

Japan Association of Microscopic Dentistry Ethics Review Rules

Established July 31, 2008
Enforced on August 1, 2014

Chapter 1 General Provisions

(Purpose)

Article 1. These regulations shall be established with the following objectives. The Japan Association of Microscopic Dentistry (hereinafter referred to as "the Association") is aiming to achieve the objectives of this corporation prescribed in Chapter 2 of the Covenant, with respect to various problems in various research activities of the Association, make its ethics judgements and give advice.

Chapter 2 Procedures for Securing Research Ethics (Business of the Ethics Review Committee)

Article 2. In order to achieve the purpose of this Regulation, the Society of the Ethics Review Committee (hereinafter referred to as the "Committee") under the direction of the President of the Society (hereinafter referred to as the "President") do the following tasks.

- (1) Recommendations on initiatives for improving members' research ethics
- (2) Report on rulings based on consultation from the president
- (3) Deliberation on revising or abolishing rules
- (4) Other operations that the Committee considers necessary

(Items to be discussed)

Article 3. The Committee shall deliberate on the following matters in order to achieve the purpose of this Regulation.

- (1) Ethical review on clinical research led by the Association.
- (2) Matters requiring ethical judgment when doing research on dentistry examination
- (3) Other matters that the Board / Committee deems necessary

(Person responsible for implementation)

Article 4. Person who supervises research led by the Society or the principal responsible person who belongs to the Association and conducts research for medical institutions and research institutions without an ethical review committee, etc.

(Application Procedure)

Article 5. The person responsible for implementation shall fill in the necessary matters in the application form for ethics examination (separate form) and submit it to the president.

2 The president consults application matters with the committee, and the committee deliberates about application matters.

3 The chairperson shall report the result of the deliberation to the President.

4 The President notifies the applicant through the discussion with the Board of Directors of the contents of the report.

(Publication)

Article 6. The Committee shall publish a summary of the records of the Committee. However, this is not the case if there is a possibility that the uniqueness of research and the intellectual property rights are infringed by the publication. In addition, when providing the retained personal information according to laws and regulations, documents shall be exchanged on the purpose of use at the submission destination, the laws and regulations of the business to be used and the form of use, etc.

(Report)

Article 7. The responsible person shall promptly report to the committee after the research is completed.

2 The responsible person shall report to the committee once a year on the progress of the research being undertaken.

3 The responsible person must report to the committee immediately if he / she knows of serious adverse events related to research and occurrence of defects.

4 In the event of any reporting required, the responsible person shall report to the committee.

(Measures for Offenders)

Article 8. The chairperson shall report to the president when the responsible person violates this rule or there is a risk of violation.

2 When receiving the report set forth in the preceding paragraph, the president may hear opinions of the committee and order correction, suspension or cancellation of the implementation plan.

(Technical Committee)

Article 9. In order to investigate and study special matters, a committee may establish an expert committee within the committee.

2 The expert adviser shall be appointed by the president by hearing the opinion of the Chairman from the academic experts on the subject matter concerned.

3 Where the Committee deems it necessary, the Committee may request the attendance of expert advisors, receive reports of investigated considerations and add them to the discussion. However, expert advisors can not participate in judgment panel. The term of office of the expert committee shall be until the date of the completion of the review of the project concerned.

(Confidential Information)

Article 10. The members of the committee and the expert advisors shall not disclose information that was known in the course of their duties without just cause. This will effect the same even after he/she retires from that position.

(Supplementary provision)

Article 11. The person responsible for implementation may attend the committee, explain the details of the application, and state the opinion.

Article 12. In order to revise or abolish this rule, the decision of the Board shall be passed.

Article 13. In addition to what is provided for in this rule, the committee separately specifies matters necessary for the implementation of this rule.

Supplementary provision 1

This rule shall come into force from August 1, 2014.