

Regulations on Biosafety Management

Established October 22, 2014

Chapter 1 General Provisions

Article 1 (Purpose) These regulations establish matters necessary for biosafety management in general, and operation and composition of Institutional Biosafety Committee (hereinafter referred to as “IBC”) in order to evaluate the biosafety of research on possibly hazardous living organisms performed within POSTECH (hereinafter referred to as the “University”) so that medical and bioscience research can be carried out safely and efficiently.

Article 2 (Scope of Application) Apart from matters specifically stated in Transboundary Movement, etc. of Living Modified Organisms Act and the integrated announcement of the same Act, risk assessment of possibly hazardous living organisms and operation of the IBC shall comply with these regulations.

Article 3 (Definitions) The definitions of terms used in these regulations are as follows:

1. The term “possibly hazardous living organism” means a genetically modified organism or biological etiological agent (e.g., microorganism, virus or viroid) expected to include or known as a pathogen.
2. The term “genetically modified organism” means an organism including newly combined genetic materials using modern biotechnology as stated below.
 - a. A technology which artificially rearranges genes, or directly injects nucleic acid into cells or cell organelle.
 - b. A technology, as a cell fusion exceeding the boundaries of taxonomy, not used in natural biological proliferation or recombination, and not used in traditional cross-breeding or selection.
3. The term “risk assessment” means a process which scientifically and objectively assesses adverse effects on human bodies and the environment, the possibilities and seriousness, and the accompanying uncertainties of research using possibly hazardous living organisms, and which determines an appropriate sealing method.

Chapter 2 Institutional Biosafety Committee

Article 4 (Composition) ① The IBC shall be composed of five to 15 members, including a chairperson.

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

③ Members shall be appointed by the President of the University and must include one or more member from each item stated below.

1. A faculty member who majored in bioscience

2. An external personnel who majored in bioscience and does not have any stake in the University

④ Members shall not participate in reviews of subjects with a shared interest, and shall not reveal or plagiarize confidential information obtained while on duty.

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

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

Article 6 (Term) ① The term of IBC members shall be two years, and can be served consecutively.

② The term of a supplementary member designated at a vacancy due to the resignation of a member or for

other reasons shall be the remaining term of the predecessor.

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

1. Risk assessment of gene recombination experiments and other research, experiments, investigations and education plans concerned of biological hazards performed within the institution, and deliberation on approvals.
2. Educate and train institution members on biosafety
3. Establish and amend Regulations on Biosafety Management
4. Manage and supervise installation and operation of research experiment facilities using possibly hazardous living organisms
5. Manage and supervise gene recombination experiments and all other experiments where biological hazards are concerned
6. Discuss other matters on how to obtain biosafety within the institution

Article 8 (Assembly and Deliberation) ① The IBC shall hold a meeting when the chairperson acknowledges its necessity, or the President of the University or more than 1/3 of incumbent members request a meeting.

② The IBC meeting shall open when a majority of incumbent members are present, and a decision shall require the majority vote of the attendees. In the case of a tie, the chairperson makes a decision.

③ The chairperson must take measures to prevent involvement of the researcher of research under review in the decision making of the IBC. However, if necessary, the chairperson may request the researcher to submit explanatory materials to the IBC or to attend and refer to opinion statement.

④ If the chairperson acknowledges that an item for review is trivial, it may be decided in writing. However, the result of the decision must be reported in the next IBC meeting.

⑤ If the chairperson decides a previously approved research plan is seriously hazardous to the safety of members of the University and the environment, he/she must revoke the approval following deliberation of the IBC.

⑥ If necessary in performing the functions of the IBC, opinion from a relevant professional may be heard in the meeting.

Article 9 (Procedure of Meeting) The chairperson may distinguish items for review into rapid review, regular review, continuous review and arbitrary decision by the chairperson and provide separate review processes for efficient review.

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

② Advisory members shall not vote.

Article 11 (Secretary) ① The IBC shall have a secretary taking care of the general affairs of the IBC; the secretary shall be the Director of Research Planning.

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

Article 12 (Allowance, etc.) Allowances and expenses within the budget may be given to external members who attended the IBC, and advisory members and related parties who participated to listen to opinions.

Article 13 (Review Expense Obligation) The IBC may obligate the researcher to pay part of the expenses needed for review.

Chapter 3 Biosafety Management

Article 14 (Biosafety Managing Officer) ① The IBC shall appoint a Biosafety Managing Officer in charge of operating and managing facilities related to biosafety in the University.

② The Biosafety Managing Officer shall be in charge of the following:

1. Implementation and supervision of biosafety compliance
2. Biosafety education and training
3. Investigation and reports on laboratory biosafety accidents
4. Other duties related to securing biosafety in the University

Article 15 (Biosafety Manager) ① The IBC may appoint a Biosafety Manager who assists the Biosafety Managing Officer.

② The Biosafety Manager shall be in charge of the following:

1. Practical affairs related to biosafety education and training
2. Practical affairs related to investigation and reports on laboratory biosafety accidents
3. Practical affairs related to other duties for securing biosafety at the University

Article 16 (Duties of Principal Research Staff and Research Staff) ① A principal research staff and a research staff among researchers at the University who are conducting or want to conduct experiments determined by related legislation must do so after reporting their research plan to the IBC in accordance with a predetermined process and gaining approval for the research and experiments.

② The principal research staff and research staff in Paragraph 1 must comply with the Regulations on Biosafety Management and related regulations, and must complete the education provided by the IBC.

③ The principal research staff and research staff in Paragraph 1 must possess the knowledge necessary to prevent biosafety accidents, and perform risk assessment of, manage, and supervise relevant experiments.

Article 17 (Operation Details) Details required for operation etc. but not specified in these regulations shall be stipulated separately by the chairperson after review by the IBC.

Addenda

1. (Effective Date) These regulations shall be established and take effect on October 22, 2014.
2. (Interim Measures) These regulations shall be applicable to ongoing researches.