Statute Section Safeguarding Good Scientific Practice at the Medical University of Innsbruck

- Good Scientific Practice –

Based on the proposal of the rectorate the senate of Medical University of Innsbruck has agreed on the Statute Section Safeguarding Good Scientific Practice at the Medical University of Innsbruck in its meeting on 16th December 2015. It reads as follows:

Preamble

Observance of and compliance with the rules of good scientific practice are fundamental prerequisites for scientific work and for the recognition of scientific work in society and the scientific community. Violations of the rules of good scientific practice are incompatible with the nature of science itself as a methodical and systematic research process aimed at gaining verifiable knowledge. They furthermore destroy public trust in the reliability of scientific findings as well as trust between scientists, an important prerequisite for the collaborative work approach defining today's sciences. The provisions in this Statute section are to be observed as supplements to national, European and international legal provisions as general principles of scientific work at the Medical University of Innsbruck.

I. Part
Rules

§ 1
Individual Responsibility of Scientists

(1) The following rules of good scientific practice are binding for all persons involved directly or indirectly in research activities at the Medical University of Innsbruck, particularly also students, who are authoring scientific degree theses (e.g. diploma theses, doctoral dissertation); this applies regardless of a possible employment by the University (hereinafter "scientists").
(2) All scientists are responsible for their conduct and actions with regard to their research activities.
(3) In this sense all scientists are required to work according to professional standards, i.e. all research activities must be carried out according to the legal provisions, ethical principles as well as the general and subject specific rules and the current state of science in the respective discipline.

§ 2
Role Model Function, Supervision of Junior Scientists

(1) Whoever assumes managerial tasks in a scientific division (organizational unit, working group etc.) has a particular responsibility to carry out scientific work in an exemplary manner and has to maintain a research environment that enables the compliance with the standards and rules of good scientific practice.

(2) All university teachers and research assistants have to teach students and junior scientists the principles of good scientific practice and have to address the issue of scientific misconduct, in order to sensitize them and generate a heightened sense of responsibility. Especially supervisors of degree theses bear the responsibility of familiarizing students and junior scientists with the standards and rules of good scientific practice.
(3) All curricula of the Medical University of Innsbruck contain courses regarding issues of good scientific practice.

§ 3
Use of Statistical Procedures, Utilization of Data

(1) When planning scientific projects that use statistical procedures, a trained expert should be consulted with regard to the design of the experiments and the statistical procedures that are to be used.
(2) The collection, storage transmission and utilization of data shall be carried out in full compliance with the applicable national and international legal provisions. Accordingly, data is to be collected diligently and documented comprehensibly, processed carefully and stored securely.
(3) Primary and original data, measurement results and results of scientific activities should be held available and stored securely for at least ten years after completion of the project or publication of the data regardless of longer legal retention requirements.
(4) Data that is not directly used for publications should be documented comprehensibly and is to be stored securely.
(5) In accordance with Section (2) and (3), original protocols and all essential documents of scientific studies are to be retained in the relevant organizational unit. The responsibility for this lies with the head of the working group, in case of student research the responsibility lies with the supervisor.

§ 4
Guidelines for Quality Control in the Laboratory

(1) For the purpose of quality control in laboratories that are directly or indirectly involved in patient care, the heads of the relevant organizational unit shall set guidelines according to the formal requirements of the rectorate and shall notify the rectorate thereof.
(2) The heads of the relevant organizational units shall verifiably inform the scientists about these guidelines and are co-responsible for ensuring the compliance with these guidelines.

§5
Clinical Research, Preclinical Research

(1) Medical research studies involving human subjects, especially in connection with clinical trials of drugs and medicinal products, are to be submitted to the Ethics Committee for evaluation and must not be commenced before a respective statement of the Ethics Committee has been made. If the Ethics Committee has to be addressed with regard to degree theses (e.g. diploma theses, doctoral dissertations), the supervisor shall undertake the necessary steps. The OE Clinical Trial

Center assists scientists in the preparation of clinical trials, especially with regard to the application to the Ethics Committee, and if applicable with the report of the clinical trial for the study registry, and if needed with the implementation of the clinical trial.

(2) Medical research studies involving animals are to be submitted to the competent authority for approval. The Ethics Committee for Animal Experimentation of the Medical University of Innsbruck supports scientists with the corresponding application. The animal protection panel provides assistance in case of questions concerning the compliance with the legal provisions regarding research involving animals.

(3) Irrespective of this, all legal provisions (e.g. gene technology law) regarding clinical and preclinical research have to be followed.

§ 6
Authorship

(1) Based on the recommendations of the *International Committee of Medical Journal Editors (ICMJE)* an authorship is the result of

   a. a substantial contribution to the conception and to the design of a project, the implementation of a research study or the collection of data, or to the analysis and interpretation of data and
   b. the drafting of a manuscript and its critical revision with regard to intellectually important content and
   c. the approval of the final version of the manuscript that will be published.

   Every person that is named as an author has to fulfill these three requirements, so-called honorary authorships are not permitted. In turn every person that fulfills all three requirements must be listed as an author.

(2) Consenting to being named as a co-author of a publication gives rise to co-responsibility for the publication's adherence to scientific requirements. This applies particularly to the part to which the co-author contributed. The co-author is responsible for the correctness of his contribution, as well as for its incorporation to the publication in a scientifically sound manner.

(3) The list of authors has to be discussed within the team and must rest on a joint decision with all (co-)authors. This decision must be recorded in written form in the authors' declaration. The authors' declaration must be signed by all (co-)authors and must either be deposited with the relevant journal or with the corresponding author.

(4) Any person that contributed to a publication, but not sufficiently in order to qualify as an author, should be mentioned in the acknowledgements. A written consent of this person should be obtained. Such contributions are e.g. a purely technical participation in the collection of data, the provision of financial or material resources, the supervision of an organizational unit, at which the research was carried out or the mere proofreading of a manuscript without an active contribution to the content.

(5) Naming a person that did not provide a contribution as laid down in (1) or (4) is not permitted and qualifies as scientific misconduct.

§ 7
Conflicts of Interest

(1) A conflict of interest may exist when academic, economic, financial or personal interests influence the objective judgement of a scientist. (cf. § 47 BDG).
(2) In order to ensure confidence in the integrity of a scientist and the quality of their work potential conflicts of interest are to be disclosed. Accordingly, (potential) conflicts of interest have to be disclosed especially in context with the procurement of third-party funding, the examination or the execution of research projects, the review of publications and in context with one's own publications and other disclosures, conference talks and presentations. Disclosure of a conflict of interest is also compulsory in the context of a function in a board, committee or in the function as a health care professional.

§ 8
Collegiality and Cooperation

(1) Collegiality and cooperativeness is of paramount importance in scientific research. Scientific works of colleagues are not to be hindered or delayed even in the case of direct competition.
(2) The review of projects, publications or academic works (works of students, habilitation dissertations) must be rejected in case of prejudice (e.g. in a case of direct competition).
(3) The results and ideas of other scientists as well as their publications must be taken into consideration in an appropriate manner and must be quoted.

§9
Scientific Misconduct

Scientific misconduct particularly includes the following serious violations:

1. Intentional or gross negligent false declarations within a context of scientific importance; the circumstances of the individual case are decisive. False declarations include but are not limited to:
    a. fabrication of data,
    b. falsification of data, e.g. through exclusion of undesired results without declaration or through manipulation of graphic depictions or images,
    c. false statements in an application or a grant proposal (including incorrect statements regarding the publication medium and publications in preparation of printing)
    d. untruthful claims that submitted works have been refereed by (certain) experts,
    e. the endorsement for publication of scientific works of others without their prior examination and
    f. publication of a scientific work that has already been published or partly published by the author(s) without referencing the earlier publication;
2. In case of a **violation of intellectual property** of another scientist especially in case of
    a. unauthorized use under presumption of authorship (plagiarism),
    b. exploitation of scientific approaches of others, particularly as an assessor (theft of ideas),
    c. the pretense or acceptance of unjustified authorship or co-authorship and
    d. unauthorized publication and disclosure to a third party before the author has published the work, discovery, hypotheses, doctrine or scientific approach;

3. In case of intentional or gross negligent obstruction of another scientist's research activity as well as in case of careless and dishonest attempts to compromise the scientific standing of another scientist;
4. In case of sabotage of research work (including damaging, destroying or manipulating the set-up of experiments, devices, documents, hardware, software, chemicals or other matters that another scientist needs to carry out his or her research);
5. In case of the unjustified denial of access to primary and original data including information regarding the collection and elimination thereof, as well as in case of the violation of the documentation and record-keeping requirements;
6. In case of **unjustified non-disclosure of the finances of research projects**, particularly through the omission of mentioning a person or institution that has supported the project through financial or material resources, or through failing to indicate economic interests that are related to the research project.

II. PART
PROCEDURE

§ 10
General Principles

(1) The representatives for good scientific practice pursuant to § 11 are the first persons to contact concerning questions regarding good scientific practice or in case of suspicion of scientific misconduct.
(2) The representatives for good scientific practice pursuant to § 11 and any other person involved in the procedure investigating suspected scientific misconduct are obliged to maintain secrecy. The obligation of secrecy persists even after the completion of the investigation or procedure.
(3) A prejudgment of the person concerned is to be avoided until a decision has been made whether or not scientific misconduct has occurred.
(4) If severe scientific misconduct is suspected, the rectorate may in particular at any time address the Austrian Agency for Research Integrity, of which the Medical University of Innsbruck is a member.
(5) A party to the proceedings is anyone, who reported the suspicion, any individual against whom the proceedings are directed as well as any person, whose rights are affected and potentially infringed, insofar as they are known.
(6) The early involvement of the general public can lead to reputational damage of the individuals concerned. Therefore parties involved must not forward any information to the public, especially not to the media.

§ 11
Representatives for Good Scientific Practice

(1) A female and a male person each from the group of the scientific personnel of the medical - theoretical divisions and of the clinical area are to be appointed by the senate as so-called representatives for good scientific practice upon their consent.

(2) The representatives for good scientific practice are appointed for a period of four years. A direct reappointment is only permitted once.
(3) The names as well as contact information of the representative for good scientific practice are to be published in the bulletin (Mitteilungsblatt) of the Medical University of Innsbruck and in an appropriate place of the homepage of the Medical University of Innsbruck.
(4) The duties of the representatives for good scientific practice include:
    a. consultancy in the context of issues regarding scientific misconduct;
    b. examining hints, suspicious facts and notifications regarding scientific misconduct;
    c. initiating a proceeding according to § 12 (3);
    d. documenting and reporting.
(5) The representatives for good scientific practice fulfil their duties independently and without being bound by directions.

§ 12
Preliminary Investigation by the Representatives for Good Scientific Practice

(1) The representatives for good scientific practice are obliged to investigate all known indications and suspicious facts pointing towards scientific misconduct. A note should be made if an indication or suspicious fact is brought forward only verbally. The representatives for good scientific practice should only investigate anonymous indications, if the indications are justified substantially and the allegations raised seem plausible.
(2) The representative for good scientific practice that was informed about the suspicion of scientific misconduct investigates the allegations and attempts to clarify them through a preliminary examination. In doing so, the person accused of scientific misconduct must be informed about the accusation and must be given the opportunity to comment on them. The clarification of relevant facts has to occur and be finalized in reasonable time.
(3) If the suspicion persists or substantiates after the preliminary examination, the representative for good scientific practice initiates the proceeding in front of the Good Scientific Practice (GSP)-Panel in accordance with § 13 f. Otherwise the proceeding is to be ceased.
(4) The rectorate, the other representatives for good scientific practice and all parties to the proceeding are to be informed in writing about the outcome of the preliminary examination including the main grounds for the decision. In case they do not agree with the cessation of the proceeding, they can demand the presentation of the case to the GSP-Panel within two weeks from notification.

§ 13
Good Scientific Practice-Panel (GSP-Panel)

(1) If the suspicion persists or substantiates after the preliminary examination according to § 12, the competence to investigate indications and accusations concerning scientific misconduct is referred to the GSP-Panel (cf. § 12 (3)). The GSP-Panel is comprised of the four representatives for good scientific practice according to § 11.
(2) The constituent meeting of the GSP-Panel is to be convened by the oldest representative for good scientific practice in terms of age immediately after the appointment of the representatives for good scientific practice in accordance with § 11 and to be headed by him or her until the

election of a chairperson. The GSP-Panel elects a chairperson and a deputy chairperson by simple majority. The chairperson is in charge of convening and heading meetings. The GSP-Panel must establish its rules of procedure. The rectorate has to authorize these rules of procedure.

(3) The GSP-Panel submits an annual report of its activities to the rectorate and the senate irrespectively of any other information and reporting duties. In the annual activity report all suspicious facts and indications of scientific misconduct received in accordance with § 12, as well as all cases, with which the GSP dealt with in the relevant period, are compiled in anonymized form. The GSP-Panel may also make appropriate recommendations for ensuring good scientific practice in its annual report.

§ 14
Procedure before the GSP-Panel

(1) The representative for good scientific practice entrusted with the establishment of relevant facts informs the other members of the GSP-Panel about the reported allegations as well as about the current status of the preliminary examination. The GSP-Panel decides after conferring about the necessity of further investigations. If the need for further investigations is confirmed, the Panel instructs one or more of its members to carry them out. If needed, the GSP-Panel can seek expert advice. It works towards a rapid settlement of the proceeding.

(2) Meetings of the GSP-Panel are not public. Members of the rectorate or individuals commissioned by the rectorate may participate at meetings. The sequence of the proceeding and all incriminating and exonerating facts including means of evidence must be documented in writing. A protocol, comprising the dates of the meetings, attendees, the verbally expressed statements as well as the essential results of the meetings of the GSP-Panel is to be made.

(3) Before the investigations are completed the GSP-Panel has to question all parties to the proceeding orally or in writing about the reported suspicion. In case of an oral questioning the parties to the proceeding may be accompanied by a confidant. It may be necessary to disclose the names of the informing individuals, if the person affected cannot defend himself or herself appropriately otherwise, particularly because the credibility and the motives of the informing person are given great significance for the clarification of the alleged case of misconduct. Upon completion of the investigation the person suspected of misconduct is to be informed about the outcome of the investigation and must be given the opportunity to make a final statement.

(4) The GSP-Panel must decide, preferably within four weeks, whether scientific misconduct has occurred. The Panel decides in accordance with the principle of free appraisal of evidence and in consideration of all incriminating and exonerating means of evidence and facts. A termination of the proceeding due to negligibility is possible, if a minor case of scientific misconduct has been established and the person concerned has contributed significantly to clarifying the circumstances and if applicable has offered measures, in particular an erratum, or has already taken steps to fix any damages made.

(5) The decision, including all significant reasons for it, is to be submitted to the rectorate and all parties to the proceeding in written form. If the GSP-Panel considers a case of scientific misconduct to be evidenced, it proposes possible consequences to the rectorate.

§ 15
Consequences in Case of Scientific Misconduct

(1) Once the GSP-Panel has ascertained a case of scientific misconduct and has informed the rectorate, the rectorate decides about the further procedure, in particular also regarding consequences concerning labor-law, public services law, civil and criminal law. The criterion here is the protection of the scientific standards and the rights of all individuals affected directly or indirectly, the nature and severity of the violation as well as the necessity to take action against it.
(2) In accordance with the data protection law a consequence of scientific misconduct may include the disclosure to third parties about the results of the proceeding and the measures taken. This may in particular include other universities or scientific institutions and associations, if they are directly affected, or if the scientist concerned holds a leading position in the relevant institution or is part of a decision-making body or a similar organ. The responsibility for such a notification lies solely with the rectorate.

§ 16
Support of Parties to the Proceeding

(1) After a proceeding before the GSP-Panel is completed, the personal dignity and scientific integrity of all individuals, who were involved in processes of scientific misconduct without any fault on their part, has to be protected from further discrimination.
(2) Informants have to be protected from discrimination, if a report suspecting scientific misconduct was made in good faith and the allegations did not prove to be completely unfounded. For junior scientists this means in particular that they should not have to face encumbrances to their professional advancement, e.g. with the writing of degree theses. Informants that are employees of the Medical University of Innsbruck should not face any professional encumbrances or impairments to their scientific career.

§ 17
Entry into Force

This statute section replaces the previous statute section “Sicherung guter wissenschaftlicher Praxis an der Medizinischen Universität Innsbruck”, which was published in the bulletin (Mitteilungsblatt) of the Medical University of Innsbruck dating 04.05.2005, academic year 2004/2005, number 115, item 27, and shall take effect with its publication in the bulletin (Mitteilungsblatt) of the Medical University of Innsbruck.