

The Academy of Clinical Dentistry

Guidelines on Conflict of Interest (COI)

(Purpose)

Article 1. The Academy of Clinical Dentistry (hereafter referred to as "the Academy") shall establish "Guidelines for Conflict of Interest (COI)" (hereafter referred to as "COI Guidelines") and fairly manage the COI status of members and non-members involved in the Academy's events, publications and other relevant activities.

(Scope)

Article 2. The COI Guidelines shall apply to the following subjects who may be in a state of COI

- 1) Members of the Academy
- 2) Presenters at academic conferences, etc. conducted by the Academy
- 3) Authors of journal articles and academic books published by the Academy
- 4) Researchers involved in research, education and surveys conducted by the Academy
- 5) Officers (directors and auditors) and advisors of the Academy
- 6) Spouse, first-degree relative, or person who shares income or property with the subject of 1) to 5)

(Activities to be covered)

Article 3. The activities covered by the COI Guidelines are as follows

- 1) Holding of academic meetings of the Academy, etc.
- 2) Publication of the Academy's journal and academic books, etc.
- 3) Research, education, and survey projects conducted by the Academy
- 4) Other business activities necessary to achieve the objectives of the Academy's members

(Self-reported disclosure of COI status)

Article 4. Presenters at academic meetings, etc. conducted by the Academy shall submit a COI Disclosure Statement on Form 1 to the President of the Academy by the time of abstract registration for the relevant presentation. At the time of presentation, the relevant COI status shall be disclosed in accordance with each of the following items on Form 2.

- 1) For lecture presentations and oral presentations, the information should be disclosed on the first or second slide.
- 2) For poster presentations, the information is to be disclosed inside the poster. However, if the information cannot be included in the poster, it must be disclosed on the outside of the poster in A4 size.

2. Authors of journals and academic books published by the Academy shall submit a COI Disclosure Statement on Form 3 to the President of the Academy by the time of submission of the relevant paper. The author(s) shall disclose the relevant COI status by stating it before the references at the end of the paper.

3. Researchers involved in research, education and surveys conducted by the Academy shall submit a COI Disclosure Statement on Form 4 to the President of the Academy at the time of submitting an application for research ethics review concerning the relevant research, education and surveys. The researcher(s) shall disclose the relevant COI status in an appropriate manner at the same time as the publication of the research results, etc.

4. Officers (directors and auditors) and advisors of this Academy shall submit a COI Disclosure Statement on Form 5 to the President of the Academy when assuming office. However, representatives, officers and employees of Supporting Members do not have to submit a COI Disclosure Statement. The COI status of the Form 5 is limited to matters related to companies, organizations and associations which are conducting the business with the Academy. If a new COI status arises during the term of office, a COI Disclosure Statement, Form 5, should be submitted to the President again as soon as possible.

(Items to be declared)

Article 5. When any of the following matters specified in the COI Guidelines applies to a relationship with a company, corporate organization, or for-profit organization, the exact situation shall be reported to the President of the Academy using the form specified in the preceding article. The specific method of disclosure and publication of the contents of the disclosure statements shall be in accordance with the COI Guidelines.

- 1) Appointment to board of directors, advisory positions, employees, etc.
- 2) Shareholdings
- 3) Receipt of patent royalties
- 4) Receipt of daily allowance (lecture fees, etc.) paid for conference attendance (presentations, etc.)
- 5) Receipt of manuscript fees for writing articles, brochure, etc. (including those in electronic form)
- 6) Receipt of research funds, grants, etc.
- 7) Receipt of scholarship (incentive) funds, donations, etc.
- 8) Affiliation with Endowed Chairs
- 9) When personnel, equipment, and facilities are provided
- 10) Receipt of travel expenses, gifts, etc. not directly related to the research

(Criteria for COI self-reporting)

Article 6. The thresholds for the preceding article shall be stipulated as follows, and the following amounts do not include consumption tax.

- 1) For directors, advisors, employees, etc., remuneration from a single company, organization, or association amounting to or exceeding JPY1,000,000 per year
- 2) Shareholdings: Annual share profits (total of dividends and gains on sales) of at least JPY1,000,000 for a single company, or at least 5% of all shares in the company
- 3) Regarding patent royalty fees, fees per right amounting to or exceeding JPY1,000,000 per year
- 4) The daily allowance (lecture fee, etc.) paid for attendance at conferences, etc. (presentation, etc.) from a single company, organization, or association amounting to or exceeding JPY500,000 per year
- 5) Manuscript fees for articles, brochures, etc. (including those in electronic form) from a single company, organization, or association amounting to or exceeding JPY500,000 per year
- 6) Research funds and grants for dental research from a single company, organization, or association amounting to or exceeding JPY2,000,000 per year
- 7) Scholarship (incentive) funds, donations, etc. for dental research provided by a single company, organization, or association amounting to or exceeding JPY2,000,000 per year
- 8) Persons affiliated with endowed chair
- 9) When personnel, equipment, or facilities are provided in the course of research
- 10) Receipt of travel expenses, gifts, etc. that are not directly related to the research from a single company, organization, or association amounting to or exceeding JPY100,000 per year

(Handling of COI Disclosure Statements)

Article 7. The COI disclosure statement submitted in accordance with Article 4 shall be kept at the secretariat under the supervision of the President and the COI Committee for two years from the date specified in each of the following items.

- 1) As for Form 1, the date of the academic meeting, etc.
 - 2) As for Form 3, the date of publication of journals and academic books, etc.
 - 3) As for Form 4, the date of publication of the research results, etc.
 - 4) As for Form 5, the date of expiration of the term of office
2. COI disclosure statements that have passed the two-year retention period shall be promptly deleted or destroyed under the supervision of the President and the COI Committee. However, deletion or destruction may be withheld if the President and the COI Committee deem it inappropriate to do so.
3. The President or the COI Committee may use the COI disclosure statement of the reporting person at any time when determining whether or not and to what extent the reporting person has a COI status and taking COI management and other measures into action. However, it shall not exceed the limit necessary for the purpose specified in these guidelines, and no information shall be disclosed to anyone other than those who are relevant in evaluation and management of COI.
4. In principle, COI information shall not be disclosed except in the case of the preceding paragraph. However, when it is necessary for the Academy to fulfill its social and moral accountability, the President, with the advice of the COI Committee and through consultation with the Board of Directors, may disclose or make public COI information within and outside the Academy to the extent necessary. In such cases, the parties concerned with the COI information to be disclosed or made public may express their opinions to the President or the COI Committee. However, this shall not apply in cases of urgency and when there is no time to hear opinions regarding disclosure or publication.
5. The COI Committee will respond appropriately under the protection of personal information in response to any reasonable request for disclosure (including legal requests) naming a specific member, and in consultation with the President.
6. The COI disclosure statement in the first clause may be recorded in electromagnetic form.

(Measures against violators)

Article 8. In the event that any doubt or social or moral problem arises with regard to the submitted COI disclosure statements, the COI Committee shall investigate and take appropriate measures such as advice and guidance in order to fulfill our social accountability.

2. If the person submitting the disclosure statement described in the preceding paragraph has a serious COI status and cannot fulfill his/her accountability, necessary measures may be taken in accordance with the following items.
 - 1) The President may take measures such as suspending the presentation at a conference or the publication of a paper by the person who is scheduled to make the presentation.
 - 2) The President may withdraw the appointment of the relevant Officers and Advisors. The documents and other information on the COI status of the officer or advisor whose appointment has been withdrawn must be kept at the secretariat under the supervision of the President and the COI Committee for two years from the date of withdrawal of the appointment.
3. In the event that a question or other problem arises with a person who has already made a presentation at an academic conference or contributed an article to an academic journal, the President will investigate the facts through the COI Committee and investigate the violation.

If the contents of the violation significantly damage the credibility of the Academy, the Academy may take the necessary measures.

4. The Chairman's authority in this Article shall be exercised with the approval of the Board of Directors. However, in some cases, a subsequent report to and approval by the Board of Directors may be substituted.

(Appeal)

Article 9. Appeal request

- 1) A person who has been notified of a decision on a violation action under Article 8.2 and 8.3 may appeal the decision by submitting a "Request for Review of Appeal" (hereinafter referred to as "Request for Review") to the President within 14 days from the date of notification of the decision by the Board of Directors.
- 2) The complainant may state his or her objections to the action in a specific and concise manner in the request for review, and attach relevant information and documents that provide the basis for the appeal in addition to the information presented to the COI Committee.

2. appeals review procedure

- 1) The President shall establish an Appeal Review Committee (hereinafter referred to as the "Review Committee") when he/she deems it necessary to review appeals. The organization and duties of the Review Committee shall be as follows
- 2) The Review Committee shall consist of a chairperson nominated by the President, a few members of the Academy and one or more external members. Members of the COI Committee may not concurrently serve as members of the Review Committee.
- 3) The Review Committee shall hold its first meeting within 30 days of the establishment of the Committee and shall conduct its review.
- 4) The Review Committee may hear from the COI Committee Chair or the Complainant involved in the allegation, as necessary.
- 5) The Review Committee shall compile a written report and submit it to the President within 60 days of the conclusion of the review of the complaint in question.
- 6) The Board of Directors will discuss the complaint and decide on the action to be taken based on the report of the Review Committee.

(Measures against violators of confidentiality obligations)

Article 10. In managing COI information, the officers, advisors, related officers and administrative staff of the Academy who have obtained COI information on individuals shall be obliged to maintain confidentiality. The Board of Directors shall take disciplinary action against any person or staff of the secretariat who intentionally divulges COI information to outsiders without following the proper procedures. The company may take necessary measures such as the following.

(Amendments)

Article 11. It is anticipated that the COI Guidelines may need to be amended in some cases due to social factors, changes in laws and regulations concerning industry-university collaboration, and other factors. The President may consult with the COI Committee on deliberations for a review of the COI Guidelines, and based on the report of the COI Committee, amendments may be adopted.

Supplementary Provisions

(Effective date)

1. These Gs shall be implemented on a trial basis from 25th November 2015 and shall be fully implemented from 1st July 2016.

(Amendments to the COI Guidelines)

2. These guidelines are based on social factors, revisions of laws and regulations concerning industry-academia collaboration, and the need for medical and clinical research. In principle, the COI Guidelines will be reviewed every two years to adapt to changes in the research environment.

(Article 8 "Measures against violators")

3. After the onset of the trial implementation of these guidelines, the enforcement of Article 8 "Measures against violators" will be suspended for the time being. During this period, the Board of Directors, together with the COI Committee, will work to disseminate the purpose of these guidelines and encourage the full implementation of COI disclosure.

Supplementary Provisions Amended on 15th April 2020

This revision of the guidelines shall come into effect on 15th April 2020.

Appendix 1. Form 1: Conflict of Interest (COI) Disclosure Statement for Presentations at Academic Meetings, etc.

2. Form 2: Conflict of Interest Disclosure

3. Form 3: Conflict of Interest (COI) Disclosure Statement for Article and Book Submissions

4. Form 4: Conflict of Interest (COI) Disclosure Statement for Research, Education, and Surveys

5. Form 5: Conflict of Interest (COI) Disclosure Statement for Appointed Officers and Advisors