

**Rules of Procedure  
of the  
*Stiftung Leibniz-Institut für Immuntherapie*  
(LIT, Leibniz Institute for Immunotherapy Foundation)  
for  
Safeguarding Good Research Practice  
dated 16 January 2023**

**Preamble**

The researchers' honesty and integrity are a prerequisite for research work. Good research practice must be taught and practiced. The following rules for good research practice are intended to help promote the quality of research work and prevent scientific misconduct.

With this objective, based on and in recognition of the legally binding reference framework of the Code "Guidelines for Safeguarding Good Research Practice" by the *Deutsche Forschungsgemeinschaft* (DFG, German Research Foundation), of the Leibniz Code for Good Research Practice of the Leibniz-Gemeinschaft (Leibniz Association) and the Guideline for Good Scientific Practice in the Leibniz Association – as amended – the Executive Board of the *Stiftung Leibniz-Institut für Immuntherapie* (LIT, Leibniz Institute for Immunotherapy Foundation) – after consulting with the LIT researchers – issues the following Rules of Procedure for Safeguarding Good Research Practice for use in the Leibniz Institute for Immunotherapy, operated by the LIT Foundation.

**I. Safeguarding Good Research Practice**

**§1 Rules of Good Research Practice**

- (1) Research publications are the product of the work of LIT staff. Quality and originality of work always take precedence over quantity in the assessment of performance for awarding academic degrees, and in terms of promotion, recruitment, appointment and allocation of funds. Other performance dimensions are also taken into account, such as individual characteristics in CVs, special commitment in teaching, academic self-government or in the interests of society as a whole, as well as the scientific attitude of the researcher, which is expressed, for example, in an openness to knowledge and a willingness to take risks.
- (2) When planning a research project, the current state of research must be fully taken into account. This requires careful research into research achievements that have already been made publicly available. The necessary framework conditions to do this, such as professional tools for research, are provided by LIT. As far as possible, methods are used to avoid unconscious bias in the interpretation of findings.

- (3) Research must be carried out in accordance with up-to-date knowledge and in compliance with discipline-related recognized principles of research (*lege artis*). Knowledge of the current literature and appropriate methods is therefore imperative. Only scientifically sound and appropriate methods are used to answer research questions. Continuous quality assurance must be applied during research. When developing new methods, particular importance must be attached to quality assurance and the establishment of standards. When research findings are made publicly available, the applied mechanisms of quality assurance are outlined, especially if new methods have been developed.
- (4) LIT is responsible for the compliance of its employees' actions with the rules and creates suitable organizational structures for this purpose. Ethical standards must be observed when conducting experiments. Rights and obligations, arising in particular from legal requirements, but also from contracts with third parties, must be taken into account. Where necessary, permits and ethics approvals must be obtained and submitted. Regarding research projects, potential consequences of the research should be thoroughly evaluated and the respective ethical aspects assessed.
- (5) Those involved in the research project shall reach documented agreements on usage rights relating to the research data and research results collected for the project at the earliest possible date. In particular, the researcher who collected the research data is entitled to use them. During a research project, those entitled to use the data decide whether third parties should have access to them (subject to data protection regulations).
- (6) Research work should be reproducible and the workflow comprehensible to others. All steps and results of an experiment or study are fully documented, in particular also those individual results that do not support the thesis. Results are not selected in this context. If the documentation cannot meet the relevant technical specifications in individual cases, the constraints and reasons for them must be explained. If research software is developed, the source code is documented. Documentation and research results must not be manipulated and must be protected against manipulation.
- (7) All findings must be consistently questioned. Prior to publication, a mutual critical review of the work is mandatory. For this purpose, primary data and interim results shall be made available to others. Software programmed by researchers themselves shall be made publicly available along with the source code.
- (8) As a rule, all results are included in scientific discourse; should this not be the case as an exception, this decision must not depend on third parties. Researchers decide autonomously whether, how and where to make their results publicly available. Once the decision to publish has been made, the results are described in full and comprehensibly. The research data and central materials on which the publication is based are stored in recognized archives and repositories in accordance with the FAIR principles ("Findable, Accessible, Interoperable, Re-Usable"). Inappropriately small publications are avoided. Personal and external preliminary work for the research project is fully and correctly documented.

- (9) Inconsistencies and errors that come to light after publication are corrected. If the inconsistencies or errors constitute grounds for withdrawing a publication, the researchers will promptly request the publisher or infrastructure provider to correct or retract the publication and make a corresponding announcement.
- (10) The applied materials and methods as well as results, including primary data, must be documented and kept for a period of ten years beginning on the date when the results are made publicly available unless other rules and regulations require a longer archiving period. The origin of all data, organisms, materials and software used in the research process is fully and correctly documented. The source code of publicly available software must be persistent, citable and documented. Data is backed up by adequate means according to the standards of the subject area. LIT ensures that the infrastructure required for this purpose is in place. If there are justifiable reasons for not archiving certain data, they must be stated. Data is backed up and archived at LIT or in cross-location repositories. Should an employee responsible for research work resign from the institute, research documents must be handed over to his or her supervisor. This includes, but is not limited to, all written and electronic records, reports, protocols, algorithms, software codes, calculations, data and presentations. Data is stored appropriately, protected from unauthorised access and the persons authorised to access it are specified. When leaving LIT, it is permitted to make and take along copies of one's own laboratory notebooks.
- (11) Strict honesty with regard to identifying contributions by participants must be maintained.
- (12) Researchers should cooperate in a responsible manner. Management tasks must be carried out responsibly.
- (13) In all publications, the intellectual authorship of others must be respected and all quotations and adoptions must be properly identified.
- (14) Researchers who assume editorship of research series and editions carefully check in advance whether the publication medium is compatible with the standards of good research practice.

## §2 Organisational Responsibility of the Institute's Management

- (1) The institute's management is responsible for creating the framework conditions for scientific work according to the principles of good research practice. The institute's management ensures that researchers are able to comply with legal and ethical standards. The tasks of leadership, supervision, quality assurance and conflict resolution are clearly assigned and communicated to the employees. Procedures and principles for personnel selection and development as well as equal opportunities are anchored in the basic concept of LIT and published in the employee concept on the LIT website (<https://www.rcii.de/en/lit/about-us/>).
- (2) Appropriate organizational measures are taken to prevent abuse of power and the exploitation of dependent relationships both at the level of individual research work units and at the level of the institute's management.

## § 3 Teaching, Training and Obligations

- (1) At the beginning of their research work at LIT, employees must be informed about the rules of good research practice and their obligation to comply with them must be recorded by including them in any employment contract with LIT. This instruction and commitment shall be repeated annually. In addition, researchers at all career levels continuously update their knowledge of the standards of good research practice and engage in a mutual exchange of their knowledge of these standards with each other.
- (2) The rules of good research practice and these rules of procedure are an integral part of teaching and training junior scientists at LIT; this also applies to taking on teaching obligations at institutions of higher education. LIT staff responsible for doctoral candidates, bachelor and master students shall instruct the students on the rules of good research practice and oblige the students to comply with them.
- (3) The Rules of Procedure for Safeguarding Good Research Practice are published on LIT's website (<https://www.rcii.de/en/>).

## § 4 Design of Structural Units and Project Groups

- (1) Within their area of responsibility, heads of structural units (departments, research groups, junior research groups, cross-sectional institutes, associated groups) and project groups have the following duties:
  - defining research priorities,
  - defining and, if necessary, adapting the responsibilities and roles within the research projects and making the researchers and research support staff involved aware of them,
  - defining workflows and their monitoring,

- preparing work programmes for doctoral candidates, bachelor and master students and providing guidance on research work,
  - conducting regular laboratory meetings with reports from the scientific staff, doctoral candidates, bachelor and master students.
- (2) Research and technical staff, doctoral candidates, as well as bachelor and master students are only allowed to pass on methods and results to third parties with the express approval of the head of the relevant structural unit or project group.
- (3) In all matters concerning the research objective, publication or utilization of research results, members of a structural unit or project group are subject to the instructions of the head of the structural unit or project group. The heads of the structural unit or project group are subject to the instructions of LIT's Executive Board.

### **§ 5 Authorship of Research Publications**

- (1) If several people are involved in a research paper, in the drafting of a scientific report or a software publication, only those who make a genuine, comprehensible contribution
- to the development and conceptual design of the research project, or
  - to the gathering, collection, acquisition or provision of data, software or sources, or
  - to the analysis/evaluation or interpretation of data, sources and conclusions drawn from them, or
  - to the design or the critical revision of the manuscript's content
- may be mentioned as author.

This also includes the scientific guidance of staff members of the structural unit. What constitutes a genuine and identifiable contribution is evaluated on a case-by-case basis. Any "honorary authorship" is excluded. If a contribution is not sufficient to justify authorship, the individual's support should be properly mentioned in the acknowledgments. Researchers shall agree in good time and on the basis of clear criteria who the author should be.

- (2) If a co-author feels that he or she has been passed over, he or she can call upon the ombudsperson according to § 10 and § 11. Co-authorship cannot be justified by only technical participation in the collection of data, nor by providing financial resources only or by the general management of the structural unit in which the research was carried out. The same applies to merely reading the manuscript without co-designing the contents.

- (3) If unpublished observations or data from other persons are quoted in the manuscript or if observations or data from other institutions are used, their written consent is required.
- (4) All employee manuscripts and data intended for publication must be presented to the head of the structural unit prior to submission or dissemination. The publication medium shall be carefully selected by the researchers involved, taking into account its quality and visibility in the respective field of discourse. The scientific quality of a contribution does not depend on the medium in which it is to be published; consideration should be given to whether academic repositories, data and software repositories or blogs would also be suitable.
- (5) Heads of structural units shall check all data intended for publication for the existence of any inventions. They are encouraged to consult with the institute's patent department regarding such matters. The existence of inventions obliges the inventors to submit a Notice of Invention to the Executive Board.
- (6) Prior to submission, the head of the structural unit or the corresponding author is responsible for presenting the final manuscript to all co-authors for consent. This also applies to resubmission after revision or resubmission to another publication medium. Without sufficient grounds, consent to the publication of research results may not be refused. Refusal of consent must be justified with verifiable criticism of data, methods or results.
- (7) By agreeing with being designated a co-author, the co-author assumes shared responsibility for the fact that the co-authored publication complies with scientific standards. This is particularly true for the area to which a co-author has contributed; he or she is responsible for both the correctness of his or her own contribution as well as for ensuring that it is included in the publication in a scientifically correct manner. The corresponding authors are responsible for the main statements of the publication.
- (8) Prior to submission, the head of the structural unit or the corresponding author must obtain a written release of the manuscript from the LIT's Executive Board. This does not apply to posters and presentations.

### § 6 Peer-Review Activity

- (1) Peer-review activities must be carried out in a confidential and competent manner. Researchers who evaluate submitted manuscripts, funding proposals or personal qualification are obliged to maintain strict confidentiality with regard to this process; this excludes the disclosure of content belonging to others to third parties and making personal use of it. This also applies to LIT employees who are members of research advisory and decision-making bodies. They shall disclose any facts which may give rise to concern about bias and shall immediately notify the competent body of any conflict of interest or bias.
- (2) If any peer-review activity is fully delegated, this must be communicated to the person who commissioned the peer review in writing.

### § 7 Junior Researchers

- (1) With their bachelor, master and/or doctoral thesis junior researchers begin working scientifically. In addition to technical skills, LIT's staff members must equip them with the fundamental ethical principles for research work and teach them responsible treatment of results and cooperation with other researchers.
- (2) Junior researchers are entitled to regular scientific supervision, advice and support from the head of the structural unit or project group. The procedures and principles for the supervision and development of junior researchers are laid down in the LIT employee concept (<https://www.rcii.de/en/lit/about-us/>), as are measures for career advancement for research support staff.
- (3) Doctoral candidates, bachelor and master students have the same rights and obligations to safeguard good research practice mentioned in these Rules of Procedure as the other researchers. They must be committed to comply with the principles of good research practice mentioned in Part I. They are required to be collegial, to regularly report on the progress of their research, to participate in internal seminars and, to a limited extent, to participate in routine tasks within the structural unit or project group.

## II Procedure for Dealing with Scientific Misconduct

### § 8 Scientific Misconduct

- (1) If researchers deliberately and intentionally or through gross negligence make false statements in the field of science, violate the intellectual property of others or seriously impair their research activities, this constitutes scientific misconduct. This also applies to technical employees.
- (2) Misrepresentation, in particular, is considered to be misconduct, such as:
  - fabrication of data,
  - falsification of data, diagrams or illustrations,
  - selection and rejection of undesirable findings without disclosure,
  - manipulation of test results (e.g. by deliberately creating special test conditions, which were not disclosed),
  - incorrect information in an application or funding proposal (including false information on the publication medium and on the publications accepted or in print),
  - multiple publication of data or texts without disclosure.
- (3) Misconduct also includes the infringement of intellectual property regarding a work created by a third party and protected by copyright; it also includes the infringement of intellectual property regarding material scientific findings, hypotheses, theories or research approaches from others, arising from:
  - unauthorised use under the pretence of authorship (plagiarism),
  - use of research approaches and ideas of others without reference to the source, in particular as an expert and/or peer reviewer (theft of ideas),
  - claim or acceptance of unjustified scientific authorship or co-authorship, as well as refusal of legitimate co-authorship toward the co-author,
  - falsification of content,
  - unauthorised publication and unauthorised provision to third parties, before the work, finding, hypothesis, theory or research approach has been lawfully published.

(4) Misconduct also includes:

- breach of trust in the case of peer-review activity or as a supervisor as well as violation of § 6,
- violation of the publication rules (§ 5), in particular § 5 (4) and § 5 (8),
- violation of the obligation to back up data according to § 1 (10). This also applies to the unlawful non-elimination of (in particular personal) data,
- serious impairment of research activities, including damage, destruction or manipulation of experimental arrangements, equipment, documents, hardware, software, chemicals or other items required by another person to carry out research work,
- deliberate alteration or removal of data records,
- intentionally rendering scientifically relevant information carriers useless.

### **§ 9 Co-responsibility for Misconduct**

(1) Co-responsibility for misconduct within the meaning of § 8 may also arise from:

- active participation in the misconduct of others,
- knowledge of falsification by others,
- co-authorship in publications affected by deliberate falsification,
- gross neglect of supervisory duties.

### **§ 10 Procedure for Dealing with Allegations of Scientific Misconduct**

- (1) The procedure for dealing with allegations of scientific misconduct begins with reporting a suspicion (§ 11) and is carried out by the ombudspersons (§ 12), and, if necessary, by a Committee for the Examination of Scientific Misconduct (§§ 13-15) and the LIT's Executive Board (§ 16).
- (2) All employees of the structural unit concerned are obliged to fully support the investigation.
- (3) This procedure does not replace other procedures governed by laws or bylaws.

### **§ 11 Reporting a Suspicion**

- (1) If individual LIT researchers have a specific suspicion of scientific misconduct, they must immediately inform an ombudsperson (§ 12) by reporting a suspicion. They have the right to choose whether to call the local ombudsperson or the supranational committee *Ombudsman für die Wissenschaft* (German Research Ombudsman) appointed by the Senate of the German Research Foundation (DFG) (<https://ombudsman-fuer-die-wissenschaft.de/?lang=en>).
- (2) Any suspicion should be reported in writing, stating incriminating facts and evidence. The

information disclosed must be provided in good faith. Knowingly false or malicious allegations may themselves constitute misconduct.

- (3) The ombudsperson shall inform the person concerned. He or she shall check whether the allegations are plausible in terms of concreteness and significance as well as potential motives. At every stage of the process, confidentiality and the basic principle of presumption of innocence apply. This applies to every stage of the process. The ombudsperson shall also check whether it is possible to disprove the allegations. Within four weeks, the result or results of the investigation shall be issued in writing, if necessary in various statements.
- (4) If the allegations cannot be disproved, the ombudsperson shall apply to the Executive Board for the formation of a Committee for the Examination of Scientific Misconduct (§13) and shall inform the heads of the structural units concerned of the initiation of investigation against the person concerned — however, due to the principle of confidentiality this information shall not include any details.
- (5) Confidentiality must be maintained to protect informants and persons concerned. Without the informants' express consent their names may not be disclosed to the persons concerned during this phase of the procedure; this does not exclude a mutually agreed to confrontation. Disclosure of names is possible if there is a legal obligation to do so or if the respondent cannot otherwise defend himself/herself properly. The complainant shall be informed before his/her name is disclosed. He/she may decide to withdraw the allegation and not to have his/her name disclosed.
- (6) Anonymous reporting is not possible.

## § 12 Ombudspersons

- (1) The researchers elect two ombudspersons by secret ballot as a point of contact for LIT staff who have allegations of scientific misconduct to make. These two ombudspersons work together and each has sole power of representation.
- (2) Suitable ombudspersons are researchers who have an employment relationship with LIT, are not members of a central management body of LIT, have long-term experience in the scientific field and enjoy a national and international scientific reputation. Furthermore, they should be professionally and personally independent and have management experience.
- (3) The institute's management shall ensure that the election by secret ballot is conducted properly. The term of office is three years; re-election is possible once.
- (4) The institute's management gives ombudspersons the acceptance and support they need to carry out their duties.

- (5) Name and contact details of the elected ombudspersons are published on the LIT website (<https://www.rcii.de/en/>).
- (6) The ombudspersons have the following duties:
  - a. As persons of trust, they advise on matters of good research practice and advise those LIT employees who inform them about a suspected case or suspicious facts of scientific misconduct within the meaning of § 8. They also act as a point of contact in the event of disputes and can mediate in conflicts related to good research practice.
  - b. In the event of a reported suspicion of scientific misconduct they shall conduct investigations in accordance with § 11 of these Rules of Procedure.
  - c. The ombudspersons are obliged to document their actions, taking into account the personal privacy rights of the informants and persons concerned.
- (7) Every LIT employee is entitled to speak personally to an ombudsperson within a short period of time.
- (8) In the event that the ombudsperson is biased or unavailable, the other ombudsperson will act as a substitute, and vice versa.
- (9) If it no longer seems possible for an ombudsperson to fulfil his or her duties reliably in the long term, or if there is no longer any confidence in the ombudsperson's ability to fulfil his or her duties properly, the ombudsperson may be voted out of office. At least two-thirds of the researchers at LIT must agree to this. The ombudspersons must be heard before a decision is made to remove them from office.

### **§ 13 Appointment of the Committee for the Examination of Scientific Misconduct**

- (1) After consultation with the heads of the structural units, the Executive Board shall appoint a Committee for the Examination of Scientific Misconduct on an ad hoc basis.

- (2) The committee is composed of:
  - three researchers,
  - the ombudspersons as guests in an advisory capacity.
- (3) The committee shall act at the request of the ombudsperson or one of the committee members.

#### **§ 14 Procedure of the Committee for the Examination of Scientific Misconduct**

- (1) The committee shall elect a chairperson and a deputy chairperson. The chairperson or, if the chairperson is indisposed, the deputy chairperson, invites members to the committee meetings, chairs the meetings and implements the committee's resolutions.
- (2) In the event that there should be any concern about bias of a member or in the event that member should be unable to carry out his or her duties, an alternate shall be designated for each member of the committee.
- (3) The committee has a quorum if at least two members or alternate members are present. The committee decides by simple majority. Minutes of the committee meetings shall be taken and shall record the main results of the meetings.
- (4) The committee may bring in other persons in an advisory capacity.
- (5) The committee shall organise its work in a manner that ensures a speedy procedure.
- (6) In order to protect the complainant as well as the respondent, the principle of confidentiality applies to all parties involved, including the investigation committee and peer reviewers involved as experts, until scientific misconduct has been proven.

#### **§ 15 Duties of the Committee for the Examination of Scientific Misconduct**

- (1) Pursuant to § 11 (3), the committee shall be made aware of the results of the investigation by the ombudsperson and decide on any further course of action. The committee may discontinue the procedure, in particular upon a justified request by the informant, or it may initiate further investigation or submit a recommendation for a decision to the Executive Board.
- (2) The committee does not deliberate in public.
- (3) Respondents and complainants are given the opportunity to comment at any stage of the procedure. They may each involve a person of trust as an advisor at hearings. This also applies to other persons to be heard.

- (4) If, for instance, an adequate defence would otherwise not be possible, the committee may disclose the names of the informants to the persons concerned. It is necessary to check whether the complainant's consent to disclosure is required. Informants must be notified in advance of this disclosure.
- (5) The committee examines in free consideration of the evidence whether scientific misconduct has occurred. It evaluates the evidence comprehensively and individually in accordance with the DFG guidelines. It normally reaches a decision within a period of six months.
- (6) If the committee considers scientific misconduct to be proven, it shall report to LIT's Executive Board on the result of its investigation in writing and suggest how the procedure should continue, also with regard to the protection of the rights of others. This report shall also be made available to the respondents and informants.
- (7) The files are to be archived for 10 years.
- (8) If it becomes apparent in the course of the investigation that a conclusive clarification of the allegations is not possible at the institute level or that the conduct of the investigation is impeded by extraordinary circumstances, the case shall be submitted to the central Ombuds Committee of the Leibniz Association. The investigation is described in § 5 of the Guidelines for Good Scientific Practice in the Leibniz Association. The option of contacting the German Research Ombudsman committee remains unaffected by this provision. If members or staff of the University of Regensburg are involved, the matter shall be forwarded to a person of trust of the University of Regensburg.
- (9) Intentional false allegations may be subject to disciplinary action under employment law. Informants must be protected from disadvantages to their scientific and professional advancement as a result of reporting a suspicion. This also applies in the event that research misconduct has not been proven, assuming that the allegations cannot be shown to have been made against the informant's better knowledge. The respondents must also be protected from disadvantages, provided that no formal finding of misconduct has been made.

#### **§ 16 Executive Board Decisions**

- (1) The Executive Board reviews committee recommendations on sanctions for scientific misconduct and decides on the further course of action. The Executive Board shall inform the Committee for the Examination of Scientific Misconduct about this decision.
- (2) The Executive Board shall review at the end of the investigation whether and to what extent scientific organisations and, if applicable, third parties, such as cooperation partners, funding agencies, scientific journals, ministries or the public with a justified interest in the decision, need to be notified.

- (3) If the person or persons concerned is employed by LIT, the following disciplinary actions under employment law may apply in case of scientific misconduct:
- warning letter,
  - extraordinary termination (including dismissal on grounds of suspicion),
  - ordinary termination,
  - notice of termination of contract.
- (4) The following consequences under civil law may apply in case of scientific misconduct:
- a ban from entering the premises,
  - claims for restitution against persons concerned (for example with regard to stolen material),
  - claims for removal or elimination as well as injunction relief arising from copyright, personality rights, patent law and competition law,
  - claims for restitution (for instance of grants, scholarships or third-party funds),
  - claims for damages by LIT or third parties in the event of personal injury, damage to property and so forth.
- (5) The Executive Board may hand over the procedure to the relevant institution of higher education for the execution of academic consequences.
- (6) In the event of criminal misconduct, the Executive Board shall report the offence.
- (7) If the suspicion of scientific misconduct has been wrongly raised, the Executive Board shall ensure the rehabilitation of the person(s) concerned.