

Sophia University Guidelines for Research on Human Subjects

Enacted 1 April 2010

(Purpose)

Article 1 The objectives of the Guidelines shall be to indicate matters to be heeded during Research on Human Subjects conducted within or outside of Sophia University (referred to herein as “the University”) to protect the human rights of Research Subjects and to facilitate the smooth implementation of research at the University.

(Subject)

Article 2 “Researchers” to whom the Guidelines apply shall mean faculty members of the University, as well as all undergraduate students, postgraduate students, and researchers engaged in research activities at the University. Research activities conducted by students must be properly supervised by a supervising faculty member familiar with the Guidelines. In particular, the supervising faculty member shall be responsible for the assessment of Research Plans.

(Definitions of Terms)

Article 3 The meaning of the following terminology in the Guidelines shall be defined as follows:

(1) “Research on Human Subjects” shall mean research activities conducted by means of the accumulation or collection of Personal Information, or information and data related to individual conduct, environment, or physical and mental condition, etc.

(2) “Personal Information” shall mean any information related to an individual that enables the particular individual to be identified by name, date of birth, or other description, including any information that can identify a particular individual when collated with other information. Therefore, individual information that has already been Anonymized by a party other than the University shall not be deemed Personal Information.

(3) Information and data related to individual conduct, environment, or physical and mental condition, etc. (referred to herein as “Individual Data”) shall mean information and data related to individual thought, behavior, environment, economic situation, or physical health, as well as material or data of human origin, including blood, body fluids, tissue, cells, genes, and excreta.

(4) “Research Subject(s)” shall be the collective term for individuals who are the subjects of research, including individuals participating in experiments as the subjects, and individuals cooperating with research as the investigation subjects in field studies.

(5) “Anonymization” shall mean that the identification of a particular individual is prevented by removing all or part of the Personal Information specified in Article 3 (2), or by adding some symbols or numbers entirely unrelated to the Research Subject after having removed all or part of the Personal Information.

(General Rules)

Article 4 Those who conduct Research on Human Subjects must respect the dignity of life and the individual, based on the founding spirit of the University, and carry out their research using scientific and socially appropriate means and methods, while adhering to the following general rules.

(1) Those who conduct Research on Human Subjects must adhere to the Guidelines, the regulations of the University, such as Sophia University Guidelines for 'Academic Research Ethics' and Regulations on Protection of Personal Information, as well as Japanese laws and regulations, the ordinances and guidelines of the relevant government offices, and the guidelines of academic societies.

(2) When implementing research, the human rights of Research Subjects must be given the highest regard and efforts must be made to conduct research that is scientifically and socially significant.

(3) Researchers must use the safest possible methods when accumulating or collecting Personal Information and Individual Data and must cause as little physical or emotional stress or pain to Research Subjects as possible.

(Informed Consent)

Article 5

(1) Prior explanation to Research Subjects

When accumulating or collecting Personal Information or Individual Data, Researchers must explain the purpose of the research, the manner of publication of the results, and the Research Plan to the Research Subjects beforehand in an easily understandable manner. Further, if any kind of physical or emotional stress, pain, or danger to the Research Subject is expected during the accumulation or collection of Personal Information or Individual Data, Researchers must, to the extent possible, explain the expected effects to the Research Subjects beforehand in an easily understandable manner.

(2) Obtaining Research Subjects' consent

When accumulating or collecting Personal Information or Individual Data, Researchers must obtain the freely exercised consent of the Research Subjects beforehand, either in writing or by another method.

a) Research Subjects' consent shall cover matters concerning the handling of Personal Information and Individual Data, and the method of publication of the related research.

b) When Research Subjects request Researchers to disclose their Personal Information or Individual Data to them, the Researchers must disclose the relevant information or data. However, an exception can be made for genetic information if there is a probability that the life, physical health, property, or other rights and interests of a Research Subject or a third party will be harmed. This exception is in accordance with the Ethical Guidelines for Human Genome / Gene Analysis Research specified by the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; and the Ministry of Economy, Trade and Industry.

c) If a Research Subject is under the age of 18, Researchers must obtain the consent of both the Research Subject and his/her parent or guardian. However, an exception is made in instances where any of the items of Article 6 apply.

d) If a Research Subject is an infant or disabled and it is difficult to verify the consent of the Research Subject him/herself, Researchers must obtain the consent of a parent or a guardian.

e) The consent of a Research Subject must be obtained in advance as a rule. In particular, if any kind of physical or emotional stress, pain, or danger to the Research Subject is expected, the Research Subject must provide written consent in advance.

f) Researchers must maintain records of consent for an adequate period of time.

However, if a Research Subject has withdrawn his/her consent, his/her Personal Information and Individual Data must be discarded promptly.

(Simplification or Waiver of Informed Consent)

Article 6 The procedures for informed consent specified in the previous Article may be simplified or waived only in the circumstances detailed below. Except for cases to which item (3) of this Article applies, the Research Subject must be given an explanation beforehand.

(1) For surveys in which the decision to respond is left entirely to the will of the Research Subject, if either of the following applies, then the act of responding to the questions may be taken as the consent of the Research Subject.

a) Anonymous surveys in which no other Personal Information is collected

b) Surveys in which the question content is expected to cause no physical or emotional stress, pain, or danger to the Research Subject

(2) Furthermore, if all of the following apply, the procedures of informed consent may be simplified or waived.

a) If the research cannot actually be implemented without simplifying or waiving the procedures of informed consent, or if such procedures would considerably undermine the merit of the research in question

b) If there is expected to be no physical or emotional stress, pain, or danger to the Research Subject from simplifying or waiving the procedures of informed consent

c) If the research in question is deemed to be of high social importance

(3) Regardless of items (1) and (2) of this Article, if revealing the true purpose of the

research would make it impossible to implement the research in question, or if it would considerably undermine the merit of the research in question, the following provisions shall apply.

a) If an explanation cannot be given beforehand because prior awareness of the true purpose of the research would alter the response of the participant in the experiment, or if giving a false explanation is necessary, then the true purpose of the research must be explained promptly after the completion of the experiment, and consent should be obtained.

b) In field research, if it is difficult to obtain prior consent because prior explanation of the purpose of the study to the Research Subject and obtaining of consent would hinder the formation of a natural relationship with the Research Subject, then the purpose of the survey must be promptly explained to the Research Subject afterwards (before the results of the survey are publicized at the latest) and consent should be obtained.

(Contracting to Third Parties)

Article 7 If Researchers contract a third party to collect Personal Information and Individual Data, then the relevant written contract must conform to the intent of the Guidelines. If requested by a Research Subject, Researchers must explain to the Research Subject directly the purpose of contracting to a third party.

(Accumulation and Collection in Classes)

Article 8 When Researchers request students to submit their Personal Information and Individual Data for research purposes during classes, drills, practicum, experiments, and

practices in the process of education, the prior consent of the students must be obtained.

Researchers must not disadvantage students in terms of their grade assessments according to whether or not they submitted their Personal Information or Individual Data.

(Examination of Research Plans)

Article 9 Examination of research plans published or implemented by Researchers conducting Research on Human Subjects (referred to herein as “Research Plans”) shall be conducted by the Sophia University Ethics Committee for Research on Human Subjects (referred to herein as “the Committee”) based on the Application for Examination of Research Plan (Form 1), Research Proposal , and other appended documentation from the Researcher (the applicant). Provisions related to the Committee shall be specified separately.

(Other)

Article 10 The Guidelines shall take precedence over the University’s Regulations on Protection of Personal Information with regard to Research on Human Subjects. For any matters not stipulated in the Guidelines, compliance with the Regulations on Protection of Personal Information and the other regulations of the University is required.

Supplementary Provisions

The Guidelines are effective from April 1, 2010.

This is an unofficial translation.

Only the original Japanese texts of regulations have effect, and the translations are to be used solely as reference material to aid in the understanding of the Japanese-language regulations.