Article Content

Title： Regulations for Organization and Operation of Human Research Ethics Review Board CH

Amended Date： 2018-05-07

Category： Ministry of Health and Welfare（衛生福利部）

Article 1 These Regulations are set forth pursuant to Paragraph 3, Article 7 of the Human Subjects Research Act (referred to as “this Act” hereafter).

Article 2 The research institutions set out in Paragraph 2, Article 3 of this Act may set up at least one Institutional Review Board (hereafter referred to as “IRB”).
The aforesaid IRB may set up sub-groups (hereafter referred to as “sub-IRBs”) for operational purposes, and the IRB and sub-IRBs shall all be subject to inspections by the central authority in charge of the sector. The resolutions adopted at meetings of a sub-IRB shall be deemed as resolutions adopted at meetings of the IRB.
The research institutions set forth in Paragraph 1 include schools, hospitals, government agencies (or offices), statutory entities and associations.

Article 3 The research institutions shall establish rules on the selection criteria, procedures, term of appointment, duties, meeting procedures, the way of reaching a resolution, operation and other related matters for the IRB members.
The name and occupation of the IRB members and their relationship with the research institution shall be disclosed to the public and reported to the central authority in charge of the sector for recording purposes.

Article 4 When reviewing a research project, the IRB shall first of all make a general assessment of the objective of study, nature of study, relevance and degree of invasion of the data, information or specimens to be collected, etc. and then judge whether it fits the criteria for the exemption from the IRB review as provided in Paragraph 1, Article 5 of this Act or for expedited review or standard review as provided in Article 8 of this Act.

Article 5 The IRB shall set down and publish the standard operational procedures for reviewing a research project, including the extent of authority and the procedures of accessing or

extracting and using various types of documents, files and databases and the regular examination and review.

Article 6 When the IRB or a sub-IRB convenes a standard review meeting, the attending members shall include at least one member without a biomedical science background outside the institution.
For an IRB or sub-IRB that consists of at least five but less than seven members, a meeting shall not be held unless it is attended by at least two-thirds of the members; for an IRB or sub-IRB that consists of seven or more members, a meeting shall not be held unless it is attended by at least half of the members.
A meeting shall not be held if all attending members are of the same gender.

Article 7 An IRB shall comply with the following criteria:
1. The IRB members, the administrative staff and expert advisors shall sign an agreement of confidentiality.
2. The IRB members and the administrative staff shall receive regular education and training.
3. It shall be manned with appropriate administrative staff whose job duties are clearly defined.
4. It shall be equipped with an office for handling administrative matters and an appropriate space for filing.
Proofs of education and training as mentioned in Subparagraph 2 above shall be reviewed by the IRB and retained properly.

Article 8 In case of any one of the following situations, IRB members shall recuse themselves from the review:
1.Being the principal investigator, co-investigator or client of the research project or sub-project under review.
2.Being the spouse of the principal investigator of the research project under review or being or having been related to the principal investigator by fourth degree blood relation or third degree affined relationship.
3.Having an employment relationship with the commissioning enterprise of the research project under review.
4.There are specific facts pointing to potential bias.
5.Other situations in which recusal is deemed necessary upon the IRB’s resolution.

Article 9 The review of a research project shall at least include the following:
1.Qualifications of the principal investigator
2.Eligibility criteria for the research subjects and the way of recruitment
3.Content of the project and way and place of execution
4.Items of agreement to be informed, the subjects to be

informed, the way and procedure of indicating agreement as provided in Article 14 of this Act
5.Protections for the research subjects, including the channel of enquiry and complaint, etc.

Article 10 The aforesaid way of making a decision in an IRB meeting is by majority rule in principle. When a decision is made by means of voting, both positive and negative votes shall be recorded. Board members not attending the meeting shall not vote.

Article 11 The expedited review as prescribed in Article 8 of this Act shall be conducted by at least one board member.
For projects under the aforesaid expedited review, the board member may exercise the approval granting power on behalf of the IRB and the result shall be reported to the IRB.
If the aforesaid project under review is not approved by the board member, it should undergo the standard review procedure.

Article 12 The minutes of the IRB meeting shall be published.
The aforesaid published content shall at least include the date of the meeting, the name of the attending and absent board members, the name of the research project, a summary of the discussion and the resolutions.

Article 13 Pursuant to Paragraph 1, Article 17 of this Act, the IRB shall conduct at least one regular audit on the execution of the approved research project; an immediate audit shall be carried out in case of any one of the following situations:
1.Any matter that may affect the rights, safety or well-being of the research subjects.
2.Occurrence of any severely adverse event or response on the part of the research subjects.
3.Occurrence of important matters or information that may influence the risk and benefit assessment of the project.
The aforesaid audit may be conducted in writing or by means of an on-site investigation.

Article 14 The principal investigator of the project shall be informed in writing of the result of the audit conducted by the IRB according to the previous Article, with any changes to the original review decision being stated.
If the conditions prescribed in Paragraphs 2 and 3, Article 17 of this Act are found as a result of the IRB’s audit, the research institution and the central competent authority of the relevant industry shall be notified within 14 days after the decision is made.

Article 15 The IRB shall request the principal investigator of the project to submit a report of the execution and results of the research after the project is completed.

Article 16 The IRB shall keep the project review report, audit report, interim report, final report and other relevant information of a research project for three years after the completion of the project, so that they can be retrieved by the central competent authority of the relevant industry at any time.

Article 17 These Regulations shall take effect upon the date of promulgation hereof.
