30].

More information can be obtained from:

Personal Data Protection Lawyer
National Commission for Data Protection (CNPD)

🕮 Read more:

Protection of personal data in the European Union (European Commission)
Protection of personal data (European Commission)
Information technology - Security techniques - Privacy framework (ISO 29100)
Opinion 4/2007 on the concept of personal data (Data Protection Working Party)
Opinion 3/2010 on the principle of accountability (Data Protection Working Party)
Opinion 05/2014 on anonymisation techniques (Data Protection Working Party)
Guidelines for responsible data management in scientific research (ORI)
Data protection reform (Access Now)

As a recipient of funding, UL has the responsibility to oversee the management and use of the research data. According to Steneck,*"to assure that (a research institution is) able to meet these responsibilities, (…) researchers cannot automatically assume that they can take their data with them if they move to another institution. The research institution that received the funds may have rights and obligations to retain control over the data"* (Steneck, N. H. (2003). ORI Introduction to the Responsible Conduct of Research. Department of Health and Human Services).

🕮 Read more:

Case studies on data ownership (ORI)

UL is the official **controller**[31] of the data which UL employees generate while having a contract with the institution. As the data controller, UL is enforced to assess potential risks, establish policies for security, inform and train staff on an on-going basis and set up restricted access controls in order to avoid undue access by administrative staff and others. The liability ultimately lies with UL while imposing the same obligations to any subcontractor (processor) – a contractual party/a provider - is imperative (Art. 22 (3) of the Law of August 2,

30 These special security measures are mentioned in Art. 23 of the Law of 2 August 2002.
31 Controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

2002). In some projects, UL can be the data processor[32], *e.g.* when personal data has been collected by a controller in a foreign country, and anonymised data has been transferred to UL. .

In any case, by signing their work contract with UL, employees give their approval to a **confidentiality agreement** stating that they avoid disclosure of any confidential information deriving from their professional activity.

More information can be obtained from:

HR Department

3.2.3.3 Organisational Measures of Security

Data Storage

All records deriving from a research project (*e.g.* documenting experimentation as enclosed information to the research data) should ideally be treated the same way in terms of location and duration of storage so that project results can be communicated, replicated, verified and reproduced (Zigmond & Fischer) (Appendix 7.10). The storage of data underlies the responsibilities of the researcher. In case the researcher(s) leave(s) UL, the superior/supervisor takes over the **responsibility** for data storage.

The **location** of all project data must be referenced and accessible to the PI and the researcher. Data in form of paper sheets, printouts or lab notebooks should be kept locked in the office. Digital records should be stored in a digital library managed by the IT service on UL server, and additional copies on USB flash drives or CD-ROMs can also be kept locked in the office.

According to Article 4 (1) d of the modified Law of August 2, 2002: *"The data shouldn't be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed"*. In this respect, a **retention period** of personal data passing the statute of limitation of 30 years has to be justified to the CNPD.

Security breaches can happen through external attacks (*e.g.* hacks of the server) or individual carelessness (*e.g.* sending personal data to the wrong email address, fax number or postal address; loss or theft of mobile devices; loss or theft of hard-copy records) [33]. In order to maintain confidentiality and protection from data theft or loss, safety regulations must be followed. The **security level** must be adapted to the sensitivity of the data. For this reason, data needs to be stored at a secure facility for the whole duration of the project as well as after the project end (Art. 23, modified Law of August 2, 2002). In this case, all personal information on (mobile) data storage devices (*e.g.* laptops, tablets, smart phones, memory sticks) as well as in emails should be secured in case these devices might be lost or stolen. For applying harmonized techniques of encryption, please contact the SIU for more information.

🕮 Read more:

Information security education day (UL)
Laboratory notebooks in the natural and physical sciences (Zigmond and Fischer)

32 Processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

Data Access

It is critical for researchers to have access to their own project data to eradicate possible hidden errors, to acknowledge the work of colleagues and lead to possible future discoveries in the data. In this view, researchers have the duty to weigh the balance between sharing data in order to facilitate scientific progress, and the obligation towards colleagues or study participants to preserve and protect data. Researchers should always ask their supervisor and/or superior about the **data sharing policy** at the beginning of a project, whether data can or cannot be shared, under which circumstances, by and with whom, and for what purposes. It has to be made clear who has access to raw as well as processed data.

Any risk of **unauthorised access** to personal data of study participants must be avoided, during as well as after the duration of the research project. For managing data access, **cryptography** can be used, personal passwords must be changed on a regular basis and should not be exchanged with colleagues. UL employees should avoid taking confidential information (*i.e.* notebooks) away from their work premises. Access should be **limited**, but should involve a minimum of two people (usually the researcher and his/her supervisor/superior) to ensure that data remains accessible if one of the persons leaves UL.

🕮 Read more:

Principles and guidelines for access to research data from public funding (OECD)

Collaborations with external UL parties need data transfer, data sharing and/or signed non-disclosure agreements (Appendix 7.4) in place and that will get approval from the Ethics committees of each party.

Personal data should not be transferred to a country outside the European Economic Area (Member states of the EU, Iceland, Liechtenstein and Norway) unless that country ensures an adequate level of protection for personal data. The European Commission has established a so-called *"**White list**"* of countries offering an adequate level of protection. If a country is not on the list, UL as the official data controller must either justify the transfer with one of the strict derogations (Art. 19 (1), modified Law of August 2, 2002) or sign a *"**standard contractual clause**"* [34] with the data importer. These contractual arrangements, either controller-to-controller, controller-to-processor or binding corporate rules [35], need additional CNPD authorisation (Chapter 4.1.2). More information on transfers of personal data to third countries can be found in Article 18 of the modified Law of August 2, 2002.

A researcher is allowed to take a **back-up copy (**preferably containing only pseudonymised data), in case any data would be lost or mistakenly destroyed at the premises of UL. However, the supervisor/ superior and the ERP must be informed about the **exact number of copies** of the data that exists (Chapter 4.1.2). The researcher must be aware that all requirements listed above that apply for original data, also apply to the back-up copy to minimize risks of unintentional disclosure of personal data.

To defend themselves against accusations of data manipulation, researchers are also granted to have unlimited access to their original data remaining at UL upon request when they leave or have left UL. **Funding**

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34 A *"standard contractual clause"* is a standard form of contract, approved by the European Commission, that provides a mechanism for parties which use the contract to transfer or export data from Europe in accordance with cross-border transfer requirements.

35 Internal rules adopted by a multinational group of companies which define its global policy with regard to the international transfers of personal data within the same corporate group to entities located in countries which do not provide an adequate level of protection.

bodies generally do not have access to research data, unless there is evidence for research misconduct (Chapter 5).

More information can be obtained from:

Personal Data Protection Lawyer

Templates for the agreements mentioned in Appendix 7.4:

Legal Affairs

🕮 Read more:

Data transfer to third countries (CNPD)
"*White list*" of countries (European Commission)
Consolidated standards of reporting trials (CONSORT)
Strengthening the reporting of observational studies in epidemiology (STROBE)
Enhancing the quality and transparency of health research (EQUATOR network)

Data Use

In 2014, the European Parliament adopted new rules (EU Regulation 536/2014) according to which it is mandatory to publish detailed results of a clinical trial. In addition, initiatives from the European Medicines Agency (EMA) or the research-based industry aim to publish data from anonymous treatments in order to make conformational studies possible. During submission, scientific journals sometimes enforce the upload of data to an external database. The EMBL ArrayExpress, for instance, represents an archive of functional genomics data that facilitates the re-use to the research community by providing these data online.

The **re-use of data** for further research needs approval by the study participants. The re-use of data in subsequent research projects will potentially increase the number of people having access to the data. This has to be made explicitly clear in the Participants' Information and Consent and also needs the prior authorisation of the CNPD (Chapter 4.1.2).

Furthermore, risks are bound to transparent research resulting from the possible misuse and misapplication of research results to cause harm (Chapter 3.2.7).

Data Destruction

When the purpose of data collection and processing is fully achieved, and in order to support the study participants' *"right to be forgotten"* [36], **sensitive data** are destroyed in a secure manner **after the project end**, either by a confidential shredding company (for paper data) and/or by the SIU (for digital data *e.g.* under the form of interview tapes, video movies, decryption code list, questionnaires).

The ERP recommends retention of anonymised data for **10 years after the funding period has come to an end (in case there is no publication) or for 10 years after the publication**, in a tamper-proof form that ensures the integrity and security, and prevents unauthorised modification (Articles 22-23, Law of August 2, 2002). Automatic ways of data destruction must be avoided under all circumstances. Only when there is good

36 The *"right to be forgotten"* describes the right to erase data when the processing is no longer necessary to achieve the initial purpose or when consent has been withdrawn.

reason (*e.g.* confidential data), data is securely destroyed by the SIU upon justified request. The researcher(s) who generated the data need to be asked for approval ***before*** data destruction will be performed.

When a project is still running, and the researcher needs to transfer his/her computer internally or externally of UL to another employee, the SIU has to apply **data sanitisation steps** to the computer unless the recipient has the rights to access the raw project data saved to the computer. Mobile devices such as laptops are not allowed to be transferred to an external person from UL, as the risk for the data to be misused or lost is too high.

More information can be obtained from:

SIU central unit
Personal Data Protection Lawyer

🕮 Read more:

Factsheet on the *"right to be forgotten"* ruling (European Commission)
Electronic data disposal - DoD-compliant disk sanitation software (Auburn University)
Data destruction policy (Stanford University)

3.2.4 Animals

To understand how a treatment affects a living organism, researchers often use laboratory animals in their experiments as many basic cell processes are similar to those of humans. The need of laboratory animals was questioned in spring 2015 as a consequence to the *"Stop Vivisection"* initiative signed by 1.17 million EU citizens. In response to the initiative, the EU Commission stated that it does share the conviction that animal testing should be phased out in Europe, but to completely ban it would be premature as *"it would risk chasing out biomedical research from Europe"* (Jyrki Katainen). The use of laboratory animals in research led to important findings in history, *e.g.* the antibody treatment for human melanoma patients due to the identification and characterisation of PD-1 and CTLA-4 genes in mice.

As there is a potential risk for misuse of animals in research, all animal experiments need to be conducted in accordance with national and EU legislation (EU Directive 2010/63) covering the use of animals in research as well as the European convention for the protection of vertebrate animals for experimental or other scientific purposes. In compliance with the Grand-Ducal Regulation of January 11, 2013 on the protection of animals used in scientific research, researchers need to ensure that the use of animals is justified, and that the principles of *Replacement, Reduction and Refinement* (3 R's) are incorporated:

- **Replace** the use of animals with alternative techniques, or avoid the use of animals altogether.
- **Reduce** the number of animals used to a minimum, to obtain information from fewer animals or more information from the same number of animals.
- **Refine** the way experiments are carried out, to make sure animals suffer as little as possible.

The **exact number** of animals should be specified and a description of the fate of the animals after the research experiments needs to be given. As biomedical research areas (*i.e.* cancer research, toxicity studies, vaccine potency studies, infectious disease studies and autoimmune disease studies) come with relatively

high percentages of pain and distress for laboratory animals, **humane endpoints** [37] should be clearly defined. After having legally acquired animals, researchers have to maintain - at all times - a protocol of animal care and examination to avoid unnecessary suffering of the laboratory animals. The OECD published a guidance document on the recognition, assessment, and use of clinical signs as humane endpoints for experimental animals used in safety evaluation (🕮 Read more).

Laboratories handling animals for research purposes and performing procedures on animals have to be accredited by the Ministry of Agriculture, Viniculture and Rural Development (for well-fare of laboratory animals) and the Ministry of Health (for research aims) in Luxembourg. In addition, the national legislation requires a research institution to have an *Animal Welfare Body* (Art. 27, EU Directive 2010/63 and Art. 26, Grand-Ducal Regulation of January 11, 2013) that provides guidance to researchers in matters concerning the welfare of the animals, the implementation of the 3 R's, the respect and of the authorized procedures.

Researchers must show proper respect and care when applying for appropriate experimental methods and procedures with the *Project Application Form* and the *Non-Technical Summary* to the Animal Experimentation Ethics Committee (AEEC). Only after ethics approval of the AEEC, the application is forwarded to the Ministries. Authorities will make a decision within 40 working days of receipt of the complete application.

More information can be obtained from:

Animal Experimentation Ethics Committee (AEEC)
Ministry of Agriculture, Viniculture and Rural Development
Ministry of Health

🕮 Read more:

European convention for the protection of vertebrate animals for experimental or other scientific purposes (European Council)
Guidance document on experimental animals (OECD)

3.2.5 Researchers

As employer and research institution, UL has the duty to identify any risks for researchers during their studies. These risks may arise while dealing with equipment and infrastructure or while dealing with human participants, biological material, personal data or animals.

Enforced by the Grand-Ducal Regulation of June 17, 1997, UL sends its employees for regular visits to the Multisectoral Occupational Health Service (Service de Santé au Travail, STM). An on-call occupational physician from the STM is available for UL staff, and responsible for monitoring the health of UL employees through regular medical examinations and assessment of jobs with risk factors. On an annual basis, risk assessment for UL employees is summarised in the inventory form of *"risk positions"* and sent to the Ministry of Health. Very frequently, **researchers** in the Life Sciences deal with exposure to blood or potentially hazardous biological agents and should therefore be vaccinated against hepatitis B for their protection. The

[37] A **humane endpoint** can be defined as *"the earliest indicator in an animal experiment of (potential) pain and/or distress that, within the context of moral justification and scientific endpoints to be met, can be used to avoid or limit pain and/or distress by taking actions such as humane killing or terminating or alleviating the pain and distress"*.

vaccination must be verified in accordance with the plan for routine vaccinations and health surveillance from the Ministry of Health and, if appropriate, to be completed.

To limit the risk of work-related accidents, sickness and disability, **standard operating procedures** (SOPs) are given by the Infrastructure and Logistics Department (Service Infrastructure et Logistique, SIL). Further, the training of new researchers with regard to standard practices in handling *biological agents* or *lasers* are crucial for the risk minimisation for the researchers.

In case the **location** in which the study takes place is different from the premises of UL, any researcher who is in contact with human participants must report the location to at least one of his/her colleagues.

Risk Assessment	***Appropriate Measures Taken***
Data collection takes place at participants' homes. Possible risks for visiting researchers' safety.	Participants will be visited by two researchers. All details of the visits (*i.e.* date, time, address, name of administrators) are kept in a database that is accessible to a group of identified people involved in the study. The study coordinator will be contacted before an interview and immediately after each interview.

More information can be obtained from:

Ministry of Health
Multisectoral Occupational Health (STM)

First Aid courses (in German and French) are regularly organised by the STM at UL.

In case of an accident in the premises of UL, the **SIL Helpdesk** must be contacted for urgent requests. In any case, the *"occupational/commuting accident report form"* must be filled out to report any injuries, diseases and dangerous occurrences. The *"AAA - Association d'assurance accident"* handles the declaration of occupational or commuting accidents.

More information can be obtained from:

SIL Secretary
SIL Helpdesk
☎ (+352) 46 66 44 6000

🕮 Read more:

SIL activities (UL)
Risk positions (UL)
First aid course (STM)
Insurance (UL)

Biological agents

Biological agents include microorganisms, cell cultures, endoparasites or genetically modified organisms (GMOs) [38] that may cause infection, allergy, toxicity or otherwise create a hazard in an exposed person or animal [39]. The **Biosafety Officers** at UL (Chapter 1.4.1) participate in the preparation of new requests asking for permission to handle GMOs to be submitted to the Ministry of Health.

The evaluation of the scientific risk assessment of new applications in research is then performed by the GMO Interministerial Committee and treated by the legal department at the Ministry of Health. To minimise any risk to the environment, biological agents should not be released under any circumstances. In this sense, the safety for the shipment and transport of infectious agents (*e.g.* airborne, droplets, contact, blood-borne) must be taken care of appropriately, in accordance with the European Agreement concerning the international carriage of dangerous goods by road (🕮 Read more).

For the generation, contained use and release of GMOs, the European community has published guidelines (EU Directives 2001/18/EC and 2009/41/EG) that need to be followed. At the national level, regulations on the protection of researchers from risks related to exposure to biological agents (Grand-Ducal Regulations of November 4, 1994, June 8, 1999) and on the contained use of GMOs (Grand-Ducal Regulation of October 17, 2002) must be respected.

More information can be obtained from:

Biosafety officers
Security and safety officers (SIL)

🕮 Read more:

Risk assessment of genetically modified organisms (European Food Safety Authority)
A code of conduct for biosecurity (ENRIO)
A code of conduct for biosecurity (Royal Netherlands Academy of Arts and Sciences)
Laboratory biosafety manual (WHO)
Laboratory biosecurity guidance (WHO)
Laboratory biosafety manual (WHO)
Biorisk management - Laboratory biosecurity guidance (WHO)
Biological agents (Health and Safety Executive, UK)
European Agreement concerning the International Carriage of Dangerous Goods by Road (UNECE)

Laser Safety

The use of lasers underlies the supervision of the **Laser Safety Officers** at each UL campus. Risk assessment and management for the involvement of lasers in a research project includes the safety regulations for class I-IV and the selection of appropriate personal protective equipment. This procedure contributes to the enforcement of the ITM regulation on the installation of laser (ITM-CL 115.1), the Grand-

38 Any organism, besides human, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

39 This general definition corresponds to categories 18 01 03 and 18 02 02 (waste from medical or veterinary healthcare and/or associated research) of the Annex I of the Law of June 17, 1994 (Grand-Ducal Regulation November 13, 2002).

Ducal Regulation of July 26, 2010 on the protection of workers from risks related to exposure to laser radiation at work.

More information can be obtained from:

Laser Safety Officers

3.2.6 Effects on the Environment

When performing research, UL employees must respect the environment, the welfare of our home planet and its resources with the goal to foster sustainable development that *"meets the needs of the present generation without compromising the ability of future generations to meet their own needs and choose their own lifestyle"*. This includes every aspect of a study that might have a potential impact on the environment, during and/or after the execution of the study. Therefore a **cost/benefit** analysis with regard to magnitude, probability, beneficiaries, and resources considers environmental dimensions on both short- and long-term. An example would be the removal of experimental set ups (*e.g.* geophysical instruments) after ending the project so that the natural environment can return to its pre-experiment state.

Pollutants

Physical, biological, or chemical agents summarised under the term *"**pollutants**"* can potentially affect the environment (including air, water and soil) as well as plants, health of humans and animals.

In general, researchers need to execute a four-step **risk assessment process**:

(1) Hazard identification,

What effects are caused by the pollutant? Is the pollutant a **toxic and dangerous** [40] substance?

(2) Appraisal of exposure,

What is the exposed area of the environment or organism, and duration of exposure?

(3) Dose-response assessment,

What are the effects at different exposures? What is the distance from the source and way of exposure?

(4) Risk characterization,

What is the extra risk of effects upon exposure?

In order to reduce exposure to toxic and dangerous substances to an acceptable level, researchers need to become familiar with the new labelling elements of chemicals as well as about the proper and safe handling of these chemicals (Classification Labelling Packaging, CLP; EC Regulation 1272/2008). The regulatory protective measures under the REACH legislation (EC Regulation 1907/2006), which came into force in June 2007, foresee the ***R**egistration* of substances of potential concern (most importantly bioaccumulative, reprotoxic, and cancerogenic), ***E**valuation* of the respective safety data sheets, as well as ***A**uthorisation and Restriction of **Ch**emicals* (manufacturing, placing on the market or the use of that chemical of concern) in order to *"ensure a high level of protection of human health and the environment"*.

Only the awareness of the researchers on the possible effects of pollutants on their own health, the health of others as well as their environment results in their responsible behaviour in research. The public can also

40 A dangerous substance is any type of substance characterised as hazardous by its nature or the activity that it generates, or made hazardous through its components or properties. Examples are infectious substances from healthcare and biomedical research (*i.e.* biological agents, and/or genetically modified organisms).

positively contribute by participating in the public consultations for the authorisation of chemicals available on the European Chemicals Agency's website.

More information can be obtained from:

Products and Chemicals Service, Environment Agency
REACH & CLP Helpdesk

🕮 Read more:

European Chemicals Agency

Particular attention should be paid to the possible impact of toxic substances (*e.g.* metallic mercury) to **pregnant and breast-feeding women**. Only the assessment of activities can reveal whether UL employees in question need to be removed from the workstation and duties changed upon request.

🕮 Read more:

Protection of pregnant and breastfeeding women (HSE-05-018-PRG, UL)
What to do in the event of accidental injury or sickness (FR 005, UL)
What to do in the event of a gas leak (FR 006, UL)
What to do in the event of accidental spillage of a dangerous substance (FR 007, UL)

Waste management

Not only the use but also the **management and segregation of toxic and dangerous waste** (irrespective of the state of matter) is of high importance for the preservation of the environment. The general waste management principles must be respected according to the EU Waste Framework Directive 2008/98/EC:

- **Prevention** of waste is defined in Article 3 (12) as *"measures taken before a substance, material or product has become waste"*,
- **Reduction** of waste quantity by using less resources in the first place,
- **Valorisation** by reusing, recycling, or composting from waste,
- **Elimination** of the sources to water or/and air pollution.

Proper waste management eliminates the breeding ground of many pests. At UL, the **Pest Control Program** includes the good management practices for waste handling and prevention as well as good house-keeping practices ensured by an external contractor to prevent infestation.

More information can be obtained from:

Security and safety officers (SIL)

🕮 Read more:

Chemical and biological waste management (HSE-05-014-FIQ-CL,UL)
Waste handling and segregation (HSE-06-002-PRP-CL, UL)
Biological emergency procedures (HSE-06-003-PRP-CL, UL)

3.2.7 Dual-Use Research of Concern

To promote graduate training and openness in research, researchers need to demonstrate confidence and openness to **share** their data with team members and collaborators internal or external to UL. After the project

is completed, presentation of conclusive findings in research occurs through original publication(s), research reports with limited distribution, conferences, documentation handed out during a congress, teaching, as well as case studies.

Scientific research needs **transparency** through free information exchange and open access of research results. Therefore, UL officially signed a collaboration agreement with the University of Liège in 2012 regarding the digital *"Open Repository and Bibliography"* (ORBi[lu]). All UL members can deposit full-text electronic copies of all peer reviewed articles and papers from published conference proceedings; as well as bibliographic references of all their scientific outputs. By doing so, they won't violate any copyright agreement they may have with their publisher as the accessibility level can be set consistent with the policy of the publisher. Increasingly, publishers request an official statement from authors about their research involving human individuals or animals being approved by an appropriate research ethics committee, before publication is even considered.

Nevertheless, there is a risk resulting from the possible misuse and misapplication of transparent research results to cause harm. According to the National Science Advisory Board on Biosecurity, **dual-use research of concern** (DURC) is *"research that (…) can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security."*

The problematics deriving from DURC can occur in nearly all research areas and the extent of possible unsafe consequences and risks is often difficult to estimate. The dissemination of results of high quality research is encouraged, but must be done **responsibly** and with an awareness of the substantial impact and consequences on all parties, on the groups they represent, on those directly involved in their life, and on others involved in the research. Dissemination of results should not lead to a discriminatory treatment of any parties involved.

Risk minimisation procedures aim to avoid or reduce direct or indirect damage to human dignity and life by undertaking profound risk/use-evaluation of the research content in question. Only these risk minimisation procedures help to limit the probability of inappropriate dual use of research results.

Research	***Possible Risk of Dual Use***
Nanobiotechnology	Development of offensive weapons
Industrial robots	Construction of war robots
Nuclear energy	Development of nuclear weapons
Pathogenic microorganisms and toxins	New bioweapons and terrorist attacks (*e.g.* anthrax)
Molecular plant genetics	Biological attacks on seed
Protection against computer viruses	Distribution and new forms of cyberwar
Psychological, medical or neurobiological research	Aggressive interrogation techniques through to torture
Linguistic research on speech recognition systems	Communication monitoring
Law and philosophical publications	Justification of human rights violations

As a measure to minimise the risks of dual-use research of concern, transparency does not collide with the fact that only relevant parts of potentially risky research results can be illustrated in a shortened way in scientific publications. According to the principles of personal data protection, only aggregate or anonymised

data can be published (Chapter 4.1.2). For statistical or other large-scale studies this obligation is easy to fulfil. In case it is not possible to guarantee anonymity (*e.g.* small-scale research or case studies), a consent of the study participant mentioning these conditions is necessary (Participants' Information and Consent).

📖 Read more:

Open Repository and Bibliography (ORBi^{lu})
Self-selected or mandated, Open Access increases citation impact for higher quality research (PLOS)
The persistence of error: a study of retracted articles on the Internet and in personal libraries (J Med Lib Assoc)
Recommendations on handling security-relevant research (Deutsche Forschungsgemeinschaft, DFG)
Responsible research publication: international standards for authors (COPE)
Dual-use research of concern (National Science Advisory Board on Biosecurity)
A new synthesis for dual use research of concern (PLOS ONE)
***"Positive"* Results Increase Down the Hierarchy of the Sciences (PLoS ONE)**
The All Results Journals
Journal of Articles In Support of the Null Hypothesis
Journal of Contradicting Results in Science
The Journal of Spurious Correlations
Journal of Serendipitous and Unexpected Results
Journal of Negative Results
Journal of Negative Results in Biomedicine
Journal of Interesting Negative Results in Natural Language Processing and Machine Learning
Journal of Pharmaceutical Negative Results

4 UL RESEARCH ETHICS REVIEW PROCESS

In times of rapid progress in research and development many ethical questions have been raised. In the previous Chapter, we extensively described which possible ethical risks and potential harm can occur in research studies. For this reason, ethics committees are established at research institutions and there is an obligation for researchers to follow good scientific practice guidelines at each step during research. Increasingly, institutions and individual researchers are required to provide funding bodies and publishers with written approvals regarding the ethical correctness and data protection issues of individual research projects before their funding or publication is even considered.

The following chapter is focusing on the ethical considerations of the Ethics Review Panel and the Animal Experimentation Ethics Committee for the reviews of research proposals (and publications[41]).

4.1 ETHICS REVIEW PANEL

Any research or data collection activity (excluding data collection for administrative purposes [42]) involving human research participants, human biological material, personal data, and/or potentially harmful changes to the environment, which is prepared, conducted or published by or with support of its Faculty, staff, junior researchers, students, or visitors; must be reviewed by the ERP [43].

All requests for advice on the ethical correctness of **research projects**, including all necessary documentation, have to be submitted in writing to the ERP *before* any activity is undertaken. The researcher should bring any risks that become apparent during the research, changes in the research plan or any regulatory, procedural or statutory changes that could affect ethical issues, to the attention of the ERP *before* related work can be continued.

Research **publications** are only reviewed upon request of the author or of a publisher, if the research concerned has already had a positive review of an ethics committee.

4.1.1 Research Ethical Considerations

Research with Human Participants

In their ethics review of projects (and publications) involving human participants and human biological material, personal data, the ERP will give proper consideration to:

- the risks to study participants and researchers;
- the anticipated benefits to the participants and others;
- the importance of the knowledge that may reasonably be expected;
- the informed consent process to be employed;

41 Research publications are only reviewed by the ERP upon request of the author or of a publisher, if the research concerned has already had a positive review of an ethics committee.

42 Data collection for administrative purposes refers to *e.g.* collecting and processing grades, creating performance statistics.

43 Irrespective of whether an explicit request of a funding body or publisher exists, and irrespective of whether the research is to take place in a reviewed project or as part of the daily work, and irrespective of prior approval obtained from another ethics committee.

- the provisions to ensure the safety of participants;
- the provisions to maintain privacy and confidentiality of participants and their data.

Research with Changes to the Environment

In their ethics review of projects involving potentially harmful changes to the **environment**, the ERP will give proper consideration to:

- the potential impacts of the research on the natural environment;
- an impact/benefit analysis, weighing any potentially adverse impacts against the expected benefits, while considering the economic, social and environmental dimensions, both short- and long-term;
- the necessary permission to conduct the research at the intended location;
- the provisions to return the natural environment to its original pre-experimental state, *i.e.* the removal of experimental apparatus, at the conclusion of the experiment.

In case the proposal involves more than minimal risk, and when requested by funding bodies or publishers, an **independent review process** should be used for appropriate scrutiny *before* work is undertaken or published. This involves the submission of the proposal and any relevant material to the ERP.

Coverage Exemptions

The ERP provides binding advice – unless otherwise required by the Faculty, Dean, Vice-President for Research, UL President, funding body or publisher – on all research mentioned in Research Ethical Considerations ***excluding*** the following:

- Activities normally **not classified as research** and typically not subject to an ethics review (*e.g.* auditing).
- Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of **educational** tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:
    1. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
    2. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation.
- Research assignments undertaken by **Bachelor or Master students** as part of their coursework. In those cases research must be submitted to the course leader for approval, including any appropriate ethical review. For any assignment or thesis the students will have to provide a research outline and complete an ethics approval application, as part of the learning assignment, which will be assessed by the course leader. The course leader decides whether approval from the ERP is required under exceptional circumstances. In case of doubt, the course leader/supervisor can contact the ERP for advice.

4.1.2 Exemplary Procedures

Procedure 1: Research for which ethics approval is required

Any research involving human participants, human biological material, personal data, and/or potentially harmful changes to the environment must obtain ethics approval from the ERP.

Procedure 2: Research for which approval has already been obtained

Where ethics approval has been granted by another Ethics committee than the ERP (*e.g.* of another University), the researcher is still required to submit an ethics application to the ERP, who has the discretion to either accept this decision or request additional information.

The University of Luxembourg is aware of its responsibilities in maintaining and safeguarding research integrity (Chapter 2.3), as well as the safety of the study participants and UL researchers. Also, the responsibilities of UL researchers towards UL are not covered by the approval from national committees (CNER and CNPD).

For this purpose all related information to the previous ethics decision should be provided to the ERP. This includes a copy of the approval letter, the application and related documentation, and of modifications made to the research design, if any.

In case personal data is collected and/or human biological material is extracted at another institution than UL, the **source** institution needs to provide the ethical approval of the respective Ethics committee (in addition to the Ethics Review Panel). This is often the case for multi-partner projects with external institutions. Conditional ethics approval can be sought from the ERP explicitly for subprojects, performed at or for UL.

Following **both exemplary procedures**, additional approval for research might be required from internal or external Ethics Committees.

Internal Committees

Research involving **laboratory animals** requires approval from the Animal Experimentation Ethics Committee (AEEC). This procedure will be treated in Chapter 4.2.

Research involving **biological agents** that could potentially harm the safety of researchers and/or the environment require further approval from the Biosafety Committee. Further information about the Biosafety Committee can be found in Chapter 1.4.

In the case of ethics reviews of research projects involving **Harrassment or Gender Issues**, the ERP may consult the Ethics Advisory Committee (EAC) or Gender Mainstreaming Committee (GMC) (Chapter 1.4).

National Committees

The ERP does not replace existing national committees on ethics and data protection. Additional ethics approval for research may be required from the National Research Ethics Committee (Comité National d'Ethique de Recherche, CNER) or the National Commission for Data Protection (Commission Nationale pour la Protection des Données, CNPD).

"Article 25. No trial, study or experiment can be performed on humans for the development of biological or medical knowledge unless the project has been previously subjected to the opinion of a research ethics committee." (Luxembourgish Law of August 28, 1998)

Research involving *"**Clinical Trials of Medication for Use in Humans**"* as defined on their website requires approval from the CNER, an independent authority established by the Ministry of Health. The CNER's decision is binding. Non-interventional trials (*i.e.* not involving clinical trials using medication) do not require CNER approval (Art. 1.1, Grand-Ducal Regulation of May 30, 2005). Prior advice can be obtained from the ERP. A copy of any correspondence with the CNER has to be sent to the ERP Chair.

Every year, a day of training on Good Clinical Practice (EFGCP certified) is organised by the CNER and other partner institutions about clinical research, the ethical aspects of research and the standard procedures in biomedical research.

🕮 Read more:

National Research Ethics Committee (CNER)
The World Medical Association Declaration Of Helsinki (64th WMA)

Research involving *"**personal data**"* might require prior notification or authorisation of the **CNPD**, an independent authority established by the Luxembourgish Law of August 2, 2002 (as amended by the Act of July 27, 2007).

- ***Prior Notification to the CNPD***

In case data is collected directly from the data subject (*e.g.* through questionnaires, forms, interviews) and processed, and there is no genetic data, a prior notification is sufficient. The processing of personal data, however, must be notified to the CNPD before it can be implemented. This serves to provide the CNPD with a view of the realities on the ground, as well as to allow the public to view the list of treatments reported. Upon receiving the notification, the CNPD publishes it in its public register.

According to the amended Law of August 2, 2002, the principle of prior notification does not apply for processings of personal data listed in Article 14 (1). In this case of more sensitive data, the authorisation procedure applies. There is also no need to notify the CNPD for processings of personal data that are exempt from notification according to Article 12 (2) or 12 (3) of the Law of August 2, 2002.

- ***Approval from the CNPD***

In case of *"further processing"* or secondary use of data, an authorisation of the CNPD is needed. This is the case when personal data is initially processed for specific purposes (*e.g.* for preventive medicine, medical diagnosis or the provision of care or treatment) and subsequently processed for historical, statistical and scientific purposes according to Article 4 (2) of the Law of August 2, 2002. If the research project contains genetic data (according to Article 6 (3) c and d), an authorisation is needed in every case (regardless of the origin of the data). The role of the CNPD consists in screening and decision making before implementation of the data processing for the purpose of research. The CNPD decision is binding. Prior advice can be obtained from the ERP. A copy of any correspondence with the CNPD has to be sent to the ERP Chair. For

any correspondence with the CNPD, the lawyer in charge of personal data protection issues has to be consulted.

More information can be obtained from:

Personal Data Protection Lawyer

- **Anonymous and pseudonymous data**

Research can involve solely the **collection or study of existing data** (*e.g.* documents, records, pathological specimens, diagnostic specimens or established cell-lines) if these sources are publicly available or if the information is recorded by the PI in such a manner that participants cannot be identified (directly or through identifiers linked to the participants).

Data that is fully anonymous or irreversibly anonymised is ***not*** subject to the Law of August 2, 2002. The use of existing data therefore does not require the approval of CNPD and is not subject to prior notification. However, the processing of pseudonymous or coded data still requires the approval of the CNPD or a prior notification to the CNPD. The storage of bio-specimens also requires ethics approval by the CNER.

🕮 Read more:

Commission Nationale pour la Protection des Données (CNPD)
Prior notification (CNPD)
Prior notification form (CNPD)

European Grants and Ethics

When applying for European projects, applicants are legally obliged to carry out all the research activities in compliance with the fundamental ethical principles (EU Regulation 1291/2013 for Horizon 2020, *e.g.* Art. 6 (1) clause 13 for FP7). Special clauses in the grant agreement define that researchers need to comply not only with the ethical framework of FP7 (clause 13), but also with national authorities in the country in which research is carried out (FP7, clause 15). In addition, special assessment is given by the European Commission for research project activities involving the use of human embryos and human embryonic stem cells (FP7, clause 14), as well as biomedical research involving human beings (FP7 clause 16, Art. 168 TFEU).

In European projects, legal bases exist for stopping scientific research on ethical grounds. In case researchers do not comply with this agreement, their proposal that contravenes fundamental ethical principles will not be selected or can be excluded at any time (FP7, clause 10). Some areas are even excluded from funding under FP7, *i.e.* human cloning for reproductive purposes, modification of the genetic heritage of human beings, creation of human embryos solely for the purpose of research or stem cell procurement (FP7, Art. 6 (2)).

More information can be obtained from:

Research Support Department

🕮 Read more:

Ethics in EU research (European Commission)
List of all special clauses applicable to the FP7 model grant (European Commission)

Ethical principles under Article 19 supported by Horizon 2020
European textbook on ethics in research (European Commission)
Ethics for researchers (European Commission)
Data protection and privacy ethical guidelines (European Commission)
Recommendations on the ethical review of hESC FP7 research projects (European Commission)
European Network for Research Integrity Offices (ENRIO)

Journal Publication Ethics

Particular prerequisites must be fulfilled depending on the journal a researcher wants to publish in. These prerequisites also include publication ethics policies which are outlined by journals and which must be followed by authors. Examples of journals having established ethics policies are published by Elsevier, Wiley–Blackwell, Springer, Taylor & Francis, Palgrave Macmillan and Wolters Kluwer. Some of the journals also have an Ombudsperson who advises them on whether the applicant followed the ethics policies of the journal (*e.g.* Lancet). This Ombudsperson may also deal with cases of alleged misconduct from the journal's side (Chapter 5).

4.1.3 Application for ERP Approval

When applying to the ERP, the following *Sections* for the research project need to be filled out in the *Application Form*:

Section	***Description***	***Guidelines***
Section 1	Project (title, applicant(s), funding, single or multiple studies, research area-specific guidelines)	Chapter 3.1
Section 2	Short summary of the project (objective, research approach, single studies, participants/ samples, collaborators)	-
Section 3	Proposed start date and duration of ethics-relevant activity for each study in the project for which approval is requested (study title, start date and duration)	Chapter 4.1.4
Section 4	Aim of each of the studies for which approval is requested (involvement of human participants, human biological material, personal data, and/or effects on the environment and society)	-
Section 5	Details of each study (ethically relevant issues related to the methodology used)	Chapter 3.2
Section 6	Health and safety risk(s) for participants and researchers (possible risks for involved individuals and measures taken), Changes to the environment and society	Chapter 3.2
Section 7	Participants' information and consent	Participants' Information and Consent
Section 8	Data Protection in terms of Pseudonymity/Anonymity, access, protection, storage, duration	Chapter 3.2.3

In addition to the *Application Form*, the following documents need to be added to the ethics review request:

(1) Previous ethics approvals for a single study/multiple studies (a copy of the approval letter, details of the approved application, a description of any modifications made to the approved research design).
(2) A version of all material used to recruit participants (*e.g.* flyers, letters).
(3) A description of equipment used
(4) Information sheet(s) for participants, legal guardians and/or other involved parties
(5) Consent form(s) for participants, legal guardians and other involved parties
(6) A version of all study materials given to the participants (*e.g.* questionnaires, assignments)
(7) A copy of any other information given to the participants

The applicants are requested to not copy paste from the original grant proposal and to rephrase in appropriate lay terms so that researchers from other research areas can easily follow. Also applicants are asked to submit only ethically relevant information and respect the character limits for the different sections in the application.

🕮 Read more:

Ethics Review Panel

4.1.4 Functioning

All requests for advice on the ethical correctness of research projects (and publications) are submitted in writing to the ERP (including all necessary documentation) in line with the time schedule of the funding agency, at least, however, *before* the start of any research activity to which the ethics approval application refers (Fig. 5). Ethics approval by the ERP will *not* be granted retrospectively. There are no limits for **amendments** in the application.

Figure 1 Time Schedule

Applications need to be submitted at least 15 working days before the scheduled ERP meeting if the application is to be considered during the respective meeting.

The applications are discussed within, and decided upon by the ERP. The ERP prepares a written advice which is binding in as far as it concerns research projects (and publications), which do not have to be submitted to the national committees, CNER and CNPD. If formal approval is required by the funding bodies or the journal, and if the advice of the ERP is positive, the Vice-President for Research will sign the respective forms.

In case a **conflict of interest** exists with one of the committee members, the complaints, reports and supporting material related to this particular case are not sent to this member. Also, the concerned committee

member will leave the room while the particular case is being discussed. His or her vote will be counted as an abstention.

As mentioned in Chapter 4.1.2, the ERP decision does *not* replace a decision by the national committees, CNER and/or CNPD, concerning their areas of expertise.

4.1.5 Voting

Decisions require a simple majority vote by hand raising, postal or email vote. Proxy voting is not possible. Ballot voting will take place if requested by a member of the ERP. In case of a tie, the Chair has the deciding vote.

Only ERP members are entitled to vote. External experts and the ERP Secretary have no voting rights. All written advice in response to a request or complaint, requires the approval of at least two thirds of the members.

The results of the discussion in the ERP meeting will be communicated by internal mail and email to the contact person named in the application. Four different decisions are possible:

(1) **Approved without conditions**

No further action is required. The ethics approval letter can be used to inform the funding body or journal, or any other institution requiring this information.

(2) **Approved with conditions**

The ethics application will have to be revised addressing the issues raised by the ERP. The revised version, together with an accompanying letter responding to the issue raised, has to be sent to the ERP. If only minor changes are requested by the ERP the resubmission will be reviewed by the Chair before the next ERP meeting and, if the conditions have been met, an approval letter will be issued. If the conditions have not been met, the ERP will decide upon the required action in its next meeting.

(3) **Not approved, resubmission required**

A revised application will have to be resubmitted at least 15 days before an ERP meeting in order to be considered in that meeting.

(4) **Does not fall within the ERP remit**

The ERP will advise on submission to the appropriate committee (Chapter 4.1.2).

More information can be obtained from:

ERP Secretary

4.1.6 Right to Appeal

The applicant can appeal against the ERP's decision. (S)he may appeal within 14 days of receiving notification on the outcome of the ethics decision. The appeal must be made in writing to the UL President and should state the reasons for the appeal.

4.2 ANIMAL EXPERIMENTATION ETHICS COMMITTEE

4.2.1 Research Ethical Considerations

Any research project involving laboratory animals, which is prepared, conducted or published by or with support of its Faculty, staff, junior researchers, students, and visitors, must be reviewed by the AEEC.

All requests for advice on ethical correctness have to be submitted in writing to the AEEC in order to be forwarded to the Ministry of Agriculture, Viniculture & Rural Development as required by the Grand-Ducal Regulation of January 11, 2013 on the protection of animals used in scientific research.

According to Article II.4.2-ter.101 of the *Internal Rules of Procedure*, the role of the AEEC is to ensure that the use of animals is justified, to provide for the welfare of those animals and to incorporate the principles of *Replacement, Reduction and Refinement*.

4.2.2 Application for AEEC Approval

Any project to be carried out within UL must be submitted to the AEEC with a request for animal testing protocol approval. The PI must be adequately educated and trained in carrying out procedures on animals and designing procedures and projects. The staff carrying out the procedures should also be trained and supervised in the performance of their tasks until they have demonstrated the requisite competence.

The PI needs to download, fill in and submit the *Project Application Form* and the *Non-Technical Summary* to the AEEC. The language commonly used by the AEEC is English. However, the Animal Experimentation proposals can be submitted either in French or German following the template provided. Two sub-committees will be established to evaluate either French or German proposals.

All applications must be addressed to the President of the AEEC, submitted at any time to aeec@uni.lu and will be dispatched to the AEEC members for evaluation.

🕮 Read more:

How to apply to the AEEC (UL)

4.2.3 Functioning and Voting

According to Article II.4.2-ter.103 of the *Internal Rules of Procedure*, the AEEC will analyse and revise applications for animal experiments. The quorum for decision-making processes should be at least two third of the committee members and must include at least one member of each category. Decisions concerning the approval or rejection of any application can be done, if necessary, by email at least two weeks before an AEEC meeting or otherwise during the meeting. The AEEC will forward accepted applications by the committee to the Ministry. The authorities will take a decision within 40 working days of receipt of the complete application. In case of rejection, advice is given and revision allowed.

Once a project, renewal, or amendment has been accepted by the AEEC and approved by the Ministry, a copy of the approval letter for the research project, and a complete set of the renewals and amendments will be sent to the PI. The maximum duration for an animal experiment approval should be four years.

More information can be obtained from:

AEEC Secretary

5 UL PROCEDURES ON SUSPECTED OR ALLEGED MISCONDUCT IN RESEARCH

As discussed in Chapter 2.3., the University of Luxembourg bears the primary responsibility for prevention and detection of misconduct in research. In case there are concrete indications that a researcher is abusing his/her research freedom, endangers or injures constitutionally protected legal interests of others, UL is not only allowed but also expected to conduct an assessment of suspected or alleged misconduct in research. This assessment will be conducted in close collaboration with the University OP. All cases will be brought to the attention of the Luxembourg Agency for Research Integrity (LARI). Cases where the outcome of the ERP assessment confirms the suspicion, will be referred to LARI who may decide to initiate an enquiry and an investigation, if deemed appropriate. Furthermore, any UL member can contact LARI directly to bring a case of alleged scientific misconduct to their attention. In this case, there will be no assessment carried out by the ERP.

🕮 Read more:

The Lab – Avoiding research misconduct (ORI)
Misconduct case summaries (ORI)

5.1 RESPONSIBILITY OF THE COMPLAINANT

Researchers have the responsibility to report cases of suspected or alleged misconduct in research in an appropriate manner. Complainants, so-called *"whistle-blowers"*, are researchers who inform the Ombudsperson (OP [44], of the wrongdoing of colleagues. The complainant who voices a concrete and justified suspicion does not damage research, in contrast to the one who commits research misconduct. Also, whistle-blowing on the grounds of research misconduct is no denouncing or disgrace. It is a necessary means to uphold the integrity and objectivity of research and a way of restoring trust and honesty.

Before acting, complainants should **be absolutely sure** that they *i)* have a clear picture of the situation, and *ii)* know the interests, duties and values of the involved people. Complaints can derive from an internal or external source (Chapter 5.2). The complaint to the OP should be made in writing. An oral complaint should be documented in writing by the OP.

🕮 Read more:

Uncovering misconduct (Nature)
Vereinigung Deutscher Wissenschaftler (VDW)
Whistleblower-Netzwerk e.V.
Office of Research Integrity (ORI)

44 The **Ombudsperson** (*Internal Rules of Procedure,* Section 3, Art. II.4.301) listens to all UL members (Art. II.4.302), offers advice about the institute's policies and procedures and helps to promote ethical conduct and values. Further, (s)he is the first person to address for voicing one's concrete suspicion of misconduct. The OP works informally, must act strictly objective, and has the duty to preserve confidentiality.

5.2 PROTECTION OF THE COMPLAINANT AND THE ACCUSED

UL has established clear **procedures** for dealing with allegations of research misconduct, which are outlined in the following paragraphs, and ensures that they are understood within the institution and disseminated appropriately. The procedures allow for **even-handed treatment** of both the complainant and the researcher against whom an allegation is made.

All parties involved in the process will be **protected** against any reprisals or discrimination. In the special case in which the complainant is in a dependent relationship to the accused researcher, *e.g.* a doctoral candidate, or administrative or technical staff, the name of the complainant will be kept confidential at any stage and will not be given to the accused researcher.

In general, the person accused by a whistleblower will be informed as soon as practicably possible in order

i) to appeal during all steps of the ERP as well as after any decision taken by the UL President (Chapter 5.7),
ii) to avoid unfairness towards a person being denounced, and
iii) to leave the possibility of self-defense and protection from whistleblowers reporting in bad faith.

Any researcher being accused falsly of scientific misconduct is also considered as misconduct in the sense of **retaliation against a UL staff member** (Chapter 5.4.3) and will act in such cases with a recommendation to the respective committee, and the UL President who will take a decision.

The accused as well as other involved researchers, especially those who through no fault of research misconduct, may be assisted by the Ombudsperson (OP, Art. II.4.301-304, *Internal Rules of Procedure*) as **counsel or/and psychological support.** The OP can function as a mediator in cases of alleged scientific misconduct, and would thus highly contribute to a balanced procedure.

Any researcher who is accused without any substantiated proof must be treated as innocent. Hence, the **presumption of innocence** should be maintained until the investigation process is complete. At all stages, the ERP does not advise a public hearing of the researchers concerned.

5.3 SEVERE MISCONDUCT

5.3.1 Falsification and Fabrication

Once the ERP has been notified of the case of suspected or alleged falsification and fabrication of research results, an assessment will be conducted with the aims to (1) gather evidence and substantiate (or not) the claim and (2) to find potential ways of mediation in close collaboration with the OP. If the suspicion is confirmed the case will be referred to LARI for further enquiry and investigation.

To ensure **maximum confidentiality** and integrity of the process, no meeting with the parties involved should be scheduled *outside* the process. UL will take the appropriate measures to ensure that allegations of misconduct in research are investigated in the strictest confidence and with all possible thoroughness and rigour.

All ERP meetings will be minuted and all correspondence with the ERP will be recorded and archived. These documents are stored on a **secured server** area for each case (provided by the SIU) and accessible only to the members of the ERP (including the ERP Secretary).

The UL President has the right to inform himself on a regular basis during all stages of the cases of suspected or alleged misconduct in research.

The Assessment

This stage involves the assessment of an internal or external complaint to determine whether a further enquiry by LARI is justified.

Internal Complaint

Internal complaints are reports about suspected or alleged cases of misconduct in research coming from a complainant within UL and being addressed to the OP or the ERP, or both (**1a.1**).

The OP takes official notes while discussing in confidentiality with the complainant (**1a.2**) in cases where there is suspicion of fabrication or falsification of research results.

In case of minor misdemeanours or misunderstandings, the OP can play a mediating role to settle the matter (**1a.3**). The OP will have the possibility to meet with the person(s) about which a claim has been made with explicit authorisation of the complainant. The OP can then ask the complainant and the accused researcher for supporting documentation, which has to be provided. At this step of the assessment stage, the accused researcher has the possibility to appeal (Chapter 5.7).

If the issue can be solved by simple discussion with the OP, the OP will mention this issue in his/her regular reporting to the UL President (**1a.4**).

If the issue cannot be solved, the OP (with explicit authorisation of the complainant) will decide to notify the ERP, the Chair of AEEC or other respective committee (Chapter 1.4) within 30 days. If a case includes an issue for the ERP as well as the AEEC, the OP and the complainant will then make a joint request to the ERP/AEEC. The issue will be followed up by the ERP with a further assessment of the issue.

If the complainant chooses not to pursue the issue, the OP will then mention this issue in her/his regular reporting to the UL President (**1a.6**).

If the complainant wishes to pursue the issue, the issue will be followed up by the ERP with a further assessment.

The complainant may be afraid of starting an assessment or enquiry and may, therefore, not wish to pursue the issue. If the OP, however, agrees to pursue the issue, it will first be discussed with the Chair of the respective committee (Chapter 1.4), and the arguments for and against pursuing the case will be carefully considered. There will be a discussion between the OP and the ERP about the reasons of the complainant, as well as the consequences of a referral to LARI that need to be respected. The OP will decide whether the issue should be directed to the Chair of the AEEC or any other committee (**1a.8**).

If reasonable grounds exist to believe that a criminal offence has been committed or that immediate risk for health and safety exists for the complainant, the institution or the general public, the OP, without authorisation of the complainant, may instigate a dialogue with the Chair of any other respective committee (Chapter 1.4)

on the need to refer the case to LARI for further emquiry and investigation en. In these special cases the OP is required to inform the complainant and the UL President. The respective committee (Chapter 1.4) will ask the OP for a statement on the issue and his/her opinion. At this step of the assessment, the accused researcher has the possibility to appeal (Chapter 5.7).

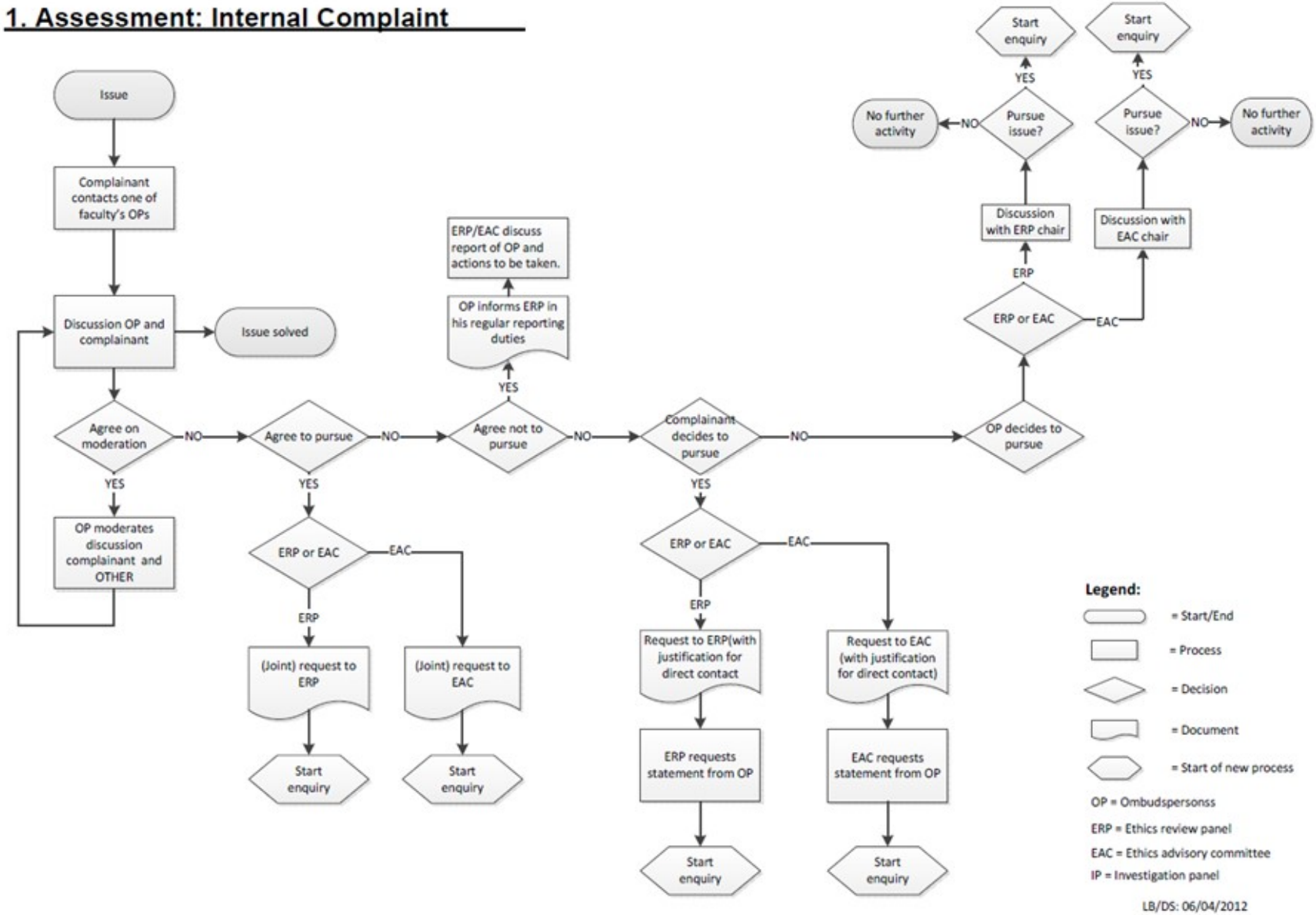
The ERP will carefully consider **eventual harm** done to the complainant. Possible solutions in such a case are for example:

- to wait with the further assessment or referral to LARI (*e.g.* until the complainant may not suffer any more from any further steps),
- to search/wait, if there might be a group of people or much more suspicious evidence.

If there is evidence for the same issue from any previous complainants, the former complainants will be asked whether they agree to follow-up the issue under these new circumstances.

In case there is eventual harm done to the accused researcher, misconduct is considered in the sense of **retaliation against a UL staff member** (Chapter 5.4.3) and the ERP will respond with a recommendation to the UL President who will take a decision.

1. Assessment: Internal Complaint



External Complaint

External complaints are reports about suspected or alleged misconduct in research coming from someone external to UL. The external complainant is *not* anonymous. These complaints are addressed directly to the ERP (**1b.1**). The ERP decides on a case-by-case basis whether to take up an external complaint or not.

The ERP will gather preliminary information, documents and other evidence on the issue from the complainant (**1b.2**), and will inform the complainant that the accused researcher will be notified, unless there are strong reasons not to do so immediately (*e.g.* for protection of people and/or data). The ERP gives the researcher(s) accused of misconduct the opportunity to appropriately comment on the complaint within a given deadline. At this step of the assessment stage, the accused researcher has the possibility to appeal (Chapter 5.7). (S)He may be assisted by the OP as counsel. At this step, the ERP decides whether to include the AEEC or any other respective committee (**1b.3**).

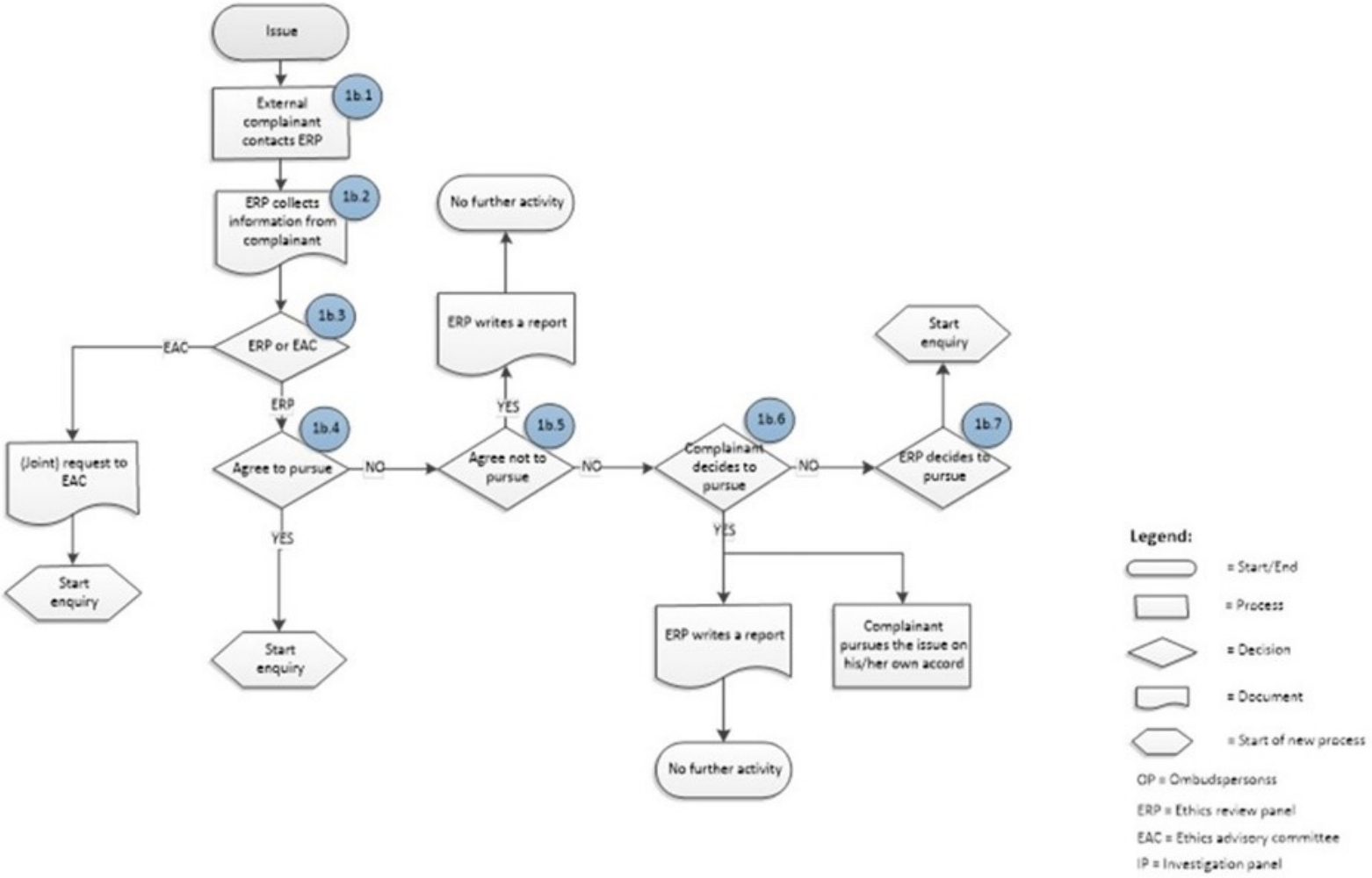
The ERP evaluates the timing, content and reasonableness, and decides whether the assessment procedure - under notification of the grounds to the accused researcher and the complainant - is to be terminated because the suspicion has not sufficiently substantiated suspected misconduct (**1b.5**), or whether to pursue the case by referring it to LARI (when both the complainant and the ERP decide) for further enquiry and investigation (**1b.4**). Either way, the ERP will include the issue in its regular reporting to the UL President.

In case the complainant wishes to pursue the issue on his/her own accord (**1b.6**) and there is enough evidence that justifies further enquiry in the interest of UL, the ERP will proceed by referring the case to LARI (**1b.7**).

🕮 Read more:

Responding to anonymous whistle blowers (COPE)

1. Assessment: External Complaint



🕮 Read more:

Investigating research misconduct allegations in international collaborative research projects (OECD)

5.3.2 Plagiarism

Project Proposal

When applying for grants, each project proposal submitted to the funding body is examined for its originality. In case, the reviewer(s) has/have found a positive match for plagiarism, the applicant is contacted by the funding body.

The information must be forwarded to the OP in the shortest time possible. Once the ERP has been forwarded the case, the degree of plagiarism is analysed. If the ERP cannot sufficiently confirm the suspicion for plagiarism, a report is written (with the accused researcher), forwarded to the funding body, and the case is closed.

If there is a (minor to major) copying of others' work, the corresponding author prepares an excuse letter in which (s)he explains in neutral terms whether there was an honest error. The ERP (possibly with the UL communications department) advises on how to prepare this letter to contact the funding body.

If there is a redundancy of one researcher's own work (self-plagiarism), it might be too late for the applicant to re-submit the project proposal to the funding body. However, if redundancy has been detected, the applicant should be cautious when applying again to the funding body.

Scientific Publication

A reviewer or reader informs the journal editor of a suspected case. Either the scientific journal has an Ombudsperson who then contacts the corresponding author. In case there is no Ombudsperson employed at the journal, the editor directly contacts the corresponding author.

The information must be forwarded to the OP in the shortest time possible. Once the ERP has been forwarded the case, the degree of plagiarism is analysed. If the ERP cannot sufficiently confirm the suspicion for plagiarism in scientific publications, a report is written (with the accused researcher), forwarded to the journal editor, and the case is closed.

If there is a (minor to major) copying of others' work, the corresponding author prepares an excuse letter in which (s)he explains in neutral terms whether there was an honest error. The ERP (possibly with UL communications department) advices on how to prepare this letter to contact the journal editor.

If self-plagiarism occurs in scientific publications, the author is asked to rephrase the text passages and express his/her apologies to the journal editor and/or reader.

If possible, a researcher accused of plagiarism should always try to rephrase the publication and publish a corrigendum. Similarly, if only a small section of an article (*e.g.* a few sentences in the *"Materials and Methods"* section) falls under plagiarism, the journal editorial board should consider whether the scientific community is better served by a correction or a retraction.

🕮 Read more:

What to do if you suspect plagiarism (COPE)
What to do if you suspect plagiarism (COPE)
Plagiarism White Paper (Turnitin)
Responding to possible plagiarism (Sciencemag)
Turnitin White Paper
Online lecture on plagiarism (Elsevier)
Impact of policies for plagiarism in Higher Education across Europe (IPPHEAE)
Déjà vu: a database of highly similar citations in the scientific literature (Errami M)
Plagiarism Sleuths (Science)
***"We know it when we see it"* is not good enough**
Principles and practice of plagiarism: Perpetrators' perspective

5.3.3 Deception

As described in Chapter 2.2.2, deception can occur in in proposing, carrying out, or reporting results from research activities. Any case of suspected misconduct of this type reported to the ERP will undergo an assessment as described for a case of severe misconduct (Chapter 5.3.1).

If deception has occurred in a research study, researchers are made responsible as they should have complied with all legal, ethical and contractual requirements. The findings and advice are eventually referred to LARI. Possible consequences of research misconduct are listed in Chapter 5.5.

5.4 Other Types of Misconduct

5.4.1 Deviation of Accepted Practice, Conspiracy, Encouraging Misconduct by Exerting Pressure

When a researcher is accused of deviation of accepted practice, conspiracy, or exerting pressure on people to confirm or reject certain outcomes (as described in Chapter 2.2.), the ERP will assess the matter by interviewing group members and, if the suspicion is substantiated, refer the case to LARI.

In case the ERP cannot sufficiently confirm the suspicion, the EAC will be asked to investigate the motives of the complainant(s).

Is the suspicion however confirmed, then the ERP will – for example – suggest to

i) send the accused researcher to additional trainings (*e.g.* GSP trainings, statistics courses), and
ii) appoint a second researcher (supervisor/superior) to control and correct the mistakes the best way possible.

Under no circumstances, a researcher should rely on the data that have been produced under suspected deviation of accepted practice.

The findings and advice are eventually reported to the UL President who will decide on the action to be taken. Possible consequences of research misconduct are listed in Chapter 5.5.

5.4.2 Conflict of Interest

When a complaint suggests that important decisions have been taken under the influence of **conflicts of interest**, the ERP will analyse the matter together with the EAC and/or Legal Affairs Office. Evidence will be collected, as well as interviews taken with the parties involved.

To determine whether there is **financial conflict of interest**, the following examplary questions need to be answered :

- Where is the funding coming from, which interests are followed by the sponsor ?
- Who will get the funding, who is gaining from the study ?
- Who will become vulnerable through lack of funding ?
- Which decisions can be influenced by financial motives ?

In cases where a conflict of interest involves one of the ERP members, the complaints or reports can also be submitted in writing to the OP, who will forward the complaint to the EAC and/or Legal Affairs Office.

The findings and advice are eventually reported to the UL President who will decide on the action to be taken. Possible consequences of research misconduct are listed in Chapter 5.5.

5.4.3 Retaliation against any Person

To avoid retaliation of any kind against a person, **confidentiality** is a highly important principle of Ethics Committees' work and must be guaranteed by all means in order to protect all people's interests, with the exception if there is an imminent risk of serious harm. In the case of the complainant of suspected or alleged research misconduct, the identity of this person acting in good faith must remain confidential. In this case, action will be followed by the EAC, and the UL President.

5.5 Consequences of Research Misconduct

Research misconduct wastes lifetime and resources, and thus slows down the process of research. Cases of severe research misconduct result in more stringent measures to control research freedom. Two **views** can be distinguished concerning the consequences of research misconduct. Most of the researchers are convinced that only self-regulation is needed to safeguard scientific integrity, while others demand – with regards to the increasingly global reach of science, its growing economic importance and facilitating cooperations – **harmonisation** of standard operating procedures for the handling of suspected research misconduct. However, circumstances of each case are different, and potential consequences can vary according to the severity of research misconduct, the standards set by the institutions, funding bodies as well as journal editors. For example, there is considerable heterogeneity in the definition of *"misconduct"* and the proposed procedures for dealing with it. Denmark, for example, is one of the only countries that has set up a specific law on *"scientific dishonesty"* (Consolidation Act No. 1064 of September 6, 2012; Parliament), and defined its legal procedures in fighting research misconduct (Executive Order No. 306 of April 20, 2009; Government/ Ministry).

5.5.1 General Public

Above all, research misconduct destroys the public's trust into science. As mentioned in Chapter 2.3, researchers have accountability towards society. When public funding has been used to finance a research project, the public's taxes are involved in research.

Study Participants

The University of Luxembourg guarantees a treatment and compensation for any damage to individuals or animals who are infringed as a consequence of participation in a research study. However, when the breach originates from a research misconduct, thus as an intentional act, the risks for humans and animals are increased. In any case, the compensation for any damage to the victims must be guaranteed (Chapter 2.3).

5.5.2 Scientific Journal

In response to readers' request for clarification, an **addendum** is published when editors decide that this notification of a peer reviewed addition of information is crucial to the reader's understanding of a paper and increases the quality of the publication.

While an **erratum** is a production error made by the scientific journal that affects the scientific integrity of a paper, a **corrigendum/correction** results from an error made by the author(s). A corrigenda note needs to be signed by all authors of the published paper.

Worst case scenario is a notification of invalid results by retracting the scientific publication. A **retraction** should usually be reserved for duplicacy/redundancy or overlaps in publication, articles that contain serious errors in findings the scientific community cannot rely upon. According to the Committee on Publication Ethics (COPE) guidelines, retractions require *"clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error)"*. Retractions should be processed as soon as possible – respecting the disciplinary hearing or institutional investigation – to minimise the number of researchers who cite the erroneous work. In this case, all co-authors must sign a retraction specifying the error and defining the extent of the effects on the scientific publication. COPE recommends to journal editors that any retractions and corrections should be open access and underlines that the main purpose of retractions as a self-cleaning activity done in the global science community is to correct the literature and to ensure its integrity rather than to punish authors who misbehave (Adam Marcus and Ivan Oransky).

In case there is reason to doubt the validity of the findings or the reliability of the data (*e.g.* if authors' institutions refuse to investigate alleged misconduct), journal editors are free to issue an **expression of concern**.

Advice from the UL communications department or/and Legal Affairs Office may be helpful to determine the appropriate wording for a notice of retraction or expression of concern to ensure that these are not abusive and do not contain personal attacks against the editors or corresponding authors. **Amendments** should be published in all versions of the journal (online, pdf and print), including the authors and title of the retracted article making it possible to easily recognise it after electronic search.

In case **co-authors do not share the same opinion** for the corrigendum or retraction, the journal editor board takes the responsibility to ask for advice from independent peer reviewers and imposes the appropriate amendment to the scientific publication.

🕮 Read more:

What to do if you suspect redundant (duplicate) publication (COPE)
Retraction guidelines (COPE)

Standard retraction form (COPE)
Guidance on retractions (UKRIO)
Correction policy (Nature)
Retraction of global scientific publications from 2001 to 2010 (Springer)
Retraction policies of top scientific journals ranked by impact factor (J Med Libr Assoc)
Why growing retractions are (mostly) a good sign (Fanelli D)
Misconduct accounts for the majority of retracted scientific publications (PNAS)
Scientific retractions and corrections related to misconduct findings (JME)

Joint Responsibility for Research Misconduct

Most journal editors consider that authorship entails some degree of joint responsibility for the integrity of the reported research. Even if the joint accountability may, *i.a.* be the result of an active involvement in the misconduct of others, it is not appropriate that indirectly culpable authors dissociate themselves from a retracted publication. Final decisions must depend upon the circumstances of each case.

5.5.3 University of Luxembourg

After receiving advice from the UL communications department and LARI, the accused researcher is retracting his/her scientific publication with his/her supervisor/superior. LARI considers, in accord with the UL management, whether and to what extent other researchers (*e.g.* former and potential cooperation partners, co-authors), academic institutions, scientific journals and publishers (in publications), funding bodies and scientific organisations, professional associations, government departments or the public should or must be notified. The UL takes official position in reaction to these communities, while keeping professional discretion at the highest level.

Scientific Community

When research data is unsound and not reproducible, research misconduct results in loss of trust, confidence and credibility among researchers throughout the world. The reputation of the team members and the institution is severely damaged. Specific steps can be undertaken in order to restore reputation through transparency, *e.g.* by informing the involved parties.

Perpetrator

Depending on the severity of research misconduct, the consequences for the perpetrator may include:

- Employment Consequences: Simple warning to dismissal from employment by contract resolution
- Academic Consequences: Information of the scientific community (*e.g.* PHS ALERT, Déjà vu database, Labtimes reports, Retraction Watch), scientific journals, funding organisations, cooperation partners or the public about the perpetrator, non-eligibility for public funding, withdrawal of academic degrees or authorisation to teach
- Civil Consequences: (temporary) suspension or definite house ban
- Criminal Penalties: Breaches of laws (Chapter 1.5, *e.g.* copyright infringement, falsification of documents, violations of personal life or secret area), formal lawsuits with the consequence of repayment of scholarships or funds

- For the disrespect of the amended Luxembourgish Law of August 2, 2002, penalties can include 8 days to one year of imprisonment, as well as 251 to 125,000 euros according to Art.28 (2).
- In the future, penalties may become more severe. In July 2015, for example, the vaccine researcher Dong-Pyou Han was sentenced to 57 months of prison for fabricating and falsifying data in HIV vaccine trials. Also he has been fined to refund US $ 7.2 million of research money. Similarly, journal editorial boards are discussing whether they should introduce a retraction penalty (Nature).

5.5.4 Funding Body

National Research Fund

When submitting project proposals to the FNR, all alleged cases of research misconduct which are detected will be investigated confidentially by the FNR with the support of the Luxembourg Agency of Research Integrity (LARI).

Further, for the funding body having sponsored a research project that resulted in a retracted article, consequences include the misuse of financial resources. Thus, after an investigation confirming the suspicion of a research misconduct, the LARI is informed as soon as possible. The FNR with the support of LARI will for their side take form of disciplinary action by, for example, rejecting projects or rendering the perpetrator non-eligible for further research grants for a defined period of time.

🕮 Read more:

Quality framework for doctoral training
A guide to good and ethical conduct of research within the framework of the FNR funding schemes

European Research Council

In 2012, the European Research Council (ERC) set up a strategy for research misconduct. The ERP will inform either the ethical advisor for European projects and/or the ERC Executive Agency (ERCEA) about suspected and detected research misconduct cases if an ERC applicant or project is involved. The ERCEA then will follow their procedure to ensure timely follow-up actions, as well as inform the European Commission as well as OLAF, its anti-fraud body.

🕮 Read more:

ERC's Scientific Misconduct Strategy (European Research Council)
A comprehensive strategy on how to minimise research misconduct and the potential misuse of research in EU funded research (European Commission)
Investigating Research Misconduct Allegations in International Collaborative Research Projects (OECD)
Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded projects (European Commission)

5.6 Right to Appeal

In case the accused researcher does not agree with the setting of the examination procedure and/or the recommendation(s) given by the ERP, (s)he has the right to appeal. The complainant has no right to appeal.

Within 14 days of receiving notification, the accused researcher has also the right to appeal against the verdicts made by the LARI investigation committee (CRI) and/or sanctions by the UL President. The appeal must be made in writing and should state the reasons for the appeal to the UL President, who will then decide about the appeal process.

An internal appeal at the University of Luxembourg should be considered as a priority, however an appeal at any external bodies, such as the Tribunal administratif or the mediator between citizens and state authorities (Luxembourgish Law of August 22 2003) is also possible.

📖 Read more:

Researcher sues over *'fraud'* sanction (Nature)
Ombudsman

6 CONTACT LIST 2016

6.1 INTERNAL CONTACTS

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7 APPENDIX

7.1 OBSERVANCE OF LEGAL REQUIREMENTS

7.1.1 University of Luxembourg

Code of Conduct

The Code of Conduct is a set of principles, values, standards, or rules of behaviour for all UL employees. It cannot address every situation and is not meant to be exhaustive. Further, researchers enjoy academic freedom as set out in Article 30 of the Luxembourgish Law of August 12, 2003 on the creation of UL.

Common sense should guide decisions and actions of UL employees so that they are consistent with UL's values and missions. Additional and more explicit policies may govern particular organisational units, functions or committees within UL. It is the responsibility of each person working in those units to learn and adhere to UL policies. For example, standard operating procedures for using lasers have been established by the SIL.
The Code of Conduct should be read in conjunction with the *Internal Rules of Procedure*.

Internal Rules of Procedure

The University of Luxembourg has established the *"Règlement d'ordre intérieur"* which is regularly amended. These rules are in accordance with the culture of the institution and should therefore not be broken, as any breaches could significantly affect the proper functioning of the institution on the short- or long-term.

Policy on Ethics in Research

The University of Luxembourg advocates the highest standards of ethics in research.

All individuals involved in conducting research at or for UL, whether as Faculty, staff, student or visitor (including contractors on campus), shall ensure that research complies with UL procedures and all applicable laws, regardless of the location of the research.

The principles outlined in the *Policy on Ethics in Research* should apply to all research work carried out at or for the UL.

7.1.2 Grand-Duchy of Luxembourg

Luxembourgish Law

A Luxembourgish Law is a national law voted by the Chamber of Deputies, then sanctioned and promulgated by the Grand Duke (Art. 34 of the Luxembourgish Constitution). In the exceptional case in which a constitutional provision or a rule of international law restricts the fundamental right of freedom, the Luxembourgish legislation body decides on the articles it intends to implement into national law.

Grand-Ducal Regulation

A Grand-Ducal Regulation is a norm enforcement of the law. Indeed, the Luxembourgish Constitution charges the Grand Duke with the task of undertaking the necessary regulations and orders for the execution of laws, without ever being able to suspend the laws themselves nor dispense their enforcement.

Arrêté

An *"arrêté"* is an administrative act from a ministerial authority or another administrative authority (*e.g.* municipal). Signed by an executive member, the *"arrêté"* is a binding written decision in application of a law in order to determine the details of execution. An example of *"arrêté"* is the annual budgetary contribution to UL.

🕮 Read more:

Legilux

7.1.3 European Union

The Grand-Duchy of Luxembourg is bound by international, bilateral or multilateral treaties. In principle, EU Directives generally must be transposed into Luxembourgish Law by means of a law. The use of a formal law is however not necessary when the Directive concerns a matter already governed by Luxembourgish Law which is not stating the opposite. The transposition of EU Directives, today, is governed by a specific enabling statute dating from August 9, 1971 (as amended by the law of December 8, 1980) whose purpose is limited to authorise the Government to execute EU Directives. Notwithstanding the standard regulatory procedure, the regulations in question must have received the assent of the working committee of the Chambre of Deputies.

Types of EU legislation	***Definition and binding force***
Regulation	A *"regulation"* is a binding legislative act. It must be applied in its entirety across the EU.
Directive	A *"directive"* is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals.
Decision	A *"decision"* is binding on those to whom it is addressed and is directly applicable.
Recommendation	A *"recommendation"* is not binding. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.
Opinion	An *"opinion"* is an instrument that allows the institutions to make a statement in a non-binding fashion, in other words without imposing any legal obligation on those to whom it is addressed. An opinion is not binding.

7.2 ERP MEMBERS

7.2.1 Regulations

Requirements: All ERP members have to have a PhD (or equivalent) and a permanent contract.

Re-appointments: One re-appointment is possible. A new appointment is possible after a minimum of 3 years.

Liability of ERP members: The ERP members cannot be held personally responsible for decisions taken by the ERP.

ERP members are required to declare any conflict of interest that could affect their objectivity in making a decision. The Chair may exclude any such member from the decision-making processes related to any matter in which the member has a conflict of interest.

Compensation: ERP members receive a compensation that reflects the actual workload, *i.e.* a reduction by 1 quarter of the teaching load or a student assistant.

7.2.2 Selection/Election Procedure and Term of Office

ERP members: The Dean of a Faculty has the responsibility for identifying an ERP member representing his/her Faculty. First, Faculty members are nominated (including self-nominations) for the position. Then, the Dean selects a person out of these candidates. Attention should be given to complementary relevant competences in the ERP. ERP members are appointed for a period of 3 years.

ERP Chair: The Faculties propose candidates for the position of ERP Chair. In case existing ERP members are nominated, the respective Faculty has to nominate a replacement ERP member. The Chair is elected by the ERP. All members can cast a vote (including the current Chair). In case of a tie, the Vice-President for Research casts a vote. The ERP Chair is appointed for a period of 3 years.

ERP Deputy Chair: The ERP appoints a Deputy Chair among the existing ERP members, to deal with those cases in which the Chair has a conflict of interest or is unable to act in the Chair's capacity for any other reasons. In case of a tie, the Vice-President for Research casts a vote. The term of office of the ERP Deputy Chair equals the regular term of office of the elected ERP member.

7.3 AEEC MEMBERS

7.3.1 Regulations

Requirements: The FSTC Faculty proposes candidates for the AEEC committee so that there is at least one member from the following categories (Art. II.4.2-ter.102. *Internal Rules of Procedures*):

- *Category A* - persons with qualifications in veterinary science and with experience relevant to the activities of the institution.
- *Category B* - suitably qualified persons with substantial recent experience in the use of animals in scientific or teaching activities.
- *Category C* - persons with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes.
- *Daily Care* - persons responsible for the daily care of animals kept for use in teaching and research activities.
- Additional members with skills and background as is deemed necessary to ensure the effective functioning of the Committee.

Official appointment and Re-appointments: Before appointment, all members of the AEEC shall acknowledge in writing their acceptance of the terms of reference of the AEEC and UL's requirements for confidentiality.

AEEC members are appointed for a term of up to 2 years and may be reappointed to serve additional consecutive terms for not more than a total of 6 years.

Liability of AEEC members: The AEEC members cannot be held personally responsible for decisions taken by the AEEC. AEEC members are required to declare any conflict of interest that could affect their objectivity in making a decision. The Chair may exclude any such member from decision-making processes related to any matter in which the member has a conflict of interest.

7.3.2 Selection/Election Procedure and Term of Office

AEEC Chair: The Chair, elected by the AEEC members and nominated by the UL President, should possess the following attributes:

- an ability to bring impartiality to the task;
- an ability to communicate, negotiate ad to resolve conflict; and
- an understanding of the ethical and animal welfare issues involved in the use of animals for scientific purposes.

AEEC Deputy Chair: A Deputy Chair, elected by the AEEC members, who shall assume the duties of the Chair in the absence of the appointed Chair. The Deputy Chair should possess the attributes as outlined for the AEEC Chair.

7.4 TYPES OF NATIONAL AND INTERNATIONAL AGREEMENTS

Types of agreement [45]	***Purpose of the agreement***	***Main rights and obligations***	***Financial contributions***
Confidentiality	Agreement enabling information to be exchanged subject to a duty of confidentiality. This agreement should not be used as a matter of course and must only be proposed if - disclosure would cause harm to UL or to the partner - the parties wish to exchange confidential information in order to examine the potential benefit of a future collaboration/ exploitation of knowledge or know-how belonging to UL, whether amounting to an invention or not Confidential information belongs either to one party (unilateral exchange) or to 2 or more parties (multilateral exchanges)	**Essential obligations**: - non-disclosure obligation - obligation not to exploit the information exchanged for industrial or commercial purposes	No
Research collaboration	Agreement enabling new knowledge and results to be created on the basis of common expertise in the context of a project with shared aims and costs Collaboration agreements should be used in preference - to IPR agreements (they define the contractual relationship more precisely), - the consortiums because they are a less complex tool.	**Ownership of results**: - the principle is that the party which generates the results owns the results - co-ownership of results: if the parties' contributions cannot be separated **Exploitation of results**: - can be negotiated between the parties - exploitation of results: one partner can negotiate an exclusive right to exploit results under a licence agreement - results can be exploited freely by all the partners (only for their own research and for a non-commercial purpose) **Obligation of means**: the parties must use their best endeavours (means) to perform their contribution to the project **Right to publish**: important for academic partners.	The parties share the costs associated with the project
Consortium	A consortium is an agreement among several academic or industrial and commercial partners (3 or +) which undertake to perform distinct tasks with a view to carrying out a common project. By virtue in particular of the decision-making and operational bodies of which it is made up, a consortium makes it possible - to organise cooperation within the consortium, - to coordinate the individual work of its members with a view to carrying out the common project. Collaboration agreements are similar to consortiums and may also be used to set up a partnership (2 or +). Use of consortium is however justified where the following needs are felt: - a project needs a specific organisational structure to be put in place (with a steering committee in particular), - a need to increase the partners' technical, material and financial capacity,	A consortium includes the same features as a collaboration agreement: **Ownership of results**: - the principle is that the party which generates the results owns the results - co-ownership of results: if the parties' contributions cannot be separated **Exploitation of results**: - can be negotiated between the parties - exploitation of results: one partner can negotiate an exclusive right to exploit results under a licence agreement - results can be exploited freely by all the partners (only for their own research and for a non-commercial purpose) **Obligation of means**: the parties must use their best endeavours (means) to perform their contribution to the project **Right to publish**: important for academic partners. A consortium also includes internal bodies making it possible to satisfy a need to steer and coordinate the project: - decision-making bodies (steering committee, general assembly), - operational bodies (coordinator).	The parties share the costs associated with the project, in particular through common use of capital equipment and of personnel belonging to the members or through subcontracting.

45 The French terms *"convention", "accord"* and *"contrat" ["agreement"]* have the same meaning: a contractual document which creates rights and obligations for the parties.

	- a need to increase the partners' chances of succeeding in tendering procedures where they could not expect to do so acting alone.	The consortium defines the tasks of these bodies, which ensure that the project is coherent and that it is properly carried out as a whole.	
Non-disclosure agreement [46]*, confidentiality, publication*	The agreement to use essentially in exceptional circumstances where the other party: - is an academic partner (not for industrial and commercial partners) - is regarded as a *"non-contracting partner"*. It contains the minimum contractual terms to prevent any future disputes on those issues.	- agreements setting out rules for sharing rights in relation to IP - contains the usual rules on confidentiality and publication - does not set out the details of the contractual relationship and therefore must be used exceptionally; the collaboration agreement should be used in preference.	No
Framework agreement	Agreement laying down the general basis for close collaboration between the parties (only to be used where there is a strong institutional will to conclude a framework agreement). As a rule it precedes the conclusion of collaboration agreements for specific projects.	- lays down general information as a framework for the collaboration (field of collaboration, term, *etc*.) - does not as a general rule establish the details for projects and refers to the conclusion of specific collaboration agreements (research collaboration agreements, agreements for the creation of research structures, thesis organisation, *etc*.) to govern the terms on which each future project will be carried out	May contain an overall budgetary envelope and/or leave the question of finance to the specific collaboration agreements
Provision of services	Agreement making it possible to use pre-existing knowledge or know-how (is different from collaboration which is aimed at discovering new results) Project relating to prior art, existing resources, analysis, routine testing, … This agreement is recommended where the laboratory allows a third party to use its expertise, a technology, models or other resources, for analyses or tests not involving inventive step. The results are owned by the industrial partner, which can exploit them freely.	The service provider (the party which performs the service): - remains the owner of the knowledge and know-how and methodology used to perform the service, - ownership of the results commissioned belong to the partner - prima facie obligation of result on the service provider (distinguishes it from collaboration agreements); - term: as a rule it should not be more than one year (likewise distinguishing it from collaboration agreements – 3 to 4 years)	The service provider bears all direct costs of the operation (personnel, travel, consumables) and indirect costs (overheads), and a profit at market price (so that there is no State aid)
Material transfer agreement (MTA)	Exchange or transfer of materials, biological material and chemical molecules between the parties. It is used where there is a transfer of innovative products, research tools or biological material, whether protected or otherwise, to a third party, for the purposes of research or for technical and commercial evaluation.	Lays down the terms for use of the material, confidentiality, IP (ownership and exploitation of the material – to be negotiated between the parties) and liability (*"non-liability provision"* between the parties relating to any consequences of use)	Agreement to be entered into consideration or otherwise. The supplier invoices at least carriage.

46 *"Non-disclosure agreement"* (NDA)

7.5 AUTHORSHIP AND INVENTORSHIP

An *"author"* is generally considered to be someone who has made substantial intellectual contributions to a published study. According to the International Committee of Medical Journal Editors (ICMJE, the Vancouver group), authorship credit should be based only on:

"1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."

Contributors who do not meet all four criteria should be acknowledged.

The ICMJE has been the first committee on outlining uniform requirements for authorship in medical research. Today, additional academic organisations have set out their criteria as rules of publishing can vary among different specialities. For example, depending on the respective research area, the **order** in which the authors are listed in the publication tells readers who did the work and should ensure that the right people get the credit for the research. The order of authors can also depend on the country the research is performed or published in.

Order of authors	***Interpretation of contribution***
Alphabetic order	All authors have made similar contributions to the publication
First-last-author-emphasis	The first and last authors' importance is highlighted
Sequence determines credit	Sequence reflects the importance of contributions in descending order
Percentage-of-contribution-indicated	The authors' contribution is expressed in terms of percentages

The COPE Discussion Document on *"What constitutes authorship?"* outlines the criteria and guidelines relevant to other research areas, such as chemistry, physics, mathematics as well as sociology, and humanities.

The University of Luxembourg encourages a culture of ethical authorship meaning that, in order to prevent **authorship disputes** and conflicts, agreements concerning contributorship should be made jointly in advance with all the parties and people involved when planning research or starting to write an article. This includes candidacy for authorship and other forms of acknowledging contributions, as well as the listing of authors. A written record of all agreements with different institutions (including a time limit) might be required.

Authorship and **inventorship** are *not* identical concepts. The patent law defines an inventor of a patentable invention as *"someone who conceives of an original, useful and non-obvious idea"*. The guidelines and rules for determining inventors are established by laws and can differ from country to country. Therefore, inventorship is legally determined by a patent attorney who examines the involvement of all parties in the original conception of the invention to subsequently name the rightful contributors on the patent. To be named all sort of mental act is considered, while it is not sufficient to perform experiments under the supervision of another person, or to amend the original idea or the general concept. In cases of an erroneously identified

"inventor" or an omitted inventor might entail serious consequences for the patent owner, *e.g.* patent being invalidated.

More information can be obtained from:

Legal Affairs

🕮 Read more:

What constitutes authorship? (COPE)
White Paper on Publication Ethics (Council Science Editors)
Authorship in scientific publications (Swiss Academies of Arts and Sciences)
Who is (and is not) an inventor? (University of Stanford)

7.6 How To Avoid Plagiarism

Plagiarism is serious but can easily be avoided. When using ideas, phrases and arguments from sources already published, paraphrasing can be used to encapsulate the work of others when citing a reference. **Paraphrasing** is restating someone else's ideas while not copying the exact phrases from the original source (verbatim). Using the verbatim in **quotation marks** in a correct citation is also acceptable.

The source and the original author should always be acknowledged and respected. In cases where results are described in secondary literature, the source the researcher actually reads as well as the primary literature source need to be mentioned in the references. Also, reference must be given in an appropriate, accurate and verifiable manner that makes it clear to which text passage it refers. **Self-citations** of authors' own past publications need to be properly referenced as any other source.

The different research areas can also determine the appropriate citation style:

7.6.1.1 Research Area	***Commonly Used Style Guides***
Life Sciences	Scientific Style and Format: the CSE Manual for Authors, Editors, and Publishers (Council of Science Editors) American Medical Association Manual of Style
Physics and Engineering	Publishing in ASCE Journals: A Guide for Authors (American Society of Civil Engineers) 7.7 IEEE Standards Style Manual (Institute of Electrical and Electronics Engineers)
Humanities and Social Sciences	ASA Style Guide (American Sociological Association) APA Style Guide (American Psychological Association)

Before sending a project proposal to the funding body or the final draft of a publication to a journal, every PI can use powerful (but easy to use) anti-plagiarism tools to investigate their own documents as a self-control mechanism. UL has joined forces with **Ephorus**, a key player in the European anti-plagiarism business. The integration with the Moodle platforms of all faculties makes the tool available to all PIs without extra efforts. Alternatively the Ephorus web portal can also be used to analyse project proposals as well as scientific publications manually.

More information can be obtained from:

SIU central unit

Submitted papers are compared with a set of documents in the Ephorus UL Database which holds free information from the internet (*e.g.* Wikipedia, scientific articles, technical reports, studies) as well as documents provided from former classes at UL. Any found similarities, even partial or corrupted copying from sources, will be highlighted in a special plagiarism report which will also include percentages of overlap and the original sources.

Others examples of anti-plagiarism tools that are widely available:

Déjà vu Database	iThenticate	CrossCheck
LexisNexis CopyGuard	Anti-Plagiarism Tools	Urkund
PlagiarismFinder	Docoloc	Sucodo
PlagAware	Plagscan	My DropBox
Scriptum	EVE	WCopyfind 2.5
Glatt Plagiarism Self-Detection Program and Screening Program	VroniPlag	Copyscape

📖 Read more:

eTBLAST
Ephorus Userguide
Citation Style Guide (MIT library)
Avoiding plagiarism, self-plagiarism, and other questionable writing practices (ORI)

7.8 PEER REVIEWER RESPONSIBILITIES

The quality assessment of articles submitted for publication in a journal or research proposals is undertaken during peer review. During this self-regulating process, scientific work is evaluated by two or more people of similar competence to the authors. Some journals have their own policy making peer reviewers aware of their ethical obligations. Such a policy can include the following responsibilities of peer reviewers:

Responsibilities	
Competence	To have adequate expertise to provide an authoritative assessment
Impartiality	To be objective in considering the scientific work and to disclose possible COI
Confidentiality	To not take advantage of privileged information and share it with anyone outside the review process
Constructive Criticism	To acknowledge positive aspects and assess negative aspects constructively
Responsiveness	To complete reviews in a timely fashion

In case peer reviewers cannot fulfil the listed responsibilities, they are ethically obliged to decline their attributed evaluation task in order to maintain the integrity of the publication record. Delaying reviews on

purpose or passing on scientific results which have been acquired in confidence is regarded as research misconduct.

In the peer review process, the identity of reviewers is often kept anonymous opposite to the authors. This results in a **lack of transparency** with regards to evaluative information about research proposals, and published articles. A handful of researchers have exploited loop-holes in the peer review system to ensure that they would review their own papers or obstruct in the review of their competitor's papers. For this reason, the peer review process should become completely open and transparent, either by a **double-blind peer review** in which the author's name is also concealed from the referee, or by letting authors equally see the reviewer's names. In addition, it would also be beneficial for readers who reviewed the article and how the authors responded (Shanahan and Olsen, JNRBM 2014).

🕮 Read more:

COPE Ethical guidelines for peer reviewers
Responsible authorship and peer review (Columbia University)

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