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New Version of the Charité – Universitätsmedizin Berlin Statute Ensuring Good Scientific Practice of 20 June 2012 (AMB Charité No. 092, p. 658)

On the basis of Section 9 Para. 1 No. 1 and Section 22 Para. 3 of the Berlin University Medicine Act [Universitätsmedizinengesetz] of 5 December 2005 (GVBl. p. 739), most recently amended by Article 7 of the law of 2 February 2018 (GVBl. p. 160), in conjunction with Section 71 Para. 1 No. 1 of the Berlin Higher Education Act [Gesetz über die Hochschulen im Land Berlin] in the version of 26 July 2011 (GVBl. p. 378), most recently amended by the law of 2 February 2018 (GVBl. p. 160), the Faculty Council of the Medical Faculty of Charité – Universitätsmedizin Berlin has re-issued the Charité – Universitätsmedizin Berlin Statute Ensuring Good Scientific Practice by way of a resolution of its meeting on 5 March 2018. The new version of the Statute was confirmed by the Executive Board of Charité – Universitätsmedizin Berlin pursuant to Section 90 Para. 1 of the Berlin Higher Education Act in conjunction with Section 13 of the Berlin University Medicine Act on 13 March 2018, and is set out in the following:

Contents

Preamble

I. Prevention of Scientific Misconduct and Requirements of Good Scientific Practice

- § 1 General
- § 2 Principles of Good Scientific Practice
- § 3 Authorship of Scientific Publications
- § 4 Young Scientists
- § 5 Collaboration and Leadership Responsibility in Working Groups
- § 6 Performance and Evaluation Criteria
- § 7 Backup and Storage of Data

II. Scientific Misconduct

- § 8 Scientific Misconduct by Scientists
- § 9 Shared Responsibility for Misconduct

III. Ombudspersons, Permanent Inquiry Panel, Office for Good Scientific Practice

- § 10 Ombudspersons
- § 11 Duties of Ombudspersons

- § 11a Permanent Inquiry Panel
- § 12 Office for Good Scientific Practice

IV. Investigation of Alleged Scientific Misconduct

- § 13 General Procedural Regulations
- § 14 Preliminary Investigation
- § 15 Main Proceedings
- § 16 Further Proceedings: Establishment of Scientific Misconduct and Sanctions

V. Entry into Force, Transitional Regulation

- § 17 Entry into Force, Transitional Regulation

Appendix 1

Preamble

Scientific work is based upon a set of fundamental principles. Foremost among them is honesty to oneself and to others. This is both an ethical standard and a cornerstone of scientific professionalism – that is to say, of *Good Scientific Practice*. Ensuring that the conditions are in place for the principle of honesty to be observed and applied in practice is a core aspect of self-governance in science. Charité – Universitätsmedizin Berlin is aware of its duty to teach *Good Scientific Practice* to students and young scientists, as well as ensuring that it is upheld at all times within Charité – Universitätsmedizin Berlin. All staff and associates of Charité – Universitätsmedizin Berlin – particularly university lecturers – have a duty to comply with, teach and model these principles of *Good Scientific Practice*.

Scientific work serves the purpose of advancing knowledge. However, this principle is conditional upon the scientist being honest. Unlike error, which can sometimes be difficult to distinguish, dishonesty in scientific work contradicts the very essence of science, as well as the scientist's responsibility towards society. Charité – Universitätsmedizin Berlin undertakes to clarify any suspicion of scientific misconduct, for the sake of both the public and the scientific community.

The honesty required of the scientist cannot be replaced by a set of rules. General legal provisions cannot prevent all misconduct in scientific work. However, regulations can be introduced to try to minimise misconduct. Similarly, scientific misconduct cannot be judged solely on the basis of general regulations; the circumstances of the individual case must be taken into account in determining the appropriate course of action.

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I. Prevention of Scientific Misconduct and Requirements of Good Scientific Practice

§ 1 General

(1) The following provisions for ensuring Good Scientific Practice are designed to help prevent scientific misconduct wherever possible, therefore increasing the quality of scientific work.

(2) Charité – Universitätsmedizin Berlin upholds its responsibility towards graduates by teaching its students (students of medicine as well as those enrolled on all other courses and programmes based at Charité) the principles of scientific work and Good Scientific Practice with reference to this Statute, and by encouraging them to practise honesty and accountability in science. The aim is to make them aware of the possibility of scientific misconduct. Doctoral and post-doctoral students are required to attend courses on Good Scientific Practice (in which the focus is on analysing original data, statistics, avoiding plagiarism, and authorship). These courses are run by either the Graduate Colleges or Charité – Universitätsmedizin Berlin.

(3) Charité – Universitätsmedizin Berlin also upholds its responsibility towards young scientists and its technical staff by informing them of the principles of scientific work and Good Scientific Practice with reference to this Statute. This instruction is provided in writing and signed as confirmation of acknowledgement. It is generally completed as part of the recruitment process.

(4) The statement of independent authorship (part of the student's dissertation or thesis) is expanded to include a declaration stating that the rules of Good Scientific Practice – as set out in this Statute – have been upheld. Doctoral and post-doctoral students must submit a declaration in which they undertake to comply with this Statute Ensuring Good Scientific Practice as a prerequisite for approval to undertake their degree programme. Charité – Universitätsmedizin Berlin monitors compliance with these rules, e.g. by requesting presentation of original data on readable storage media or in a lab book, by tracing results and illustrations back to original data, and by checking dissertations and theses for plagiarism and proper referencing.

(5) All staff of Charité – Universitätsmedizin Berlin are obligated to comply with this Statute. The same applies to doctoral students, post-doctoral students, guest scientists and scholarship recipients, who are not employed by Charité – Universitätsmedizin Berlin.

(6) Irrespective of this Statute, the legal provisions (e.g. the Berlin Data Protection Act [Berliner Datenschutzgesetz], the Federal Data Protection Act [Bundesdatenschutzgesetz] and the Berlin State Hospitals Act [Landeskrankenhausgesetz Berlin]) applicable to Charité – Universitätsmedizin Berlin and the

transfer of duties of the Executive Board of Charité – Universitätsmedizin Berlin with regard to responsibility for implementation of data protection must be observed when processing (collecting, storing, modifying, transferring, blocking, deleting and using) personal data in accordance with the Berlin Data Protection Act within the scope of scientific activity.

The scientist undertakes to comply with the rules of data protection, observing the applicable legal provisions and utilising the patient information and consent forms approved and set as legally binding by the Data Protection Officer. The scientist declares that he/she is aware of the relevant regulatory and penal provisions. The reporting requirement for automated processing of personal data pursuant to the Berlin Data Protection Act must be met by the scientist. Personal data must be stored within the institute/clinic of Charité – Universitätsmedizin Berlin for the set period and in such a way that it cannot be accessed by unauthorised third parties. For samples, the aforementioned applies with the stipulation that biomaterial accompanied by a minimal set of data must be stored at the Central Biomaterial Bank of Charité – Universitätsmedizin Berlin (ZeBanC). They may only be transferred to places outside of the institute/clinic of Charité – Universitätsmedizin Berlin specified in the legally binding patient information in an anonymised form, or, in the event that the purpose of the research cannot be achieved with anonymised data, in a pseudonymous form, on the basis of the declaration of consent provided.

If the patient withdraws his/her consent, the scientist must ensure that the relevant data is anonymised or deleted, unless any legal provision contradicts such.

A data protection check must be performed by the responsible Data Protection Officer prior to automated processing of data that is subject to a professional or official duty of confidentiality.

§ 2 Principles of Good Scientific Practice

(1) The general principles of scientific work particularly include:

- treating patients, test subjects, animals and the environment with respect, and protecting their integrity.
- working in line with the latest level of knowledge and in possession of the necessary qualifications/training. As such, knowing the current state of research and the appropriate methods is essential.
- keeping records; methods used and findings made must be documented in writing, using photographs, or in a similar manner. It must be ensured that such documents are retained on permanent, secured storage media for at least 10 years after publication (§ 7 Para. 1 of this Statute). Retention periods set out in legal provisions and measures taken to protect personal data are not affected thereby. Precise logging and documentation of scientific procedures and results is mandatory for experimental work because repeatability of experiments is a characteristic feature of such research;
- consistently questioning your results;
- being completely honest with regard to contributions from partners, competitors and predecessors;

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- sharing scientific results with the scientific community through publications. In this sense, like the scientific observation or scientific experiment itself, scientific publications represent results of scientists' work.
- complying with the recognised principles of scientific work in the individual disciplines.

(2) All staff of Charité – Universitätsmedizin Berlin and all persons set out in § 1 Para. 5 of this Statute are responsible for observing these principles themselves, as well as ensuring that they are observed by all employees under their supervision. They form an integral part of teaching and of the education, training and further/advanced training of young scientists and the education, training and further/advanced training of technical staff. They do not merely represent theoretical knowledge and technical skills, but convey how to conduct oneself ethically when engaging in scientific work (recurring component of the curriculum). If an ethics vote is required or an ethics committee needs to be consulted, such must be done before the commencement of research work. The right to informational self-determination must be upheld by strictly observing the data protection legislation.

§ 3 Authorship of Scientific Publications

(1) Co-authors of scientific publications always bear joint responsibility for their content. "Honorary authorship" is not permitted. Where publications are intended to be a report on new scientific results, they should

- describe the results fully and clearly, specifying or referring to all methodological details,
- completely and correctly set out (cite) all preliminary work completed by the authors and by third parties,
- restate previously published results in a clear manner and only insofar as is required to understand the context.

All co-authors should confirm release of a manuscript for publication by means of their signature. The proportion of work contributed by each individual or working group must be documented (e.g. using the publisher's form or by way of separate agreement). If unpublished research results of other persons are cited or findings of other institutions are used in the manuscript, the written consent of the party concerned must be obtained, unless other procedures are recognised within the relevant discipline.

(2) The authors of an original scientific publication are all – and only those – persons that made a significant contribution to the design of the studies or experiments, to the development, analysis and interpretation of the data or to the formulation of the manuscript itself, and

have agreed to its publication, i.e. have agreed to bear joint responsibility. Persons that made a significant contribution to the design of the studies or experiments or to the development, analysis and interpretation of the data must be given the opportunity to collaborate in the drafting of a manuscript and become co-authors in the publication of the results. Other – even significant – contributions, such as

- responsibility for obtaining funds,
- providing space, equipment, staff or other resources,
- providing important research materials, e.g. generally gathering information on relevant test subjects and/or patients,
- coaching co-authors in established methods,
- participating in data collection and collation,
- simply reading the manuscript without influencing its content, and
- managing the institution or organisational unit within which the publication was created

are not, in and of themselves, considered sufficient to justify authorship under the definition set out here.

Charité – Universitätsmedizin Berlin expressly supports the guidelines on scientific publications and authorship set out in the latest versions of "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals" and "Clinical Trial Registration"¹.

(3) Providing consent to being named as a co-author means taking joint responsibility for ensuring that the publication meets scientific requirements. This particularly applies to the area to which the co-author contributed. The co-author is responsible for ensuring that his/her own contribution is both correct and published in a scientifically justifiable manner.

(4) If individual scientists are named as co-authors in a publication without their consent and consider themselves unable to provide such consent, they are expected to clearly make their opposition to being named as a co-author known to the main person responsible and/or to the editorial board of the applicable journal or publishing house.

(5) Before a manuscript is submitted to a scientific journal or sent to a publishing house for publication in a book, all experiments and results must be documented in lab books, and all electronically stored data backed up (see § 7 of this Statute). In addition, an authorship agreement specifying the contribution of each author to the manuscript must be drawn up and stored safely.

§ 4 Young Scientists

(1) Educating and encouraging the next generation of scientists is one of Charité – Universitätsmedizin Berlin's most important duties. Alongside methodological skills, Charité – Universitätsmedizin Berlin will instil in them an ethical attitude towards scientific work, responsible handling of results and collaboration with other scientists.

¹ <http://www.icmje.org/recommendations/>; (Accessed: 11 January 2018, 15:50) and N. Engl. J. Med. 2004; 351:1250-51

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(2) Wherever possible, doctoral students and other young scientists should be supervised by at least two experienced scientists, one of which should come from a different working group or institute to the young scientist. The names of the supervising scientists must be documented in writing upon commencing work. Supervising scientists should be available to provide help and advice, as well as mediating in conflict situations if necessary. Each young scientist must have a primary mentor within the working group, who is also responsible for teaching him/her about Charité – Universitätsmedizin Berlin's Statute Ensuring Good Scientific Practice.

(3) If other statutes – especially examination, doctoral or post-doctoral regulations – already call for a young scientist to be supervised, this shall be considered supervision within the meaning of Paragraph 2.

§ 5 Collaboration and Leadership Responsibility in Working Groups

(1) Each scientist is responsible for his/her own conduct. In addition, those with leadership duties are responsible for the environment within the entire unit that he/she is in charge of. Lively communication within the working group and sound supervision are the most effective ways of preventing the team slipping into dishonest behaviour. Leaders of working groups are responsible for ensuring that these conditions are met at all times.

(2) The leader of a scientific working group should create organisational structures that permit results achieved in specialised sub-groups to be shared, scrutinised and integrated into the shared knowledge.

(3) Leaders of research groups are responsible for following an organisational method that ensures that the tasks of leadership, monitoring, conflict resolution and quality assurance are clearly assigned and actually fulfilled.

§ 6 Performance and Evaluation Criteria

As a performance and evaluation criterion for examinations, in bestowing academic titles, in granting teaching licences, for promotions, recruitment and appointments and in allocating funds or resources, quality always takes precedence over quantity.

§ 7 Backup and Storage of Data

(1) The primary test of any scientific result is whether it can be reproduced. Experiments and numerical calculations can only be reproduced if all of the key steps can be retraced. They must be fully recorded so that someone with knowledge in the field can follow the experiments and related considerations. All data

collected at source or commissioned to be collected within the scope of a scientific project is considered original data. This is used to generate what is known as "primary data", which forms the basis for the results set out in scientific publications.

(2) Original data must be stored on durable, secured storage media within the working group/department where it was gathered, and remain accessible to authorised employees in accordance with the statutory provisions, however for no less than ten years from collection or ten years from the release of the scientific publication based on the data. Early separation of personally identifiable data from study data is encouraged.

(3) The scientist is responsible for compiling the data storage media. He/she must provide evidence of proper logging. The scientist shall be permitted to make copies if such is permissible under data protection legislation.

(4) It is recommended that primary data (as a basis for publications in journals, books, dissertations or theses) be brought together in a separate folder and kept accessible in accordance with the statutory provisions, however for no less than ten years from the release of the publications based on it. Separate regulations in ordinances and statutes issued by Charité – Universitätsmedizin Berlin and/or stipulations made by editors and publishing houses must be observed.

(5) The logbook/workbook ("lab book") must have a hard cover and numbered pages. Pages must not be torn out. Electronic lab books must meet the requirements of the relevant version of 21 CFR Part 11² of the United States Food and Drug Administration. The original data stored in electronic lab books must not be available outside of Charité – Universitätsmedizin Berlin; it must only be available internally, via the intranet. Loss of original data during the retention period is not possible if proper diligence is exercised. Such would represent justification for suspecting culpable scientific misconduct. The same applies to original data that, by its nature, can only be stored on electronic storage media. Such data must be recorded in the logbook. The scientist must store original data out of sight in locked containers.

(6) Original data is the property of the Faculty and must not leave Charité – Universitätsmedizin Berlin at any time without legal grounds for doing so. Copies may be taken away by the involved scientists as long as this does not breach any data protection regulations. When a scientist leaves, handover of original data (e.g. logbooks, electronic storage media, directory information, original images, etc.) must be documented in a suitable format by the scientist, along with the time and the scope of the data and a signature from the party taking receipt of the data. The receiving institution is then responsible for and will monitor the whereabouts of the original data. Files must be stored in their original format on Charité – Universitätsmedizin Berlin's central server. The Dean and his/her authorised representative are entitled to inspect the original data or request the data from the relevant institution for the purposes of inspection at any time.

² https://www.ecfr.gov/cgi-bin/text-idx?SID=af72d6868f621bbfa18a7f3719dab095&mc=true&tpl=/ecfrbro_wse/Title21/21cfr11_main_02.tpl
(Accessed: 24 January 2018, 09:30)

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II. Scientific Misconduct

§ 8 Scientific Misconduct by Scientists

(1) The Medical Faculty of Charité - Universitätsmedizin Berlin treats every allegation of non-compliance with Good Scientific Practice in research, teaching or patient care with the utmost attention and stringency. Breaches of Good Scientific Practice particularly include:

- a. fabrication of data (inventing data and/or results) and publication thereof;
- b. falsification (manipulating data, suppressing data or modifying experimental conditions that were not properly taken into account in the evaluation);
- c. plagiarism (using others' or one's own ideas, notes, results, arguments or diagrams without citing sources and giving proper credit);
- d. presumption or unsubstantiated acceptance of scientific authorship or co-authorship, assertion of co-authorship of another party without his/her consent;
- e. culpable obstruction of the research activities of other scientists and attempts to diminish another scientist's reputation;
- f. sabotage of research activities (including damaging, destroying or tampering with experimental set-ups, devices, documents, hardware, software, chemicals or other objects that another person requires to carry out his/her research);
- g. culpable destruction of original data and breach of the documentation and retention requirements set out in § 7 of this Statute;
- h. culpable removal of samples or test materials from Charité – Universitätsmedizin Berlin.
- i. grossly negligent breaches of the principles of scientific practice set out in § 2 of this Statute.

(2) Scientific misconduct within the meaning of Paragraph 1, Sentence 2 shall not be deemed to have taken place if the scientist has deviated from the standards of good scientific practice for reasons outside of his/her control. In such a case, the bodies listed as responsible in this Statute or in other regulations shall seek to ensure a rapid, mutually agreed remedy to the breach.

§ 9 Shared Responsibility for Misconduct

(1) Shared responsibility for misconduct may apply in cases such as

- involvement in another's misconduct,
- knowledge of another's falsification,
- gross neglect of supervisory duties.

(2) Shared responsibility within the meaning of Paragraph 1 requires culpability.

III. Ombudspersons, Permanent Inquiry Panel and Office for Good Scientific Practice

§ 10 Ombudspersons

(1) The Faculty Council shall elect at least three experienced scientists with doctoral degrees who have been working for Charité – Universitätsmedizin Berlin for a long time and have a permanent employment or government contract or are retired as points of contact (ombudspersons) for anyone that wishes to make an allegation of scientific misconduct. A person should not be appointed as an ombudsperson if he/she may be obligated to take action based on the information that he/she receives (e.g. as Dean or Vice Dean). The term of office for ombudspersons is two and a half years. They may be re-elected.

(2) The ombudspersons are independent in their roles, and as such are not subject to instruction. They must maintain secrecy regarding all matters that they become aware of in their role of ombudsperson at all times, including after the end of their activity as an ombudsperson; Section 84 of the German Administrative Procedure Act [Verwaltungsverfahrensgesetz] shall apply accordingly.

§ 11 Duties of Ombudspersons

Ombudspersons have the following duties:

- As an elected point of contact, they advise those that inform them of a suspected incident of scientific misconduct within the meaning of § 8 of this Statute and act upon relevant indications, including those that they obtain via third parties.
- They examine allegations for plausibility and decide whether the preliminary investigation proceedings (as per § 14 of this Statute) can be discontinued, or propose to the Faculty Management that the main proceedings be initiated.
- In consultation with the Office for Good Scientific Conduct (§ 12 of this Statute), they report to the Dean annually on their work. In particular, they provide information on the number of incidents investigated, the number of incidents passed on to the Inquiry Panel and the nature of allegations, insofar as this is possible in an anonymous form.
- They meet regularly to share thoughts and experiences with representatives of the Business Division Corporate Policy & International Affairs, the Vice Dean for Research and the Office for Good Scientific Practice. A representative of the legal department or another legally trained person may be called to attend the meetings if necessary.

§ 11a Permanent Inquiry Panel

(1) Charité – Universitätsmedizin Berlin shall set up a permanent Inquiry Panel to investigate allegations of scientific misconduct following preliminary investigations (§ 14 of this Statute). It shall be responsible for the main proceedings (§ 15 of this Statute).

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- (2) The members of the Inquiry Panel and their proxies are independent and not subject to instruction.
- (3) The members and their proxies must maintain secrecy regarding all matters that they become aware of in their role on the Inquiry Panel at all times, including after the end of their membership of the Inquiry Panel. Section 84 of the German Administrative Procedure Act shall apply accordingly.
- (4) In particular, upon appointment, the members of the Inquiry Panel and their proxies must undertake to act in a conscientious and impartial manner, and to maintain secrecy (Paragraph 3).
- (5) Sections 20 and 21 of the German Administrative Procedure Act shall apply accordingly to the exclusion of members from acting on the Inquiry Panel and to the suspicion of partiality.
- (6) The Inquiry Panel shall abide by a set of rules of procedure, which, in particular, set out information on procedures within the Inquiry Panel, the duties of the Chairperson and the Panel's collaboration with the Office for Good Scientific Practice (§ 12 of this Statute). The rules of procedure require confirmation from the Faculty Management and are announced in Charité – Universitätsmedizin Berlin's official bulletin (Amtliches Mitteilungsblatt (AMB)).
- (7) The Inquiry Panel is made up of five members and their proxies. Most of the Panel should be staff of Charité – Universitätsmedizin Berlin, be scientists and not hold managerial roles within the Faculty's autonomous administrative bodies. One member and his/her proxy should be members or proxy members of the doctoral committee. For the remaining Charité – Universitätsmedizin Berlin members, up to three proxies will be appointed; if two or three proxies are appointed, their order of representation shall be defined upon appointment. Up to two members and their proxies will be from outside Charité – Universitätsmedizin Berlin; one of these members and his/her proxy should be lawyers qualified to hold the position of judge.
- (8) The members of the Inquiry Panel and their proxies shall be appointed by the Faculty Management for a period of two and a half years, with the consent of the Faculty Council. The positions to be filled shall be advertised in Charité – Universitätsmedizin Berlin's official bulletin as early as possible. The names of the members and their proxies are published in Charité – Universitätsmedizin Berlin's official bulletin.
- (9) They may be re-elected. Former members may be appointed as proxies, and former proxies may be appointed as members.
- (10) Their period in office shall begin with the constitutive meeting. It shall take place immediately after appointment. At this meeting, a Chairperson and a Vice Chairperson shall be elected from the members of the Charité – Universitätsmedizin Berlin Inquiry Panel.
- (11) The proxies shall represent the member in the order set out in Para. 7 if he/she is temporarily unable to fulfil his/her role; if the member leaves the post before the end of his/her period in office, the proxies shall represent him/her for the remainder of said period. The second and third proxy members are appointed for the event that the first or second proxy is unavailable; each person shall move up a level if the proxy above has taken the place of the member or proxy or if a member or proxy leaves.
- (12) With the consent of the Faculty Council, the Faculty Management may dismiss a member of the Inquiry Panel or a proxy for just cause. Just cause shall particularly be deemed to apply if the member or proxy grossly violates one of his/her obligations, proves to be unworthy or is no longer able to properly fulfil his/her role on the Inquiry Panel.
- (13) The Inquiry Panel shall be quorate when at least three members or their proxies – of which at least two must be staff of Charité – Universitätsmedizin Berlin or their proxies – are present, after having been duly invited.
- (14) The Inquiry Panel shall consult and pass resolutions orally. In justified exceptional cases, other discursive procedures (such as telephone and video conferencing, e-mail correspondence or the internet forum made available to members by the Office for Good Scientific Practice) may be used to consult and pass resolutions. Resolutions may also be passed in writing (circulation procedure) as long as no member is opposed to such. More information is set out in the Inquiry Panel's rules of procedure.
- (15) Consultations, including the outcome, are confidential. Members of the Office for Good Scientific Practice shall have access to the meetings; the Inquiry Panel may allow further persons to attend a meeting.
- (16) The Inquiry Panel shall pass resolutions by means of majority of the votes submitted. Abstention from voting is not permitted. In the event of a tie, the Chairperson shall have the deciding vote.
- (17) Minutes shall be kept of every consultation of the Inquiry Panel, setting out the key results of the consultation and any resolutions passed. The minutes shall be signed by the Chairperson and the minute-taker. More information is set out in the rules of procedure.
- (18) Further members or proxies cannot join once consultation on a matter has begun. If the Inquiry Panel ceases to be quorate, the consultation must begin again once it has regained its quorum.

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§ 12 Office for Good Scientific Practice

The duties of the Office for Good Scientific Practice are to coordinate and monitor measures taken to ensure Good Scientific Practice. It

- supports the development and implementation of curricula focused on Good Scientific Practice for undergraduate and postgraduate students;
- coordinates and supports the work of the ombudspersons (§ 11, 14 of this Statute) and the permanent Inquiry Panel (§ 13, 15 Para. 1 to 9 of this Statute);
- advises and supports persons that are directly or indirectly affected by scientific misconduct (e.g. informants, accused persons, colleagues from the working groups);
- works on committees to investigate allegations of scientific misconduct in an advisory capacity;
- uses software to check for plagiarism;
- advises the doctoral and post-doctoral committees of Charité – Universitätsmedizin Berlin (e.g. regarding matters of plagiarism and in inspecting random samples of dissertations and theses);
- helps to coordinate exchange with national and international experts on the topic of Good Scientific Practice;
- provides the Dean with an annual report (in an anonymised form) of its work in investigating allegations of scientific misconduct and the number of incidents investigated through preliminary and main proceedings (§ 13-15 of this Statute).

IV. Investigation of Alleged Scientific Misconduct

§ 13 General Procedural Regulations

(1) Preliminary investigations (§ 14 of this Statute), main proceedings (§ 15 of this Statute) and further proceedings (§ 17 of this Statute) shall be conducted quickly, in a proportionate manner, according to transparent criteria and with due discretion. To maintain due discretion, the following general principles must be followed, in particular:

- a. Care, fairness and objectiveness towards the persons involved.
- b. All accused persons and incidents shall be treated as confidential.
- c. The person affected by an allegation shall be involved as early as possible.
- d. Protection of the privacy of the person that made the allegation (informant).

(2) Informants that provide specifiable information on a suspicion of scientific misconduct in good faith must not be in anyway disadvantaged in their own scientific and professional progression; Charité – Universitätsmedizin Berlin must take appropriate action to ensure this

protection. Anonymous and pseudonymous indications may also be relevant. If, as is generally to be encouraged, the informant provides his/her name, it shall be treated as confidential; § 15 Para. 5 of this Statute shall not be affected.

(3) The allegation must be made in good faith. Allegations must not be made without being checked and without sufficient knowledge of the facts. Reckless use of allegations of scientific misconduct – including deliberately making false allegations – can be a form of scientific misconduct in itself.

§ 14 Preliminary Investigations

(1) Immediately upon becoming aware of an allegation of non-compliance with Good Scientific Practice, the person that has the suspicion, the affected person or the manager responsible for the relevant division must inform one of the ombudspersons or the Office for Good Scientific Practice. These shall pass the information on to one another.

(2) The Office for Good Scientific Practice shall bring together the documents pertaining to the allegation, prepare them and then make them available to the ombudspersons.

(3) The ombudspersons shall appoint one of their members to be responsible for the proceedings.

(4) The responsible ombudsperson shall decide when to initiate the preliminary investigation. It shall be initiated if false information has been ruled out and the allegation cannot be rejected based on a lack of substance. In such a case, the ombudsperson shall inform the Office for Good Scientific Practice, which shall then inform the Faculty Management. Should the ombudsperson decide not to initiate a preliminary investigation, he/she shall inform the Office for Good Scientific Practice, which shall inform the informant.

(5) In agreement with the Office for Good Scientific Practice, the ombudsperson shall decide on the temporary measures required to support the preliminary investigation (e.g. seizing original or primary data). If necessary, a corresponding application shall be made to the Faculty Management. If other scientific institutions are involved, they shall be asked for their cooperation in clarifying the allegation.

(6) As part of the preliminary investigation, the scientist affected by the allegation of misconduct will be informed of the allegations made against him/her and given the opportunity to make a statement, without being told the name of the informant. It must be highlighted that he/she is free to choose to comment on the allegation or not, and to seek legal counsel at any time. A reasonable period must be set for receiving the statement; it must be no less than three weeks.

(7) The affected scientist is obligated to present the original data required for confidential investigation of the allegation (§ 7 Para. 4 and 5 of this Statute).

(8) Should the result of the preliminary investigation be that the allegations are unfounded, the responsible ombudsperson shall cease the preliminary investigation and inform the Office

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for Good Scientific Practice, which shall then inform the Faculty Management, the affected scientist and the informant, as applicable. If an allegation cannot be cleared up, the Faculty Management shall, at the suggestion of the ombudsperson, decide to initiate the main proceedings (§ 15 of this Statute).

§ 15 Main Proceedings

(1) The main proceedings shall commence once the decision to initiate the main proceedings has been passed on to the Inquiry Panel. It shall be provided with all of the necessary data and original documents by the Office for Good Scientific Practice.

(2) The Inquiry Panel shall decide quickly and in unbiased consideration of evidence whether scientific misconduct has taken place. The affected person must be given appropriate opportunity to respond, verbally if he/she desires such. It must be highlighted that he/she is free to choose to comment on the allegation or not, and to seek legal counsel at any time. If other persons are consulted, they shall also be given the opportunity to express themselves verbally. After once again hearing the affected persons against whom the allegations have been made, and after hearing all other involved parties, the Inquiry Panel shall submit a report to the Faculty Management and to any other responsible departments (e.g. doctoral committee, post-doctoral supervisor). The report shall state whether the Panel believes that there has been a culpable breach of the rules of Good Scientific Practice (§ 2 of this Statute). It should also include a recommended course of action. It cannot be contested.

(3) During the main proceedings, the Inquiry Panel may expand the subject of investigation if there is further suspicion of scientific misconduct by the same group of people, without another preliminary investigation having to be conducted. The affected persons must be informed of this decision immediately.

(4) The Inquiry Panel may consult specialists in the scientific matter to be assessed, experts in handling such cases or legal advisors and obtain professional opinions.

(5) Should the affected person require to know who the informant was in order to defend him/herself adequately, he/she must be provided with the name. The informant must be informed of this beforehand. He/she may raise an objection with the Inquiry Panel within three weeks; it shall rule on the objection within two weeks of receipt by itself or by the Office for Good Scientific Practice.

(6) If legal or disciplinary proceedings are taking place at the same time concerning the same allegations, the Inquiry Panel may decide to suspend the main proceedings.

(7) The persons involved in the proceedings, informed of the proceedings or consulted as part of the

proceedings must treat all information and processes as confidential. External persons must agree to maintain confidentiality by means of a special written declaration; further information is set out in the Inquiry Panel's rules of procedure.

(8) The files pertaining to the main proceedings shall be kept for 30 years.

§ 16 Further Proceedings: Establishment of Scientific Misconduct and Sanctions

(1) On the basis of the report from the Inquiry Panel (§ 15 Para. 2 of this Statute), the Faculty Management shall decide swiftly whether it believes that scientific misconduct has taken place (§ 8 of this Statute). If it responds in the positive, it shall take the measures set out in Paragraph 2, subject to other responsibilities as set out in Paragraph 3 (Sentence 2, second clause). If it responds in the negative, it shall inform the affected person and all persons involved in the proceedings immediately.

(2) If the responsible decision-making body believes that scientific misconduct has taken place (§ 8 of this Statute), it shall, at its discretion, take the measures required to correct the scientific misconduct and restore trust in the integrity of scientific research and teaching.

This shall particularly include:

- a. In the case of culpable scientific misconduct, a reprimand may be issued. The retraction of publications may be recommended or demanded. The publisher or the person responsible for the journal, book or other source shall decide on the possibility of resubmission following correction.
- b. In the event of a culpable breach of the documentation and retention requirements, retraction of the corresponding publication may be demanded.
- c. In the case of deliberate falsification/manipulation/fabrication of data, retraction of the corresponding publication must be demanded.
- d. If falsified results have been published deliberately (§ 16 Para. 3 lit. c of this Statute), the public may be informed.
- e. Those affected by scientific misconduct, e.g. specialist journals, or those robbed of their intellectual property should be informed.

Other measures going beyond this may be taken if required to correct or punish the scientific misconduct.

(3) Responsibility for the measures set out in Paragraph 2 lies with the Faculty Management. For measures set out in Paragraph 2 Sentence 3, this shall only apply if no other responsibilities exist.

(4) Measures set out in disciplinary law, employment law, penal law, civil law, regulatory law, budgetary law and academic examination law shall not be affected.

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V. Entry into Force, Transitional Regulation

§ 17 Entry into Force, Transitional Regulation

(1) The new version of the Statute set out above shall enter into force on the day following its announcement in Charité– Universitätsmedizin Berlin's official bulletin. At the same time, the Charité– Universitätsmedizin Berlin Statute Ensuring Good Scientific Practice of 20 June 2012 (AMB Charité No. 092, p. 658), in its current version, shall cease to apply.

(2) The authority of Inquiry Panels that have been employed up to this point under the previous regulations shall not be affected. Proceedings that have already commenced shall be continued in accordance with the new version of the Statute set out above.

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Appendix 1

On the basis of this Statute, the voluntary posts of the members and proxy members of the permanent Inquiry Panel must be filled soon. Most of the Panel should be staff of Charité – Universitätsmedizin Berlin, be scientists and not hold managerial roles within the Faculty's autonomous administrative bodies. Up to two members and their proxies will be from outside Charité – Universitätsmedizin Berlin; one of these members and his/her proxy should be lawyers qualified to hold the position of judge.

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