

Ethical Procedures Checklist

- ◆ Please check all boxes that apply to your presentation.
 - ◆ If your presentation includes research that falls under multiple categories, please check all relevant categories.
 - ◆ For details of category classification, please refer to the *Guidelines on Ethical Procedures for the Submission of Abstracts to Scientific Meetings* drawn up by the Research Ethics Committee of the Japanese Medical Science Federation.
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■ Category I: Specified Clinical Research

(Both boxes below must be checked for this category.)

- ☐ The research complied with the requirements of the Clinical Trials Act, including review by a certified review board; implementation of monitoring and audits; compliance with implementation standards, including conflict of interest management; obtaining informed consent; protection of personal information; and record keeping.
- ☐ The research was conducted after submitting the implementation plan to the Minister of Health, Labour and Welfare, following consultation with a certified review board authorized by the Minister of Health, Labour and Welfare.

■ Category II: Basic Research Using Human ES Cells, Human iPS Cells, or Human Tissue Stem Cells; Clinical Research Related to Regenerative Medicine; or Research on Human Gene Therapy or Human Fertilized Embryos

(Please check all applicable boxes below for this category.)

- ☐ The research was conducted in accordance with the relevant laws and guidelines listed under “About Regenerative Medicine” on the Ministry of Health, Labour and Welfare website.
- ☐ If the research involves human gene therapy, it was conducted in accordance with the *Guidelines for Clinical Research on Gene Therapy*.
- ☐ If the research involves human fertilized embryos, it was conducted in accordance with the *Guidelines on Assisted Reproductive Technology Research Involving the Creation of Human Fertilized Embryos* and the *Guidelines on Research Using Gene-altering Technologies on Human Fertilized Embryos*

■ Category III: Research Involving Invasive Procedures or Interventions

- ☐ Prior approval from the head of the institution, based on a review by the ethics committee, has been obtained, and informed consent has been received from the participants or their legal representatives.

(This box must be checked for this category.)

- ☐ For interventional research, registration in a public database such as jRCT has been completed prior to the commencement of the research.

(Please check this box if applicable.)

- ☐ If the research involves invasive procedures (excluding minimally invasive procedures) and interventions, appropriate measures have been taken for the management of serious adverse events, as well as for the storage and management of research samples and information. Monitoring and audits, where necessary, have also been conducted.

(Please check this box if applicable.)

Notes:

- Studies involving additional blood sampling, tissue collection, or invasive examinations conducted for research purposes generally fall under this category, even when observational.
- Even for questionnaire-based surveys involving patients, this category should be considered if the questions address psychological trauma and are expected to cause mental distress to participants.

■ **Category IV-A: Research Involving the Acquisition of New Samples and/or Information**

- ☐ Approval from the head of the institution, based on a review by the ethics committee, has been obtained.
(This box must be checked for this category.)

- ☐ Research involving the use of samples obtained from the human body
(If this box is checked, the following box must also be checked.)

- ☐ Written informed consent has been obtained from the participants or their legal representatives. If written informed consent is not obtained, oral informed consent has been received, and a record documenting the method and content of the explanation, as well as the content of the consent provided, has been created.

- ☐ Research not involving the use of samples obtained from the human body
(If this box is checked, the following box must also be checked.)

- ☐ Appropriate consent has been obtained from the participants or other relevant individuals. For research where simplification of the consent procedure has been approved, necessary procedures, such as providing an opt-out opportunity, have been implemented.

Notes:

- Studies that newly administer patient questionnaires for research purposes, as well as studies that prospectively collect patient information, generally fall under this category.
- However, even for patient questionnaires, Category III should be considered if questions addressing psychological trauma are included.

■ Category IV-B: Research Involving the Use of Existing Samples and/or Information

- ☐ Approval from the head of the institution, based on a review by the ethics committee or a similar advisory committee, has been obtained.

(This box must be checked for this category.)

- ☐ Research involving the use of samples obtained from the human body

(If this box is checked, the following box must also be checked.)

- ☐ Written informed consent has been obtained from the participants or their legal representatives. If written informed consent is not obtained, oral informed consent has been received, and a record documenting the method and content of the explanation, as well as the content of the consent provided, has been created. For research where simplification of the consent procedure has been approved, necessary procedures, such as providing an opt-out opportunity, have been implemented.

- ☐ Research not involving the use of samples obtained from the human body

(If this box is checked, the following box must also be checked.)

- ☐ Informed consent has been obtained. For research where simplification of the informed consent procedure has been approved, necessary procedures, such as notifying or disclosing relevant information to participants and providing an opt-out opportunity, have been implemented.

- ☐ Research involving the provision of existing samples and/or information from other institutions

(If this box is checked, both boxes below must also be checked.)

- ☐ The status of the samples and/or information, including informed consent, information from the source institution, and the history of acquisition of the sample and/or information, has been confirmed, and a record of their provision has been created.

- ☐ The providing institution has taken appropriate measures regarding the provision of existing samples and/or information, and the recipient institution has followed appropriate procedures in accordance with those measures, including providing an opt-out opportunity where necessary.

Notes:

- Retrospective studies using existing medical record information, secondary use of existing hospital databases, and studies using laboratory test results already obtained during routine clinical practice generally fall under this category.
- Studies that extract clinical information held by the institution for research purposes and use it with an assigned research ID are generally not regarded as “research using pre-existing anonymized information”; rather, they should be reviewed under this category.

■ **Category V: Research Outside the Scope of the *Ethical Guidelines for Medical and Biological Research Involving Human Subjects***

(Please check all applicable boxes below for this category.)

- ☐ Case reports excluding studies falling under Categories I to IV.
- ☐ For presentations involving participants, appropriate consideration has been given to the protection of personal information.
- ☐ Research not involving human subjects, including animal experiments, genetic modification experiments, humanities and social science research, and research on medical systems where no human participants are involved.
- ☐ Research conducted in accordance with statutory requirements, or research falling within the scope of statutory standards (e.g., [post-marketing surveillance](#), [early post-marketing phase vigilance](#)).
- ☐ Research using samples and/or information that have already established academic value, are widely used for research purposes, and are generally available (e.g., [analysis using only literature published on the internet or public databases](#); [meta-analysis](#)).
- ☐ Research using existing information that does not constitute personal information.
- ☐ Research using pre-existing anonymized information (e.g., [research using only anonymized data provided by external organizations](#)).
- ☐ Research consisting solely of analysis of published literature or public databases/guidelines.
- ☐ For case reports involving the provision of complex new medical technologies or unapproved new medical products, appropriate procedures have been taken.

Notes:

- Even for surveys not involving patients, such as surveys of medical staff, if the study concerns education, medical systems, work improvement, or medical safety where no human participants are involved, this category should be selected.
- Even for surveys targeting medical staff, if personal information is collected and analyzed as research, this category should not be uniformly selected. Confirm with the ethics committee of the affiliated institution whether it is applicable.
- Studies that extract clinical information held by the institution for research purposes and use it with an assigned research ID are generally not regarded as “research using pre-existing anonymized information.”