

Regulations on the Operation of the Institutional Review Board

Established October 22, 2014

Article 1 (Purpose) These regulations seek to review the ethical and scientific validity of human subject researches at POSTECH (hereinafter referred to as “University”) in order to secure bioethics and safety, and to guarantee the rights and safety of research subjects by forming an Institutional Review Board (hereinafter referred to as IRB), and to regulate matters required for composing and operating the IRB.

Article 2 (Scope of Application) The operation of the IRB and review of human subject or human-derived materials research shall follow these regulations.

Article 3 (Definition) The terms used in these regulations shall be defined as follows:

1. “Research” shall mean a systematic investigation including developing a generalizable knowledge or research, tests, or evaluations designed to contribute thereto.
2. “Human subject research” shall mean research performed by physical intervention or interaction such as communication or personal contact, or research using personal identification information.
3. “Human-derived materials research” shall mean research which directly investigates and analyzes materials derived from human bodies.

Article 4 (Composition) ① The IRB shall be composed of five to 15 members, including a chairperson. However, the members must include both genders.

② The chairperson shall be elected by mutual vote among members.

③ Members shall be appointed by the President of the University, and must include one or more members from each following category:

1. A person with abundant research experiences and professional knowledge in bioscience, medicine, or human subject research.
2. A practitioner in a field besides bioscience or medicine who can evaluate the ethics, scientific validity and social effects of human subject research.
3. A person not working at the University who can represent the public interest regarding bioethics and safety.

④ Members must not participate in reviews where the members have an interest in the subject under review, and must not reveal or plagiarize confidential information obtained while on duty.

Article 5 (Duties of Chairperson) ① The chairperson shall represent and direct overall matters of the IRB.

② If the chairperson cannot perform his duty due to unavoidable circumstances, a member designated by the chairperson shall perform duties thereof on behalf of the chairperson.

③ The chairperson may request information to the principal research staff and the research client if additional information is necessary to protect the rights, safety and welfare of research subject

④ The chairperson must prevent the principal research staff and the research client from affecting the members of the IRB and from participating in the decision-making process of relevant biomedical research.

⑤ The chairperson must provide a standard operating guideline after deliberation by the members of the IRB to efficiently and consistently review the items in Article 7, Clause 1.

Article 6 (Term) ① The IRB members shall serve for two years, but may be reappointed.

② The term of a supplementary member designated when a vacancy occurred due to the resignation of a member or for other reasons shall be the remaining term of the predecessor.

Article 7 (Functions) The IRB shall have the following functions:

1. Review of the following items:

- a. Bioethical and scientific validity of research plan
 - b. Whether consent was received from research subjects, etc. through a legitimate process
 - c. Matters related to the safety of research subjects, etc.
 - d. Measures to protect the personal information of research subjects, etc.
 - e. Other matters related to bioethics and safety in the institution
2. Investigate and direct the progress and results of research performed on campus.
 3. Other activities related to bioethics and safety, such as:
 - a. Educate researchers and practitioners
 - b. Establish measures to protect vulnerable research subjects, etc.
 - c. Provide a guideline on ethics for researchers

Article 8 (Assembly and Decision) ① The IRB shall hold a meeting if the chairperson acknowledges that it is needed or if the President of the University or more than 1/3 of incumbent members request a meeting.

② The IRB meeting shall begin when a majority of incumbent members are present, and a decision must require a majority vote of the attendees. If there is a tie, the chairperson shall make a decision.

③ The chairperson must take measures so that the researcher of the research under review cannot be involved in the decision making of the IRB. If required, however, the researcher can submit explanatory materials to the IRB or the researcher's opinion stated at the meeting may be referred to.

④ If the chairperson acknowledges that an item for review is minor, a vote in writing is possible. Provided, however, that the result of a vote in writing is reported in the next IRB meeting.

⑤ If a previously approved research plan is determined to be seriously hazardous to the safety of members of POSTECH and the environment, the chairperson should revoke approval by the decision of the IRB.

⑥ If necessary in performing the functions of IRB, an opinion from a relevant professional can heard at the meeting.

⑦ A meeting where external members are not present is invalid.

Article 9 (Meeting Process) For efficiency, the chairperson may distinguish items for review into rapid review, regular review, continuous review and arbitrary decision by chairperson and provide separate review processes.

Article 10 (Advisory Members) ① If advice is needed when reviewing items of the Committee, the IRB may have advisory members in accordance with appointment by the chairperson.

② Advisory members shall not vote.

Article 11 (Secretary) ① The IRB shall have a professional secretary and an administrative secretary taking care of the general affairs of the IRB; the professional secretary shall be appointed by the chairperson among members.

② The professional and administrative secretaries shall take minutes of decision proceedings and review results, and keep the minutes after getting signatures and seals from the chairperson and attendees.

③ The administrative secretary shall be the Director of Research Planning.

Article 12 (Subcommittee, etc.) ① If necessary, a subcommittee or a professional committee may be created under the IRB to efficiently perform the duties thereof.

② The matters necessary for establishing and operating a subcommittee or a professional committee shall be determined by the chairperson after deliberating with the IRB.

Article 13 (Allowance, etc.) Allowances and expenses that are within the budget may be given to external members who attended the IRB, advisory members, and related parties who participated to listen to opinions.

Article 14 (Review Expense Obligation) The IRB may obligate the researcher to pay part of the expenses needed for review.

Article 15 (Operation Details) Details required for operation, etc. not defined in these regulations shall be

stipulated separately after going through review by the IRB.

Addenda

1. (Effective Date) The present regulation shall be established and take effect on October 22, 2014 following approval by the President of the University.
2. (Interim Measures) These regulations shall be applicable to ongoing research.