

Nanzan University Ethical Guidelines for Conducting Research Involving Human Subjects

1. Aim

The following are the ethical guidelines governing the behavior and attitudes of all people (hereinafter referred to as “researchers”) gathering information and data directly from human subjects on their behavior, environment and physical and mental state for use in research activities (hereinafter referred to as “human subjects research”) carried out both within and outside the University, and the matters to be considered when screening such research plans etc.

2. Principles of Research

In keeping with the educational ideology of Nanzan University, people engaged in research involving human subjects must respect the dignity of life and the dignity of the individual and execute their research using scientifically and socially appropriate methods and means.

- (1) Those carrying out research involving human subjects must observe the laws of Japan, the declarations and guidelines issued by the relevant government agencies and the Nanzan University Regulations Governing the Protection of Personal Information.
- (2) When carrying out research, respecting the human rights of the subject is of utmost importance and must be given priority over any potential benefits to science and society.
- (3) When gathering information and data on individual subjects, researchers must use safe and secure methods, doing their utmost to avoid inflicting any physical or mental burden or pain on the subjects.
- (4) Researchers engaged in research, or duties related to research, must have received the necessary education and training to enable them to execute their roles, and possess experience in carrying out the said research.

3. Definitions

For the purposes of these Guidelines, the information and data gathered from individual human subjects on their behavior, environment and physical and mental state (hereinafter referred to as “personal information”) is defined as information or data pertaining to the thoughts, behavior, personal environment and physical state of the subject, and materials or data that is representative of or derived from people, (blood, bodily fluids, tissue, cells, genes or excreta etc.)

- (1) “Providers” are those who provide their information and data for the purposes of research.
- (2) “Personal information” refers to information pertaining to an individual, including their name and date of birth, or other entries that allow the individual to be identified, including details that when simply matched against other information, allows a specific individual to be identified (Nanzan University Regulations Governing the Protection of Personal Information, Article 2).

4. Responsibility of Researchers to Explain

When gathering personal information and data on subjects, researchers must give prior explanation to the providers, in easily understandable terms, of the research plan, including such things as the goals of the research and the method of the release of its results.

In gathering personal information and data on subjects, if any kind of physical, mental burden or pain or risk can be foreseen for the provider, the researchers must explain

this in easily understandable terms at the earliest possible juncture.

5. Informed Consent

Researchers must obtain the prior consent of the providers when gathering personal information and data.

(1) The Consent of the Providers will include details such as the handling of personal information and data (how it will be managed, period of storage, method of disposal etc.) and the method of release of research results.

(2) Researchers must disclose the personal information or data to a provider when requested to do so by that person.

(3) When the researchers judge that the provider is not capable of giving consent, they must obtain consent from someone who can represent the provider.

(4) As a rule, the consent of the provider shall be obtained in writing. If any kind of physical, mental burden or pain or risk can be foreseen for the provider, consent must be obtained in writing. The researcher must store the records pertaining to such consent for an appropriate period of time.

(5) If the provider withdraws their consent, the researchers must destroy the information and data gathered from that person.

(6) Researchers must destroy all personal information and data gathered as soon as their research is completed. However, in situations in which it is expected that researchers may subsequently be requested to disclose information, based on (2) above, personal information or data that allows an individual to be identified must be stored for five years.

(7) In the event that researchers wish to use personal information and data gathered beyond the end of the research project in question, they must first request permission from the Nanzan University Research Screening Committee, and then explain the situation to, and gain permission from, the provider(s).

6. Commissioning Third Parties

When researchers commission third parties to gather personal information or data, they must enter into a contract based upon the content of these Guidelines.

When providers request from the researcher an explanation of such matters as the aims of the research, this must be given directly by the researcher.

7. Gathering Information in Classes etc.

When teaching staff request personal information and data for research purposes from students in the classes, seminars, practical skill-training sessions, laboratory classes or practical sessions and educational sessions they must obtain the prior consent of the students involved.

Teaching staff must not in any way disadvantage students in terms of grades because personal information was either provided or withheld.

8. Storage of Personal Information and Data etc.

(1) When storing personal information and data etc., researchers must manage it with care, anonymizing it to the greatest extent possible. Furthermore, personal information and data etc. that no longer needs to be stored must be disposed of in an appropriate manner.

(2) The period that personal information and data etc. is stored must be in keeping with the provisions of the guidelines for storage of research data.

9. Screening of Research Plans

At Nanzan University, implementation plans for research and plans for the release of results by researchers involved in research (hereinafter referred to as research plans etc) involving human subjects are screened by the Nanzan University Research Screening Committee (hereafter referred to as the Committee) on the basis of the submission of an application (prescribed by the Committee) from the researcher/applicant providing the research plan and other relevant materials. Screening is carried out pursuant to Article 2 Clause 4 of the Nanzan University Regulations for Research Screening. Depending upon

the importance of the research content, the screening will either be carried out straightaway with an abbreviated process or through the full process. Normally, a small number of Committee members are appointed by the Committee Chairperson to carry out the screening straightaway, with their decision conveyed to the applicant and a report submitted to the Committee. The full Committee will pass judgment on cases in which research content is deemed to be of particular importance, for which the screening is not able to be carried out straightaway.

However, research that is not judged to pose any major ethical problems and meets any one of the following criteria is not required to apply for ethical screening.

(1) Research that only uses data gathered through surveys carried out based upon legal regulations.

(2) Research that only uses information derived from material through which the identity of the subjects can no longer be traced.

(3) Research by people sent for training from organizations such as local government bodies, that only uses materials related to the person's own area of responsibility in a form in which the identity of the subjects within the University can no longer be traced.

10. Administration

Research Promotion Office within the Division of Educational and Research Administration will administer the Guidelines.

11. Revisions

Any amendments to or deletions from these Guidelines must be made with the approval of the University president, after being considered by the Research Screening Committee and the Faculty Senate.

Supplementary Provision

These Guidelines come into force from April 1, 2007.

Supplementary Provision

These Guidelines come into force from April 1, 2009.

Supplementary Provision

These Guidelines come into force from December 1, 2009.

Supplementary Provision

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