

**In the Name of God**

**Guideline on Establishment, Ranking and  
Terms of Reference for Research Ethics  
Committees in Biomedical Studies  
(National, Academic and Organizational Ethics  
Committees)**

٢٠١٣

## **Executive Summary**

### **Introduction**

Ethics committees in biomedical research are established for ethical supervision over such studies, and rely on international instruments and their adaptation to the Iranian culture and law, in order to offer ethical consultation to research participants, executors, sponsors, employers, organizations and other related bodies; ensure the conformity of research proposals with established and approved ethical, national and international requirements; issue "ethical decisions" for research execution in case of non-compliance with ethical requirements; and supervise the execution of research projects. The findings and results of biomedical research projects, with proposals not approved by relevant research ethics committees, shall be not only considered as invalid and unsuitable for publication or reference, but also subject to legal and official consequences. Scientific and ethical requirements for biomedical research involving human participants have been internationally emphasized by the Council for International Organizations of Medical Sciences (CIOMS), the World Health Organization (WHO), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and the United Nations Educational, Scientific and Cultural Organization (UNESCO). In our country, the Ministry of Health and Medical Education followed national and religious instructions and values, along with international standards to develop and communicate ethical codes and establish ethics committees for supervising the approval and execution of research endeavors. For that purpose, the National Committee for Ethics in Biomedical Research was founded in ۱۹۹۸ by the Research Department of the mentioned ministry, and culminated in the establishment of local research ethics committees in universities and research institutes within the next year. After over a decade of their activity in regard to medical sciences, and with the growing development of research projects in quality and quantity, as well as higher experience for ethical supervision in the country, the Research and Technology Department of the Ministry of Health and Medical Education has proceeded to revise the guideline for the establishment and terms of reference for research ethics committees, in accordance with Paragraphs ۱ and ۲, Article ۱ of the Act on Structure and Duties of the Ministry of Health and Medical

Education (۱۹۸۵) that requires the mentioned ministerial department to supervise biomedical research. This revision included comparative studies, international experiences, expert opinions of Iranian scholars, researchers, legislators, executives and medical ethics specialists, and then conformed to the executive and scientific conditions of the country. This guideline is comprised of ۵ sections and ۳۵ articles, as presented briefly below.

### **Section ۱: Definitions**

This section, in one article and ۲ paragraphs, defines the terms used in this guideline.

### **Section ۲: National Committee for Ethics in Biomedical Research**

This committee is the highest decision-making body for biomedical research in terms of research ethics principles, which is convened in the Ministry of Health and Medical Education under the chairpersonship of the Research and Technology Department. The National Committee is authorized to guide and supervise research ethics committees; prepare research ethics guidelines and guidances; provide consultation to academic ethics committees; and process complaints about research projects considered by academic ethics committees, in regard to cloning, cell therapy, stem cells, clinical trials and international studies. The National Committee is comprised of eleven natural or juridical persons as members. The mandates for the Chairperson and members of the National Committee are issued by the Minister of Health and Medical Education for an extendable period of three years.

### **Section ۳: Academic Committees for Ethics in Biomedical Research**

Academic committees are convened in medical universities, in order to establish and supervise organizational ethics committees, and they are authorized to process complaints about the decisions of organizational committees, and supervise research projects in regard to cloning, cell therapy, stem cells, clinical trials and

international studies. An academic committee is chaired by the relevant university chancellor, and is comprised of nine natural and juridical persons as members, whose mandates are issued by the Chairperson for an extendable period of three years.

#### **Section 4: Organizational Committees for Ethics in Biomedical Research**

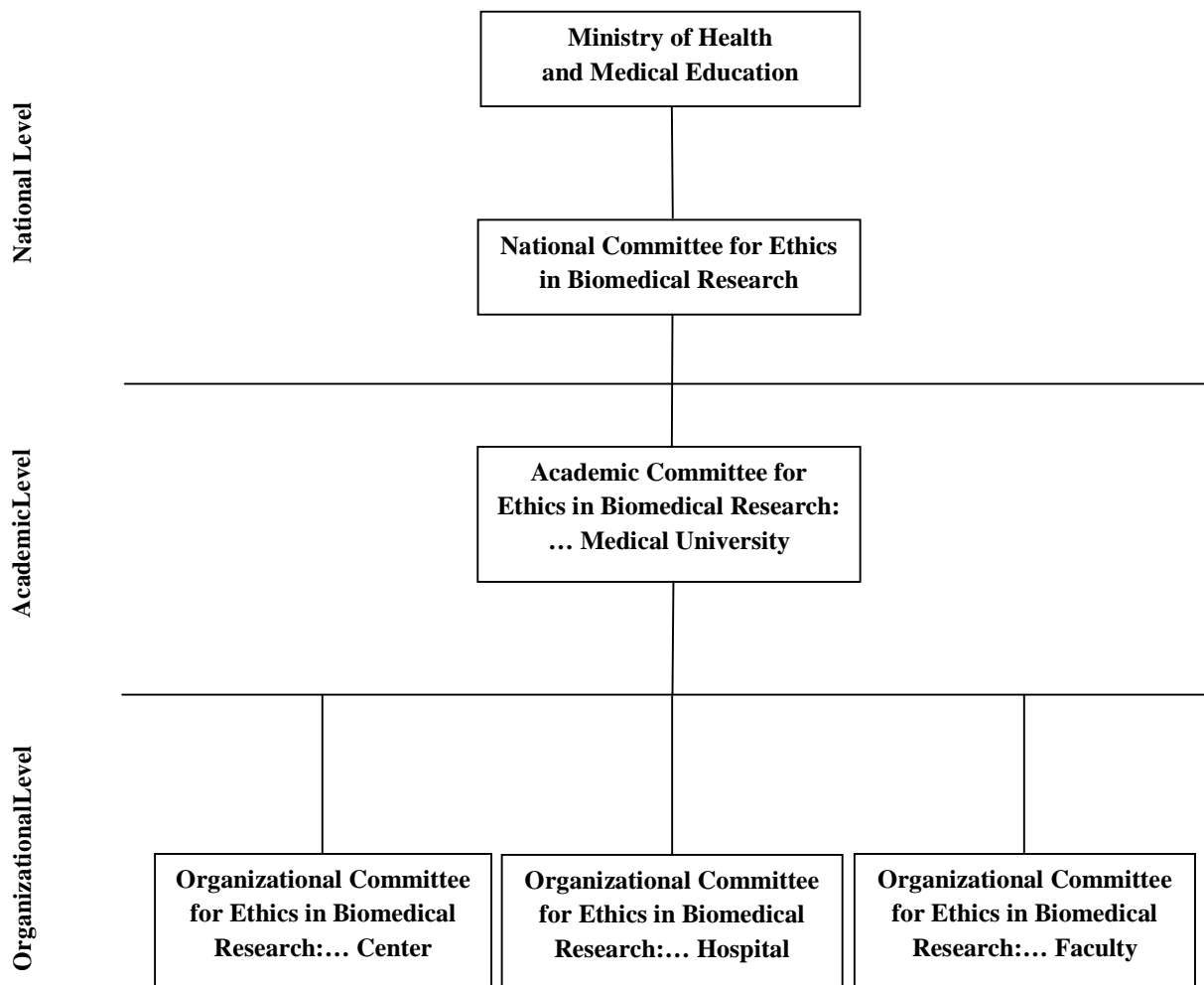
This section describes the structure and terms of reference for organizational committees as the first level for ethical consideration of research projects. Organizational committees are convened in organizations, higher education institutes, and public or private research centers, as approved and supervised by the relevant academic ethics committees. The mandate for the Chairperson is issued by the university chancellor. The committee is comprised of nine natural or juridical persons as members, whose mandates are issued by the Chairperson for an extendable period of three years. Apart from research projects in regard to cloning, cell therapy, stem cells, clinical trials and international studies, other proposals for biomedical research subject to this guideline need to be considered and approved by organizational committees. Decisions of organizational committees may be appealed and modified once in the relevant academic ethics committees.

#### **Section 5: General Principles Governing Ethics Committees for Biomedical Research**

Ethics committees for biomedical research are convened at three organizational, academic and national levels. This section presents the general principles and decision-making basis for ethics committees, and clarifies that all such committees shall consider and supervise research projects in regard to biomedical sciences, especially those involving human participants, through observing justice and impartiality, and in compliance with ethical principles and regulations, legal and religious standards, and all ethical codes approved by the Ministry of Health and Medical Education.

The following chart depicts the organizational structure of the ethics committees for biomedical research in Iran:

**Chart 1:**  
**Organizational structure and levels of ethics committees for biomedical research in Iran**



## **Section ۱: Definitions**

### **Article ۱**

The terms used in this guideline shall bear the following meanings:

- ۱.۱ **Ministry:** Iranian Ministry of Health and Medical Education;
- ۱.۲ **National Committee:** The National Committee for Ethics in Biomedical Research has been established with the aim of promoting ethical supervision and standards in biomedical research. This committee is the national authority for policy-making and guaranteeing compliance with research ethics principles;
- ۱.۳ **Academic committee:** An academic committee for ethics in biomedical research may be convened in any medical university of the country, and be in charge of establishing and supervising organizational research ethics committees within the jurisdiction of that university;
- ۱.۴ **Organizational committee:** An organizational committee for ethics in biomedical research may be convened in organizations, higher education institutes, and public or private research centers, and serve as the first level for ethical consideration of research projects;
- ۱.۵ **Natural committee member:** An individual nominated, introduced and appointed as a member of an ethics committee, based on his/her scientific or social status;
- ۱.۶ **Juridical committee member:** An individual entering membership of an ethics committee as a result of his/her position, and whose membership shall be terminated upon the termination of that position. Membership and participation in the ethics committee shall be considered as a part of the juridical member's duties;

- ۱.۷ **Competent official:** A public juridical person responsible for health affairs, currently the Minister of Health and Medical Education, or individuals appointed by the Ministry as competent officials for health affairs;
- ۱.۸ **Proposal:** A document including a research question, details and description of the scientific, technical and physical arrangements to achieve a reasonable financial or non-financial result or achievement within a detailed specified timeframe. A proposal shall be approved by a competent scientific authority, and fully conform to the requirements of national ethical codes. Altering the name or contents of such a document into a thesis, study, research project, survey, proposal or protocol shall not exempt it from compliance with the provisions of this guideline;
- ۱.۹ **Ethical decision:** A letter provided by the Chairperson or Secretary of an ethics committee to research executors, in regard to the approval and ethical considerations of a proposal in the relevant committee;
- ۱.۱۰ **Research sponsor:** A natural or juridical person totally or partially supplying the research budget, work force, medicines, equipment, and the like as required in the proposal;
- ۱.۱۱ **Participant:** A participant, healthy volunteer, patient, user, relative of the deceased, employer or another individual that cooperates with a research project under its proposal, agreement or regulations, and the research project studies their person, biological matter or information;
- ۱.۱۲ **Executor in charge:** An individual designated as responsible for designing, guiding, executing and observing ethical requirements in a research project, who shoulders the legal responsibility thereof through signature of a research agreement. In cases where more than one executor in charge can be identified for a research project, even with equal rights, one natural person from among them shall be appointed and introduced in the proposal as the lead executor in charge;
- ۱.۱۳ **International studies:** Studies conducted jointly between Iranian public or private institutes, and international or foreign organizations or entities. Studies

financially or intellectually supported by international organizations or institutes shall be considered as subject to this definition;

- ۱.۱۴ **Multicenter studies:** Studies conducted by a number of research centers under the jurisdiction of different academic committees. Studies by research centers under one academic committee shall not be considered as subject to this definition;
- ۱.۱۵ **Clinical trials:** Studies that try new drugs, medical equipment or treatment methods on human participants;
- ۱.۱۶ **Iranian Registry of Clinical Trials:** An electronic system for registering clinical trials conducted in Iran ([www.irct.ir](http://www.irct.ir));
- ۱.۱۷ **Ethical codes:** Ethical regulations, requirements or guidelines communicated by the competent official to meet ethical considerations;
- ۱.۱۸ **Good Clinical Practice:** The internationally established standards for conducting medical trials, adapted in our country by the Food and Drug Administration, and communicated by the Ministry of Health and Medical Education;
- ۱.۱۹ **Approval:** Written announcement of the definite favorable decision of an ethics committee shall be considered as approval, and if emphasizing on definite "non-approval", as rejection;
- ۱.۲۰ **Conflict or community of interests:** Financial or intellectual conditions that might influence individuals' opinions, and induce partiality in their decision or conclusion about the issue. Such conflict or community of interests may occur in regard to researchers, sponsors, committee members or other parties involved in the project. Instances of conflict or community of interests shall be vividly mentioned in all relevant documents; and
- ۱.۲۱ **Competent scientific authority:** Research councils, technical or scientific committees or the like that are convened in universities or organizations, and consider research projects in terms of necessity, methodology and other technical or scientific considerations.



**Section ٢:**  
**National Committee for Ethics in Biomedical Research**

**Article ٢: Competences**

- ٢.١ Preparing and communicating research ethics guidelines and guidances, approved by the committee or other competent authorities in accordance with legal requirements;
- ٢.٢ Supervising the implementation of communicated guidelines and guidances, and the performance of academic and organizational committees for research ethics;
- ٢.٣ Receiving and processing complaints about research projects considered by academic ethics committees, in regard to cloning, cell therapy, stem cells, clinical trials and multicenter projects. The decision of the National Committee in these respects shall be considered as final;
- ٢.٤ Supporting experimental research in regard to research ethics;
- ٢.٥ Empowering and providing consultation to academic and organizational ethics committees;
- ٢.٦ Preparing and implementing strategic and operational programs to promote research ethics in the country; and
- ٢.٧ Establishing organizational ethics committees in independent institutes not subordinate to any medical universities.

**Article ٣: Members**

- ٣.١ The National Committee shall have eleven members, as follows:
  ١. Deputy Minister of Health and Medical Education for Research and Technology;

٢. A member of clergy, familiar with fiqh and biomedical ethics (preferably holding a doctorate or equivalent degree);
  ٣. A jurist (preferably holding a doctorate degree);
  ٤. A specialist in biomedical ethics;
  ٥. A specialist in biostatistics or epidemiology;
  ٦. Chairperson of the Clinical Trials Committee of the Food and Drugs Administration;
  ٧. An active member of the pharmaceutical industry;
  ٨. Director General for Medical Equipment of the Ministry of Health and Medical Education;
  ٩. Two distinguished researchers, holding a degree of associate professor or higher in any medical specialty; and
  ١٠. An unspecialized individual, representing the society.
- ٣.٢ At least two ladies shall be included among the members of the National Committee.
- ٣.٣ Upon the members' discretion, each committee meeting may also be attended by distinguished executives or clinical specialists, experts in non-medical fundamental sciences, owners or managers of pharmaceutical factories, developmental psychologists, relatives of psychological patients, officials responsible for children's affairs, including public bodies or NGOs, representatives from religious minorities or immigrants, and the like as advisors to provide their opinions without a voting right.
- ٣.٤ Upon the discretion of the National Committee, members of academic or organizational ethics committees may be invited to attend the meetings.
- ٣.٥ The membership of individuals included the committee on the basis of their positions (juridical members) shall be terminated upon the termination of that position.

## **Article ٤: Appointment of Members**

- ٤.١ The Deputy Minister of Health and Medical Education for Research and Technology shall chair the National Committee, under a mandate issued by the Minister of Health and Medical Education.
- ٤.٢ Other members of the National Committee shall be nominated by the Chairperson, and approved by mandates issued by the Minister of Health and Medical Education for an extendable period of three years.
- ٤.٣ Within two months after expiry of membership or resignation of a member, the Minister of Health and Medical Education shall appoint a substitute for that member.

## **Article ٥: Conditions for Membership**

- ٥.١ Members shall pass the relevant research ethics training courses arranged by the competent official, and possess the required skills for analyzing affairs and communicating with others for team work purposes within the committee.
- ٥.٢ At the time of appointment, members shall announce their consent to participation in the National Committee meetings and the relevant courses.
- ٥.٣ Members shall be aware of the conditions for membership and activity in committees, publication of their names and surnames, formalities, appointment, substitution, deposal, resignation, period of membership, conflict or community of interests, and other details, announce and sign their consent, and attend meetings in person.
- ٥.٤ The unspecialized member, as mentioned in paragraph ٣.١.١٠ above shall not have been employed in a field directly related to medical affairs for the past ten years as a minimum, and shall not have a history of cooperation with biomedical research involving human participants as executor or colleague. Such members may be selected from among the retired.

## **Article ٦: Secretariat**

٦.١ For the optimal performance of the National Committee, the Chairperson shall establish the Secretariat at the Research and Technology Department of the Ministry of Health and Medical Education, and appoint an individual as the Secretary.

**Note:** The Secretary may not be a natural or juridical member of the committee.

٦.٢ The Secretary shall possess the following qualifications:

١. Familiarity with principles and considerations of biomedical and biological ethics, and the relevant regulations and guidelines;
٢. Ability to establish suitable communication and interaction;
٣. Sufficient history of planning, managing and conducting research; and
٤. Proficiency in English.

٦.٣ The responsibilities of the Secretariat shall include:

١. Managing committee meetings in the absence of the Chairperson;
٢. Preparing the agenda, inviting members and recording their presence or absence, designating and inviting advisors, conducting correspondence and issuing committee decisions; and
٣. Managing financial affairs of the committee.

٦.٤ The budget required for the operation of the Secretariat shall be supplied from the credits of the Ministry of Health and Medical Education.

## **Article ٧: Holding Meetings**

٧.١ The quorum for formal convention of committee meetings shall be half plus one of the total members of the National Committee (i.e. minimum ٧ people). The quorum for voting shall be two thirds of the present members.

- ٧.٢ Meetings shall be convened while observing highest levels of confidentiality and good will, and without any conflict or community of interests. At the beginning of each meeting, all members shall sign the forms for declaring conflict or community of interests with the projects and proposals being considered at that meeting.
- ٧.٣ The presence of the Chairperson or Secretary shall be requisite for the formal convention of meetings.
- ٧.٤ Written comments of the absent members may be presented in meetings in order to clarify points or discussions, but only members present in meetings may vote on decisions. Written comments of the absent members shall be recited during the meeting and appended to the minutes thereof.
- ٧.٥ Meeting minutes of the National Committee shall include:
١. Complete date (day, month and year), time and length of the meeting, venue, name and surname of the individual preparing the minutes, as well as names, surnames and titles of the present and absent members;
  ٢. Projects and issues being considered, recommendations, details of discussions and decisions, and the comments of all members, including those in favor and opposed; and
  ٣. Names, surnames, positions and scientific degrees of present committee members to be signed by them.
- ٧.٦ All meeting minutes shall be prepared by the Chairperson or Secretary, and signed by the participants therein.
- ٧.٧ All minutes and decisions shall be kept in the Secretariat of the National Committee for a minimum period of ten years.

## **Article ٨: Processing Complaints**

Reports of academic committees and complaints regarding decisions of such committees may be considered by the National Committee within ٩٠ working days after their submission, and the results communicated accordingly.

**Section ٣:**  
**Academic Committees for Ethics in Biomedical Research**

**Article ٩: Competences**

- ٩.١ Considering and approving the establishment of organizational committees;
- ٩.٢ Processing complaints regarding decisions of organizational committees;
- ٩.٣ Responding to inquiries of, supporting and empowering organizational committees;
- ٩.٤ Supervising the activities of organizational committees;
- ٩.٥ Planning and empowering faculty members, researchers and students in regard to research ethics;
- ٩.٦ Considering and approving ethical validity of proposals in regard to cloning, cell therapy, stem cells, and international studies;
- ٩.٧ Considering proposals referred thereto by organizational committees, on the grounds of conflict or community of interests;
- ٩.٨ Preparing and implementing strategic and operational programs to promote research ethics in the university; and
- ٩.٩ Dissolving organizational committees that fail to observe the required standards and regulations in their performance.

**Note ١:** An academic committee may delegate its jurisdiction for considering proposals to one or more competent organizational committees; and

**Note ٢:** In universities type II and III that lack the capacity for establishing organizational committees, the responsibilities of such committees shall be fulfilled by the academic committee as well.

## **Article 10: Members**

10.1 An academic committee shall have nine members, as follows:

1. Chancellor of the university;
2. Research Deputy of the university;
3. A specialist in biomedical ethics;
4. A jurist (preferably holding a doctorate degree);
5. A member of clergy, familiar with biomedical ethics;
6. A specialist in biostatistics or epidemiology;
7. An unspecialized individual, representing the society; and
8. Two researchers in regard to clinical sciences, fundamental sciences, pharmaceutical sciences, dentistry, paramedicine, etc.

**Note:** Researchers with membership in academic ethics committees shall hold a degree of associate professor in a medical specialty.

10.2 At least two ladies shall be included among the members of each academic committee.

10.3 Upon the members' discretion, each committee meeting may also be attended by distinguished executives or clinical specialists, experts in non-medical fundamental sciences, owners or managers of pharmaceutical factories, developmental psychologists, relatives of psychological patients, officials responsible for children's affairs, including public bodies or NGOs, representatives from religious minorities or immigrants, and the like as advisors to provide their opinions without a voting right.

10.4 The university chancellor shall chair the relevant academic ethics committee.

10.5 The membership of individuals included the committee on the basis of their positions (juridical members) shall be terminated upon the termination of that position.

### **Article 11: Appointment of Members**

- 11.1 The mandates for members shall be issued by the Chairperson for an extendable period of three years.
- 11.2 Within two months after expiry of membership or resignation of a member, the Chairperson shall appoint a substitute for that member in accordance with the provisions of this guideline.

### **Article 12: Conditions for Membership**

- 12.1 Members shall pass the relevant research ethics training courses arranged by the competent official, and possess the required skills for analyzing affairs and communicating with others for team work purposes within the committee.
- 12.2 Members shall be aware of the conditions for membership and activity in committees, publication of their names and surnames, formalities, appointment, substitution, deposal, resignation, period of membership, conflict or community of interests, and other details, announce and sign their consent, and attend meetings in person.
- 12.3 The unspecialized member, as mentioned in paragraph 10.1.4 above shall not have been employed in a field directly related to medical affairs for the past ten years as a minimum, and shall not have a history of cooperation with biomedical research involving human participants as executor or colleague. Such members may be selected from among the retired.

### **Article 13: Secretariat**

- 13.1 The Research Deputy of the university shall be appointed as the Secretary for the relevant academic committee, as mandated by the university chancellor.
- 13.2 The responsibilities of the Secretariat shall include:
  - 1. Managing committee meetings in the absence of the Chairperson;



၂. Preparing the agenda, inviting members and recording their presence or absence, designating and inviting advisors, conducting correspondence, signing committee decisions, and obtaining signed forms for declaring conflict or community of interests from members; and
၃. Managing financial affairs of the committee.

### **Article ၁၄: Holding Meetings**

- ၁၄.၁ Committee members shall be allowed sufficient time to consider the relevant documents before meetings.
- ၁၄.၂ All members of academic ethics committees shall attend meetings in person.
- ၁၄.၃ The presence of the Chairperson or Secretary shall be requisite for the formal convention of meetings.
- ၁၄.၄ Meetings shall be convened while observing highest levels of confidentiality and good will, and without any conflict or community of interests.
- ၁၄.၅ Members of the committee shall declare their conflict or community of interests with the executor in charge, sponsor(s) or other executors of the research projects being considered. In such cases, that member shall be considered without a voting right for approving or rejecting that proposal, and shall leave the meeting when the proposal is being considered.

**Note:** All members shall sign the attached forms for declaring conflict or community of interests with the projects and proposals being considered at that meeting.

- ၁၄.၆ The quorum for formal convention of committee meetings shall be half plus one of the total members of the committee (i.e. minimum ၀ people). The quorum for voting shall be two thirds of the present members.

**Note:** In case a meeting does not achieve the quorum for voting, the relevant proposal shall be voted on during the next committee meeting.

١٤.٧ All meeting minutes shall be prepared by the Chairperson or Secretary, and signed by the participants therein.

١٤.٨ Meeting minutes of the committee shall include:

١. Complete date (day, month and year), time and length of the meeting, venue, name and surname of the individual preparing the minutes, as well as names, surnames and titles of the present and absent members;
٢. Important identity information for decisions of organizational committees subject to complaints, including project identification code, complete title and type of the research, the executor's name, surname and organizational affiliation, and identification code and name of the authority approving the proposal or modifications thereto (decisions of organizational committees shall be mentioned in full);
٣. Other issues being considered, recommendations, details of discussions and decisions; and
٤. Names, surnames and scientific degrees of present committee members, along with their position in the committee to be signed by them.

١٤.٩ Comments in favor and opposed shall be recorded in the minutes and maintained with confidentiality.

١٤.١٠ Written comments of the absent members may be presented in meetings in order to clarify points or discussions, but only members present in meetings may vote on decisions. Written comments of the absent members shall be recited during the meeting and appended to the minutes thereof.

### **Article ١٥: Processing Complaints**

١٥.١ Proposals, claims, reports or complaints regarding the decisions of organizational committees shall be considered within ٧٠ working days after their submission, and the results communicated accordingly.

١٥.٢ Requests to and correspondence with the academic ethics committee shall be provided by the litigating executor in charge of projects, or the Chairperson or

Secretary of the organizational committee involved. The academic committee may request the executor in charge to respond to the inquiries by the committee.

١٥.٣ For any complaint considered and decided upon by an academic committee, a document including the following items shall be prepared:

١. Name and surname of the executor in charge, or the complaining party;
٢. Title and specifications of the proposal;
٣. Date of receiving the complaint;
٤. Summary of the complaint;
٥. Results of committee consideration as to approval or rejection of the proposal, or response to the complaint;
٦. Signature of the committee Secretary; and
٧. Names of committee members involved in the relevant consideration meeting.

١٥.٤ The decision of the academic committee on a complaint regarding the decision of an organizational committee shall be final and unobjectionable.

١٥.٥ Complaints regarding the decisions of the academic committee may be submitted to the National Committee, and the executor in charge or other beneficiaries of research projects may complain about the decisions made in regard to their respective proposal(s). The complaining party shall submit his/her written complaint to the Secretariat of the National Committee within ٣٠ working days from receiving the decision in question, along with the required documents, the committee's explanation in regard to the reasons for rejecting the proposal, and the appellant's response thereto.

## **Article ١٦: Budget**

The budget required for considering, assessing, holding meetings, attendance fees for members and other expenses of Secretariats of organizational committees shall

be supplied from ethical consideration tariffs of projects, funds of research projects and other credits of the relevant universities.

### **Article ۱۷: Reports**

۱۷.۱ Within six months after the end of each year (Iranian Calendar), each academic committee shall submit its annual report to the National Committee.

۱۷.۲ Annual reports subject to this article shall include:

۱. Names, surnames and affiliations of committee members;
۲. Number and dates of meetings;
۳. A list of considered projects, including their types and decisions on each (number of projects received for consideration, their types, and number of projects approved and rejected);
۴. Dates of reception and making final decisions on each application or complaint;
۵. Training courses for the committee and its members;
۶. Other issues and decisions;
۷. Progress reports on strategic and operational programs to promote research ethics; and
۸. Summary activity report on organizational committees supervised by that academic committee.

**Section 4:**  
**Organizational Committees for Ethics in Biomedical Research**

**Article 18: Establishment**

- 18.1 With the approval of the relevant academic committee, any organization with at least 30 researchers at master's or doctorate levels may proceed to establish an organizational ethics committee.
- 18.2 A number of research centers or institutes may jointly establish a single organizational ethics committee, with the approval of the relevant academic committee.
- 18.3 The Secretariat for organizational committees may be established at research centers or institutes, faculties or hospitals, if agreed by the highest official of that organization. Such committees shall only be established under this guideline to advance research ethics, and be independent from other committees and councils of that organization.
- 18.4 The organization shall provide the required space, equipment and official support to the relevant organizational committee.
- 18.5 The organization applying for the establishment of such a committee shall submit its application to the Chairperson of the relevant academic committee, along with the list of proposed natural and juridical members, and sufficient justification of the need for the establishment of that organizational committee. The academic committee shall consider the application and communicate its approval through the Chairperson of the academic committee if the required qualifications existed.
- 18.6 In universities type II and III, where the limited number of projects could not foster the required capacity for an organizational committee, the university may establish one ethics committee, in coordination with the National Committee, in order to fulfill all duties and responsibilities defined in this guideline.

## **Article 19: Competences**

Proposals for biomedical research projects subject to this guideline and not related to cloning, cell therapy, stem cells, and international studies shall be considered and approved by organizational ethics committees.

## **Article 20: Members**

20.1 An organizational committee shall have nine members, as follows:

1. Chief Executive Officer or Research Deputy of that organization or institute;
2. A member of clergy, familiar with biomedical ethics;
3. A jurist;
4. A specialist in biomedical ethics (holding a master's or doctorate degree in biomedical ethics, or if not possible, a researcher in biomedical ethics);
5. A specialist in biostatistics or epidemiology;
6. Three researchers (holding a degree of associate professor in clinical sciences, fundamental sciences, pharmaceutical sciences, dentistry, paramedicine, etc.); and
7. An unspecialized individual, representing the society.

20.2 At least one lady shall be included among the members of each organizational committee.

20.3 Advisors to parties related to research projects, such as distinguished executives or clinical specialists, experts in fundamental sciences and agriculture, owners or managers of pharmaceutical factories, developmental psychologists, relatives of psychological patients, officials responsible for children's affairs, including public bodies or NGOs, representatives from non-medical universities, and the like may attend committee meetings and provide their opinions without a voting right.

## **Article 21: Appointment of Members**

21.1 The head of an organization shall chair the relevant organizational committee, under a mandate issued by the Chairperson of the relevant academic committee.

**Note** 1: In organizations not subordinate to a university, the mandate for the organizational committee Chairperson shall be issued through the required process by the Chairperson of the National Committee, and the organizational committee shall operate under an academic ethics committee covering the relevant geographical area.

21.2 Within two months after expiry of membership or resignation of a member, the Chairperson shall appoint a substitute for that member in accordance with the provisions of this guideline.

## **Article 22: Conditions for Membership**

22.1 Membership in organizational committee shall be for an extendable period of three years.

22.2 The unspecialized member, as mentioned in paragraph 20.1.4 above shall not have been employed in a field directly related to medical affairs for the past ten years as a minimum, and shall not have a history of cooperation with biomedical research involving human participants as executor or colleague. Such members may be selected from among the retired.

22.3 A member's infraction from ethics committee regulations may result in his/her removal from the committee by the Chairperson through a majority vote of the members.

22.4 Members shall possess the professional and scientific degrees and rankings (officially documented) as required by this guideline.

22.5 To the extent possible, members shall be distinguished individuals in the field of research ethics, and sufficiently interested in biological ethics and participation in the related activities.

- २२.६ Members shall pass the relevant research ethics training courses arranged by the competent official, and possess the required skills for analyzing affairs and communicating with others for team work purposes within the committee.
- २२.७ Members shall announce their consent for the publication of their names, surnames and positions in the minutes, decisions, reports, etc. of the committee.
- २२.८ Members shall accept their duties and the conditions for their membership and activity in committees, and committee meetings shall be convened while observing highest levels of confidentiality and good will, and without any conflict or community of interests.

#### **Article २३: Secretariat**

२३.१ For the optimal performance of the organizational committee, the Chairperson shall appoint an individual familiar with ethical considerations related to biomedical research as Secretary.

२३.२ The responsibilities of the Secretariat shall include:

१. Managing committee meetings in the absence of the Chairperson;
२. Preparing the agenda, inviting members and recording their presence or absence, designating and inviting advisors, conducting correspondence, signing committee decisions, and obtaining signed forms for declaring conflict or community of interests from members; and
३. Managing financial affairs of the committee.

**Note:** The Secretary shall possess a voting right in committee meetings if s/he is also a member of the committee.

२३.३ The Secretariat of an organizational ethics committee shall receive applications for procedure from executors in charge of research projects, or their legal representatives. The organizational ethics committee may request the executor in charge to respond to the inquiries by the committee.



## **Article ٢٤: Holding Meetings**

- ٢٤.١ All members of organizational ethics committees shall attend meetings in person. The presence of the Chairperson or Secretary shall be requisite for the formal convention of meetings.
- ٢٤.٢ Committee members shall be allowed sufficient time to consider the relevant documents before meetings. Any modifications shall be approved by the ethics committee and communicated to the executor in charge.
- ٢٤.٣ The quorum for formal convention of committee meetings shall be half plus one of the total members of the committee (i.e. minimum ٥ people). The quorum for voting shall be two thirds of the present members.
- ٢٤.٤ All meeting minutes shall be prepared by the Chairperson or Secretary, and signed by the participants therein. Meeting minutes of the committee shall include:
١. Complete date (day, month and year), time and length of the meeting, venue, name and surname of the individual preparing the minutes, as well as names, surnames and titles of the present and absent members, and number of approved and rejected projects;
  ٢. Important identity information for decisions of organizational committees subject to complaints, including project identification code, complete title and type of the research, the executor's name, surname and organizational affiliation, and identification code and name of the authority approving the proposal or modifications thereto in full. In case the research project is a student thesis, the minutes shall include the academic level, as well as the names and surnames of the student and advising professor involved;
  ٣. For projects already considered in previous meetings, and referred to the committee again, the information required by paragraph ٢٤.٤.٢ shall be supplemented by date and number of such previous meetings;

- ξ. Ethical topics, conditions, recommendations and decisions of the committees, as well as the comments in favor and opposed for each project;
  - ο. Other issues being considered, including the topics and decisions; and
  - ϖ. Members' names, surnames and positions in the committee to be signed by them.
- ϣξ.ο All documents and evidences provided by the executors in charge, as well as the minutes and reports received shall be kept by the committee for a minimum period of ten years.

#### **Article ϣο: Considering Projects**

- ϣο.1 Proposals shall be submitted to the organizational ethics committee for consideration, by the executors in charge or the Research Deputy of the organization on their behalf.
- ϣο.2 Proposals, claims, reports or complaints regarding the decisions of organizational committees shall be considered within ξο working days after their submission, and the results communicated accordingly.
- ϣο.3 Members of the committee shall declare their conflict or community of interests with the executor in charge, sponsor(s) or other executors of the research projects being considered. In such cases, that member shall be considered without a voting right for approving or rejecting that proposal.

**Note 1:** Proposals whose executor in charge is a member of the organizational committee shall not be considered by that committee, but referred to another organizational committee for consideration.

**Note 2:** All members shall sign the attached forms for declaring conflict or community of interests with the projects and proposals being considered at that meeting.

- २०.६ Rejection of a proposal, or decisions on its modification or correction, shall be informed to relevant executor in charge, accompanied by the reasons therefor.
- २०.७ The executor in charge may submit the proposal to the organizational committee for reconsideration, once the required modifications have been implemented.
- २०.८ In case modifications occur in the proposal after its being approved by the ethics committee, the executor in charge shall be responsible for informing the relevant organizational committee accordingly.
- २०.९ Written comments of the absent members may be presented in meetings in order to clarify points or discussions, but only members present in meetings may vote on decisions. Written comments of the absent members shall be recited during the meeting and appended to the minutes thereof.
- २०.१० For multicenter research projects conducted in more than one university, the proposal shall be approved by a minimum of two organizational committees involved.

**Note:** For multicenter research projects conducted under the jurisdiction of one university, approval of the proposal by one organizational committee shall suffice.

- २०.११ In order to expedite the process of response to applying project executors, the organizational ethics committee may establish a working group for preliminary consideration and screening of the proposals submitted thereto.
- २०.१२ The working group mentioned in paragraph २०.११ above shall comprise three individuals, appointed and mandated by the committee Chairperson, one of whom shall be appointed in charge of the screening working group, in order to coordinate the activities and prepare meeting minutes.
- २०.१३ The members of the screening working group shall study and consider all submitted proposals, and report to the committee Secretariat within three weeks after their reception date.

٢٥.١٢ For projects including observation, fundamental sciences, management, and the like, the organizational meeting may proceed to issue ethics decisions and inform the executors accordingly.

**Note:** Clinical trials shall be considered and approved by the organizational committee, and the mere approval of the screening working group shall not suffice for issuing the ethics decision.

٢٥.١٣ All decisions of the screening working group shall be considered and approved at the first meeting of the organizational ethics committee.

٢٥.١٤ For each proposal considered by the organizational committee, an ethics decision shall be issued by the committee and communicated to its executor in charge.

٢٥.١٥ The ethics decision of an organizational committee for each proposal shall include:

١. Details of the organizational committee issuing the decision;
٢. Names, surnames and personal details of the project sponsor and executor in charge;
٣. Identification code of the committee decision;
٤. Project title;
٥. Submission date of the proposal final version;
٦. Consideration date;
٧. Committee consideration results (approval or rejection);
٨. List of documents considered by the committee, in addition to the proposal;
٩. Any explanations for pursuit and submission of the required reports during the project execution;
١٠. Reminding the executor in charge about the necessity for reporting any serious and possibly lethal side effects observed during project

execution to the ethics committee and other relevant authorities. Unawareness of this requirement shall certainly not relieve the executor in charge of such responsibility; and

۱۱. Signature of the committee Chairperson or Secretary.

### **Article ۲۶: Budget**

The budget required for considering, assessing, holding meetings, attendance fees for members and other expenses of Secretariats of organizational committees shall be supplied from ethical consideration tariffs of projects, funds of research projects and other credits of the relevant universities or organizations.

### **Article ۲۷: Reports**

۲۷.۱ Within four months after the end of each year (Iranian Calendar), each organizational committee shall submit its annual report to the relevant academic committee, with a carbon copy to the National Committee.

۲۷.۲ Annual reports subject to this article shall include:

۱. Names, surnames, affiliations and positions of committee members;
۲. Presence/absence status of committee members in meetings;
۳. Number and dates of meetings;
۴. A list of considered projects and decisions as the approval or rejection of each;
۵. Dates of reception and making final decisions on each application;
۶. Training courses for the committee and its members;
۷. Other issues and decisions;
۸. Analysis of the committee's annual performance;

9. Annual budget and expenditure of the committee; and
10. Progress reports on strategic and operational programs to promote research ethics; and
11. Other committee activities.

**Section ๑:**  
**General Principles Governing Ethics Committees for Biomedical Research**

**Article ๒๘**

Ethics committees shall consider, supervise, comment or advise on research proposals involving human participants, or regarding or affecting human health, with complete justice and impartiality, in compliance with the provisions of the present guideline, as well as the regulations and instruments governing it. Proposals for all medical research projects involving human participants shall be submitted for approval to organizational or academic ethics committees. Obtaining such an approval from ethics committees shall be the responsibility of the executor in charge, and failing to obtain the approval shall be construed as research misconduct on the part of the executor in charge, resulting in cessation of the project execution or publication of the results thereof at any stage.

**Note:** Until especially relevant regulations and guidelines are developed and communicated, consideration and approval of research projects not involving human participants (including research on animal samples, etc.) shall depend on the discretion of ethics committees.

**Article ๒๙**

In designing and executing research projects, the parties involved shall duly consider established research ethics norms, especially respect for human essential dignity; non-discrimination toward special groups; attention and sensitivity for vulnerable groups; possible benefits and damages of the project for participants and other individuals, living creatures and environment; fair distribution of possible benefits and damages of the project; confidentiality of participants' information and secrets; respect for individuals' privacy and civil rights; respect for participants' informed decisions, and abstention from threatening or coercing them; and all ethical codes and guidelines approved by the Ministry of Health and Medical Education. The reasonable expected benefits resulting from the research project shall outweigh its damages, and such benefits and damages shall justly and

equally affect all beneficiaries, including participants and society. In case the project benefits cannot be ascertained, the damages resulting from the project shall be slight or negligible, as assessed by the relevant ethics committee. Participants shall cooperate with research projects voluntarily and in full consent. Moreover, highest degrees of confidentiality shall be observed for executing and reporting results of research projects. In order to safeguard human dignity, the approving ethics committee shall continuously supervise the project throughout its execution, and may absolutely or conditionally terminate its approval for project continued execution, publication of its findings or application of its achievements, if the committee at any time discovers that the research team has violated the ethical conditions mentioned in the ethics decision, or new conditions need to be considered.

#### **Article ۳۰**

In considering and approving research proposals, ethics committees shall ensure compliance with the following requirements:

۱. Research ethics codes and criteria (whether general or special) before, during and after the completion of project execution, as well as when submitting articles or publishing results;
۲. Establishment of effective verbal and operational communication among all parties involved in the research project, with due consideration to ethnic diversity of the Iranian population;
۳. Approval of a competent scientific authority;
۴. Scientific competence of executor in charge and other members of research team;
۵. Ethical principles applicable to researchers and sponsors, such as declaration of any conflict or community of interests;
۶. Exemption of participants from any charges for their mere participation or cooperation in the research project;



- ∪. Complete confidentiality in executing and reporting results of the project;
- ∧. Research conditions for vulnerable groups; and
- ∩. Compensating damages from the beginning of the project.

Through an official and valid contract, the executors, sponsoring organization or a domestic insurance company shall undertake the compensation of damages resulting from the project, and submit the documents thereof to the relevant ethics committee as annexed to the research proposal.

#### **Article ۳۱**

Academic and organizational ethics committees shall obtain the required scores in the evaluation process conducted by the National Committee.

#### **Article ۳۲**

All academic and organizational ethics committees shall be registered with the Secretariat of the National Committee and receive an official license.

#### **Article ۳۳**

In order to achieve their objectives, ethics committees may directly or indirectly contact participants, researchers, sponsors, officials, health organizations and relevant experts.

#### **Article ۳۴**

Ethics committees shall consider and decide upon proposals submitted thereto, or alterations to an approved proposal from an ethical viewpoint in a timely and independent manner. In case the approval of the ethics committee depends on consideration and verification of the scientific nature of the project, the committee may include the opinion of a competent scientific authority in its considerations.

Absence of an explicit approval shall be construed as rejection. Committee approvals shall be unconditional. Committees may request alterations in proposals to be approved. The proposal shall be approved by the committee once the requested alterations have been implemented by the executor in charge. Committees shall decide independently from any political, organizational, professional or economic influence, and without conflict or community of interests in any form. The above mentioned requirements shall be implemented in accordance with relevant articles, and commensurate to the level of the ethics committees.

### **Article ۳۵**

Any member of an ethics committee, participant, researcher or official of health-related services shall report any possible deficiency or shortcoming observed in health-related research projects, or affecting it or other research involving human participants, to the Chairperson of the approving ethics committee. The committee shall then proceed to relay the report to the competent official.

**This guideline in ۳۵ articles was communicated in April ۲۰۱۴ by the Minister of Health and Medical Education of the Islamic Republic of Iran.**

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