

## **Detailed Rules for the Policy on Conflicts of Interest in the Japan Diabetes Society**

The Japan Diabetes Society hereby sets forth the following Detailed Rules for the Policy on Conflicts of Interest, pursuant to the Policy on Conflicts of Interest in the Japan Diabetes Society, 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

When presentations and speeches on medical research are conducted at academic meetings, lecture meetings (annual academic meetings, Progress in Diabetology, and others), lectures open to the public, regional chapter conferences held by chapters, and other venues held by this society, whether by members or non-members, the lead presenter shall make a declaration via the designated forms of this Society as to the existence of a COI situation in the past year counted from the time of the submission, regarding financial relationships with businesses, corporate organizations, or other for-profit groups related to medical research, in terms of the title of the presentation, including the presenter's spouse, first-degree family members and persons with whom expenses are shared.

The lead presenter shall announce the relevant COI situation in the first presentation slide (or in the slide after the one that introduces the title and presenters), or in the designated form at the end of a poster.

#### Paragraph 2

"Businesses, corporate organizations, or other for-profit groups related to medical research" refers to businesses, organizations, or groups that are related to medical research in the following ways.

- (1) They have commissioned medical research or conducted it jointly (whether for compensation or not)
- (2) They share patent rights or other rights in related to treatment methods, drugs, instruments, etc. that are assessed in the medical research
- (3) They provide drugs, equipment, etc. used in the medical research at no charge or at a significant discount
- (4) They provide research grants, donations, etc. for the medical research
- (5) They provided unapproved pharmaceuticals, medical instruments, etc. in the medical research
- (6) They sponsor endowed lectures or similar

#### Paragraph 3

"Medical research" related to the title of the presentation refers to medicine-related research conducted with the aim of improving methods of disease prevention, diagnosis or treatment in the field of medicine, understanding the causes or pathology of diseases, or improving patient quality of life. Medical research on humans shall include specimens from humans that enable

individuals to be identified or research on data that enable individuals to be identified. Whether specimens or data are deemed to enable identification of individuals shall be determined pursuant to the relevant provisions of the Japan Ministry of Health, Labour and Welfare's *Ethical Guidelines for Clinical Studies*.

#### 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 and advisors of a business, corporate organization, or other for-profit group related to medical research (hereinafter, "business, organization, or group"), the amount of compensation from such business, organization, or group is ¥1,000,000 per year or more.
- (2) Regarding the holding of stock, the profit (cumulative total of dividends and gains on sales) from the stock of one company in one year is ¥1,000,000 or more, or the holdings constitute 5% or more of all shares of the company's stock.
- (3) Regarding patent rights and royalties from a business, organization, or group, the annual royalty fee from a single patent in one year is ¥1,000,000 or more.
- (4) Regarding per-diem compensation (lecture fees, etc.) paid from a business, organization, or group for the researcher's time and labor taken up by meeting attendance (presentation), the total of lecture fees from one business or group in one year is ¥500,000 or more.
- (5) Regarding manuscript fees paid by a business, organization, or group for the authoring of pamphlets, etc., the total manuscript fee from one business, organization, or group in one year is ¥500,000 or more.
- (6) Regarding research fees provided by a business, organization, or group, the total amount paid from one business or group for medical research (contracted research fees, joint research fees, etc.) in one year is ¥2,000,000 or more.
- (7) Regarding scholarship (grant-in-aid) donations by a business, organization, or group, the total amount paid from one business, organization, or group to the declarer as an individual, the department (course, field) to which the declarer belongs, or the representative of the laboratory in one year is ¥2,000,000 or more.
- (8) The declarer is affiliated with the endowed lecture provided by a business, organization, or group.
- (9) Regarding the furnishing of other travel, gifts, etc. not directly related to the research, the total amount received from one business, organization, or group in one year is ¥50,000 or more.

However, regarding (6) and (7), declaration is required in cases where research expenses, scholarship donations, etc. have been provided from businesses, groups, etc., with which there is a COI relationship that should be disclosed in connection with the presentation of the research results, to the presenter or the department (course, field) or laboratory to which the presenter belongs.

### Article 3 (Announcement of Notified Matters in this Society's Journals, etc.)

All authors who make presentations (research reviews, original research papers, etc.) in this Society's journals (Diabetology International, Diabetes) or other publications must notify the Society's Secretariat of any COI situations in the past year dating from the date of submission, in advance, using the forms stipulated in the submission rules. The content entered into this COI Self-Report Form or COI Report by Self-Declaration will be displayed at the end of the research paper, in the acknowledgments, or before the references. If there are no regulated COI situations, a statement such as, "No potential conflicts of interest were disclosed," will be displayed in the same place.

### 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 Conflicts of Interest in the Japan Diabetes Society, this Society's officers (Chairman of the Board of Directors, Directors, and Auditors), chairpersons of academic meetings and lecture meetings (annual academic meetings, Progress in Diabetology, regional chapter conferences held by chapters, and others), facilitators, all 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 the existence of any COI situations in the past year dating from the time of assumption of 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. However, 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

The 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 in the Japan Diabetes Society. 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 past year dating from the time of assumption of 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 must 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 entrustment has been finalized must 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 entrustment. COI self-declarations that have exceeded the two-year period shall be promptly 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 COI situation for the individual based on the submitted self-declaration in accordance with these Detailed Rules, and if this Society conducted 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 the degree required for the usage purposes, and disclosure must not be carried out for persons other than those for which disclosure is deemed necessary in view of the abovementioned usage purposes.

#### Paragraph 3

COI information shall be kept confidential in principle, except in the cases provided in Article 5 Paragraph 2. When COI information is necessary in order to fulfill the social and moral explanatory obligations of this Society in connection with academic meeting 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 making 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 specifically named member (including a legal demand), if there is reason to deem it suitable, the COI Committee will appropriately 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 of the 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, the committee meeting will be held as quickly as possible and the findings shall be reported.

#### Article 6 (COI Committee)

Several of the 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 the COI information learned about members. The COI Committee shall coordinate with the Board of Directors to carry out management so as to prevent the COI situations of members from 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 the COI self-declaration items submitted by authors presenting in this Society's journals (Diabetology International, Diabetes) and other publications, as well as planned presenters at lecture meetings, etc. held by this Society, the COI Committee may 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 situation and the committee is unable to fulfill its explanatory obligations, the Chairman of the Board of Directors may take the necessary measures after deliberation within the Board of Directors based on the report from the COI Committee. In cases where questions or other issues arise after a presentation has already been given, the Chairman of the Board of Directors may conduct a factual investigation and take measures such as rescission of the 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 the 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 of the Board of Directors shall promptly convene a meeting of the Board of Directors, and may then 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 Chairman of the Board of Directors with regard to presentations (journals of academic institutions, academic lecture meetings, etc.) in the projects of this Society disagrees with the results, such 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 Chairman of 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 a inquiry request for 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. The 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 starting from the date that the committee was first convened in connection with the inquiry, and submit the findings to the Chairman of the Board of Directors.

4. The decision of the Provisional Advisory Committee shall be considered final.

#### Article 9 (Modification of the Detailed Rules)

These Detailed Rules are predicted 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 the COI Committee members may also serve as subcommittee members.

#### Supplementary Provisions

##### Article 1(Effective Date)

These Detailed Rules shall go into effect for a trial period of two years starting on June 1, 2011, and thereafter they will go into full effect.

##### Article 2 (Revisions to these Detailed Rules)

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

##### 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.

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