Society of Automotive Engineers of Japan: Ethical Guidelines for Research Involving Human Subjects

Introduction

Studies based on a variety of research (experiments, investigations, and observations) involving human subjects are a prerequisite for achieving a safer and more secure vehicle-based society. Accordingly, such research must be carried out with a firm ethical foundation to guarantee the safety of the research subjects, human rights, and social consensus with respect to the research. The Society of Automotive Engineers of Japan (JSAE) has formulated these ethical guidelines for research involving human subjects as a recommended code for achieving this purpose.

Scope

These guidelines shall be applied to research in the field of automotive engineering that involves a person or persons as research subjects. All persons presenting research (presentations, manuscripts, contributions, and the like) through the JSAE shall follow these guidelines.

Section 1 Basic Principles for Researchers Performing Research Involving Human Subjects

Note that the terminology in these guidelines is defined in Section 2.

1.1. Ensuring validity from scientific, ethical, and other standpoints

Researchers performing research involving human subjects (abbreviated to “research” below) shall follow the items listed below when planning and performing the research.

(1) The contents of the research shall have sufficient scientific and ethical validity, and shall respect the dignity and human rights, and ensure the safety of the research subjects.

(2) Detailed checks shall be made of the required information before planning and performing the research. A clear and specific research plan shall be prepared that reflects these checks.

(3) Before starting the research, the research plan shall be examined by an Ethics Review Board or similar organization, and approval obtained from the Chief or equivalent person of the research institution to which the researcher belongs. The same procedure shall be followed if the research plan is changed.

1.2. Protection of personal information

Data, information, or the like relating to research subjects shall be handled appropriately.

All personal information shall be protected. Personal information obtained in the course of the research shall not be disclosed to a third party without due reason. This shall apply even after the person responsible for the research or the person or persons conducting the research have left their posts.

1.3. Acquisition of informed consent

Before carrying out any research, informed consent shall be obtained in advance from the research subjects. The details of explanations given to the research subjects and the method of confirming consent shall be clearly stated in the research plan.

1.4. Measures when announcing results

The necessary measures shall be carried out to protect the personal information and privacy of research subjects when the research results are announced.

1.5. Guidance obligation of person or persons responsible for the research

The person or persons responsible for research involving human subjects shall guide and monitor the person or persons conducting the research to ensure that the research satisfies all necessary items, including points 1.1 to 1.4 above.

Section 2 Definitions of Terminology in the Basic Principles

2.1. Research

The research covered by these guidelines is likely to result in the collection of a variety of data and samples relating to people or groups of people under various conditions. The collection methods can be broadly categorized in accordance with the means of collecting the data or samples into experiments, investigations, and observations.

(1) Experiments

Experiments are methods of actively collecting data or samples by artificially establishing conditions or environments for an individual or specified group. For example, experiment methods include the comparison of results before and after applying certain conditional controls or between groups that are subjected or not subjected to certain controls, or the extrapolation of the effects of establishing factors within a certain environment.

(2) Investigations

Investigations are methods of actively collecting data or samples when the artificial establishment of conditions or environments is carried out on only a minor level. For example, investigation methods include the use of language, numbers, or the like to identify the response

of individuals, specified groups, or unspecified general groups based on questions (paper-based, interviews, and the like) or the contents of recorded natural action states in vehicle usage scenarios.

(3) Observations

Observations are methods of collecting data or samples without active intervention and with the artificial establishment of conditions or environments kept to a minimum, and then using these results to identify the natural behavior, action states, or the like of individuals, specified groups, or unspecified general groups.

2.2. Research subjects

In research involving human subjects, the scope of the term “research subjects” covers the person or persons that are being researched, the person or persons who requested the research, and the person or persons who provided human-derived samples (for example, saliva, urine, blood, and the like) or human-derived information (for example, related to lifestyles, behavior, preferences, impressions, and the like) used in the research. Research subjects include individuals, specified groups, or unspecified general groups.

2.3. Person or persons responsible for the research

These people are defined as the person or persons that take responsibility for planning and performing research involving human subjects, and who administer, manage, and monitor work related to that research.

2.4. Person or persons conducting the research

These people are defined as the person or persons involved in the collection, analysis, management, and the like of data, samples, and so on in the planning, experiments, investigations, and observations of research involving human subjects. These people also include persons engaged in auxiliary roles such as measurement, analysis, and the like.

2.5. Third party

A third party is anyone related to the research not covered by the definitions of the person or persons responsible for the research, the person or persons conducting the research, or the research subjects.

2.6. Ethics Review Board, etc.

This is an organization with the multifaceted role of investigating, deliberating, and advising the planning of research involving human subjects from various ethical standpoints, including

the personal dignity, human rights, and safety of the research subjects, while considering the social and scientific aspects of the research.

2.7. Personal information

Of the information obtained from the research subjects and the like or the information used in the research and the like, this covers information related to individual research subjects. This is information that can be used to identify specific individuals from descriptions, images, or the like, including names, dates of birth, and so on, which results in violations of an individual's privacy, dignity, safety, and so on. It also includes information that may be easily verified against other information to identify specific individuals.

2.8. Necessary measures to protect personal information, privacy, and the like

These are measures that should be carried out so that individual research subjects cannot be identified when the results of the research are announced.

2.9. Informed consent

This refers to the process that shall be carried out by the person or persons conducting the research when requesting someone to become a research subject. This process involves an explanation from the person or persons conducting the research so that the potential research subjects can determine whether to agree to participate in the research. This explanation shall enable the potential research subjects to fully understand the contents of the research, to make an intentional judgment and agreement for themselves about whether to become a research subject, and to consent with respect to the handling of data, samples, personal information, and the like obtained in the research.

Section 3 Supplemental Explanation of Basic Principles

3.1. Deliberations of research plans by Ethics Review Board or the like

(1) Key points to be noted when formulating research plans

- Hazards or risks in excess of the minimum levels faced by research subjects in their daily lives shall be predicted. If the Ethics Review Board or the like judges that the plan does not contain measures capable of avoiding these hazards or risks, such research shall not be planned on principle.

- The research plan shall contain all the specific information required by the Ethics Review Board or the like to judge the ethical validity of the research. The following points are examples of items that shall be included in the plan.

The action plan for the research itself (*)

The disadvantages, hardships, and risks involved in the research, and the methods to prevent them or ensure safety

The details of explanations about the research to research subjects and methods to confirm consent (i.e., the informed consent procedure)

Whether or not participating in the research involves any form of compensation, and if so, the details of the compensation

Methods of announcing the results (including the necessary measures to protect personal information) and the like

(*) Details of action plan

The research duration, person or persons responsible for the research, person or persons conducting the research, locations where the research is to be conducted, purpose of the research, research methods (devices to be used, measurement items, as well as the likely burden to be imposed on the research subjects, issues related to the work, time required to spend participating in the research, and the like), information related to the research subjects (including payment information), and so on

(2) Deliberations by Ethics Review Board or the like

- The aim of the deliberations by the Ethics Review Board or the like is to examine the individual research plans from ethical and scientific standpoints and to provide advice to improve the research plan by expressing opinions about its details and the like so that the research can be carried out appropriately and smoothly.

- If the research organization does not have an Ethics Review Board or the like, it shall establish such a function as soon as possible. While this function is being established, the organization shall obtain confirmation from a suitable third-party that the research plan in question complies with the Ethical Guidelines for Research Involving Human Subjects prepared by the JSAE. Note that a "suitable third-party" refers to a person or persons with the necessary experience to take responsibility for ethical and legal compliance. This experience shall have been obtained, for example on the Ethics Review Board of another organization or in the organization in question.

- The Ethics Review Board or the like shall consist of people with various backgrounds to ensure that the deliberations can be carried out fairly and impartially from a number of different standpoints.

- The members of the Ethics Review Board or the like shall not disclose information obtained in the course of their work without due reason. This shall apply even after the member has left the Ethics Review Board or the like.

- Persons related to the research plan to be deliberated (i.e., the person or persons responsible

for the research, the person or persons conducting the research, and the like) may not participate in deliberations about the research.

(3) Management in the research implementation stage

- The research shall be suspended or stopped in the following events: if the risks are judged to outweigh the expected merits of the research, if a serious accident occurs, if the research meets its targets by obtaining sufficient results prior to the initially planned completion of the research, or if it is no longer meaningful to perform the research.

- Systems and procedures in the event of an accident or the like shall be established in advance. The person or persons conducting the research and the like shall have thorough knowledge of these procedures and shall follow the procedures without fail.

- The necessary systems to protect personal information related to the research shall be established. Safety procedures shall be followed when the person or persons conducting the research or the like handle personal information.

3.2. Protection of personal information

- In principle, data and samples that include personal information in research shall be anonymized. Anonymizing personal information refers to the removal of all or part of information capable of identifying individuals from that personal information to prevent disclosure of personal information outside the research. The removed information shall be replaced by symbols or codes.

- There are two methods of anonymizing personal information, traceable and untraceable anonymization. Traceable anonymization involves applying a new symbol or code for a research subject to ensure that person can be identified as necessary, and maintaining a table that explains the meanings of the symbols or codes. In untraceable anonymization, such a table is not created.

- When research results are announced, it shall not be possible to identify individual research subjects from the results. However, if there is value in announcing the results in a format that is capable of identifying individual research subjects (for example, research using facial expressions), then the consent of the research subjects shall be obtained in advance.

Supplement: Paragraph 1 of Article 50 of the Japanese Act on the Protection of Personal Information makes exclusions to the application of this Act in reference to the basic human right of academic freedom guaranteed under the Japanese Constitution. Therefore, legal obligations and other regulations may not be applicable when a university or other institute that aims to perform academic research handles personal information. However, even in these cases, Paragraph 3 of Article 50 of the same Act requires such institutes to voluntarily establish measures to secure personal information when it is handled. It is preferable that academic

research should be carried out in accordance with the details of related governmental codes in the medical research field and the like.

3.3. Informed consent

- In principle, informed consent shall be obtained using a written explanation of the research details. Consent to participate in the research shall also be obtained in writing using a consent form.

Supplement: There shall be no need to obtain written consent in the case of anonymous questionnaires and the like. In these cases, filling out the questionnaire itself may be regarded as consent.

- Explanations for potential research subjects shall be written in such a way that the research subjects can thoroughly understand the details of the research and make a free judgment for themselves about whether to participate. The research subjects may refuse to participate in the research after reading and thoroughly understanding the explanation. The written explanation shall contain specific descriptions with all the information necessary to make a judgment about participation. In addition, the explanation shall not cause misunderstanding or be at variance with the facts. Specialist terminology shall be avoided whenever possible and the explanation shall be written in plain language. The following points are examples of items that shall be included in the explanation.

The action plan for the research itself (*)

The disadvantages, hardships, and risks involved in the research, and the methods to prevent them or ensure safety

Whether or not participating in the research involves any form of compensation, and if so, the details of the compensation

Methods of handling the research data and announcing the results (including the necessary measures to protect personal information)

The right to refuse to participate and the right to stop participating at any time

Contact details for queries or complaints about the research

(*) Details of action plan

The research duration, person or persons responsible for the research, locations where the research is to be conducted, purpose of the research, research methods (measurement items, details of any personal information or human-derived samples, as well as the likely burden to be imposed on the research subjects, issues related to the work, time required to spend participating in the research, and the like), information related to the research subjects, and so on

- Informed consent shall be obtained directly from the actual potential research subject, providing that person is capable of expressing the intention to participate. If the potential

research subject is living but cannot effectively express the intention to participate, then informed consent shall be obtained from a proxy (a legal representative capable of representing the intentions and interests of the research subject, or a close family member). If the potential research subject is deceased, then informed consent shall be obtained from the family of the deceased (spouse, adult child or grandchild, sibling, parent, grandparent, a family member that cohabited with the deceased, or an equivalent person).

- If informed consent is not obtained in this way, or informed consent is obtained through a proxy, then the appropriateness of the consent shall be deliberated by the Ethics Review Board or the like.

End

Permission was obtained from the Japan Ergonomics Society to reference its Code of Conduct for Ergonomic Research in formulating these guidelines.

Related materials

- World Medical Association: Declaration of Helsinki
- Ministry of Health, Labour and Welfare: Ethical Guidelines for Epidemiological Research
- Ministry of Health, Labour and Welfare: Ethical Guidelines for Clinical Research
- Nuremberg Code
- Belmont Report: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Research Ethics Committee
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