

○ Hosei University Ethical Regulations for Research Involving Human Subjects

Regulation 1141
Partially revised January 1, 2016

Purpose

Article 1. The purpose of these Regulations is to provide ethical behavior guidelines that researchers must observe in the conduct of research involving human subjects, among other research activities subject to the Hosei University Research Ethics Regulations.

Principles of Research

Article 2.

1. When conducting research involving human subjects, researchers must respect individual dignity and fundamental human rights and, in line with the Declaration of Helsinki, execute their research using scientifically and socially appropriate methods.
2. When conducting research involving human subjects, researchers must observe laws and regulations, notifications, guidelines, and other instruments from government agencies, and the Hosei University Regulations Regarding the Protection of Personal Information and Handling of Specific Personal Information.
3. When conducting research involving human subjects, researchers must minimize the physical and mental stress or pain of research subjects using safe and reliable methods.

Definitions

Article 3. Terms used in these Regulations shall have the following meanings:

- (1) "Research involving human subjects" shall mean clinical and on-site survey and experiments in any field of natural sciences, humanities, or social sciences which include the collection and harvesting of information or data from individuals or groups of individuals concerning, among others, their behaviors, mental and physical state, and environment.
- (2) "Individual information or data" shall mean information or data concerning, among others, the ideas, feelings, body, behavior, and environment of individuals, or of groups of individuals as their collective characteristics.
- (3) "Researcher(s)" as used in these Regulations shall mean a faculty member(s) or a research staff member(s) of the University, or any other person(s) engaging in research activity at the University. Students in undergraduate faculties and graduate schools shall also be deemed to be researchers.
- (4) "Research subject(s)" shall mean a person(s) who supplies his/her individual information or data for research.

Accountability of Researchers

Article 4.

1. Researchers must be able to explain to society the purpose and significance of their research as well as the appropriateness and risk of the method adopted for their research.
2. Prior to collecting or harvesting individual information or data, researchers shall explain to each research subject the purpose and plan of their research, the way the results of their research are to be published, and other necessary details to research subjects in a manner research subjects will understand.
3. Prior to collecting or harvesting individual information or data, researchers shall, in principle, explain any anticipated physical or mental stress or pain which each research subject may experience so that research subjects will understand under what circumstances such stress or pain may take place.

Informed Consent

Article 5.

1. When collecting or harvesting individual information or data, researchers shall obtain consent from each research subject in advance.
2. When obtaining consent from each research subject under the preceding paragraph, researchers shall ensure that research subjects agree on how information or data on individuals collected or harvested will be handled and how the results of research will be published.
3. Researchers shall explain to each research subject that they have the right to withdraw their consent and discontinue their cooperation with the research at any time, as well as to request disclosure of their individual information or data collected or harvested, during the term of research without fear of unfair treatment.
4. In cases where research subjects are considered incapable of providing consent, researchers must, in principle, obtain consent from their parents, guardians, or legally authorized representatives.
5. Consent from research subjects must be, in principle, in writing, and researchers shall keep the record of consent for at least five (5) years from the date on which the record of consent is obtained.

6. In the case where research subjects withdraw their consent, researchers shall dispose of their individual information or data promptly.
7. Researchers shall obtain consent from each research subject prior to publishing the results of their research for which the research subjects have supplied their individual information or data.

Entrustment to Third Parties

Article 6. In the case where researchers entrust a third party to collect or harvest individual information or data, researchers and the third party shall conclude a contract that reflects these Regulations.

Collection and Harvesting during Classes, Etc.

Article 7. If researchers collect or harvest individual information or data from students attending their lectures, seminars, practices, experiment/practical training, and others for their research, they shall obtain consent from the students in advance.

Review of Research Plans, Etc.

Article 8.

1. The Research Ethics Committee formed in each faculty, department, graduate school, and other units of the University shall, upon application from researchers, review their research plans and other issues.
2. Review procedures and other details shall be stipulated separately.

Revision and Abolition of These Regulations

Article 9. Decisions on the revision or abolition of these Regulations may be made by the President after deliberation by the Research Ethics Committee.

Supplementary Provisions

1. These Regulations shall be enforced on November 27, 2013.
2. These Regulations shall be enforced on January 1, 2016, after partial revision.