

上智大学人を対象とする研究に関する倫理委員会規程 Sophia University Regulations for the Human Research Ethics Committee

Enacted April 1, 2010

Amended July 1, 2011 April 1, 2014 April 1, 2015

(Purpose)

Article 1

These Regulations shall prescribe the necessary matters concerning the organization and administration of the Ethics Committee for "Research Involving Human Subjects" (hereinafter referred to as "the Committee").

(Objective of the Committee)

Article 2

The Committee, based on the Sophia University Guidelines for Research Involving Human Subjects, aims to conduct ethical reviews and take other necessary measures for the appropriate and facilitated implementation of research activities involving human subjects conducted by collecting or extracting information and data related to personal information, individual behavior, environment and psychosomatic matters (hereinafter referred to as "Human Research").

(Matters of consultation)

Article 3

The Committee shall report to the President of Sophia University the following matters in accordance with consultations by the President:

- (1) Matters regarding the ethical review of the research plan for Human Research (hereinafter referred to as "Research Plan Review"). However, matters regarding a conflict of interest shall be addressed by the Committee for Conflict of Interest;
- (2) Matters regarding the enactment and amendment of regulations and guidelines regarding Human Research; and
- (3) Other matters consulted by the President in relation to Human Research.

(Ethical review criteria)

Article 4

Ethical review criteria shall be based on ethics criteria that are acknowledged to be appropriate in general, as well as on the following:

- (1) Sophia University Guidelines on Academic Research Ethics;
- (2) Sophia University Guidelines Research Involving Human Subjects; and
- (3) Ordinances and guidelines enacted by relevant ministries and agencies; and guidelines of academic societies.

(Structure)

Article 5

The Committee shall comprise the following members delegated by the President:

- (1) Vice President for academic Research Affairs;
- (2) One (1) faculty member nominated by the Vice President for Academic Research Affairs;
- (3) One (1) faculty member nominated by the Sophia University Institute of Bioethics;
- (4) One (1) faculty member who belongs to and is nominated by the Faculty of Theology;
- (5) One (1) faculty member who belongs to and is nominated by the Faculty of Human Sciences;
- (6) One (1) faculty member who belongs to and is nominated by the Faculty of Science and Technology or the Graduate School of Science and Technology; and
- (7) A few experts from within and outside the University, as required by the President.

2 Efforts shall be made to formulate a gender-balanced Committee.

(Term of office)

Article 6

The term of office of the Committee member stipulated in paragraph 1, item 1 of the preceding article shall coincide with the duration of term of office as Vice President for Academic Research Affairs.

2 The term of the Committee member stipulated in paragraph 1, item 2 of the preceding article shall be in conjunction with that of the member stipulated in item 1

3 The term of the Committee members stipulated in paragraph 1, items 3 through 7 of the preceding article shall be two (2) years. However, a member may be reappointed.

4 Where a Committee member has resigned during his term, the term of the successor filling the vacancy shall be for the duration of the remaining term of his/her predecessor. (Chair and Vice-chair)

Article 7

Committee shall appoint a Chair and a Vice-chair.

2 The Chair shall be assumed by the Vice President for Academic Research Affairs.

3 The Vice-chair shall be assumed by the members stipulated in Article 5, paragraph 1, item 2/

4 The Chair shall lead and represent the Committee.

5 The Vice-chair shall support the Chair, and in the case of absence or disability of the Chair, the Vice-Chair shall assume Acting Chair.

(Specialist Committee members)

Article 8

The Chair may set up a Specialist Committee within the Committee where there is a need to investigate and deliberate on specialized matters.

2 The Chair delegates the persons with academic experience regarding the relevant specialized matter to become a member of the Specialist Committee.

3 A Specialist Committee member may participate in the deliberations of the Committee meeting and offer his/her opinions where it is deemed necessary by the Chair. However, he/she shall not be included in the voting.

4 Specialist Committee members shall resign when the surveys and discussion regarding the relevant specialized matters have been completed.

(Management)

Article 9

Committee meetings shall be held, in principle, once every month and they shall be convened by the Chair. The Chair may convene meetings as he/she deems necessary.

2 Committee meetings shall be chaired by the member stipulated in Article 5, paragraph 1, item 2. However, if this member cannot chair the meeting for inevitable circumstances, the Chair shall name a facilitator from Committee members.

3 The attendance of two-thirds or more Committee members and agreement by a majority of Committee members is required for the Committee to perform a recommendation.

4 The Chair may have the applicant of a Research Plan Review attend Committee meetings to explain the contents of the application where it is deemed necessary by the Chair.

5 In the case where a Committee member stipulated in Article 5 applies for a Research Plan Review, the member shall not state any opinions regarding the said ethical review.

(Application for ethical review)

Article 10

An applicant of a Research Plan Review (hereinafter referred to as "Applicant") shall submit the Research Plan Review Application Form (Form No. 1) to the Chair via the head of his/her affiliation.

(Method of ethical review for Research Plan Review)

Article 11

The Research Plan Review shall be carried out, in principle, in the Committee meetings stipulated in Article 9; however, in some cases round-robin ethical reviews may be alternately conducted.

(Round-robin ethical reviews)

Article 12

Where the Chair deems that the circumstances correspond to one of the following items, a round-robin ethical review may be conducted.

(1) In the case where the circumstances do not allow for a regular Committee meeting;

(2) In the case where it has been judged that there is an urgent need; or

(3) In the case where the contents of the Research Plan Review Application Form correspond to one of the following:

i. Ethical review regarding minor changes made to a Research Plan that has already been approved by the Committee;

ii. Ethical review of a Research Plan that has been conditionally approved by Committee; or

iii. Ethical review of a Research Plan that contains no risks exceeding minor risk (risk that does not exceed the possible limits of physical, mental or social risk imposed in daily life and are socially accepted) for the research subject.

2 Regarding the requirements for the validity and approval of a round-robin ethical review, the provisions of Article 9, paragraph 3 shall apply mutatis mutandis. In the case where opinions require coordination, the Chair or the Vice-chair who has been commissioned by the Chair shall perform the coordination and compile a decision.

3 The Chair shall notify all Committee members of the decision stipulated in the preceding paragraph.

(Further review)

Article 13

In the case where two (2) or more Committee members oppose to the ethical review results stipulated in paragraph 3 of the preceding article or where an objection is filed pursuant to Article 16, the Chair exposes the said application to further review.

2 Further review shall be conducted in meetings and the proceedings shall be expedited pursuant to Article 9.

(Ethical review results)

Article 14

Chair shall promptly report the results of the Research Plan Review to the President on the Notification of Ethical Review Results (Form No. 2) and notify the applicant.

2 Chair shall report to the President the outcome of deliberations regarding matters other than the Research Plan Review.

(Modifications to Research Plans)

Article 15

In the case where an applicant of a Research Plan Review who has received notification of the results pursuant to the preceding article should modify items of its Research Plan that are relevant to the ethical review criteria stipulated in Article 4, the applicant shall

gain approval of Committee.

2 Chair shall report to President the outcome of deliberations regarding matters other than the Research Plan Review.

(Filing of Objections)

Article 16

Applicants with objections to the decision of the ethical review may appeal the decision to the Committee via the head of their affiliation, by submitting the Notice of Objection (Form No. 3).

2 Regarding procedures of further review, Articles 11 through 14 shall apply mutatis mutandis.

(Report of status of implementation and onsite surveys)

Article 17

Committee may, in the case where Committee deems necessary regarding a research, demand the applicant to report on the status of implementation

2 Committee may conduct onsite surveys as required to investigate whether the research is being appropriately implemented in accordance with the Research Plan.

(Recommendation to change or suspend research)

Article 18

In the case that the Chair finds the results stipulated in the preceding article to be inappropriate, the Chair shall recommend change or suspension of the research and shall report as such to the President.

(Disclosure of summary of proceedings)

Article 19

Matters applying to the following items shall be disclosed. However, the President may decide the non-disclosure of parts that bear the risk of violating the human rights of the human research subject, the originality of the research, intellectual rights or competitive status:

(1) Summary of Committee meeting proceedings (title of research, applicant, research period and ethical review results, etc.)

(2) Structure of Committee and name and affiliation of Committee members, etc.

(Preservation of records)

Article 20

Records of ethical reviews conducted by the Committee shall be preserved for five (5) years from the academic year following the academic year in which the research ended or was suspended, unless otherwise stipulated by law.

(Obligation of secrecy)

Article 21

Committee members shall not leak or use for personal purposes, secrets (including information regarding the research subject and methods that may be deemed intellectual property in the broad sense) that they may have come to know in their work engagements. This shall apply after Committee members have left office.

(Alternate implementation of ethical reviews)

Article 22

In the case where other schools under the Sophia School Corporation, which manages Sophia University, find it difficult to individually establish an Ethics Committee, the Ethics Committee of the University shall alternatively conduct the reviews.

2 Where the ethical review is alternately conducted, Article 3 shall apply mutatis mutandis as ethical review criteria, and other procedures shall be implemented pursuant to this article.

3 Matters required for the alternate implementation of ethical review shall be separately prescribed.

(Secretariat)

Article 23

Administrative matters regarding the Committee shall be supervised by the Center for Research Promotion and Support of the Bureau of Academic Research and Information

(Amendment and abolishment of regulations)

Article 24

The amendment and abolishment of these provisions shall be conducted pursuant to the procedures provided for by the Sophia School Corporation.

Supplementary provision

The Regulations shall be effective as of April 1, 2010.

Supplementary provision

The Regulations shall be amended and be effective as of July 1, 2011.

Supplementary provision

The Regulations shall be amended and be effective as of April 1, 2014.

Supplementary provision

The Regulations shall be amended and be effective as of April 1, 2015.

Note: The English translation is provided for information. The original Japanese version remains the sole official version. If there is any discrepancy between the two versions, the Japanese original should take precedence.