

Sophia University Guidelines for ‘Research on Human Subjects’

Established: 1 April 2010

(Objectives)

Article 1 The objectives of the Guidelines (hereinafter as “The Guidelines”) shall be to indicate matters to be heeded in research on human subjects conducted within or outside of Sophia University (hereafter 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’ hereinafter shall mean faculty members of the University, all undergraduate students, postgraduate students and Researchers engaged in research activities at the University. Research activities conducted by students must be properly supervised by the supervising faculty member familiar with the Guidelines. In particular, the supervising faculty member shall be responsible for the assessment of research plans.

(Definitions)

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 the accumulation or collection of Information and Data related to Personal Information,

Personal Conduct, Environment and Psychosomatic Information.

(2) 'Personal Information' shall mean any information related to an individual that particular individual can be identified by its name, date of birth or other description, including any information that can identify a particular individual by referring to other information. Therefore, such information as in which personal information has already been anonymized by anybody other than the University shall not be Personal Information.

(3) 'Information and Data related to Personal Information, Personal Conduct, Environment, and Psychosomatic information' (hereinafter as the 'Personal Data') shall mean information and data related to personal thought, behaviour, environment, economic situation and health and material or data of human origin, including but not limited to, blood, fluids, tissue, cells, genes and excrement.

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

(5) 'Anonymizing' shall mean to forestall the identification of a particular individual by removing all or any part of the Personal Information specified in Article 3 (2), or removing all or any part of the Personal Information and adding some marks or numbers totally-unrelated to the Research Subject to that information instead.

(General Rules)

Article 4 Those who conduct researches on human subjects must respect the dignity of life and the individual, based on the founding spirit of the University, and carry out their researches with scientific and socially appropriate means and methods, while adhering

to the following general rules.

(1) Those who conduct researches on human subjects must adhere to the Guidelines, the regulations of the University, such as the Sophia University Guidelines for the Ethics of Academic Research and the Regulations for the Protection of Personal Information, the ordinances and guidelines of related government offices and the guidelines of academic societies.

(2) In the implementation of research, the human rights of Research Subjects must be given the highest regard; endeavours must be made to conduct research that is scientifically and socially significant.

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

(Informed Consent)

Article 5 Prior explanation to Research Subjects

When accumulating or collecting Personal Information or Personal Data, Researchers must explain the purpose of the research, the manner of publication of the results and the research plan to the Research Subject beforehand so that they can understand well.

Further, if any kind of physical or emotional stress, pain or danger to the Research Subject is expected in the accumulation or collection of Personal Information or Personal Data, Researchers must explain the expected situation to the Research Subject as easily as possible beforehand.

(2) Consent of the Research Subject

When accumulating or collecting Personal Information or Personal Data, Researchers must obtain the consent of the Research Subject in writing or other manner beforehand, at the free will of the Research Subject.

a) 'Consent of the Research Subject' shall include the matters concerning the handling of Personal Information and Personal Data, and the method of publication of the related researches.

b) When Researchers are required to disclose Personal Information and Personal Data of Research Subjects, the concerned individuals must be informed about this disclosure. This shall not apply to genetic information if there is a probability that the life, health, property or other rights and interests of Research Subject or a third party will be harmed, according to the Ethical Guidelines for Human Genome Research specified by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labor and Welfare, and the Ministry of Economy, Trade and Industry.

c) Researchers must obtain the consent of Research Subject and its parent or guardian, if the Research Subject is under the age of 18. This shall not apply in instances where any of the items of Article 6 shall apply.

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

e) The consent of the 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 a written consent in advance.

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

Provided, however, a Research Subject has withdrawn his/her consent, his/her Personal Information and Personal Data must be discarded promptly.

(Simplification of and Exemption to Informed Consent)

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

(1) In surveys in which the responses are left entirely to the will of the Research Subject, if any of the following applies, then the act of responding to the question may be taken as the consent of the Research Subject.

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

b) Those in which no physical or emotional stress, pain or danger to the Research Subject is expected by the question

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

a) If the research actually cannot be implemented except by the method in question or if it 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 using the method in question

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

(3) Regardless of the items (1) and (2) of this Article, if the research in question cannot be implemented by revealing the true purpose of the research, 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 experiment 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 Personal Data, then such a contract must be signed to conform to the intent of the Guidelines. If requested by a Research Subject, Researchers must explain the purpose of contracting to a third party, to the Research Subject directly.

(Accumulation and Collection in Classes)

Article 8 When Researchers request students in classes, drills, practicum, experiments and practices in the process of education to submit their Personal Information and Personal Data for research, the prior consent of the students must be obtained.

Researchers must not disadvantage students' grade assessments according to whether or not they submitted their Personal Information or Personal Data.

(Examination of Research Plans)

Article 9 The examination of publicized or implemented research plans by Researchers conducting research on human subjects (hereafter as ‘research plans’) shall be conducted by the Sophia University Committee for Ethics of ‘Research on Human Subjects’ (hereafter as ‘the Committee’) based on the Application for Examination of Research Plan (Form 1), the research plan and other appended documentation from the Researcher (applicant). Provisions related to the Committee shall be specified separately.

(Other)

Article 10 The Guidelines shall be applied to ‘research on human subjects’ in precedence to the Regulations for the Protection of Personal Information. Any matters not stipulated in the Guidelines shall comply with the Regulations for the Protection of Personal Information and the regulations of the University.

Supplementary Provisions

The Guidelines are effective from 1 April 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 Japanese regulations.