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Regulations on the Institutional Review Board (IRB)

Enacted on 11/10/2015, Regulation No. 45

Wholly Amended on 07/14/2016, Regulation No. 82

Chapter 1. General Provisions

Article 1 (Name) This committee shall be referred to as the Ulsan National Institute of Science and Technology (UNIST) Institutional Review Board (UNIST IRB; hereinafter "Committee").

Article 2 (Purpose) The purpose of these Regulations is to establish the Committee to review the ethical and scientific validity of human materials research and human subject research conducted at UNIST and thereby ensure the bioethics and safety of research, protect the rights and safety of research subjects, and comply with relevant laws, and to prescribe the necessary matters regarding the composition and operation, etc. of the Committee.

Article 3 (Scope) Any review of research on humans and human materials, etc. and operation of the Committee shall be as prescribed herein unless otherwise stipulated in the Bioethics and Safety Act, the Enforcement Decree and Enforcement Rules of the same act, or the Korea Good Clinical Practice (KGCP) of the Rules on the Safety of Drug Products, etc. of the Ministry of Food and Drug Safety.

Article 4 (Definitions) The definitions of terms used herein shall be as follows:

1. "Research" means deduction of knowledge that can be generalized through systematic investigation, research and development, testing and assessment, etc. and all activities that contribute thereto.
2. "Human subject research" means research conducted with human subjects by

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physical intervention, communication, interpersonal contact, or other interaction, or research specified by Ordinance of the Ministry of Health and Welfare where personally identifiable information is used.

3. "Research subject" means a person who is a subject of human subject research.

4. "Human materials" means any tissue, cell, blood, body fluid, or other human component collected or sampled from the human body, or any serum, plasma, chromosome, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), protein, etc. isolated therefrom.

5. The definition of any other term shall be in accordance with the definitions prescribed by the associated laws, rules, and standards pursuant to Article 3.

Chapter 2. Functions of the Committee

Article 5 (Functions) ① The Committee shall perform the following functions:

1. Review matters corresponding to the following:

A. Ethical and scientific validity of research protocols;

B. Whether consent has been obtained from research subjects, etc. in accordance with legitimate procedures;

C. Matters regarding the safety of research subjects, etc.;

D. Measures to protect the personal information of research subjects, etc.;

E. Other matters regarding bioethics and safety.

2. Investigate and supervise the progress and results of research being conducted at UNIST.

3. Other activities to ensure bioethics and safety as follows:

A. Training the researchers and workers of the organizations concerned;

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B. Formulating measures to protect vulnerable research subjects, etc.;

C. Preparing ethical guidelines for researchers.

4. Prepare and manage a list of Committee members and documents stating their qualifications, meeting minutes, and documents regarding reviews.

Chapter 3. Committee Composition and Duties

Article 6 (Composition and Operation) ① The Committee shall consist of at least five and up to twenty members including one chair. It shall include members of both sexes, at least one person with the experience and knowledge to assess social and ethical validity, and at least one person who does not work for the organization concerned.

② Members shall be appointed (internally) or commissioned (externally) by the President, and the chair shall be elected from among the members.

③ The Committee shall have an expert administrative secretary to be in charge of the administrative affairs of the Committee such as receiving research protocols, preparing minutes, and implementing meetings.

④ The President shall ensure that the Committee is able to maintain independence and shall provide administrative and financial support.

⑤ Where any research conducted at UNIST is affected or is likely to be affected by any serious risk to bioethics or safety, the President shall immediately convene the Committee to review the matter and shall report the results thereof to the Minister of Health and Welfare.

Article 7 (Term in Office) ① Members shall be in office for a two-year term and may serve consecutive terms.

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② In the event of a vacancy due to the resignation of a member or any other grounds, a successor shall be appointed immediately. The term in office of the appointed supplementary member shall be the remaining term of the predecessor.

Article 8 (Duties of the Chair) ① The chair shall represent and oversee the affairs of the Committee.

② If the chair is unable to perform his or her duties due to unavoidable circumstances, a member determined by the Committee shall perform the duties on behalf of the chair.

③ If additional information is necessary to protect the rights and safety of research subjects, the chair may request the principal researcher to provide such information.

④ The chair shall ensure that any principal researcher is unable to influence Committee members or take part in any decision-making process for matters associated with the research concerned; provided that, when necessary, the researcher concerned may be requested to submit explanatory materials to or attend a review meeting so that his or her statement of opinion may be used as a reference.

⑤ The chair shall prepare a standard operating procedure (SOP) via Committee review to ensure the efficient and consistent review of matters pursuant to Article 5, paragraph 1.

Article 9 (Duties of the Expert Secretary) The expert secretary shall be appointed by the chair from among members with extensive experience, perform duties delegated by the chair, and oversee the expedited reviews of the Committee and the enactment and amendment of the standard operating procedure (SOP).

Article 10 (Duties of the Administrative Staff) ① The Committee shall appoint one administrative staff to ensure the smooth operation of the Committee.

② The administrative staff shall handle such matters as the administrative affairs of

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the Committee, receipt and preliminary consideration of matters for review, notification of review results, preparation for meetings, minute taking, recording and management of materials and documents, implementation and management of Committee-supervised education, and preparation of the standard operating procedure, researcher bioethics guidelines, and measures to protect research subjects.

Article 11 (Meetings and Voting) ① Meetings shall be convened and presided over by the chair in the event of any of the following:

1. When convocation is requested by the chair;
2. When convocation is requested by at least one-third of the registered members; and
3. Other cases where convocation is deemed necessary by the chair.

② The administrative staff shall notify each member of the date and time, venue, and agenda of the meeting at least five days prior to the date of the meeting; provided that members may be notified as late as one day prior to the meeting in the event of urgent and unavoidable circumstances.

③ A meeting of the Committee shall commence with attendance by a majority of the registered members and shall make decisions by majority vote of the members in attendance.

④ Meetings to review and assess research protocol shall take place in the presence of at least one non-affiliated member pursuant to Article 6, paragraph 1.

⑤ The chair may request any stakeholder or external expert to attend a meeting to present his or her opinions or provide a written statement regarding any matter submitted to the Committee.

⑥ The chair may convene a separate steering committee to discuss the operation and agenda of the Committee.

Article 12 (Member Exclusion and Avoidance) ① If a member falls under any of

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the following, the chair may exclude the member from reviewing or voting on the relevant matters for review:

1. If the member is involved in research, development, or use, etc. in regard to the relevant matters for review:

2. If the member is deemed to have any other conflict of interest in regard to the relevant matters for review.

② If a member falls under any of the subparagraphs of paragraph 1, he or she may voluntarily avoid reviewing or voting on the matter concerned.

Article 13 (Advisory Members) ① When advice from a subject matter expert is necessary in regard to a matter for review by the Committee, the chair may appoint advisory members; provided, however, that advisory members shall not participate in any vote.

② Advisory members shall not have a conflict of interest with any research or principal researcher subject to review, and shall not be invited to a review or provide written advice on condition of maintaining confidentiality.

Chapter 4. Review of Research Protocols

Article 14 (Review of Research Protocols) ① Any person who intends to engage in human subject research or human materials research shall prepare a research protocol and undergo a Committee review prior to engaging in the research.

② Notwithstanding paragraph 1, when there is only minor risk to research subjects, donors of human materials, and the public, any research that has been reviewed by the National Bioethics Committee and that meets requirements specified by the Ordinance of the Ministry of Health and Welfare may be exempt from Committee

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review.

③ Exemption from review pursuant to paragraph 3 shall be determined by the Committee.

④ A separate review procedure may be prepared as necessary to ensure the efficient review of research protocols.

⑤ When a potentially serious issue is recognized and confirmed with respect to any research activity or affairs that have been approved, measures such as temporary suspension or revocation of approval may be taken against the approved research, etc.

Chapter 5. Supplementary Provisions

Article 15 (Allowances) Members, stakeholders, and external experts may, within the limits of the budget, receive allowances, payments for expenses, etc. for attending Committee meetings, reviewing, providing advice, etc.

Article 16 (Confidentiality) All members of the Committee including the chair shall sign a confidentiality agreement prescribed by the Committee and submit it to the Committee prior to commencing their term of office. Any confidential information acquired during the course of the duties concerned shall not be disclosed or stolen.

Article 17 (Applicable Provisions) Any matter not prescribed herein shall be in accordance with the Bioethics and Safety Act and the Enforcement Decree, Enforcement Rules, etc. of the same Act.

Article 18 (Specific Matters) Specific matters not prescribed herein that are necessary for the operation of the Committee shall be determined by Committee review.

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Addenda (11/10/2015)

Article 1 (Enforced Date) These Regulations shall enter into force on the date the President grants approval.

Article 2 (Interim Measures) The essential matters of these Regulations shall also apply to research currently in progress.

Addenda (07/14/2016)

These Regulations shall enter into force on the date the President grants approval.