

Policy on Conflicts of Interest in the Japan Diabetes Society

Preamble

Progress in medicine and medical services in recent years has been dramatic. It goes without saying that appropriately sharing the results of medical research with society and the medical front to help raise the level of healthcare in Japan is an obligation of those engaged in medical research. At the same time, the more active academic research via industry-academia collaborations becomes, the more deeply involved scholarly societies, which are public organizations, and their members become with the activities of particular businesses. This involvement necessarily and unavoidably results in situations where the responsibilities of the scholarly societies collide or conflict with the benefits individuals garner in association with industry-academia collaboration activities. Such situations are referred to as “conflicts of interest” (COI), and the appropriate management of these conflict-of-interest situations is an important organizational challenge for scholarly institutions and groups in the appropriate advancement of industry-academia collaboration activities. It is in line with current trends for this Society to establish a baseline policy regarding conflicts of interest (COI) in order to ensure proper management of conflict-of-interest situations involving Society members and related persons, as well as to fulfill the obligation to explain these matters to the general public.

The Japanese Society of Internal Medicine has formulated a common policy on COI in medical research in cooperation with 13 other internal-medicine-related scholarly societies (Japanese Society of Gastroenterology, Japan Society of Hepatology, Japanese Circulation Society, Japan Endocrine Society, Japan Diabetes Society, Japanese Society of Nephrology, Japanese Respiratory Society, Japanese Society of Hematology, Japanese Society of Neurology, Japanese Society of Allergology, Japan College of Rheumatology, Japanese Association for Infectious Diseases, and Japan Geriatrics Society).

The Japan Diabetes Society hereby sets forth its policy concerning COI based on the common policy, in adherence with the actual conditions in this Society.

1. Objective

Since its establishment in 1957, the Japan Diabetes Society has contributed greatly not only to academic research on diabetes, which is the mission of this Society, but also the advancement of the diagnosis and treatment of diabetes in Japan. The rapid rise in the number of diabetes sufferers in recent years is creating awareness of the present grave threat to citizens' healthy life-spans and lifestyles that is posed by this disease, and this Society considers its role in society to be further increasing the importance placed on this circumstance. Moreover, the scholarly activities of this Society and its members demand not only the pursuit of truth but also social responsibility and refined ethical character. In view of this point, this Society sets forth its Policy on Conflicts of Interest (hereinafter abbreviated to “this Policy”) to enable the appropriate execution of industry-academia collaboration activities by its members. The objective of this policy is to fulfill this Society's obligations to the general public by contributing to progress in the prevention, diagnosis, and treatment of the diseases included in the field of diabetology by properly promoting the presentation of research results, as well as dissemination, awareness-raising, and related activities, while maintaining neutrality and impartiality, through this Society's appropriate management of conflict-of-interest situations

involving its members and related persons.

2. Basic Philosophy of the Policy

This Policy gives the basic considerations on COI for members and related persons, and requires this Society's members and related persons to disclose their own COI status to this Society in an appropriate manner via self-declaration when they participate in any type of project and make presentations, and otherwise to adhere to this Policy. Based on this Policy regarding COI, this Society will act in accordance with the following basic guidelines to secure its social responsibility as a scholarly society.

- (1) This Society will contribute to society by creating intellectual property through academic research on diabetes and passing on the results to society. To achieve this, it will promote scholarly activities through active industry-academia collaborations.
- (2) It will maintain a system for appropriately managing COI that could arise incidentally in the course of industry-academia collaborations.
- (3) It will ensure the transparency of its scholarly activities through appropriate management of COI information. It will also earn the trust of society by fulfilling the obligations of this Society to explain these matters to the general public.
- (4) COI management does not constrain the scholarly activities of Society members in their industry-academia collaborations, but rather respects their autonomy to the maximum extent. At the same time, COI management aims to ensure that this Society fulfills its obligations to the general public and maintains an environment in which members can engage in their scholarly activities with peace of mind.

3. Persons Subject to this Policy

This Policy applies to the following persons for which COI situations could arise.

- (1) Members of this Society
- (2) Person who present at this Society's academic lecture meetings or similar events
- (3) This Society's officers (Chairman of the Board of Directors, Directors, and Auditors), persons responsible for scientific meetings (congress presidents, etc.), Committee chairpersons and members, who have been provided in the bylaw clause 7, and the authors and reviewers of diagnosis and treatment guidelines and other materials published by this Society
- (4) This Society's administrative staff members
- (5) Spouses and first-degree family members of persons listed in (1) through (4), as well as persons who share their income and/or assets

4. Activities Subject to this Policy

This Policy applies to all projects and activities conducted by this Society.

- (1) The holding of academic lecture meetings (including annual academic meetings), academic lecture meetings put on by chapters, etc.
- (2) The issuing of academic journals, academic books, and similar publications
- (3) The execution of research and surveys
- (4) The encouraging of research and the commending of research results
- (5) The credentialing of specialists and the accreditation of certified educational facilities
- (6) The promoting of lifelong learning activities
- (7) Liaisons and cooperation with related scholarly societies
- (8) The promoting of international research cooperation
- (9) Other projects necessary for achieving the objective

In particular, the following activities demand especially careful adherence to the Policy in their execution.

- 1) Presentations at academic lecture meetings (hereinafter, “lecture meetings, etc.”) and similar events held by this Society
- 2) Announcements in academic journals and other printed publications
- 3) The formulating of diagnosis and treatment guidelines, manuals, and similar documents
- 4) Work in investigative committees, advisory committees, and other provisionally formed committees

5. Matters to be Declared

If a person subject to this Policy exceeds the standards provided in the Detailed Rules for any of the following items (1) through (9) in connection with “businesses, corporate organizations, or for-profit groups related with medical research”, that person shall make a declaration of the precise circumstances to this Society’s Chairman of the Board of Directors. Note that the specifics on how the declared content will be disclosed and announced are provided separately in the Detailed Rules.

- (1) Assumption of the position of officer, advisor, employee, etc. at a business, corporate organization, or group subject to this Policy
- (2) Holding of stock in a business subject to this Policy

- (3) Royalties from patents or other sources from a business, corporate organization, or group subject to this Policy
- (4) Per-diem compensation (lecture fees, etc.) paid from a business, corporate organization, or group subject to this Policy for the time and labor taken up by a researcher's attendance (presentation) at a meeting
- (5) Manuscript fees paid by a business, corporate organization, or group subject to this Policy for the authoring of pamphlets or similar materials
- (6) Medical research fees (contracted research fees, joint research fees, etc.) provided by a business, corporate organization, or group subject to this Policy
- (7) Research fees (donations, etc.) provided by a business, corporate organization, or group subject to this Policy
- (8) Taking part in an endowed lecture sponsored by a business, corporate organization, or group subject to this Policy
- (9) Receipt of travel expenses or other gifts provided by a business, corporate organization, or group subject to this Policy

6. COI Management System and Implementation

(1) Establishment of COI Committee

- 1) A COI Committee is to be established as an organ of this Society.
- 2) The chairperson of the COI Committee is appointed by the Chairman of the Board of Directors, and the members are appointed by the Chairman of the Board of Directors based on the recommendations of the committee chairperson.

(2) Role of the COI Committee

If, during any project conducted by this Society, a major COI situation arises involving a member or a question of the inappropriateness of a COI declaration is indicated, the COI Committee will conduct an investigation via hearing or other means in order to confirm the COI situation of the member, and report the results of the investigation to the Chairman of the Board of Directors.

(3) Establishment of Detailed Rules

This Society may establish Detailed Rules required for the operation of this Policy.

(4) Obligations of Members

When presenting medical research results at academic lectures or similar events, members shall appropriately announce the COI situation regarding the execution of such research using the designated forms upon submission of abstracts and upon giving presentations, in accordance with the Detailed Rules of this Society. If there is any indication that this Policy has been violated in connection with presentation of research, etc., the Board of Directors will request deliberation by the COI Committee that is authorized to handle COI-related matters, and will take suitable measures based on the

findings of the committee.

(5) Obligations of Officers, etc.

This Society's officers (Chairman of the Board of Directors, Directors, and Auditors), persons responsible for academic lecture meetings (annual academic meeting chairpersons, facilitators of Progress in Diabetology, etc.), chairpersons of each committee, members of certain committees, and members of working committees have important roles and obligations regarding all projects and activities this Society is engaged in, and therefore such persons shall conduct self-declarations concerning their COI situations with regard to the relevant projects upon assuming their positions, in accordance with the designated forms of this Society. Furthermore, if new conflict-of-interest situations arise after assuming their positions, such persons shall conduct modified declarations in accordance with the provisions.

(6) Role of the Board of Directors

If a major COI situation arises with an officer, etc. in the execution of a project of this Society, or if it is deemed that a COI self-declaration is inappropriate, the Board of Directors may consult the COI Committee and direct improvement measures, etc. to be taken based on the committee's findings.

(7) Role of Persons Responsible for Academic Lecture Meetings

When the results of medical research are to be announced at an academic meeting, the persons responsible for academic lecture meetings (annual academic meeting chairpersons, facilitators of Progress in Diabetology, etc.) verify that such announcement accords with this Policy, and may halt or take other measures regarding the presentation of any subject that violates this Policy. In such cases, such persons shall promptly inform the scheduled presenter of the measures taken, along with the reasons for the measures. Note that in taking these measures, the person responsible may consult with the COI Committee and direct improvement measures, etc. to be taken based on the committee's findings.

(8) Role of the Society Journal Editorial Committee

When original research papers on research results, review papers, diagnosis and treatment guidelines, editorials, opinion pieces, or other articles are to be presented in academic journals or other printed publications, the Society Journal Editorial Committee verifies that such presentation accords with this Policy, and may halt or take other measures regarding the publication of any article that violates this policy. In such cases, the committee will promptly inform the relevant submitter of the research paper of the measures taken, along with the reasons for the measures. If it is discovered that a research paper has violated this policy after it has been published, such fact may be announced publicly under the editorial committee chairperson's name in the relevant printed publication. Note that in taking these measures, the editorial committee chairperson may consult with the COI Committee and direct improvement measures, etc. to be taken based on the committee's findings.

(9) Establishment of COI Consultation Service

A COI consultation service is to be established in order to forestall any COI issues.

(10) Others

The chairpersons and members of each committee in this Society verify that the

respective Society projects they are involved with are implemented in accordance with this Policy, and promptly explore improvement measures to address any violations of this Policy. Note that such persons may consult with the CIO Committee regarding the handling of these matters, and that the Board of Directors may direct improvement measures, etc. based on that committee's findings.

7. Matters to be Avoided

(1) Matters to be Avoided by All Persons Subject to this Policy

The announcement of medical research results and the formulation of diagnosis and treatment guidelines are to be conducted based purely on academic grounds and judgment, or based on public benefit. In creating the content of announcements of the results of medical research, interpretations of such results, or diagnosis and treatment guidelines, manuals, etc. based on scientific grounds in medical research, this Society's members, etc. shall not be influenced by the arbitrary intentions of the individuals or businesses that fund such medical research, and shall not enter into contracts with funding providers that make such influence unavoidable.

(2) Matters to be Avoided by Persons Responsible for Medical Research Trials

Persons with the general responsibility for, and discretion in, planning and implementing medical research (including clinical trials and drug trials) are to be selected from among researchers who are publicly assessed as not having any major COI situations (having little relation with the party commissioning the research) regarding the following items, and such persons are to maintain such status after their selection.

- 1) The holding of stock in the business commissioning the medical research
- 2) The acquiring of patent royalties, patent rights, etc. for products or technologies derivable from the results of medical research
- 3) Being an officer, director, advisor, etc. of a business or other for-profit group commissioning the medical research (scientific consulting without compensation is excluded)

However, even researchers for whom 1) through 3) apply may assume the position of the person responsible for the relevant medical research trial if such researchers are indispensable to the planning and execution of the relevant medical research and the medical research has extreme medical significance, on the condition that the fairness, impartiality, and transparency of such judgments and measures are clearly secured.

8. Measures for Policy Violators and Accountability

(1) Measures for Policy Violators

This Society's Board of Directors has the authority to deliberate on actions that are in violation of this Policy, and if a major Policy violation is deemed to have occurred as a result of deliberations within the Board of Directors based on reports from the COI Committee, the necessary measures may be taken according to the severity of the violation.

When actions to be taken against a policy violator are finalized, such information shall be

provided to the head of related scholarly societies to which the member is considered likely to belong.

(2) Statements of Disagreement

Persons against whom measures are taken may submit a statement of disagreement to this Society. This Society's Chairman of the Board of Directors will, upon receipt of the same, will promptly form a committee (provisional advisory committee) to deliberate on the statement of disagreement, entrust the matter to deliberation, confer on the findings within the Board of Directors, and inform the submitter of the statement of disagreement of the result.

(3) Accountability

If there is deemed to be a major violation of this Policy in connection with the results of medical research announced at a venue this Society is involved with, this Society must immediately fulfill its obligation to explain the matter to the general public after conferral of the Board of Directors.

9. Modification of the Policy

This Policy shall be periodically reviewed and revised in order to accord with societal factors, amendments or improvements to laws regarding industry-academia collaboration, and conditions surrounding medicine and research.

10. Effective Date

This Policy shall go into effect on June 1, 2011.

Revised: May 16, 2012