

## **Guideline on Research Misconducts Procedures**

Considering the emphasis of the Constitution and other substantive legislations of the Islamic Republic of Iran on pursuing good moral character in all aspects of life, and the emphasis on the unique status of ethics in fundamental legislations pertaining to the field of sciences, research and technology, especially the National Scientific Master Plan, the policies stipulated by the Supreme Leader for science, technology and health, the Act on Appending Two Paragraphs to Article ۷ of the Law of Disciplinary Regulation of the Faculty of Iranian Universities and Research and Higher Education Institutes (approved by the Parliament of the Islamic Republic of Iran on ۲۷ January ۲۰۰۹) that has included among disciplinary misconduct of university faculty members any violation of ethical requirements and regulations for research in medical sciences (communicated by the Ministry of Health and Medical Education in accordance with the codes approved by that Ministry in order to protect human participants), and abuse of intellectual property pertaining to practical and theoretical research findings of other parties, previously published or patented, and other relevant regulations, this guideline has been developed and communicated for the activities of national and academic committees on biomedical research ethics, as expert bodies for research misconduct procedures in universities and institutes subordinate to the Ministry of Health and Medical Education, so that competent authorities may seek the expert consultation of such committees in accordance with their regulations. The responsibility for proper implementation of this guideline rests with the head of each university or institute as the chairperson of the related research ethics committee, and the National Committee for Ethics in Biomedical Research of the Ministry of Health and Medical Education will ensure the guideline is satisfactorily implemented.

## **Chapter ۱: Definitions and Applicability**

### **Article ۱: Definitions**

- ۱.۱ Research misconduct shall mean any violation of requirements, regulations, guidances, guidelines and codes to protect human participants, as approved by the Ministry of Health and Medical Education for designing, executing and reporting results of biomedical research, and abuse of intellectual property pertaining to practical and theoretical research findings of other parties.
- ۱.۲ Competent committees for research misconduct procedures shall include:
  - A) National Committee for Ethics in Biomedical Research of the Ministry of Health and Medical Education, hereinafter known as "National Committee"; and
  - B) Academic committees on biomedical research ethics of universities and institutes subordinate to the Ministry of Health and Medical Education, established under the Code for Establishment, Ranking and Terms of Reference for Research Ethics Committees, and granted approval by the Secretariat of the National Committee to establish a committee at the academic level, hereinafter known as "academic committees".
- ۱.۳ Competent authorities shall mean authorities within and without medical universities, to which research misconducts may be referred by competent research ethics committees subject to paragraph ۱.۲ above for the necessary actions, as required individually or collectively. Such authorities may include councils for misconduct procedures of university faculty members, councils for personnel's official misconduct procedures, students' disciplinary committees, professional organizations, such as the Iranian Medical Council, Iranian Nursing Organization, universities, education or research institutes, the defendants' respective organization or entity (foreign or domestic), the Supreme Council of the Cultural Revolution, professor or student selection boards, faculty employment boards, and auditory boards of universities and higher education institutes.

## **Article ۲: Applicability**

Based on the order of occurrence in the research process, research misconducts shall be divided into three general categories:

- ۲.۱ Misconduct before commencing the research process, mainly in designing the research proposal or protocol, which may include, inter alia:
  - A) Failing to register biomedical research proposals under any name or title, including plan, research plan, research project, study, thesis or the like with the relevant university or institute;
  - B) Failing to obtain the relevant license(s) from research ethics committees;
  - C) Failing to register clinical trials at the Iranian Registry of Clinical Trials;
  - D) Failing to obtain relevant licenses from the Food and Drug Administration for clinical trials related to drugs and other products;
  - E) Exploiting research ideas of other parties without observing their intellectual property rights;
  - F) Failing to comply with official regulations and requirements, and ethical codes in selecting sponsors or concluding the related contracts;
  - G) Failing to comply with publication ethical standards in preparing the research proposal;
  - H) Failing to announce research sponsors; or
  - I) Failing to clarify or announce the existence of any conflict of interests among research executors or other parties involved.
- ۲.۲ Misconduct during research process, including breach or infraction of the provisions of any special or general ethical codes, approved by the Ministry of Health and Medical Education, especially those aiming at protecting human participants in biomedical research, which may include, inter alia:
  - A) Failing to obtain valid informed consent, through providing correct research information, and uncertainty about proper understanding of the issue(s) by the research participant(s);

- B) Secrecy of any sort, such as having failed to report serious risks and side effects on participants during the research project;
  - C) Violating confidentiality, and disclosing data and information related to research participants; or
  - D) Deviating from the provisions of the research proposal, and failing to obtain the approval of the relevant research ethics committee for any changes in the proposal, including altered criteria for entry and exit of participants from the research project, replacement of lead researchers or their colleagues, or the emergence of conflict of interests, altered manner or amount of financial assistance, or changed sponsors.
- ۲.۳ Misconduct after research completion, occurring in the process of publishing or deciding not to publish research findings, which may include, inter alia:
- A) Forging data, including fabrication, recording or publication of research results or data that were partially or totally non-existent;
  - B) Falsifying data, including effective alteration or deletion of a portion of data, research process or method, equipment and materials used or research findings, in a manner that those results or data would differ with real results or data;
  - C) Plagiarizing, including partial or total duplication of works, articles or proposals of other parties, without proper reference to the author(s) or intellectual property owner(s); or
  - D) Falsifying author(s), including deletion of the individual(s) with authorship status from the authors' list of a scientific work, and addition of individuals without such status as the author, or publishing research results without mentioning the individual(s) involved in authoring a work or article.

**Note:** In addition to the instances mentioned in this guideline, research misconduct shall include violation of other guidelines approved by the Ministry of Health and Medical Education, such as the decisions of the National Committee, the Code for Establishment, Ranking and Terms of

Reference for Research Ethics Committees in Biomedical Studies (۲۰۱۴), the General Ethical Guidance for Medical Research with Human Participants in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Clinical Trials in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Research on Gametes & Embryos in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Medical Genetic Research in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Research on Stem Cells in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Research on Human Tissues and Organs in the Islamic Republic of Iran (۲۰۱۳), the Ethical Guidance for Research on Vulnerable Groups in the Islamic Republic of Iran (۲۰۱۳), the Special Guidance for Medical Research on HIV/AIDS in the Islamic Republic of Iran (۲۰۱۰), the Ethical Guidance for Research on Animals (۲۰۰۵), the National Ethical Guidance for Publishing Research Works in Medical Sciences (۲۰۱۰), and the subsequent amendments and annexations thereto.

## **Chapter ۲: Consideration Procedures**

### **Article ۳**

Research misconduct consideration shall be possible with the announcement of any natural or juridical persons. Such announcement shall be submitted in written form to the secretariat of a competent committee.

**Note ۱:** In cases where the complaint on research misconducts is directly submitted to the preliminary committee responsible for disciplinary misconduct procedures of university faculty members, the head of the preliminary committee may refer the case to the relevant ethics committee in accordance with Article ۱۲ of the Act on Disciplinary Regulations of the Faculties of Iranian Universities.

**Note ۲:** If the defendant(s) were not affiliated with a university at the time of committing the misconduct, the complaint shall be submitted to their affiliated university at the time of filing the complaint. If the defendant(s) are not affiliated with any institute or university, the complaint shall be submitted to the plaintiffs' affiliated university. If the plaintiff(s) are not affiliated with any institute or university either, the complaint shall be submitted to university of the residence city of the defendant(s), and in case the defendant(s) do not reside in Iran, to the university of the residence city of the plaintiff(s). If none of the above conditions is realized, the complaint shall be received by the Secretariat of the National Committee, and referred to a competent academic committee to be processed.

**Note ۳:** In case of numerous misconducts, the jurisdiction shall be determined on the basis of the most recent misconduct before the procedure is commenced.

### **Article ۴**

In addition to a written account of the misconduct, the reporting party shall append the required information to the report, including full personal details and contact information of him/herself, the defendant(s), possible witnesses and other evidences and documents.

**Note:** In case the plaintiff(s) are members of the research ethics committee of the related university, the case shall be referred to the National Committee to be processed.

#### **Article °**

The committee secretariat shall designate a paginated folder to each submitted report and hold all the related documents therein. The folder shall be considered as "Highly Confidential", and the highest levels of confidentiality shall be observed therefor during and after the procedure.

#### **Article ʘ**

At the beginning of the procedure, the ethics committee shall fully inform the defendant(s) of their rights and the details of the procedure.

#### **Article ʙ**

A complaint filed with the secretariat of an academic research ethics committee shall be considered and decided upon in the official meeting(s) of the ethics committee.

**Note:** The initial stages of processing, such as consulting experts recognized by the committee and certified as committee consulting expert, inviting the defendant(s) for the initial hearing, and obtaining the related responses and information, may be conducted by the committee secretary before official consideration of the case in the committee meeting.

#### **Article ʌ**

According to the legal principles of civil security and immunity, and privacy protection, committee members and consulted experts shall not investigate into the defendants' private life under any circumstances. During the consideration and

expert consultation of the case, any investigations that would prejudice the defendants' reputation without strong evidences of the occurrence of the misconduct shall be prohibited. Disclosing information, evidences, locations and methods of access thereto shall be kept at a minimum, limited to the parties involved in the procedure and to the extent that satisfies procedural demands.

#### **Article 9**

In order to promote procedural efficiency and transparency, the committee chairperson may invite individuals from inside the university or other scientific entities to attend committee meetings, or cooperate in expert consultation, investigation or commenting on the received reports and complaints. The provisions of this guideline shall also apply to such individuals.

#### **Article 10**

The names of committee members and invited experts shall be publically announced. In case the defendant(s) or plaintiff(s) submit sufficient evidence for any conflict of interests with a committee member or consulting expert, the issue shall be considered and decided upon by the committee. If such conflict is confirmed by the committee, measures shall be taken to select a substitute for the relevant individual(s), and if rejected, the committee shall proceed with its ordinary procedure. The issue shall be mentioned in the final decision of the committee meeting.

**Note 1:** Conflict of interests shall include one of the following conditions:

- A) Approved joint research projects or articles with one of the litigants; or
- B) Grounds nullifying judgment capacity under Article 91 of the Judicial Procedure of Public and Revolutionary Courts for Civil Affairs, including:
  - 1. The individual has a blood or in-laws relation up to third level of any side with one of the litigants;

٢. The individual serves as a guardian or employer of one of the litigants, or has one of the litigants as administrator, executor of affairs or representative for him/herself or him/her spouse;
٣. The individual, his/her spouse or children is identified as heir to one of the litigants;
٤. The individual has previously commented on the same case in any manner;
٥. The individual, his/her spouse or children has an ongoing legal case in judicial or official courts with one of the litigants, his/her spouse or children, or a legal case concluded less than ٧ years ago; or
٦. The individual, his/her spouse or children has personal interests in the case being processed.

**Note ٢:** Any conflict of interests shall be informed to the ethics committee chairperson by committee members or consulting experts. A document attesting the absence of any conflict of interests shall be signed by committee members and recorded before the consideration process commences.

### **Article ١١**

In any case, the consulting expert(s) shall comprehensively consider the entire report, and the relevant documents and evidences, report the results to the committee, and interview the defendant(s) and plaintiff(s) separately.

### **Article ١٢**

During the consideration and investigation process, the defendant(s) shall be allowed to defend him/herself, ask questions, present information, witnesses and documents, and obtain information, comment and defend him/herself in regard to testimonies and reports related to different stages of the procedure.

**Note 1:** In addition to attending the ordinary meetings of the committee, when invited, the defendant(s) may request to attend an extraordinary committee meeting to defend him/herself.

**Note 2:** Upon the failure of the defendant(s) to attend meetings or respond accordingly, the committee shall prepare a report containing all the available arguments and documents, issue its expert decision and take appropriate measures in accordance with Article 20 and further of this guideline.

### **Article 13**

The defendant(s) and plaintiff(s) may acquire legal advisors and attorneys. By presenting an official power of attorney, the attorney may represent or accompany his/her clients in attending consideration and investigation meetings, studying the case, and requesting the correspondence to be forwarded to his/her office. The committee may also invite the defendant(s) or plaintiff(s) to attend meetings in person as well.

### **Article 14**

In addition to comments on whether a research misconduct has occurred and the type thereof, the case shall also include the details of the measures taken to consider and investigate the issue, documents, evidences and arguments used or considered in the process, records of the defendants' or their attorneys' defense or objections to the reports, and the details of all assistance and cooperation the defendant(s) received from various sources to execute the research project.

## **Chapter ٣: Processing Principles**

### **Article ١٥**

No natural or juridical persons shall retaliate against the litigants, witnesses, committee members and consulting experts. Any violation of this principle shall be reported to competent authorities.

### **Article ١٦**

Cases on research misconducts shall be considered and investigated fairly, and bearing the rights of all involved individuals and parties in mind. All individuals shall be responsible to observe fairness and impartiality throughout the procedure.

### **Article ١٧**

Highest levels of confidentiality shall be maintained during consideration, investigation, report preparation and submission thereof to the competent committee. In order to prevent undue information disclosure, the committee chairperson shall obtain signed non-disclosure agreements from all the individuals involved in such processes, including committee member, experts, related official personnel and the like. Confidentiality principles shall be fully observed in regard to witnesses as well.

**Note ١:** The text of non-disclosure agreement shall be prepared by the National Committee, and communicated to all committees, after being approved by the Legal Studies and Codification Bureau of the Ministry of Health and Medical Education.

**Note ٢:** Apart from the individuals mentioned in this guideline, no other individual or party shall know the defendant(s) or plaintiff(s), or the case involving them. In order to complete the consideration and investigation process, minimum required information according to this guideline may be provided to third parties only if the necessity for that is recognized by the processing committee. The third party shall

be briefed about the required confidentiality principles, and then informed about the defendant(s), plaintiff(s) and case progress in compliance with highest confidentiality levels. All information, evidences and documents of the case shall be considered as "Highly Confidential", and the committee chairperson shall take the required measures to guarantee confidentiality.

**Note 3:** Confidential documents related to research misconducts shall be stored in accordance with the Code on Storage Methods for Governmental Confidential and Secret Documents, approved on 22 December 1970.

#### **Article 18**

If the procedure fails to ascertain the reported misconduct, the defendant(s) shall be fully supported. All individuals engaged in the procedure, including committee members, consulting experts and others shall make utmost efforts not to jeopardize the rights, positions, occupations and reputations of the defendant(s) and plaintiff(s). The related ethics committees shall hold the responsibility for safeguarding individuals' reputations during the investigation process. If the procedure fails to ascertain the reported misconduct, the defendant(s) shall be compensated for all financial and social damages inflicted as a result of the investigation, and the required measures shall be taken for their political rehabilitation. The related university shall also attempt to compensate for such financial and social damages to the extent possible.

#### **Article 19**

If the plaintiffs' dishonesty or intention to disturb the defendant(s) becomes evident at any time during the procedure, the committee shall refer the issue to competent authorities. The injured individual(s) shall also reserve the right for judicial prosecution in such cases.

## **Chapter 4: Issuing Decision**

### **Article 20**

After receiving a complaint, the committee shall commence considering the case in a meeting held not later than two weeks from the date of reception and registry of the report, and issue its firm decision accompanied with the related arguments within three months of the mentioned date. Finalized decisions of research ethics committees may be utilized as a basis for issuing enforcement orders by competent authorities.

### **Article 21**

Interested parties may appeal the committee decision through a written request submitted to the Secretariat of the National Committee, within two weeks of receiving the decision. The National Committee shall proceed to consider and decide upon such request in accordance with Chapters 2, 3 and 4 of this guideline.

### **Article 22**

The finalized decision of the committee shall be communicated to the following authorities to decide and issue decrees upon:

- A) For board members of universities and higher education institutes, to the preliminary committee responsible for disciplinary misconduct procedures of university faculty members, in accordance with Paragraph 3, Article 11 of the Executive Code of the Act on Disciplinary Regulations of University Faculty Members (approved on 26 July 1986);
- B) For personnel of executive bodies, to the committees responsible for official misconduct procedures, in accordance with Article 10 of the Executive Code of the Act on Official Misconducts Procedures (approved on 18 October 1994); and

- C) For university students, to the relevant disciplinary committees, in accordance with Note ٣, Article ١٢ of the Decision of the Supreme Council of the Cultural Revolution, entitled "Supplementing Student Disciplinary Code" (approved on ٤ September ١٩٩٧).

**Note:** Considering and issuing decisions by competent ethics committees shall not relieve legal authorities of their responsibility for considering, investigating, and issuing orders to enforce the required punishments and penalties.

### **Article ٢٣**

The decision issued by the committee shall include precise details of the litigants and their attorneys, if applicable, a summary of the issue and proceedings, proof of the occurrence and type of misconduct, or else refutation thereof. Moreover, the committee shall also comment, in its expert opinion, about type, number, repetition, conditions, and motives of the misconduct, as well as the impacts thereof on the participant(s) and breach of public trust as a result.

### **Article ٢٤**

When the occurrence of the misconduct is ascertained, the committee shall communicate its decision to the competent authorities mentioned in Paragraph ١.٣, Article ١ of this guideline, and then consider type, number and repetition of the misconduct to recommend the related university to appoint a direct supervisor on future research activities of the defendant(s) for a defined period, and to remove the article(s) emanated from or resulting to the misconduct from the publishing magazine or periodical, while announcing the relevant committee decision by the same publication.

**Note:** When the occurrence of the misconduct is ascertained, the committee shall consider type, number and repetition of the misconduct to recommend the competent authorities to enforce penalties (such as halting the promotion process for the relevant university faculty members, or demanding resubmission of student dissertations), and if applicable, report the misconduct to other competent

authorities, including judicial, disciplinary and professional bodies, and pursue the result thereof.

#### **Article ۲۵**

All files and decisions related to research misconducts shall be registered with the Secretariat of the National Committee, and all academic committees issuing decisions shall forward a complete copy of the file including the final decision to the National Committee.

## **Chapter ٦: Other Requirements**

### **Article ٢٦**

Research misconducts committed by individuals that hold positions as chairperson, deputy or member of governing board, university trustee, fixed member of Medical Sciences Academy, member of academic ethics committees, and director general or higher of the Ministry of Health and Medical Education, at the time of complaint submission, shall be processed by the National Committee in accordance with the regulations and procedures specified in this guideline.

**Note ١:** In cases mentioned in this article, the complaint submitted to the academic committee and a justified letter attesting the individual's incompetence shall be forwarded by the chairperson of the academic ethics committee to the National Committee.

**Note ٢:** Deposal of the defendant(s) after the receipt of the complaint by the National Committee shall not relieve the case from being processed.

### **Article ٢٧**

In case of the defendants' official or temporary appointment to one of the positions specified in Article ٢٦ above, before the final decision of the committee was issued, the case shall immediately be transferred to the National Committee for further processing and issuance of the final decision.

### **Article ٢٨**

The expenses related to processing research misconduct cases shall be supplied by research departments of the relevant universities of medical sciences and health-treatment services, in accordance with relevant legislations and regulations.

**This guideline in ٧٨ articles was approved by the Minister of Health and Medical Education on .....(date)....., and shall enter into force on .....(date).....**

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