

Soka University Detailed Rules Regarding Ethics Review Procedure for Human Research

(Purpose)

Article 1 These detailed rules shall set forth matters concerning the ethics review procedure for human research according to Paragraph 7, Article 9 of the Soka University Code of Ethics for Human Research (hereinafter referred to as the “Code of Ethics for Research”).

(Application)

Article 2 A person who wishes to apply for an ethics review for human research must fill in and submit the “Soka University IRB Application Form” to the Institutional Review Board for Human Research (hereinafter referred to as “Review Board”) with the following documents.

- (1) Documents related to informed consent such as guidelines for human subjects, letters of consent for participation in the research (These documents shall be deemed unnecessary in the event that the Review Board in accordance with Paragraph 3, Article 5 of the Code of Ethics for Research approve them to be exempted from submission.)
- (2) Documents related to contents of surveys such as proposals for questionnaire items and questions in interviews
- (3) A resume of a researcher (only in the case that the Research and Survey involving members of the University is conducted by a person from outside the University)
- (4) A letter of consent from an administrator in an affiliate institution (applies only for any Research and Survey conducted in collaboration with an affiliate institution outside of the University)

2 In the event that it is difficult to obtain consent from an administrator in an affiliate institution before an ethics review in the case of (4) in the preceding paragraph, a statement of reasons must be submitted to the Review Board.

3 The due date of applications shall be at 12:00 p.m. on 10th of every month except August and all applications shall be reviewed at one time.

- (1) In the event that the 10th is Sunday or holiday, the due date of application shall be at 12:00 p.m. of the previous weekday of the 10th.
- (2) In principle no review shall be conducted in August.

(3) The start date of the research must be on or after the first day of the following month for the submission of the application.

4 In the event that the Research and Survey involving persons from outside the University is planned for research pertaining to an academic dissertation of a graduate student in the University, the Research and Survey must be applied before 4 months prior to the submission due date of the academic dissertation.

5 In the event that a researcher in Soka University Graduate School of Teacher Education plans to conduct Research and Survey at an affiliated cooperative school or school the researcher belongs, Soka University Graduate School of Teacher Education Preliminary Review Board (hereinafter referred to as “Preliminary Review Board”) shall review on behalf of the Review Board.

(1) The details of the review procedure shall be stipulated separately.

(2) The review results shall be reported to the Review Board.

(3) The Review Board shall review in the event that the Preliminary Review Board deems it necessary.

(Review Categories)

Article 3 The criteria for a chairperson of the Review Board to perform the review procedure in accordance with Article 9 of the Code of Ethics for Research shall be as follows.

(1) The “Chairperson Review” shall be exercised in the event that the researcher in the University intends to use data originally collected in the course of the usual educational activities in his/her own classes and without the intention to use such data in any research conducted after its collection, or the researcher intends to make a public announcement of the result of the research, provided, however, that data in these cases must be processed in a group and class scale and be described without specifying individuals.

(2) The “Expedited Review” shall be exercised for Continuous Plan that had been approved in the past and in the event that the researcher in the University or a research collaborator intends to conduct the survey according to a plan in the course of usual educational activities for the purpose of the research.

(3) The “Full Review” shall be exercised in the event that researches and surveys do not fall under (1) or (2) of this Article or the chairperson of the Review Board deems it necessary.

(Decision of Review)

Article 4 The Review Board shall make one of the following decisions for the review.

(1) Approval

(2) Approval with Conditions

(3) Continuous Review

(4) Disapproval

- 2 “Approval” shall be decided in the event that a research plan is made in compliance with the Code of Ethics for Research and does not require any amendment.
- 3 “Approval with Conditions” shall be decided in the event that matters in the research plan require some slight amendment. The Review Board shall notify the researcher of the matters requiring amendment and then the “Approval” shall be decided upon confirmation of the result of the amendment by the Review Board.
- 4 “Continuous Review” shall be decided in the event that matters in the research plan require some considerable amendment. The researcher may apply for a second review after revising the research plan. The application procedure for this review shall be the same as that stipulated in Article 2.
- 5 “Disapproval” shall be decided in the event that the research plan is deemed to conflict with Article 4 of the Code of Ethics for Research.

(Second Review Due to an Objection)

Article 5 An applicant who wishes to make an objection to the decision of the Review Board may apply for a second review to the Review Board with those materials which are the source of the objection. In the event that due to the objection the application for the second review is submitted, a Full Review shall be exercised by the Review Board in accordance with Paragraph 5, Article 9 of the Code of Ethics for Research.

(Change or Suspension of Research Plan)

Article 6 In the event that the researcher changes the contents of an approved research plan, the researcher shall submit the specified form to the Review Board in advance and obtain approval.

- 2 In the event that the contents of the change in the research plan are deemed to conflict with Article 4 of the Code of Ethics for Research by the Review Board, the Review Board may suspend or terminate the Research and Survey in the research plan.

(Report on Completion of Research)

Article 7 The researcher shall submit the specified form to the Review Board immediately after completing the approved research plan and report on its completion at the request of the Review Board.

(Administrative Duties)

Article 8 Administrative duties for review procedures shall be managed by the Faculty Affairs Office.

(Revision or Abolition)

Article 9 Revision or abolition of these detailed rules shall be conducted by the Soka University Education and Research Council after a discussion with the Review Board.

Supplementary Provisions

These detailed rules shall come into effect as of April 1, 2014.

These detailed rules shall come into effect as of October 1, 2014.

These detailed rules shall come into effect as of April 1, 2014.

These detailed rules shall come into effect as of June 20, 2016.

These detailed rules shall come into effect as of April 1, 2017.

These detailed rules shall come into effect as of April 1, 2021.