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Institutional Review Board (IRB) Standard Operation Guideline

CHAPTER 1 GENERAL PROVISIONS

Article 1 (Purpose) This guideline aims to define matters on organization and operation of institutional Review Board of SUNY Korea (hereinafter, referred to as 'Board') established according to the 「Bioethics and Safety Act」.

Article 2 (Definition of Terms) Definitions of terms used in this guideline are as follows.

1. 'Research' refers to systematic investigation including research and development, tests and assessments designed to develop generalizable knowledge or contribute thereto.
2. 'Research on human subject' refers to research carried out through physical intervention or through interaction such as communication or personal contact with people, or research using information capable of identifying individual.
3. 'Human research subject' refers to human being who becomes a subject of research on human subject.
4. 'Human derived materials' refers to human body components such as tissue, cell, blood or body fluid gathered or collected from human body, or serum, plasma, chromosome, DNA, RNA, protein or the like separated therefrom.
5. 'Research on human derived materials' refers to research directly investigating and analyzing human derived materials.
6. Other terms used in this guideline follow definitions stated in the 「Bioethics and Safety Act」.

Article 3 (Applicable Scope) Reviews on research on human subject and human derived materials and operation of Board follow the rules defined in this guideline unless there are special regulations in the 「Bioethics and Safety Act」.

CHAPTER 2 ORGANIZATION AND FUNCTION OF BOARD

Article 4 (Organization and Operation of Board) ① Board is organized with 5 or more members including 1 chairperson, shall not be organized with just one gender, and must include one or more members having experiences and knowledge to assess social and ethical validity and one or more members who are not employed by the institute.

② Members of the Board are appointed by the president of the University, and chairperson is elected among the members.

③ Term of members is 2 years and members can be reappointed.

④ Chairperson may appoint vice-chairperson among the members and have the vice-chairperson act for the chairperson during the absence of the chairperson.

⑤ Chairperson shall appoint professional secretary among the members.

⑥ Board has administrative secretary in charge of administrative work for receiving documents for review and
holding a meeting.

⑦ When necessary, Board may appoint advisors to listen to expert opinions. However, advisors cannot participate in the decision of Board.

⑧ Members and administrative secretary must maintain confidentiality on all information learned from Board.

⑨ When there is a conflict of interest regarding tasks and activities of Board, members must go public with this in advance.
⑩ For improving efficiency of Board operation, research on human subject board and research on human derived materials board may be combined and operated.

Article 5 (Board Meeting) Chairperson convenes Board meeting when corresponding to any one of the following:

1. When the president of the University requests for a meeting
2. When more than 1/3 of registered members of Board request for a meeting
3. Other cases when chairperson acknowledges the necessity

Article 6 (Function of Board) Board performs each of the following tasks.

1. Review of matters corresponding to each of the following:
    a. Ethical and scientific validity of research proposal
    b. Whether consent is obtained from human research subject and the like according to a lawful procedure c. Matters regarding safety of human research subject and the like
    c. Measures of privacy protection for human research subject and the like e. Other matters on bioethics and safety in the institute
2. Investigation and supervision on the process and results of research in progress in the corresponding institute
3. Other activities of each of the following for bioethics and safety
    a. Educate researchers and staff of the corresponding institute
    b. Establish measures for protecting vulnerable human research subject and the like c. Prepare ethics guideline for researchers

CHAPTER 3 REVIEW PROCEDURE AND TYPE

Article 7 (Application for Review) ① Researcher to conduct research on human subject shall submit documents of each of the following to Board for review. In this case, Board may request addition, correction or the like of materials depending on the type of research, etc..

1. Application form for review
2. Research proposal
3. Explanatory note for human research subject and consent form
4. Statement of reasons for exemption of written consent (when applicable)
5. Survey, various recording papers relating to research, etc.
6. Documents relating to human research subject recruit
7. Written oath on observance of bioethics

② Researcher to conduct research on human derived materials shall submit review documents of each of the following to Board. In this case, Board may request addition, correction or the like of materials depending on the type of research, etc.

1. Application form for review
2. Research proposal

3. Consent form for research on human derived materials (legal form)
4. Statement of reasons for exemption of written consent (when applicable)
5. Survey, various recording papers relating to research, etc.
6. Documents relating to human derived material donor recruit
7. Written oath on observance of bioethics

Article 8 (Decision) ① Meeting is opened with an attendance of majority of registered members, and decision is made with an approval of a majority of members in attendance. However, one or more members who are not employed by the institute need to attend to open a meeting, and even when these members are present, the decision is not effective if they do not participate in the decision.
② Members having a conflict of interest cannot participate in the decision for the corresponding review case.

Article 9 (Minutes) ① After meeting, Board needs to take and manage minutes including each of the following.

1. Date of meeting
2. Status of attendance: Names of attending members, List of members who do not participate in the vote due to reasons such as a conflict of interest, and the like
3. Report progress in review
4. Status of Vote: Number of participating members, Number of against/abstention, Reason for abstention
5. Review results and grounds
6. Matters discussed in meeting and solutions
7. Period of research approval
8. Whether consent form is exempted or not and its grounds
9. Whether conflict of interest is determined or not and its grounds
10. Other matters considered to require recording as matters discussed in meeting

② Minutes needs to be circulated to members before finalization, and finalized minutes must include signatures or seals of chairperson and professional secretary.

Article 10 (Notification of Review Result) Board shall review documents on research submitted by a lead researcher within the period set by Board, and record and keep name of research, reviewed documents, date of review, and review opinions according to the classification of each of the following, and shall notify the review result to the lead researcher in a written form.

1. Approval: Contents in research proposal accord with ethical and academic validity and there is no objection in conducting the research
2. Approval after correction: Minor correction or supplementation is required, and beginning of research is conditionally approved on the assumption that supplementation is made on time
3. Supplementation: There are problems in ethical or academic validity when conducting research, however, the problems can be solved by correcting research proposal
4. Return: Research cannot be conducted due to scientific and ethical problems

Article 11 (Raising of Objection) When a lead researcher has an objection on the decision of Board, the lead researcher may request re-review in a written form, and Board shall notify the result to the lead researcher in a written form.

Article 12 (Type of Review) ① Chairperson or professional secretary decides a method of review such as full review or expedited review based on review documents received.
② In principle, all new projects submitted to Board are subject to full board review.
③ Expedited review is expedited review delegating review authority of Board to two or more specific members regardless of full review meeting schedule, and expedited review is allowed for research having low risk, minor changes in research within the period of already approved research, cases corresponding to review on serious allergies, and continued review for research in progress as research initially approved by expedited review.
④ Research proposal having a research period of longer than 1 year is subject to continued review at least once a year.
⑤ When risks affecting human research subject, human derived material donor and the public are insignificant, review may be exempted, and in this case, the researcher shall submit application for review exemption to Board. However, research that may be subject to review exemption is limited to research defined in Article 13 and Article
33 of the 「Detailed Enforcement Regulations for Bioethics and Safety Act」.
⑥ When research in progress is conducted differently from Board requirements or decisions, or when unexpected serious risks occur to human research subject, Board may decide early termination or temporary stop of the corresponding research. In this case, Board shall immediately notify the decision and reasons thereof to the president of the University and the lead researcher.

CHAPTER 4 HUMAN RESEARCH SUBJECT PROTECTION AND CONSENT

Article 13 (Consent from Human Research Subject, etc.) ① Person to perform research on human subject shall obtain written consent including each of the following from human research subject before conducting research on human subject:

1. Purpose of research on human subject
2. Period, procedure and method of human research subject participation
3. Risks and benefits expected for human research subject
4. Matters on privacy protection
5. Compensation for loss caused by participation in research
6. Matters on providing personal information
7. Matters on consent withdrawal
8. Other required matters acknowledged by Board

② Person to conduct research on human derived materials shall receive 「Detailed Enforcement Regulations for Bioethics and Safety Act」 Form Annex 12 (consent form for research on human derived materials) from human derived material donor before research on human derived materials.
③ Despite Paragraphs 1 and 2, in the case of human research subject and human derived material donors who do not have ability for consent or are imperfect, written consent from a representative needs to be obtained. In this case, consent from the representative shall not be against the intention of the human research subject and the human derived material donor.
④ Despite Paragraphs 1 and 2, written consent from human research subject and human derived material

donor may be exempted with an approval of Board when conditions of each of the following are all satisfied. However, even in this case, written consent from a representative specified in Paragraph 3 is not exempted.

1. Obtaining consent from human research subject and human derived material donor is practically impossible in a research progress process or seriously affects research validity
2. There are no reasons to assume nonconcurrence from human research subject and human derived material donor, and risks affecting human research subject and human derived material donor are extremely low even when exempting consent

Article 14 (Protection for Human Research Subject, etc.) ① Researcher needs to assess physical and psychological influences research and research environments may have on human research subject in advance, and plan safety measures, and when research in progress has a possibility of causing serious malaise on individual and society, this shall be immediately reported to the president of the University and proper measures shall be made.
② When violation of rights of human research subject participated in already-approved research occurs or human research subject and the like participating in the corresponding research demand due rights, Board has responsibility of identifying the corresponding issue and instructing proper handling.

Article 15 (Provision of Personal Information, etc.) ① When written consent is obtained from human research subject regarding provision of personal information, researcher on human subject may provide the personal information to a third party through a review of Board.
② When researcher on human subject provides personal information to a third party according to Paragraph
1, it needs to be anonymized. However, this does not apply when human research subject agrees on including personally identifiable information.

Article 16 (Provision of Human Derived Materials, etc.) ① When written consent is obtained from human derived material donor regarding provision of human derived materials, researcher on human derived materials may provide the human derived materials to human derived material banks or other researchers through a review of Board.
② When researcher on human derived materials provides human derived materials to other researchers according to Paragraph 1, it needs to be anonymized. However, this does not apply when human derived material donor agrees on including personally identifiable information.

Article 17 (Record Keeping and Information Disclosure) ① Researcher shall record and keep matters relating to research.
② Human research subject may request disclosure of information of his/her own, and researcher receiving such request shall disclose the information unless there are special reasons.
③ Specific matters relating to record keeping and information disclosure follow related laws.