

Detailed Rules for the Policy on Conflict of Interest (COI) for a Specified Non-profit Corporation: the Japanese Society of Periodontology

The Japanese Society of Periodontology (hereafter called “this society”) hereby sets forth the following Detailed Rules for the Policy on Conflict of Interest, pursuant to “the Policy on Conflict of Interest (COI) of the Japanese Society of Periodontology”, to ensure the equitable management of conflict-of-interest (COI) situations involving this Society and its members.

Article 1 (Declaration and Announcement of COI-related Matters in this Society’s Lecture Meetings, etc.)

Paragraph 1

For presentations and speeches on dental research associated with this Society that are conducted at scientific meetings, clinical workshops, lectures open to the public, and other venues, whether by members or non-members, and for presentations and speeches by members at lecture meetings, seminars, luncheon seminars, and evening seminars co-hosted by companies or commercial institutions, all presenters shall make a declaration via the designated forms of this Society regarding the existence of a COI in the year prior to the time of submission. This COI could include financial relationships with businesses, corporate organizations, or other for-profit groups related to dental research, in terms of presentation, and include the presenter’s spouse, first-degree family members, and persons with whom expenses are shared. All presenters shall announce the relevant COI in the first presentation slide (or in the slide after that with the title and presenters), or in a designated form at the end of a poster.

Paragraph 2

“Businesses, corporate organizations, or other for-profit groups related to dental research” refers to businesses, organizations, or groups with the following relationships to dental research:

- (1) Commissioning or joint conduct of dental research (with or without compensation).
- (2) Shared patent rights or other rights related to treatment methods, drugs, instruments, etc. that are assessed in dental research.
- (3) Provision of drugs, equipment, etc. used in dental research at no charge or at a significant discount.
- (4) Provision of research grants, donations, etc. for dental research.
- (5) Provision of unapproved pharmaceuticals, medical instruments, etc. for dental research.
- (6) Sponsorship of endowed lectures or similar activities.

Paragraph 3

“Dental research” related to the title of the presentation refers to dentistry-related research conducted with the aim of improving methods of disease prevention, diagnosis or treatment in the field of dentistry, understanding the causes or pathology of diseases, or improving patient quality of life. Dental research on humans shall include specimens from humans or data analysis from which individuals can be identified. Specimens or data deemed to enable identification of individuals shall be defined pursuant to the “Ethical Guidelines for Medical and Health Research Involving Human Subjects” of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare of Japan (December 2014).

Article 2 (On the Standards for COI Self-Declaration)

The standards for monetary amounts, etc. requiring COI self-declaration are as follows.

- (1) For officers, advisors, consultants, and employees of a business, corporate organization, or other for-profit group (hereinafter, “business, organization, or group”) related to dental research, the amount of compensation from such business, organization, or group is ¥1,000,000 or more per year.
- (2) For holding of stocks or bonds of a business, organization, or group, the profit (cumulative total of dividends and gains on sales) from the stock of one business in one year, regardless of whether it is listed or pre-listed, is ¥1,000,000 or more, or the holdings constitute 5% or more of all shares of the company’s stock.
- (3) For royalties, etc. from a business, organization, or group, the annual royalty fee from a single patent in one year is ¥1,000,000 or more.
- (4) For per diem compensation (lecture fees, etc.) paid from a business, organization, or group for time and labor of the person concerned for meeting attendance (presentation), the total lecture fees from one business, organization, or group in one year are ¥500,000 or more.
- (5) Regarding manuscript fees paid by a business, organization, or group for authoring of pamphlets, websites, etc., the total manuscript fees from one business, organization, or group in one year are ¥500,000 or more.
- (6) For dental research fees (clinical trial fees, clinical research fees, contract research fees, scholarship donations, etc.) provided by a business, organization, or group, the total amount paid from one business, organization, or group in one year is ¥1,000,000 or more.
- (7) The declarer is affiliated with or serves concurrently as a lecturer in an endowed lecture provided by a business, organization, or group.
- (8) For furnishing of other travel, gifts, etc. not directly related to research, the total amount received from one business, organization, or group in one year is ¥50,000 or more.

Regarding (6), declaration is also required in cases where research expenses, scholarship

donations, etc. have been provided by businesses, groups, etc., with which there is a COI relationship that should be disclosed in connection with the presentation of research results to the presenter or the department (faculty or division) or laboratory to which the presenter belongs.

Article 3 (Declaration and announcement of conflicts of interest in this Society's Journals, etc.)

All authors with publications (original research papers, etc.) in this Society's Journal (the Journal of the Japanese Society of Periodontology) or other publications must notify the Society's Secretariat of any COI in the year prior to the date of submission, in advance using the forms stipulated in the submission rules.

Article 4 (Submission of COI Declarations by Officers, Committee Chairpersons, Committee Members, etc.)

Paragraph 1

Regarding Section 5: "Matters to be Declared" in the Policy on Conflict of Interest of the Japanese Society of Periodontology, this Society's officers (Chairman of the Board of Directors, Directors, and Auditors); person in charge of scientific meetings, clinical workshops, lectures open to the public, lecture meetings, etc.; chairpersons of each committee and committee members; members of working committees; and employees of the Society must submit a COI self-declaration to the Board of Directors upon assuming their positions and each year thereafter, disclosing any COIs in the year prior to the time of starting the position, in accordance with the designated forms of the Society. A COI self-declaration need not be submitted if one has already been submitted. COI self-declarations are limited to those related to businesses, corporate organizations, or other for-profit groups involved in projects conducted by this Society.

Paragraph 2

COI situations to be detailed in the self-declaration are those provided in Section 5: "Matters to be Declared" in the Policy on Conflicts of Interest of the Japanese Society of Periodontology. The monetary amounts requiring self-declaration for each item to be disclosed or announced shall be based on the standard amounts provided in Article 2, and the portion during the year prior to the time of starting the position shall be entered according to the designated forms of this Society, with the calculation period clearly indicated.

Article 5 (Handling of COI Self-Declarations)

Paragraph 1

The COI self-declaration to be submitted when registering an abstract for an academic meeting presentation or submitting a research paper to this Society's journals will be stored under

stringent conditions at the Society's Secretariat under the supervision of the Chairman of the Board of Directors for a period of two years from the date of submission. Similarly, documents containing COI information related to persons who have ended their terms as officers and persons whose withdrawal from committee membership has been finalized will be stored under stringent conditions at the Society's Secretariat under the supervision of the Chairman of the Board of Directors for a period of two years from the end of the final term in the position or the date of withdrawal from committee membership. COI self-declarations that have exceeded the two-year period shall be deleted and disposed of under the supervision of the Chairman of the Board of Directors. However, in cases where the Board of Directors deems deletion or disposal to be inappropriate, a required period of time shall be designated and the deletion and disposal of the COI information from the declarer shall be delayed for that period of time.

Paragraph 2

This Society's Directors and related officers shall determine the existence and degree of a COI for an individual based on the submitted self-declaration, in accordance with these Detailed Rules. If this Society conducts management and takes measures in line with such determinations, the COI information of the declarer shall be usable as needed. However, the information must not be used in excess of that required for usage purposes, and disclosure must not be carried out for persons other than those for which disclosure is deemed necessary for these usage purposes.

Paragraph 3

COI information shall be kept confidential, except in cases provided for in Article 5 Paragraph 2. When COI information is necessary in order to fulfill social and moral explanatory obligations of this Society in connection with society's activities, committee activities (including ancillary full-time subcommittees and other activities), provisional committee activities, etc., such information may be disclosed or announced within this Society and externally to the extent necessary, after deliberation within the Board of Directors. However, this provision shall not preclude entrustment to particular Directors who handle such issues and make the decision based on the advice of the COI Committee. In such cases, the person whose COI information is to be disclosed or announced may state his or her opinion to the Board of Directors or the Directors entrusted with making the decision. However, this may not be possible in situations where disclosure or announcement is urgent and there is no latitude to hear such opinions.

Paragraph 4

When there is a demand for disclosure of a COI of a named member (including a legal demand), if there is reason to deem this suitable, the COI Committee will handle the situation while

protecting personal information, after consulting with the Chairman of the Board of Directors. However, in cases where it is deemed that the COI Committee is unable to handle the situation, a COI Investigative Committee shall be established consisting of several members of this Society appointed by the Chairman of the Board of Directors and at least one outside committee member, and this new committee shall be consulted. After receiving the disclosure demand, a committee meeting will be held as soon as possible and the findings will be reported.

Article 6 (COI Committee)

Several members of this Society appointed by the Chairman of the Board of Directors and at least one outside committee member shall comprise the COI Committee, and a committee chairperson shall be selected by appointment of the Chairman of the Board of Directors. The COI Committee members bear the obligation of retaining the confidentiality of COI information learned about members. The COI Committee shall coordinate with the Board of Directors to carry out management to prevent COI situations of members becoming serious and to handle violations, pursuant to the relevant provisions of the COI Policy and these Detailed Rules. The provisions of Article 5 shall apply *mutatis mutandis* to the reporting of COI matters regarding members and the handling of COI information.

Article 7 (Measures for Violators)

Paragraph 1

If there are questions or social or moral issues arising in connection with COI self-declaration items submitted by authors publishing in this Society's journals (Journal of the Japanese Society of Periodontology) and other publications, as well as scheduled presenters at scientific meetings, etc. held by this Society, the COI Committee may report to the Board of Directors and take appropriate measures to fulfill this Society's obligations to explain these matters to the general public, after sufficient investigations and hearings have been conducted. In cases where there is a serious COI and the committee is unable to fulfill its explanatory obligations, the Board of Directors may take the necessary measures based on the report from the COI Committee. In cases where questions or other issues arise after a presentation has already been given, the Board of Directors may conduct a factual investigation and take measures such as retraction of a published research paper if a violation is found, and may take measures against the member's qualifications, etc. in accordance with the Articles of Incorporation of this Society, in the event that the content of the violation would significantly damage the public's trust in this Society.

Paragraph 2

If an issue is indicated with COI items declared by this Society's officers, chairpersons of each

committee, committee members subject to COI self-declaration, and candidates for the same before or after taking up their positions, the chairperson of the COI Committee shall report the matter to the Chairman of the Board of Directors in writing. The Chairman shall promptly convene a meeting of the Board of Directors and may take the necessary measures after deliberations.

Article 8 (Statement of Disagreement)

Paragraph 1: Request for Statement of Disagreement

Pursuant to Article 7 Paragraph 1, if a person who has received notice of a decision for measures to be taken from the Board of Directors with regard to presentations (in this Society's journals, at scientific meetings, etc.) of projects of this Society disagrees with the results, such a person may request an inquiry within seven days, starting from the date on which the notice of the result of the Board of Directors resolution was received, by submitting a Statement of Disagreement Inquiry Request to the Society's Secretariat, addressed to the Board of Directors. The inquiry request shall concisely state the specific objections or dissenting opinion on the reasons for the measures that were indicated in writing by the committee chairperson. In such cases, relevant information to serve as evidence for the reasons for opposition, in addition to the information disclosed to the committee chairperson, may be indicated in writing.

Paragraph 2: Statement of Disagreement Inquiry Procedures

1. When an inquiry request on a statement of disagreement is received, the Chairman of the Board of Directors must promptly form a Statement of Disagreement Inquiry Committee (hereinafter, "Provisional Advisory Committee"). The Provisional Advisory Committee will consist of several members of this Society appointed by the Chairman of the Board of Directors and at least one outside committee member, and the committee chairperson shall be selected by mutual vote among the committee members. COI Committee members are not permitted to serve as Provisional Advisory Committee members. The Provisional Advisory Committee will convene and conduct the inquiry as quickly as possible after the receipt of the inquiry request.
2. The Provisional Advisory Committee may hear the opinions of the chairperson of the COI Committee with regard to the statement of disagreement, as well as the person submitting the statement of disagreement, when necessary.
3. Except in extenuating circumstances, the Provisional Advisory Committee will compile its findings regarding the statement of disagreement in writing within one month from the date that the committee was first convened in connection with the inquiry, and submit the findings to the

Board of Directors.

4. The Board of Directors will decide the matter based on the report from the Provisional Advisory Committee. A motion to disagree with the decision will not be acceptable.

Article 9 (Modification of the Detailed Rules)

These Detailed Rules are likely to require partial changes in individual cases due to changes in societal factors and laws regarding industry-academia collaboration. The COI Committee chairperson may, as necessary, form subcommittees to consider COI Detailed Rules under the direction of the Chairman of the Board of Directors, conduct inquiries to review these Detailed Rules, and make changes to these Detailed Rules after passing resolutions in the COI Committee and the Board of Directors. Note that COI Committee members may also serve as subcommittee members.

Supplementary Provisions

Article 1 (Effective Date)

These Detailed Rules were enacted on October 18, 2014 and have been used tentatively from April 1, 2015. They will go into full effect on April 1, 2017.

Article 2 (Revisions to these Detailed Rules)

These Detailed Rules shall, as a general rule, be reviewed every few years in accord with societal factors, amendments or improvements to laws regarding industry-academia collaboration, and changes in conditions surrounding medicine and medical research. Revision of these Detailed Rules must be approved by the Board of Directors.

Article 3 (Special Provision on Application to Officers, etc.)

When enforcing these Detailed Rules, they shall be applied *mutatis mutandis* to persons who have already assumed positions as this Society's officers, etc. to have them promptly conduct the prescribed reporting.

Tentative use of the Detailed Rules started on April 1, 2015

Rules will be enforced from April 1, 2017