

Ethics Guidelines for Human Subject Research
Institute of Human and Social Sciences, Kanazawa University

1. Purpose

The purpose of these guidelines is to set forth items related to research plan reviews and ethical guidelines for behaviors and attitudes required of researchers implementing research that involves: human beings treated as subjects and collection and extraction of information and data on the behaviors, environments and physical/mental conditions of individual persons (hereafter referred to as “human subject research”) at the Institute of Human and Social Sciences, Kanazawa University (hereafter referred to as the “the Institute”).

2. Definitions

The following sections define specific terms used in these guidelines:

(1) Information and data collected and extracted from human beings, including those related to their behaviors, environments and physical/mental conditions (hereafter referred to as “personal information or data, etc.”) is defined as information and data dealing with individual thinking, behavior, environments and physical bodies, as well as physical samples (blood, body fluids, tissues, cells, genes, excrement, etc.).

(2) Researchers are defined as full-time instructors (including instructors at Kanazawa University’s affiliated educational institutions and former faculty members of the Institute still engaged in research activities at the Institute), administrative staff, research workers, students and others engaged in research activities within the Institute.

(3) Providers are defined as subjects of research who provide personal information and data.

3. Research Fundamentals

(1) When conducting human subject research, researchers must follow scientifically and socially acceptable methods and procedures, in full accordance with the Kanazawa University Researcher Behavior Standards (enacted January 22, 2008). Above all, respect on the dignity of life, the dignity of individual persons and fundamental human rights must be given higher priority than scientific or social benefit.

(2) If researchers conduct investigations and experimental research that work to collect behavioristic, physical/ mental information on human subjects, particularly in context to the fields of medicine, humanities or social sciences, the researchers must strictly adhere to: Kanazawa University National University Corporation Personal Information Management Regulations (April 1, 2005 Regulation No. 367), Japan’s laws and regulations and ethical guidelines and regulations established by the researchers’ affiliated academic societies and groups.

(3) When researchers collect or extract personal information or data, etc., they are required to adopt safe and secure methods. Researchers must also minimize any physical or mental burden and pain experienced by the providers to the greatest extent possible.

4. Guideline Exemptions

(1) These guidelines mentioned above are not applicable to the type of human subject research in which the *Ethics Guidelines Concerning Human Subject Medical Research* or the *Ethics Guidelines Concerning Human Genome and Gene Analysis Research*

established by the Japanese government, medical research and invasive research (the research which could cause mental or physical trauma or considerable burden to research subjects by means of punctures, incisions, drug administration, irradiation, traumatic questioning, etc.).

(2) In the event that these guidelines cannot be properly observed due to the characteristics of research procedures, researchers shall observe the guidelines of academic societies or other associations directly related to the research in question.

5. Explanatory Responsibilities of the Researcher

(1) Before researchers collect or extract personal information or data, etc., the purpose of the research, the research plan, how results will be published, and other details must be explained to the providers.

When using a questionnaire, this explanation may be implemented with descriptions in writing in lieu of an oral explanation.

(2) When researchers expect or foresee that the collection or extraction of personal information or data, etc. will be accompanied by danger or any sort of physical or mental burden or pain to the provider, they must explain those foreseen conditions to him/her in advance.

6. Informed Consent

(1) When researchers collect or extract personal information or data, etc., they must obtain prior consent from providers in written form, based upon the ways of explanation described in Item 5.

If research uses a questionnaire-based group investigation or collects data via postal mail, researchers can consider consent as given, when the questionnaire is answered and returned. When consent is obtained in this manner, this fact must be clearly written on the relevant documentation, which shall include description of the providers' right to refuse to answer.

(2) Provider consent shall include items related to the handling, publication method and other items related to personal information or data, etc.

(3) When researchers are requested by a provider to disclose the provider's own personal information or data, etc., the data must be disclosed to the extent that there is no conflict with the protection of personal data of any third-parties. However, disclosure is limited to cases in which the information or data, etc. related to the specific provider can be identified within the data pool.

(4) In the event that the provider is less than 15 years of age or may not have the capacity for consent due to mental disability or other reason, researchers must obtain the consent of another individual capable of making an appropriate judgment on the provider's behalf (for example, the provider's close relative, spouse, child, elementary or junior high school teacher, or similar individual).

7. Information Management

(1) Researchers shall appropriately store collected information and data and research records related to the providers for a certain period needed to implement later inspections.

(2) Researchers shall not divulge personal information and data acquired through the implementation of the research without the consent of the provider. However, this does not apply when related Japanese laws or the Kanazawa University National

University Corporation Personal Information Management Regulations stipulate otherwise.

(3) In the event that the provider withdraws consent, if there is information or data that identify the provider, that information or data must be destroyed immediately.

8. Collections and Extractions in the Context of Educational Activities

(1) Instructors must ensure that students' grade evaluation is not negatively impacted based on the acquisition or refusal of consent in regard to the provision of personal information or data, etc.

(2) When students conduct human subject research, the research must be conducted under the proper guidance of the advising instructor, with strict adherence to these guidelines.

9. Commissions to Third Parties

(1) When researchers collect and extract personal information or data, etc. through a commission to a third party, the researchers must request that the third party adhere to these guidelines.

(2) Researchers shall explain to providers, in person, the goals of the research and other information if necessary.

10. Reviews of Research Plans and Other Matters

(1) When a researcher planning to conduct human subject research within the Institute applies for review, the Institute will review the applicant's research implementation plan, publication plans, etc. (hereafter referred to as the "research, etc."). However, simplified review procedures (including review exemption) to be described separately can be adopted in special circumstances, such as (a) when the review of the relevant research requires a particular urgency, (b) when the answers are entrusted to the will of providers in unsigned (anonymous) questionnaires and the research is to be conducted exclusively on statistical analysis of the results, and (c) when the result of the review can be clearly inferred based on past review precedents.

(2) In order to achieve the goals of the preceding items, the Institute of Human and Social Sciences Ethics Committee, Kanazawa University shall establish the review committee within the Institute.

(3) Matters related to review procedures and other necessary details will be specified separately.

11. Others

(1) Provision of Remuneration

When remuneration is given to providers in the form of money or goods, the amount must be set within a socially acceptable range. The researcher must appropriately manage payments and receipts of any such remuneration.

12. Revision and Abolition

The revision or abolition of these guidelines shall be decided by the Dean of the Institute of Human and Social Sciences, upon deliberation by the Kanazawa University Human and Social Education and Research Committee's Board of Representatives.

13. Work Authority

Related business to these guidelines shall be administered by the Human and Social Administration Department.

Supplemental Provisions

1. These guidelines come into effect on July 29, 2016.
2. The guidelines concerning the Ethics of Human Subject Research within the Institute of Human and Social Sciences, Kanazawa University are hereby repealed.