

Excerpts from the guidelines on ethical procedures for submitting abstracts to academic conferences

From the Japan Medical Association Union Research Ethics Committee

If you would like to read the full guidelines, please contact the conference secretariat.

■ 5. Category V: Research outside the scope of the "Life and Medical Guidelines"

5.1 Case reports

Case reports must comply with the Personal Information Protection Act and related laws and regulations. Case reports that do not involve research-related actions are outside the scope of the "Life and Medical Guidelines"3) (category V), but when research-related actions such as invasive procedures or interventions are involved, or when analysis methods for observational studies are used, the "Life and Medical Guidelines"3) apply regardless of the number of cases, and ethical procedures corresponding to the appropriate category according to the research design are required.

In addition, when a case report is made when medical care9) is provided using highly difficult new medical technologies or unapproved new medical products, appropriate procedures must be taken for each case.

In this guideline, there is no limit on the number of cases in a case report. In other words, so-called case series, which present multiple cases without invasive or interventional research purposes and without comparative studies or statistical analysis, are also treated as case reports.

1) In case reports, "personal information" and "personal identification codes" as stated in the "Ethical Guidelines for Life Science and Medical Research Involving Human Subjects", including the name, hospitalization number, initials, or "name" that can identify individual research subjects, should not be included. For example, the following points should be noted. 1. The address of the research subject should not be included. However, if the location of the disease is involved in the pathology, it is acceptable to limit the description to the area. (Kanagawa Prefecture, Yokohama City, etc.)

2. The date is often necessary to know the clinical course, so if it is determined that the individual cannot be identified, the year and month may be included.

3. If the research subject can be identified by comparing the name of the medical department with other information, do not include the name of the medical department.

4. If the subject has already been diagnosed or treated at another hospital, do not include the

name or location of that facility. However, this does not apply if it is essential to include the origin of transportation, such as in emergency medical care.

5. When presenting a photograph of the face, the eyes should be hidden. In the case of eye diseases, a close-up photo of only the eyeball should be used so that the entire face cannot be seen.
6. Any numbers contained in biopsy, autopsy, or image information that could identify the case should be deleted.

2) If there is a possibility that individuals may be identified despite taking the above precautions, obtain consent for publication from the research subject, etc., or obtain permission from the head of the research institution after the ethical review committee or the institution's committee that determines the appropriateness of case reports has reviewed the suitability of the ethical guidelines (similar to 4.2 Category IV-B).

3) When providing medical care using highly difficult new medical technologies or unapproved new medical products, the Ministry of Health, Labor and Welfare's Special Research Group on Science and Technology, "Research Group on the Evaluation and Improvement of Clinical Practice Guidelines Related to the Introduction Process of Highly Difficult New Medical Technologies," has set out basic principles for medical safety when introducing highly difficult new medical technologies.⁹⁾ In these cases, procedures must be in accordance with the policies of each institution even for case reports that are not for research purposes.

4) With regard to regenerative medicine, legal compliance is required not only for "research" but also for "treatment," so care must be taken when reporting cases.