

# Ajou University Institutional Bioethics Committee Operating Rules

Established: September 17, 2013

## Article 1. Purpose

The purpose of this regulation is to establish and operate the Institutional Bioethics Committee (IBC) of Ajou University, which is installed under the “Act on Bioethics and Safety” (hereinafter referred to as the “Bioethics Act”).

## Article 2. Scope of Application

This regulation applies to research projects conducted by members of the university (excluding the medical school) and members of institutions that have signed an agreement with the university.

## Article 3. Functions

1. The IBC shall review the following matters for human subject research (including research using human-derived materials, research using embryonic stem cell lines, and research using information that can identify individuals):
  - (1) Ethical and scientific validity of the research proposal
  - (2) Whether or not consent is obtained from research subjects in accordance with the legal procedures
  - (3) Safety of research subjects
  - (4) Personal information protection measures for research subjects
  - (5) Other matters related to bioethics and safety of research
2. The IBC may investigate and supervise the progress and results of research being conducted at the university.
3. In addition to the above two paragraphs, the IBC may perform the following activities for bioethics and safety:
  - (1) Education for researchers and staff of the university
  - (2) Establishment of protection measures for vulnerable research subjects
  - (3) Development of ethical guidelines for researchers
  - (4) Other matters related to bioethics and safety
  - (5) Matters necessary for the operation of the committee

## Article 4. Status

1. The IBC shall maintain independence in its operation and receive administrative and financial support for this purpose.
2. The IBC shall register with the Minister of Health and Welfare and receive supervision and support from the National Bioethics Review Committee and the Minister of Health and Welfare in

accordance with the Bioethics Act.

#### **Article 5. Composition**

1. The committee shall be composed of at least five members, including a chairperson, and shall not be composed of only one gender. At least one member shall have experience and knowledge in evaluating the social and ethical validity of research, and at least one member shall not be employed by the university.
2. In addition to the members, the committee may have a reserve member to replace the members who are absent from the meeting due to the provisions of Article 7 or unavoidable reasons, and to supplement the expertise.
3. The members of the committee (including the reserve members) shall be appointed by the President (the members of the university shall be appointed), and the chairperson shall be elected by the members.
4. The committee shall have a full-time professional secretary who is well-versed in the relevant knowledge and a few office assistants to handle the administrative affairs and assistance of the committee, and the President shall appoint them.

#### **Article 6. Term of Office**

1. The term of office of the members (including the reserve members) shall be two years, and they may be reappointed.
2. The term of office of a member who is newly appointed due to resignation or other vacancies shall be the remaining term of the predecessor.
3. Even if the term of office expires, the term of office of the member shall be deemed to be extended until the successor is appointed.

#### **Article 7. Disqualification, objection, and avoidance of members**

1. A member shall be disqualified from the relevant review and decision if he or she falls under any of the following items:
  - (1) If the member or his or her spouse or former spouse is involved in the research, development, or use that is the subject of review.
  - (2) If the member has or had a family relationship with the applicant in the matter at hand.
  - (3) If the member has or had been involved as a representative of the applicant in the matter at hand.
2. The person subject to review and decision may file a request for objection if there are special circumstances that make it difficult to expect fairness from the member.
3. If the member himself or herself believes that he or she falls under the reasons of Paragraph 1 or Paragraph 2, or that there are reasons that make it difficult to have a fair review, he or she may avoid the review and decision of the matter.

## **Article 8. Meetings**

1. The committee shall hold regular meetings at least once a month.
2. The chairperson shall convene an extraordinary meeting in the following cases:
  - (1) When the president requests a meeting
  - (2) When at least one-third of the regular members (excluding reserve members) request a meeting
  - (3) When the chairperson deems it necessary
3. At least one member who is not affiliated with the university shall attend the meeting of the committee. The committee shall decide by a majority vote of the regular members present and a majority vote of the present members. The number of regular members is calculated excluding reserve members.
4. Reserve members may participate in meetings and decisions in place of members who are absent due to Article 7 or unavoidable reasons.
5. The chairperson shall preside over the meeting, and if the chairperson is unable to preside over the meeting, the senior member of the university-affiliated attending members shall preside over the meeting.

## **Article 9. Minutes**

1. The minutes shall record the progress and results of the committee's meetings, and shall be signed and kept by the chairperson and all present members.

## **Article 10. Consultation and Opinion-Gathering**

1. The committee may, if necessary, consult with an advisory member appointed by the chairperson. However, advisory members may not participate in the decisions of the committee.
2. The committee may also request advice from reserve members who do not participate in the decisions and gather their opinions.

## **Article 11. Budget, Settlement, and Expense Standards**

1. The budget and settlement of the committee shall be in accordance with the budget and accounting regulations of the university.
2. The research principal who requests the review of the research plan shall pay the progress costs (review fee, review fee, and certificate fee) of the research plan by research plan according to the standard.
3. The members of the committee may be paid the necessary expenses such as allowances and travel expenses within the scope of the budget.

## **Article 12. Compliance with Secrecy**

1. Members and persons involved in the review shall not disclose any secrets that they have learned

in the course of their duties.

#### **Article 13. Handling of Administrative Affairs**

1. The chairperson shall be responsible for the overall administrative affairs necessary for the performance of the committee's duties under Article 3 (Functions). However, the chairperson may delegate the authority to make decisions to the professional secretary for the following matters:
  - (1) Request for payment of expenses related to the committee and processing of income expenses related to the review (up to 1 million won)
  - (2) Document classification, storage, and control
  - (3) Management of office assets
  - (4) Other matters delegated by the chairperson
2. The chairperson shall report to the president on matters that are necessary for the operation policy of the committee or that are particularly important.
3. If any matter requiring cooperation with other departments on campus occurs during the committee's work, it shall be implemented with the cooperation of that department.

#### **Article 14. Application**

1. Matters not specified in this regulation shall be applied to the Bioethics Act, the Enforcement Decree of the Bioethics Act, and the Enforcement Rules of the Bioethics Act.

#### **Article 15. Operating Standards**

1. The committee's operating standards shall be determined by separate standards.

### **Supplementary Provisions**

**Article 1. Effective Date** This regulation shall come into effect on September 17, 2013.

**Article 2. Transitional Provision** Matters that have been implemented before this regulation shall be deemed to have been implemented in accordance with this regulation.