上智大学「人を対象とする研究」に関するガイドライン
Sophia University Guidelines for Research on Human Subjects

Enacted 1 April 2010
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Article1: Purpose
The objectives of the Guidelines (referred to herein as “the Guidelines”) shall outline considerations on Research on Human Subjects conducted within or outside of Sophia University (referred to herein as “the University”) to protect the human dignity and human rights of Research Subjects, emphasize the significance of social responsibilities, and promote research activities smoothly at the University.

Article 2: Subject
“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 who understands the Guidelines. In particular, the supervising faculty member shall be responsible for examining the research plans of their students.

Article 3: Definitions of Terms
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 “information and data related to emotions, thoughts, behaviors, environment, or physical and mental condition, etc. of individuals or groups,” specified in Item (3).
(2) “Personal Information, etc.” shall mean “Personal Information” defined in Article 2 Clause 1, “Personal Information Requiring Special Care” defined in Article 2 Clause 2, “Pseudonymized Personal Information” defined in Article 2 Clause 6, “Anonymized Personal Information” and “Personal Related Information”defined in Article 2 Clause 6 (information relating to a living individual which doesn't fall under Personal Information, Pseudonymized Personal Information and Anonymized Personal Information), which are all specified in the Regulations for the Protection of Personal Information of the University (referred to herein as “the Personal Information Protection Regulations”).
(3) “Information and data related to emotions, thoughts, behaviors, environment or physical and mental condition, etc. of individuals or groups” (referred to herein as “Personal Information and Data, etc.”) shall mean information and data related to characteristics, emotions, cognitions, thoughts, beliefs, behaviors, experiences, habits, environment, economic situation, or physical health of individuals or groups (results of examinations and measurements related to movement, exercise, physical conditions, etc.), as well as material or data of human and human origin (blood, body fluids, tissue, cells, genes, etc.).
(4) “Research Subject(s)” shall refer to the collective term for individuals who are the subjects of research (including those who are requested to participate in experiments as the subjects) and individuals who provided existing specimens and information to Researchers. It also includes individuals who participate in experiments or cooperate in field studies as Research Subjects.

Article 4: General Rules
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 the Personal Information Protection Regulations, 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 methods to collect Personal Information and Data, etc., in order to minimize the risks of physical or emotional stress or pain for Research Subjects as little as possible.

Article 5: Informed Consent
(1) Prior explanation to Research Subjects
a) When conducting Research on Human Subjects, Researchers must provide an easy-to-understand manner explanation to the Research Subject beforehand, regarding the purpose of the research, the method of presenting the research results, and the research plan.

b) When any kind of physical or emotional stress, pain or danger to the Research Subject is expected during the collection process of Personal Information and Data, etc., Researchers must explain the expected effects of the research participation as easy as possible to the Research Subject beforehand.
(2) Obtaining Research Subjects' consent
When Researchers conduct Research on Human Subjects, Researchers must obtain the freely exercised consent of the Research Subjects beforehand, either in writing or by another method.
a) "Research Subjects' consent" shall include the matters concerning research purpose, handling of Personal Information and Data, etc. and the method of presentation or publication.
b) Researchers must respond to requests from the Research Subjects for disclosure, correction, deletion, suspension of use, etc. (referred to herein as "disclosure, etc.") of Personal Information and Data, etc.. If Personal Information and Personal Information Requiring Special Care are included in the request, the provisions of Articles 17 to Article 19 of the Personal Information Protection Regulations shall apply to the procedures. When there is a probability that the life, physical health, property, or other rights and interests of Research Subject or a third party could be harmed, Researchers could stop disclosing genetic information by following 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 from the Research Subject as well as a guardian or a person with parental authority of the Research Subject(referred to herein as "Parental Authority, etc."). 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, Researchers must obtain the consent of the Parental Authority, etc.
e) If a Research Subject could provide her/his intension to participate in research, Researchers must gain their understandings and give an easy-to-understand and sufficient explanation to Research Subject, even if Researchers obtain consent from the Parental Authority etc..
f) Unless there are special circumstances, Researchers must obtain the consent from the Research Subject in advance. 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.
g) Researchers must maintain provided consent records securely for an appropriate period of time. However, Researchers must discard information and data promptly if a Research Subject withdrawn his/her consent.

Article 6: Simplification or Waiver of Informed Consent
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 answers and cooperation are left to the will of the Research Subject, if either of the following applies, the responding act of the Research Subject to the questions may be substituted for the consent of the Research Subject.
a) Anonymous surveys that do not collect Personal Information, etc.
b) Surveys in which the questions are assumed to pose no physical or emotional stress, pain, or danger to the Research Subject (except the cases to obtain special care-required personal information).
(2) When all of the following apply, the procedures of informed consent may be simplified or waived (except the cases to obtain Personal Information Requiring Special Care).
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 urgency
(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 (except the cases to obtain Personal Information Requiring Special Care).
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.

Article 7: Contracting to Third Parties
(1) If Researchers contract a third party to collect and analyze Personal Information and Data,etc., Researchers must contract with the third party in accordance with the Guidelines and Personal Information Protection Regulations.
(2) When a Research Subject requests Researchers for an explanation, Researchers must explain it to the Research Subject regarding the purpose of the intention of contract with a third party.

Article 8: Requests to participate in research in classes and other educational settings
(1) Researchers must obtain the consent from students in advance, when Researchers unavoidably request students to submit their Personal Information and Data, etc. for research in the educational implementations or courses such as classes, seminars, practical skills, experiments, practical training, and other educational practices.
(2) Due to the presence or absence of the provision of Personal Information and Data etc., Researchers must not disadvantage students in grade or other related evaluations.

Article 9: Examination of Research Plans
(1) 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).
(2) Provisions related to the Committee shall be specified separately.

Article 10: Other
In addition to stipulated definitions in the Guidelines, Researchers will be responsible for following and complying with the Personal Information Protection Regulations.

Supplementary Provisions

The Guidelines are effective from April 1, 2010.
The Guidelines are effective from May 1, 2023.

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.