Policy to ensure good scientific practice at Helmholtz Munich

Date:	Author	Note
Entry into force November 1, 2022	Dr. N. Ukert, J. Mühlenberg, Prof. Dr. Dr. H.-E. Wichmann, Prof. Dr. R. Holle, Dr. K. Hürkamp, S. Opitz, Dr. D. Lahne	The policy to ensure good scientific practise (the "Policy") replaces the rules for safeguarding good scientific practice at Helmholtz Munich dated 6 October 2015

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PREAMBLE

The main task of Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH) (in this Policy referred to as "Helmholtz Munich") is to conduct research into common diseases in connection with environmental factors, lifestyle and individual genetic disposition, to develop new methods of prevention, diagnosis and therapy and to disseminate scientific knowledge in these fields.

Scientific work is based on the principles of scientific honesty, conscientiousness, integrity and open discourse which apply in all scientific disciplines and internationally. Good scientific practice is a prerequisite for excellent, internationally recognised scientific work.

Helmholtz Munich is committed to maintaining good scientific practice and has established the following binding regulations for this purpose in accordance with the Code of Conduct "Guidelines for Safeguarding Good Research Practice" of the Deutsche Forschungsgemeinschaft e.V. (hereinafter referred to as „DFG") of September 2019.

SCOPE OF APPLICATION

All Helmholtz Munich employees working in science (hereinafter referred to as "scientists") undertake to observe and implement the following rules in their daily scientific practice. These regulations summarize the central standards of good scientific practice and describe the procedure in case of their non-observance at Helmholtz Munich.

The following regulations also apply to Helmholtz Munich employees who do not work directly in science, insofar as such application appears suitable.

STANDARDS OF GOOD SCIENTIFIC PRACTICE – PRINCIPLES

§ 1 General principles

Individual researchers are responsible for ensuring that their own conduct complies with the standards of good scientific practice. The following aspects are to be observed in particular as general principles of scientific work at Helmholtz Munich:

- We work according to the latest state of knowledge (*lege artis*). We respect the discipline-specific regulations for planning research work as well as for obtaining, selecting and processing data.
- We maintain strict honesty with regard to our own contributions and those of scientists, colleagues, partners, competitors and predecessors.
- We critically question all results and are open to criticism and doubts expressed by scientists.
- We do not hinder the scientific work of others.
- We prevent and avoid scientific misconduct.

Furthermore, it goes without saying that we respect all applicable legal and ethical frameworks at the national, European and international level.

§ 2 Professional ethics

(1) Scientists are responsible for implementing the fundamental values and norms of scientific work in their actions and for standing up for these. Teaching the basics of good scientific work begins at the earliest possible stage in academic teaching and scientific training. Scientists at all career levels regularly update their knowledge of the standards of good scientific practice and the state of research.

(2) Experienced scientists and early-career investigators support each other in the process of continuous learning and further education, engaging in regular dialogue.

§ 3 Responsibility of the Management

(1) The Management of Helmholtz Munich establishes the conditions for scientific work in accordance with good scientific practice. It is responsible for ensuring that good scientific practice is observed and communicated, and for providing appropriate career support for all scientists. The Management is committed to creating the conditions in which scientists are able to comply with applicable legal and ethical standards. These conditions include clear and written procedures and principles for personnel selection and development as well as for the promotion of early-career investigators and equal opportunities.

(2) Gender equality and diversity are taken into account in staff selection and development. Appropriate support structures and -concepts have been established for early-career investigators. Scientists are advised on career paths and further training opportunities.

(3) Helmholtz Munich establishes an appropriate institutional organisational structure to ensure that, depending on the size of the individual scientific organisational units (e.g. department, institute, division or working group), the tasks of management, supervision, quality assurance and conflict regulation are clearly assigned and appropriately communicated to the respective scientists.

§ 4 Responsibility for the management of organisational units

(1) The management of a scientific organisational unit is responsible for implementing these regulations. Interaction within the scientific organisational units is organised in such a way that the latter are able to fulfil their tasks as whole entities, that the necessary cooperation and coordination take place and that all members are aware of their roles, rights and responsibilities. In particular, the management is also responsible for ensuring appropriate individual supervision of early-career investigators – embedded in the overall concept of the respective institution – as well as providing career support for scientists. Any abuse of power or exploitation of dependent relationships is prevented by appropriate organisational measures, both at the level of the individual scientific work unit and at the level of the management of scientific institutions.

(2) The size and organisation of the scientific organisational units are designed in such a way that management tasks can be adequately fulfilled, in particular the teaching of skills, academic supervision, and the responsibilities of supervision and mentoring.

(3) A balance is struck between giving scientists support and allowing them to take on independent responsibility as appropriate to their career level. They enjoy an appropriate status, including the relevant involvement in decision-making processes. They are empowered to shape their own career by being given increasing independence.

(4) The activities of students and doctoral candidates in scientific working groups are appropriately supervised. A primary contact person is to be appointed in the working group for each individual. Supervision includes the teaching of good scientific practice, also based on the regulations established by Helmholtz Munich for this purpose.

§ 5 Dimensions of performance and evaluation criteria

(1) The assessment of scientists' performance follows a multidimensional approach, enabling other aspects to be taken into account in addition to academic performance. The assessment of performance primarily follows qualitative standards, whereby quantitative indicators can feed into the overall assessment in a differentiated and carefully conceived manner. Providing they are submitted voluntarily, individual characteristics in CVs are also included in the assessment – in compliance with the General Equal Treatment Act.

(2) A binding and transparent catalogue of key performance indicators is available.

(3) Periods of academic inactivity for personal, family or health-related reasons are taken into account appropriately, as are extended qualification periods alternative career paths and comparable circumstances resulting from such causes.

§ 6 Ombudsperson

(1) The ombudsperson at Helmholtz Munich fulfils the role of an impartial and qualified arbitrator. They have the task of preventing unfair treatment of employees based on any failure to observe good scientific practice. In this function, the ombudsperson strives to settle disputes on issues of good scientific practice while keeping bureaucracy to a minimum.

This is done in particular as follows:

- independent consideration of the dispute
- weighing of the arguments put forward by both sides
- analysis of the damage caused
- recommendation of a solution

(2) At Helmholtz Munich, there are usually two to three ombudspersons, but at least one. They are available to all scientists who wish to voice concerns relating to issues of good scientific practice or in cases of suspected scientific misconduct.

(3) Ombudspersons are independent and respected scientists with a good knowledge of the internal affairs of Helmholtz Munich, especially those who do not belong to a management body at Helmholtz Munich. All the relevant offices at Helmholtz Munich provide the ombudspersons with the necessary substantive support and cooperation in the performance of their duties. In cases where ombudspersons perform other tasks at Helmholtz Munich that restrict their capacity to fulfil their responsibilities as an ombudsperson, Helmholtz Munich provides for appropriate relief measures.

(4) Ombudspersons are appointed by the Management for a period of three years at the proposal of the Management Committee (hereinafter referred to as "MC"). They may be re-appointed once.

(5) The contact details of the ombudspersons are published on the intranet and on the Helmholtz Munich website. As a rule, a substitute is provided for each ombudsperson if there are concerns as to potential bias or in case of incapacity.

(6) It is also possible to contact the DFG's German Research Ombudsman. The ombudsperson of the Helmholtz-Gemeinschaft Deutscher Forschungszentren e. V. (hereinafter referred to as „HGF") is also available for questions relating to the HGF.

STANDARDS OF GOOD SCIENTIFIC PRACTICE – RESEARCH PROCESS

§ 7 Quality assurance in research

(1) Scientists carry out each step in the research process on a *lege artis* basis. When research results are made publicly available (in the narrower sense in the form of publications, but also in the broader sense via other communication channels), a description is always provided of the quality assurance mechanisms applied. This is especially true when new methods are developed.

(2) Continuous quality assurance accompanying research involves the following in particular:
- compliance with subject-specific standards and established methods
- adherence to processes such as the calibration of devices
- the collection, processing and analysis of research data
- the selection and use of research software, its development and programming
- the keeping of research documentation records

(3) The origin of data, organisms, materials and software used in the research process is identified, and subsequent use and original sources are documented.

(4) The willingness to interpret research results in an unbiased manner and to consistently question them critically is an essential characteristic of good scientific practice. This also includes discussion of scientific findings with colleagues specialising in the relevant subject discipline.

(5) Research results that have been made publicly available and which subsequently reveal inconsistencies or errors must be corrected accordingly.

(6) Wherever possible, research results are adequately checked for reproducibility prior to publication.

§ 8 Actors, responsibilities and roles

The roles and responsibilities of the scientists involved in a research project are clearly defined at every stage of the research project. Participants in a research project are in regular contact with each other. They define their roles and responsibilities appropriately and adapt them as necessary. Adaptation is necessary in particular if there is a change in the focus of a participant's work.

§ 9 Research design

(1) Scientists take the current state of research into account when planning a scientific project. The identification of relevant and appropriate research questions requires careful research of

existing relevant research outputs that are publicly available. Helmholtz Munich provides the necessary framework for this.

(2) Methods to avoid (unconscious) bias in the interpretation of findings, such as the blinding of experimental series, are applied as far as is possible and appropriate. Researchers check whether and to what extent gender and diversity might be of significance to the research project (with regard to methods, programme of work, goals, etc.). When interpreting findings, the respective framework conditions are taken into account.

§ 10 Legal and ethical framework, rights of use

(1) Scientists make responsible use of their constitutionally granted freedom of research. They observe obligations, in particular those arising from legal, regulatory and ethical requirements, from third party rights and/or from contracts with third parties. The legal framework of a research project also includes documented agreements on the rights of use of research data and research results arising from the project. The researcher who has collected the research data and arrived at the research results has a particular entitlement to their use.

(2) Before the start of each research project, an appropriate assessment is also carried out of the consequences of the research, in particular with regard to dual use, and the relevant ethical aspects are considered.

(3) Necessary approvals and statements by ethics committees are obtained prior to the start of a research project.

§ 11 Methods and standards

Researchers use scientifically sound and verifiable methods to answer research questions. When developing and applying new methods, they place particular emphasis on quality assurance and the establishment of standards.

§ 12 Documentation

(1) Researchers document all information relevant to the achievement of a research result as carefully and verifiably as is necessary and appropriate in the field concerned in order to be able to verify and evaluate the results. This particularly includes recording the research data that is used or generated, the steps pursued in terms of method, evaluation and analysis and, where applicable, the origin of the hypothesis, ensuring the verifiability of citations and, as far as possible, allowing third parties access to this information. In the case of research software development, the source code is documented. Documentation also includes individual results that do not support the research hypothesis; any selection of results must be avoided in this connection. If the documentation does not meet these requirements, the restrictions are to be recorded in writing along with an appropriate rationale.

(2) Documentation must not be manipulated and must be protected against manipulation as effectively as possible.

(3) Scientists working on experiments are provided with a laboratory book (bound book with logo, table of contents, consecutively numbered pages) by their immediate superiors, in which all experimental steps/considerations/observations are recorded along with data and results. Loose data sheets are glued in or archived elsewhere. Stored data/analyses and otherwise archived data sheets are referred to in the laboratory books. A brief summary of the results and plans arrived at in meetings ensures the verifiability of an investigation.
The same specifications apply accordingly to electronic laboratory notebooks. These must meet the requirements of evidence-proof, long-term archiving by preserving both the completeness, integrity and authenticity of the data as well as long-term verifiability.

(4) Each scientist is responsible for the proper documentation of their scientific work. The records are to be accessible to all employees of the working group, unless this conflicts with obligations of confidentiality. In case of doubt, a decision is made by the head of the respective organisational unit.

(5) In addition to person-related documentation, project-related documentation (including the date and name in each case) is also possible. Appropriate references ensure verifiability. The leaders carry out random checks of the documentation notebooks to ensure quality assurance in the keeping of records.

(6) The acquisition, processing and evaluation of digital data in the course of scientific work is documented by creating a central directory in a documentation book (name of the data carrier, file name, date of creation, cross-references, etc.). Digital data is backed up and stored at regular intervals in a form that cannot be overwritten.

(7) Where necessary, standard operation procedures (hereinafter referred to as "SOPs") are provided for processing, documenting and archiving primary data, processed data, programmes, software applications and the results of analyses. Procedures and SOPs are kept up-to-date and available on central drives.

§ 13 Making research results publicly accessible

(1) As a matter of principle, scientific results are the property of the scientist who generated them. Scientists make the results of their research accessible to scientific discourse. Insofar as they are legally independent, they are responsible for deciding whether and to what extent there are reasons to deviate from this principle in individual cases.

(2) Publications of research results describe these completely and verifiably. As far as is possible and reasonable, this also includes acting in accordance with FAIR principles, i.e. in particular ensuring the research data, materials and information on which the results are based are findable, accessible, interoperable and reusable. The methods applied are to be described in detail, as well as the software and work processes used. Researchers must provide complete and correct evidence of their own and others' preparatory work.

(3) Inappropriately fragmented publications are to be avoided. Scientists should limit repetition of the content of their publications as (co-)authors to the extent necessary for an understanding

of the context. They are to cite results previously made publicly available unless, in exceptional cases, this is deemed unnecessary by the general conventions of the discipline.

§ 14 Authorship

(1) An author is someone who has made a genuine, verifiable contribution to the content of a scientific text, data or software publication. All authors agree to the final version of the work to be published, generally in writing but at least in accordance with the customary practice of the scientific community. They bear joint responsibility for the publication, unless explicitly stated otherwise.

(2) Whether or not a contribution is genuine and identifiable has to be assessed in each individual case and will depend on the subject area in question. A genuine, verifiable contribution is when a researcher is involved in a scientifically significant way, in particular in the following:
- the development and conception of the research project or
- the elaboration, collection, procurement, provision of the data, software, sources or
- the analysis/evaluation or interpretation of the data, sources and the conclusions drawn; or
- the writing of the manuscript.

(3) Honorary authorship where no such contribution has been made is not admissible. A management or supervisory function does not in itself constitute co-authorship.

(4) Scientists agree on who is to be the author of the research results. Agreement on the order of authors is reached in good time, as a rule not later than when the manuscript is being written, based on verifiable criteria and taking into account the conventions of each subject area.

(5) In connection with this agreement, the required consent to a publication may not be refused without sufficient reason. Refusal of consent must be justified based on a verifiable criticism of data, methods or results.

(6) If a contribution is not sufficient to justify authorship, this support can be appropriately acknowledged in footnotes, the preface or the acknowledgement.

(7) Every scientist at Helmholtz Munich is entitled and obliged to publish the results of their work in accordance with the Helmholtz Munich publication regulations (https://hint.helmholtz-munich.de/fileadmin/Intranet/SPR_ZB/Dokumente_DE/Veroeffentlichungsordnung_des_Helmholtz_Zentrums_Muenchen.pdf).

§ 15 Publication medium

Authors choose their publication medium carefully, taking into account its quality and visibility in the respective field of discourse. In addition to subject-specific journals and books, specialist repositories, data repositories and blogs, etc. are particularly worthy of consideration. In principle, the assessment of the quality of a research article does not depend on the publication medium in which it is made publicly available.

Scientists who take on the role of editor should carefully consider the publication media involved. New or unknown publication media are to be assessed for their integrity. One essential criterion in the selection decision is whether the publication medium has established its own guidelines for good scientific practice.

§ 16 Confidentiality and neutrality in reviews and consultations

(1) Scientists who review submitted manuscripts, funding proposals or the credentials of individuals, etc. are obliged to maintain strict confidentiality in this regard. The confidentiality of the third-party content to which access is granted excludes disclosure to third parties and own use.

(2) Scientists are to immediately disclose to the competent body any conflicts of interest or bias with regard to the research projects or persons to be reviewed or with regard to subjects of deliberations and are to disclose all facts that give rise to the concern of bias.

a. The writing of scientific reports commissioned by public (or other) institutions is an important instrument in ensuring the scientific expertise of Helmholtz Munich is made available to the public. This requires a particularly high degree of personal and scientific integrity and neutrality on the part of the report writer. The report must reflect the state of the art in science; sources used must be carefully documented.

b. Peer review of research projects or publications can only fulfil its intended function if the members of the scientific community are prepared to carry out such reviews fairly and without bias based on the relevant expertise. Information and ideas obtained in the course of this review activity are to be treated confidentially and may not be used to gain a competitive advantage. The requirements imposed by funding institutions and publishers of scientific journals with regard to confidentiality and the disclosure of conflicts of interest or bias are to be strictly fulfilled by Helmholtz Munich employees. The management of each organisational unit is to promote the willingness and ability of employees with scientific experience to act as reviewers. If review work is delegated, the name of the employee in question must be stated.

c. The obligation to maintain confidentiality and to disclose facts that may give rise to concerns of bias also applies to members of the scientific advisory and decision-making bodies at Helmholtz Munich.

(3) Conflicts of interest between science and business

In the context of collaborations with commercial enterprises, potential areas of conflict may also arise due to the collision of scientific interests with economic, financial or political interests. For example, conflicts may arise over the practice of applying for property rights (patents), the implementation of research contracts and publication of the results generated, and the confidentiality of unpublished data. Secondary activities as a reviewer or consultant can also lead to conflicts, especially if a certain result is desired by the client but cannot be achieved based on the objectively available data. Membership of company committees or shares in companies that are active in a scientist's own research field can also lead to considerable

conflicts of interest. For this reason, links with industry should be established as equal partnerships. Economic considerations do not take precedence over scientific freedom.

In order to prevent conflicts of interest, all persons involved in a research project must disclose their financial and other interests insofar as they might potentially conflict with their research activities.

(4) Individual scientists may be publicly discredited or discriminated against because of the undesirability of their research results. Accusations may focus on the integrity of science, the research centre or the individual. The Helmholtz Munich is committed to protecting the personal rights of its employees. In such cases, the Commission for Issues of Good Scientific Practice pursuant to § 19 (3) of these regulations is convened to investigate such cases and advise the Management.

§ 17 Archiving

(1) Scientists are to adequately secure publicly accessible research data and research results, along with the underlying central materials and, where applicable, the research software used, in accordance with the standards of the discipline concerned, and are to preserve them for an appropriate period of time. Helmholtz Munich ensures that the necessary infrastructure is in place to enable archiving.

(2) According to the capabilities of the individual disciplines, all important steps of experiments/investigations and all primary data are recorded on non-manipulable data carriers (such as bound protocol books, audit-proof computer programmes) and are archived for 10 years as a rule. In justified exceptional cases, shortened retention periods may be appropriate; an appropriate and plausible rationale is to be provided. The retention period begins on the date on which public access is established.

(3) The basic data of a publication, diploma, doctoral thesis or post-doctoral thesis (complete data set, manuscript, correspondence) are archived at the institute of the responsible author(s) at Helmholtz Munich and remain there for ten years. In the event of closure, the archiving obligation falls to the relevant department.

(4) Different recording rules may apply (e.g. contractually defined) or may be required in any case in connection with developments that may lead to inventions, as well as in connection with clinical trials and collaborations. Unless special regulations stipulate a longer retention period, these data/data carriers are also retained for ten years; they are the property of Helmholtz Munich. Copies for use beyond internal purposes may only be made with the consent of the head of the institute/department.

(5) All data carriers are to remain at Helmholtz Munich, even after termination of the employment relationship. The consent of the supervisor(s) is required to make or take copies.

(6) Deletion of data, destruction of biospecimens

If study participants legitimately wish to have their data deleted or their biospecimens destroyed, this must be done in accordance with the regulations set out in the respective consent form. The subsequent deletion of data that has already been included in publications or research reports is inadmissible, unless deletion is required by law. Furthermore, the deletion

of data may be permissible if an obligation to this effect has been contractually agreed (e.g. health insurance data).

PROCEDURE IN THE EVENT OF NON-COMPLIANCE WITH GOOD SCIENTIFIC PRACTICE

§ 18 Complainants and respondents

(1) All bodies called upon to investigate allegations of scientific misconduct are to take appropriate action to protect both the complainant and the respondent. As a matter of principle, the respondent should not suffer any disadvantages to their scientific or professional advancement as a result of the allegations or the investigation of the suspicion until scientific misconduct has been shown to have occurred. The complainant must not suffer any disadvantages to their own scientific or professional advancement as a result of the allegations unless it can be proven that the allegations were made against their better knowledge.

(2) The investigation of allegations of scientific misconduct is expressly carried out with due regard for confidentiality and the presumption of innocence.

(3) The allegations should not lead to delays in the qualification of the complainant, especially in the case of early-career investigators, nor should the preparation of theses and doctorates be disadvantaged; this also applies to working conditions and possible contract extensions.

(4) The complainant must have objective evidence that standards of good scientific practice may have been violated. The complainant's allegations must be made in good faith. If the complainant cannot check the facts themselves or if there are uncertainties in the interpretation of the Policy with regard to an observed event, the complainant should contact an ombudsperson at Helmholtz Munich to clarify their suspicion.

(5) Disclosures made anonymously can only be investigated if the complainant provides the party investigating the allegations with solid and sufficiently concrete facts.

(6) If the complainant is known by name, the investigating body is to treat the name confidentially and may not disclose it to third parties without appropriate consent. The only exception to this applies if there is a legal obligation to do so or if the respondent would not otherwise be able to defend themselves properly because, by way of an exception, the ability to do so depends on the identity of the complainant. The complainant is informed immediately before their name is disclosed; the complainant may decide whether to withdraw the allegations if their name is likely to be disclosed. The complainant is also to be protected in the event of unproven scientific misconduct, unless it can be proven that the allegations were made against their better knowledge.

(7) The confidentiality of the procedure is restricted if the complainant makes the suspicion public themselves. The investigating body decides on a case-by-case basis how to deal with the complainant's breach of confidentiality.

§ 19 Procedure in the event of suspected scientific misconduct

(1) Scientific misconduct

Scientific misconduct occurs when there is a serious deviation from the generally accepted practice of scientific activity, in particular when falsehoods are stated intentionally or in a grossly negligent manner, intellectual property rights are violated or another person's research activity is impeded.

Scientific misconduct may particularly involve the following:

- falsification of scientific facts, for example by inventing, fabricating or falsifying results,
- misrepresentations in funding proposals or reports on the use of funding, publications, applications etc.,
- violation of intellectual property rights, for example by
- unauthorised use involving the presumption of authorship (plagiarism) and claiming
- authorship or co-authorship, or assuming the latter without justification, in particular if no genuine, identifiable contribution was made to the research content of the publication,
- exploitation of others' unpublished scientific ideas or
- research approaches (theft of ideas),
- publishing material or making it available to third parties without the consent of the rights holder,
- wilful damage, destruction or manipulation of equipment or results,
- making unjustified accusations about the alleged misconduct of others,
- removal of primary data to the extent that this violates legal provisions or the discipline's accepted principles of scientific work,
- duplicate or multiple publications.

Examples of shared responsibility for the misconduct of others include the following:

- participation in others' misconduct,
- co-authorship of publications containing falsifications,
- gross neglect of supervisory responsibilities.

Not every violation of the rules of good scientific practice automatically constitutes scientific misconduct.

(2) Review by ombudspersons

Allegations of scientific misconduct can be submitted to an ombudsperson responsible for issues of good scientific practice. The allegations must contain objective evidence that the standards of good scientific practice may have been violated.

If an ombudsperson receives allegations of scientific misconduct, usually submitted in writing, they will ask the respondent to submit a statement. The statement must generally be submitted within four weeks.

The ombudsperson ensures that in less serious cases of the violation of good scientific practice, i.e. if no scientific misconduct has occurred within the meaning of § 19 (1) of these regulations, the violations of the rules are remedied in direct contact with the scientist concerned. If there is

no sufficient suspicion of scientific misconduct, the procedure is discontinued and archived by the ombudsperson responsible.

The proposed discontinuation is communicated to the complainant by the ombudsperson. If the complainant does not agree with the discontinuation, they have the right to object within two weeks to the Commission for Issues of Good Scientific Practice according to § 19 (3) of these regulations.

(3) Investigation by the Commission for Issues of Good Scientific Practice

Helmholtz Munich has a *Commission for Issues of Good Scientific Practice* to deal with issues of scientific misconduct. In addition to the ombudspersons (who act in an advisory capacity), the members of this Commission are a senior scientist at Helmholtz Munich proposed by the MC (chair), the chairperson of the Spokespersons' Council or their deputy, a representative of the Management and the Compliance Officer. Each member is to nominate a deputy to the MC. The Commission reports to the Management Committee and the Management on its activities.

If the ombudsperson's inquiry has not been able to dispel the suspicion of scientific misconduct, a formal investigation is initiated by the Commission for Issues of Good Scientific Practice. The ombudspersons are to notify the Chairperson of the Commission and the Chief Executive Officer in writing. The Chairperson convenes the Commission.

The respondent and the complainant are to be given the opportunity to comment in an appropriate manner within two weeks. Both are to be heard orally at their request.

In specific cases where the participation of a Committee member would create the appearance of a conflict of interest, that Committee member does not participate in the hearing. At least four members of the Commission must be present to constitute a quorum.

In justified individual cases, the Commission may call in experts and other specialists.

The Commission examines the evidence freely. If the Commission finds that misconduct has been proven sufficiently and a sanction is necessary, it submits the results of its investigation and a recommendation for action to the Management. The Commission takes its decision by simple majority. Otherwise, the proceedings are discontinued. The respondent and the complainant are likewise informed.

The Management informs the Commission of its decision and arranges for the necessary measures to be taken.

(2) Possible consequences of scientific misconduct

The consequences of scientific misconduct depend on the circumstances of the individual case and on the severity of the proven misconduct. Depending on the facts of the case, the following measures may be initiated with corresponding procedures – if necessary, also in consultation with the universities involved, and with any other third parties who claim a justified interest being notified:

- Correction or revocation of scientific publications
- Consequences under labour law (e.g. warning or dismissal)
- Academic consequences (e.g. in the form of withdrawal of academic degrees)

- Consequences under civil law (e.g. issuing an exclusion order prohibiting the individual from entering the premises, or claims for damages)
- Criminal consequences.

§ 20 Entry into force

These regulations shall enter into force after signature by both Managing Directors as of November 1, 2022.

Neuherberg, October 25, 2022

Prof. Dr. med. Dr. h.c. Matthias H. Tschöp
(CEO)

Daniela Sommer
(CFO and CTO)

Appendices:

- ORI Amendment for US collaborations