

The Principles of Hannover Medical School (MHH) for the safeguarding of good scientific practice and procedural rules for dealing with scientific misconduct



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# The Principles of Hannover Medical School (MHH) for the safeguarding of good scientific practice and procedural rules for dealing with scientific misconduct

### Preamble

These principles take up the guidelines of the German Research Foundation (DFG) and the German Rectors' Conference (HRK) on the safeguarding of good scientific practice, and in part draw on wording used by the HRK and the DFG regarding the same subject.

The text describing these principles is accessible online to each researcher (link: <u>https://www.mh-hannover.de/qwp1.html?&L=1</u>). They are also incorporated into Section 7 of the contract of employment for physicians and research associates and are thus to be regarded as binding guidelines for all scientific work at Hannover Medical School (MHH). These principles shall apply from the day of their adoption by the MHH Senate.

The code 'Guidelines for Safeguarding Good Scientific Practice' was approved by the DFG in July 2019 has come into force on August 1<sup>st</sup>, 2019. The code replaces the former White Paper 'Safeguarding Good Scientific Practice'. The above documents and the 'Procedural Guidelines on Good Scientific Practice' published by the DFG in April 2016, can be downloaded from the DFG homepage (link: http://www.dfg.de/en/research\_funding/principles\_dfg\_funding/good\_scientific\_practice/index.html).

Where these scientific activities constitute research projects involving human patients or subjects, specific rules must be observed whose objectives are both ensuring the quality of data and protecting the patient or subject. Proposals for research projects of this nature must, therefore, be submitted to the independent Ethics Committee of MHH before the project commences (further details are Ethics Committee's provided by the Internet presence; link: https://www.mhhannover.de/16575.html; not yet available in English). Furthermore, MHH's Research Ethics Committee (link: https://www.mh-hannover.de/gwp00.html; not yet available in English) is also available in an advisory capacity, specifically in connection with the implementation of the Guidelines on Transparency in Research with regard to a responsible approach to freedom of research and research-related risks

#### Section 1

### Honesty as the fundamental principle in scientific activities

Honesty towards oneself and others is the basic principle underlying scientific work in all scientific institutions and disciplines worldwide. Honesty is the ethical norm of all scientific work, however greatly the rules of scientific work may differ between disciplines. It is the task of the self-government of science to ensure compliance with the rules of good scientific practice in this sense. All members and affiliates of MHH are required to observe the principles of good scientific practice and inculcate them in others.

## Section 2 Principles of good scientific practice

The scientific staff and the staff assigned to them are required to apply the principles of good scientific practice and to lead by example in doing so. They are also required to convey to students and junior researchers the principles of good scientific practice. This applies in particular to university teachers. Based on the DFG's recommendations, good scientific practice covers the following rules in particular:

- Applying state-of-the-art methods and techniques;
- Documenting results, including the securing and storing of primary data (e.g. in one's MHH laboratory journal or in clinical studies in accordance with the principles of good clinical practice (GCP));
- Consistently questioning and critically reviewing all of one's own findings;
- Practising strict honesty with regard to the contributions of partners, competitors and predecessors;
- Responsibly supervising junior scientific staff;
- Clearly assigning and assuming responsibility for leadership in work groups;
- Jointly (together with all authors) assuming responsibility for scientific publications.

MHH has further information on various aspects of good scientific practice (GSP), on GSP-related events and e-learning opportunities available online; follow this link: <u>https://www.mh-hannover.de/Ombudsperson.html</u>.

## Section 3 Publications, authorship

Authors of scientific publications assume joint responsibility for their contents. Only those who have made a significant contribution to a scientific publication can be given authorship status. So-called 'honorary authorship' is not permitted. In publications that present scientific findings, these are to be described in full and in a readily comprehensible and transparent manner. One's own and others' previous work must be fully and correctly cited. Previously published findings are to be cited so that they are clearly identified as such, and to the extent that they are necessary for understanding the relationship between previous and present findings.

The only persons to be mentioned as the authors of an original scientific publication shall be those authors who have themselves made a significant contribution to the design of studies or experiments, to the preparation, analysis and interpretation of data and the wording of the manuscript, and who have agreed to its joint publication, i.e. those who share responsibility for publication. This means that all persons who have contributed to the design of studies or experiments, or to the production, analysis and interpretation of data, must be given the opportunity to be involved in the preparation of the manuscript.

The DFG expresses a similar view in its position statement on 'Safeguarding good scientific practice', dated 3 February 1998, augmented on 3 July 2013:

"Authors of scientific publications always bear joint responsibility for their content. So-called 'honorary authorship' is not an option. [...] The only individuals to be named as the authors of an original scientific publication shall be those, and only those, who have themselves made a significant contribution to the design of studies or experiments, to the preparation, analysis and interpretation of data and the wording of the manuscript, and who have agreed to its joint publication, i.e. those who share responsibility for publication. [...]".

 This means that even being in charge of an institution or organizational unit in which the publication originates, is not deemed sufficient grounds for authorship.

As a rule, in terms of responsibility for scientific publications, only those scientists can share authorship who are substantially involved in the project on which the publication is based. Among the criteria for potential substantial involvement is whether the head of a scientific institution put the framework in place for executing the project, especially if relevant external funding has been allocated to him or her upon request. In this case, the criteria for project leadership are satisfied. However, the acquisition of external funding does not, per se, constitute automatic entitlement to co-authorship. This depends on factors such as the nature of the application for external funding (external funding awarded in response to a proposal or funding allocated by industry, etc.) and is, in case of doubt, to be discussed in a frank and open manner within the project group.

Remarks above chiefly address shared authorship in terms of shared responsibility for the publication; the not infrequently disputed order in which the authors are placed remains unaffected by these guidelines. The following recommendations are made regarding this matter:

Provision concerning doctoral students

Doctoral students who have completed their dissertation and whose dissertation is to be published in consultation with the supervisor, are entitled to lead authorship if, to a large extent, they write the manuscript independently. In many cases, dissertations are subprojects of a comprehensive scientific programme. In such cases, for planned publications that include findings taken from the completed dissertation, lead authorship is credited to those who prepare the manuscript. The doctoral student is to be named as a co-author of such publications.

• First author and last author:

As a general rule, the author who writes a manuscript for publication can also claim lead authorship. Lead authorship may also be shared among two or more contributors. The last author named for a given publication, the senior author, is generally the person in charge of the project, who in many cases is also the corresponding author. The person in charge of the project is the individual who was the chief initiator of the project on <u>which</u> the publication is based, who played an active or advisory role in the project's execution and, based on his or her experience, provided input into the project himself or herself in the form of guidance and ideas. The mere fact that the project leader put in place the scientific framework for executing projects, obtained external funding and/or holds overarching responsibility for scientific operations within his or her remit, shall not entitle him or her to last-author / corresponding-author status.

#### Section 4

## Copyright arrangements for dissertations, postdoctoral theses and other publications (leaflets, brochures)

The most important copyright arrangements that must be adhered to when writing dissertations (including postdoctoral theses) are as follows:

- When using published images, texts and the like in connection with doctoral and postdoctoral degrees, copyright problems may arise, as the publishers that originally published the work frequently secure sole usage and publication rights. This may relate to both one's own publications and others' publications.
- For students' scientific theses, such as cumulative dissertations or postgraduate theses (*Habilitationsschriften*), which have appeared in a journal as a published essay, permission for secondary publication must always be obtained. Whether the publisher's layout can be adopted must be decided on an individual basis in consultation with the publisher. The same applies to other publications such as leaflets and brochures.
- Use, in doctoral and postgraduate theses, of excerpts from already published articles may be covered by citation law in accordance with Section 51 of the German Copyright Act (UrhG) (link: http://www.gesetze-im-internet.de/urhg/51.html). If one's own previously published articles form part of a work that is a new scientific work in its own right and are used to illustrate its contents, and the source is acknowledged, the incorporation of the publication is permitted as a 'large quotation'.

## Section 5

## Approach to dual-use research of concern

Scientists responsible for conducting research must consider whether the planned experiments are at risk of misapplication that falls into the category 'dual-use research of concern' (DURC). If this is the case, the opinion of MHH's Biological Safety Officer must be obtained (see Contacts at the end of these guidelines). The criteria for DURC category research activities are available online at MHH's Virtual Research Center (Center: Safety Management) by following the link: <u>http://www.mh-hannover.de/forschung-vrc.html</u>, and should be viewed by head researchers.

#### Section 6

### Responsibility for implementing the rules of good scientific practice

Each scientist shall be personally responsible for his or her own conduct in the context of scientific work. Those who lead a work group shall be responsible for ensuring that the conditions experienced are conducive to good scientific practice within this group, and that the relevant rules are adhered to. This necessitates active communication within the work group and, in particular, the disclosure of scientific data in the context of ongoing internal discussion within the group. It is, therefore, the task of leaders of scientific work groups to ensure that all members thereof are aware of their rights and obligations in relation to good scientific practice. Leaders of scientific work groups are required to create an environment in which this code is complied with. It is seen as particularly important that hypotheses, theories and (first and foremost) scientific data generated by individual members of the group are openly discussed and hence also critically examined. Leading a scientific work group requires presence and awareness. If these requirements are not adequately fulfilled, leadership functions must be delegated to qualified third parties.

## Section 7 Written records pertaining to doctoral students

The supervision of doctoral students is regarded as a leadership function. Each supervisor of a scientific work must therefore be familiar with the rules of good scientific practice. It is recommended that, before the work itself begins, the supervisor and the doctoral student jointly prepare a written outline on the execution and aims of the planned project. Both the supervisor and the doctoral student are to have a copy of this outline before work commences. The outline shall contain a written note to the effect that the doctoral student has been informed by the supervisor as to the rules of good scientific practice. If conflict situations between the persons involved arise during the course of the work, the Ombudsperson may be consulted to help resolve the issue. Further details are covered by the doctoral-degree regulations (*Promotionsordnungen*) of MHH; follow this link: <u>http://www.mhhannover.de/129.html</u> (not yet available in English).

## Section 8 Documentation requirement

Primary data that serve as the basis for publications must remain stored and accessible for 10 years on durable data media within the work group in which they were generated. The scientist concerned shall assume responsibility for this and is required to be able to furnish proof that the data have been properly recorded. Moreover, each experiment and each numerical calculation is to be recorded, including all the detailed steps involved, in order that, if so required, someone with the required knowledge can repeat the experiment and understand the basis for the calculation. For logging purposes, one's MHH laboratory journal should generally be used, which must be registered for a given user within the SharePoint content management system (*Bereiche -> Forschungsdekanat -> Laborbuch*) / Organizational units -> Office of the Dean of Research -> Laboratory journal). No pages may be removed from laboratory journals. Related data whose format means they cannot be recorded in the laboratory journal must be clearly identifiable by means of references made in the journal, and must, like laboratory journals, be stored securely for at least 10 years. Where alterations are made to entries in the MHH laboratory journal, each alteration must be signed and dated (stating the time). In the case of clinical studies, the statutory provisions on safeguarding the rights of subjects or patients must be observed, as must statutory archiving requirements (information on this is available can be viewed by following this link: https://www.mh-hannover.de/16578.html (not yet available in English).

The loss of original data from a laboratory is an infraction of basic principles of careful scientific practice and implies gross negligence or even dishonesty. If a scientist moves to a different institution, the original data shall remain at the place where they were obtained. Under individual agreements between the previous institution and the new one, individualized arrangements for storing original data may be made. The agreement as to where these records are to be kept shall be recorded on the original data medium and signed by the persons involved.

## Section 9 Infringements of the rules of good scientific practice

Scientific misconduct is defined as occurring when, in a context of scientific importance, the requirement for due care is not complied with in a wilful or grossly negligent manner, involving, for example, misrepresentation, infringement of the intellectual-property rights of others or impedance of others' research activities. Each individual case shall be decided on its own circumstances.

The following, in particular, may be considered as serious misconduct:

- a. Misrepresentation
  - Fabrication of data;
  - Falsification of data, as for example:
    - i. by the non-disclosed, specific selection of findings;
    - ii. by manipulation of a description or figure.
  - Incorrect information in an application for employment or funding (including misrepresentation concerning the medium of publication and articles awaiting publication)
- b. Infringement of intellectual-property rights

Relating to any pieces of work created by someone else that are protected by copyright, or substantial scientific findings, hypotheses, teachings or approaches to research established or made by someone else, involving the following:

- Unauthorized use while claiming authorship (plagiarism);
- The use of approaches to research and ideas of others (theft of ideas), especially in one's capacity as reviewer;
- The presumption or unfounded acceptance of scientific authorship or co-authorship;
- Falsification of content;
- The unauthorized publication and unauthorized disclosure to a third party, prior to the publication of the work, finding, hypothesis, teaching or approach to research.
- c. Claiming the (co-) authorship of others without the latter's consent
- Sabotaging research work (including damaging, destroying or manipulating experimental facilities, equipment, documentation, hardware, software, chemicals or other items required by another person to carry out an experiment)
- e. Eliminating primary data wherever this violates statutory regulations or recognized principles of scientific work specific to the particular discipline
- f. Co-responsibility for misconduct may in particular result from:
  - participating in the misconduct of others;
  - knowledge of falsifications by others;
  - co-authorship of publications tainted by falsification; or
  - neglecting supervisory obligations.

## Section 10 Ombudsperson and GSP Committee

The MHH Senate shall appoint an Ombudsperson to serve as a neutral and qualified contact on questions concerning good scientific practice. The term of office shall be three years, with re-election possible. This individual is to be a member of the MHH teaching staff. The predecessor in this office shall be Deputy Ombudsperson. If required, the Senate may appoint another person to this role. The Ombudsperson has his or her own discretionary powers. The Ombudsperson shall carry out the preliminary review relating to the reported case.

The Committee for Good Scientific Practice (subsequently referred to as the GSP Committee) shall also be appointed by the Senate. The Committee consists of five members, four of which are each drawn from one of the four Sections at MHH, with the fifth member a legal expert. The term of office is three years, with re-election possible. The Committee has its own discretionary powers. The GWP-Kommission shall generally be requested by the President to conduct a formal investigation. If allegations are made against the Ombudsperson or the President, the GWP-Kommission may act on its own initiative.

A list of personnel serving on both bodies must be publicly displayed throughout MHH.

The GWP-Kommission shall, from among its members, elect a Chair and a Deputy Chair for a given term of office. The GWP-Kommission shall make decisions by simple-majority vote. The Ombudsperson, the Deputy Ombudsperson, and the Dean are members of the GWP-Kommission in an advisory capacity.

The preliminary review and the formal investigation shall not replace other procedures governed by law or statute (such as regulatory proceedings carried out by the higher-education institutions, disciplinary proceedings, proceedings before industrial tribunals, and criminal proceedings). Where necessary, these are to be initiated by the relevant bodies or organizational units of MHH.

The work of the Ombudsperson and the GWP-Kommission shall be supported by assistants (*Referenten*) based in separate offices.

### Section 11

## Procedure for dealing with scientific misconduct

The Ombudsperson and the GWP-Kommission shall, in their activities, be subject to the following procedural rules.

In exercising their due discretion, they shall in particular observe the following principles:

- a. Fairness and objectivity towards all persons in question, and concern for their wellbeing;
- b. Absolute confidentiality;
- c. Involvement of the persons concerned from an early stage;
- d. Protection of individual rights;
- e. Confidential treatment of the identity of whistleblowers. Forwarding the name of a whistleblower to the person(s) concerned can be considered only after the Ombudsperson or the GWP-Kommission has carefully weighed up the individual circumstances.
- f. A report submitted by a whistleblower must be based on specific and factual information and is to be presented in a plainly understandable manner, generally in writing.

## Section 11.1 Preliminary review

- a. Allegations of scientific misconduct shall be received by the Ombudsperson. This information may be provided either orally or in writing. If allegations are made orally, a written note of the suspicion shall generally be recorded by the Ombudsperson, along with the circumstances underlying the allegation and any supporting evidence.
- b. The Ombudsperson is entitled, in the event that scientific misconduct is suspected, to have the relevant documents submitted and to question the person(s) concerned or, if necessary, to also question persons from relevant institutions or persons known to all those concerned, generally in one-to-one interviews and/or in an interview together with both or several parties. At the request of the person(s) concerned, another person of their choice may also be present; this individual must be a member or affiliate of MHH. The same applies for other persons to be questioned. As required, the Ombudsperson may also summon individuals; this is binding for members and affiliates of MHH. If necessary, the President may be included in the process at a non-public meeting. The preliminary review must generally be completed within approximately

six weeks of an allegation being noted. This assumes full cooperation on the part of all those involved, and excludes periods where the proceedings are delayed by those involved.

- c. If there are grounds for an objection of partiality, the Ombudsperson must report this to the President. The reasons for this concern must be stated in writing. A decision on this matter shall be made by the President.
- d. The Ombudsperson shall generally submit a final report to the MHH President. Once approved by the President, this either in full or, as appropriate, extracts thereof, and/or with relevant text blacked out shall be provided to the person(s) concerned by the Ombudsperson, stating the further proceedings. Findings, agreements and measures specified in the final report are to be implemented by all those involved, this being a binding requirement. This implementation may be reviewed without prior notice by the Ombudsperson at a later date. If the preliminary review was unable to dispel the suspicion of scientific misconduct, the President shall make a decision on whether the GWP-Kommission should instigate a formal investigation.
- e. In the event of a mediation process involving the Ombudsperson, which may be completed with an agreement that includes all the parties in question, a final report shall not be prepared; instead, a final agreement shall be recorded, of which all those involved shall receive a copy and which shall be archived for 10 years. In these cases, too, the actual implementation of the agreed measures can subsequently be reviewed by the Ombudsperson.
- f. Records of the main points arising from the interviews, which are generally made during the preliminary review, are to be stored in the Ombudsperson's office at MHH for 10 years, as are all other documents pertaining to the proceedings in question. Inspection of the files is expressly not envisaged at any time other than for the purposes of a further review after the GWP-Kommission has received approval for this. Furthermore, use of the documents by other institutions or bodies (whether part of MHH or external) shall be precluded.
- g. The preliminary review is subject to the strictest confidentiality for all those involved. This shall also apply after the procedure has ended.

#### Section 11.2

#### **Formal investigation**

- a. Primarily on the instruction of the President, allegations of scientific misconduct shall be fully investigated by the GWP-Kommission while maintaining confidentiality. The GWP-Kommission is required, after due assessment of the circumstances, to carry out and implement the appropriate measures necessary to investigate the matter.
- b. If there are grounds for an objection of partiality on the part of the GWP-Kommission or individual members, the reasons for this concern must be stated in writing. A decision on this matter shall be made by the President.
- The persons suspected of misconduct shall be informed in a timely manner by the GWPc. Kommission concerning the instigation of a formal investigation. Subsequently, after the documents have been viewed, the person(s) concerned shall, being advised about the Ombudsperson's final report and, as appropriate, being informed about incriminating facts and evidence, be given the opportunity to make a written statement within a specified time limit. If required, the GWP-Kommission may summon the person(s) concerned or, where necessary, other individuals from institutions or known to the person(s) concerned, to an oral hearing. This summons is binding for MHH members and affiliates. Unless otherwise envisaged by the GSP Committee, the person(s) concerned may generally, at their own request, be given the opportunity to speak at an oral hearing. At the request of the person(s) concerned, another person of their choice may also be present, but only someone, who is a member or affiliate of MHH. The GWP-Kommission may, at its own discretion, call in consultants specializing in the academic field to which the facts of the case pertain, as well as additional experts, and/or may temporarily accept these individuals as further members of the GWP-Kommission in an advisory capacity.
- d. The deliberations of the GWP-Kommission are to be held orally and in camera. The formal investigation shall be subject to the strictest confidentiality for all concerned. This shall also apply after the procedure has ended. Neither those involved nor third parties shall be permitted to view relevant files while the procedure is ongoing. The GWP-Kommission shall, taking all evidence into account in an unbiased manner, consider whether scientific misconduct has occurred.

- e. It may be necessary to disclose the name of the informant if it is not otherwise possible for the person concerned to properly defend him- or herself, because (for example) the credibility and motives of the informant require investigation with regard to the allegation of possible misconduct. The GWP-Kommission shall decide this on a case-by-case basis. The GWP-Kommission may suspend or terminate the proceedings if a legal dispute on the same matter is initiated with the involvement of courts or a public prosecutor.
- f. If the Committee regards misconduct as not proven, the proceedings shall be definitively discontinued and the President informed thereof, stating the chief reasons. The persons concerned shall be notified in writing, by the President, of the discontinuation of the proceedings.
- g. If the GWP-Kommission regards misconduct as proven, it shall submit the findings of its investigation to the President with a recommendation on how to proceed further, partly in order to safeguard the rights of others, for the purpose of taking any further action deemed appropriate.
- h. The person(s) concerned is/are to be notified by the President, in a timely manner and in writing, of the chief reasons that have led to a finding of scientific misconduct. The extent to which the whistleblower and/or the public are to be informed shall be decided on a case-by-case basis. There is no complaints procedure in place for appealing against the GSP Committee's ruling.
- i. If evidence is obtained during the GSP proceedings that give grounds for suspicion of a serious infringement of the GSP rules on the part of one or more persons, the GWP-Kommission may inform the Ombudsperson of this.
- j. The procedural steps (as laid down in the standard operating procedure for Ombudsperson proceedings) shall be documented, stating the date.
- k. The records of the formal investigation shall be kept for 10 years after the conclusion of the proceedings. IT systems may be used for this purpose. Inspection of the files is expressly not envisaged at any time, except by the President, the GWP-Kommission and the Ombudsperson.

## Section 11.3

### Further procedure and punitive outcomes

- a. If scientific misconduct is confirmed by the GWP-Kommission to have occurred, then appropriate steps are to be taken by the President at the recommendation of the GWP-Kommission with, where appropriate, the necessary involvement of official MHH bodies. This is intended both to uphold MHH's scientific standards and the rights of all those both directly and indirectly affected. The penalties for scientific misconduct shall be determined by the circumstances of each individual case.
- b. In the event of culpable scientific misconduct at MHH, the following steps in particular may be taken either singly or in combination:
  - Correction of lists of authors;
  - Withdrawal or correction of publications, monographs, etc.;
  - Request for proposals on prevention of repeated infringements with subsequent documentation of successful implementation;
  - Cutting and withholding federal-state funds for research;
  - Written reprimand;
  - Notification of current employer;
  - Notification of external-funding providers;
  - Notification of former and/or current collaborating partners or co-authors;
  - Notification of the following in particular: scientific institutions, scientific journals and publishers (if publications are involved), funding bodies and scientific organizations, professional associations, government ministries and/or the public;
  - Withdrawal of the licence to teach;
  - Suspension of the ongoing process involved in obtaining a doctoral degree or postgraduate lecturing qualification (*Habilitation*);
  - Revoking of academic degrees.
- c. Furthermore, the President may, appropriate to the circumstances of a given case, take action under employment, civil or criminal law and/or regulatory/disciplinary measures by following appropriate procedures.
- d. The President shall, in a timely manner, inform the GWP-Kommission of the steps he/she has initiated and shall, if his or her recommendation differs from the decision made by the GSP

Committee, outline in writing the reasons which led to it.

These principles applicable at MHH shall apply from the day of their adoption by the MHH Senate at its meeting of 10 February 1999 and their updated versions dated 10 September 2008, 12 October 2011 and 18 October 2017. In signing their contract of employment – Section 7 of which states that compliance with the latest version of the rules of good scientific practice adopted by the MHH Senate is among the contractual obligations – all MHH staff employed in teaching and research commit to complying with these rules in their scientific activities.

This implies that research associates assigned responsibility by MHH in the form of their role as supervisors of junior scientists shall, in the context of writing dissertations such as doctoral or Master's theses, provide a sufficient and comprehensive introduction to the guidelines of good scientific practice. In this connection, face-to-face instruction sessions on good scientific practice are available at MHH; in conjunction with Goethe University Frankfurt, an e-learning course on good scientific practice is also offered (link: <a href="https://www.mh-hannover.de/Ombudsperson.html">https://www.mh-hannover.de/Ombudsperson.html</a>).

## Important contacts:

#### Ombudsperson

Prof. Dr. Thomas Ändreas Werfel Forschungsabteilung Immundermatologie und experimentelle Allergologie Termine/Anfragen über die Geschäftsstelle Ombudswesen: Dr. Beate Schwinzer, Referentin der Ombudsperson Tel.: +49 511 532-6002 E-Mail: <u>Ombudsperson@mh-hannover.de</u>

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