

Guidelines for Conflict of Interest Issues Related to Clinical Studies in Artificial Organs

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Guidelines for Conflict of Interest Issues Related to Clinical Studies in Artificial Organs

Conflict of Interest Committee, The Japan Society for Artificial Organs

Introduction

The Japan Society for Artificial Organs aims to contribute to the advancement and dissemination of surgical medicine by providing opportunities for the presentation of research conducted by Society members, exchange of knowledge, and research collaboration and related communication among Society members, as well as with related academic societies, and thereby make a positive contribution to our academic culture.

The research presented in the academic conferences and publications of the Japanese Society for Artificial Organs includes a large number of clinical studies focusing on the standardization of treatments as well as the use of new drugs, medical equipment and technology. Many of these studies and development programs have involved collaborations between academia and industry. Such research in turn benefits the clinical community, and the necessity and importance of collaborative clinical research is increasing on a daily basis.

Collaborative clinical research by academia and industry has the potential to result not only in achievements obtained through the fulfillment of academic and ethical responsibilities that benefit society (public benefit), but also monetary gain, status and rights acquired through collaboration (individual benefit). A researcher faced with these two benefits is said to have a conflict of interest (COI). COI issues are difficult to avoid due to the complexity of modern social activities, and consequently legal restrictions have been implemented for specific instances. Nevertheless, the possibility remains that COI issues will occur with regard to activities that fall outside of those regulated by law. In serious cases, such issues may distort the interpretation of research results, the analysis of data and the research methods. Furthermore, even if the results of the research are sound, their evaluation may not be conducted in a fair and reasonable manner. The Japanese Society for Artificial Organs must therefore clarify the COI guidelines for its members and ensure fairness in research and development conducted through academic-industrial collaboration as a part of efforts to actively promote clinical research.

1. Purpose of Guideline Implementation

Clinical research differs from many other fields of academic research in that the research subjects are humans. This has been well documented in the Helsinki Declaration and by the Japanese authorities in Ethical Guidelines for Clinical Research (Notification no. 225, Ministry of Health, Labour and Welfare, 2003) and Ethical Guidelines for Epidemiological Research (Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour

and Welfare, 2007). As a result, due consideration must be given to the protection of human rights and the lives of subjects, in addition to the safe implementation of research.

The Japanese Society for Artificial Organs, in view of the high ethical standards and social responsibility required in its activities, has formulated a set of guidelines known as the Guidelines for Conflict of Interest Issues in Clinical Research (hereinafter referred to as the COI Guidelines). The Japanese Society for Artificial Organs, through the appropriate management of COI issues of its members, aims to promote the presentation of research findings as well as their dissemination and awareness in a manner that maintains neutrality and fairness, thereby fulfilling its social obligation by contributing to the advancement of the prevention, diagnosis and treatment of surgical diseases.

The core purpose of the COI Guidelines is to present the Society's basic philosophy regarding COI for its members and to enable researchers participating in and giving presentations at Society activities to appropriately declare COI. All members of the Japanese Association for Thoracic Surgery shall agree to abide by the following COI Guidelines:

II. Subjects of COI Guidelines

The COI Guidelines shall apply to individuals who may face COI issues as follows:

- i. Members of the Japanese Society for Artificial Organs
- ii. Employees of the Japanese Society for Artificial Organs Secretariat
- iii. Any individual making a presentation to the Japanese Society for Artificial Organs
- iv. Any individual attending a board meeting, committee or working party of the Japanese Society for Artificial Organs

III. Activities covered by the COI Guidelines

The COI Guidelines shall apply to any and all activities involving the Japanese Society for Artificial Organs. In particular, researchers making a presentation at an academic conference, symposium, or lecture meeting of the Japanese Society for Artificial Organs or publishing research in the journal, publications, or books of the Japanese Society for Artificial Organs must acknowledge that the present COI Guidelines apply to all clinical research related to the prevention, diagnosis, and treatment of surgical diseases.

Individuals delivering an educational lecture for members of the Japanese Society for Artificial Organs or an open lecture for the general public must pay particular attention to the COI Guidelines, due to the large social impact of these activities.

IV. Items for Disclosure

In the event that a subject exceeds the criteria defined separately with regard to any of the

descriptions i. through vi. below, the subject is required to accurately disclose their COI according to a specified format. Furthermore, in the event that the spouse or any first-degree relations of a subject, or an individual who shares income and assets with the subject, exceeds the criteria defined separately with regard to any of the descriptions i. through iii. below, the subject is required to accurately inform the Society of the situation. Moreover, the subject in question shall be responsible for the contents of these self-declarations. Detailed methods of disclosure for each type of activity will be specified separately in the supplement.

- i. An executive officer or senior advisor of a company or a commercial organization
- ii. A shareholder
- iii. Licensing royalty from a company or commercial organization
- iv. A daily stipend (lecture fees, etc.) paid by a company or commercial organization for the time and effort taken by a researcher for attendance (presentation) at a conference
- v. Manuscript fees from a company or commercial organization for writing an article for a pamphlet, etc.
- vi. Research funds from a company or commercial organization

V. Avoiding Conflicts of Interest

1) What all individuals subject to these guidelines must avoid

Publication of the results of clinical studies should be performed purely on the basis of scientific judgment or public benefit. In relation to decisions on whether to present the results of a clinical study at a conference or in a publication, and to the essential content of the presentation—results of the study and their interpretation—members of the Japanese Society for Artificial Organs (JSAO) should not be influenced by any intention or motive of a person or company financing the clinical study, nor should they enter into any agreements or contracts that make such influence unavoidable.

2) What trial directors of clinical studies must avoid

Trial directors—the doctors who have the right to decide on planning and implementation of clinical studies (including clinical trials and tests)—must be selected from among individuals who do not face any of the conflicts of interest defined below. Trial directors must also avoid conflicts of interest after their selection. (Note that this requirement does not apply to the doctors in charge of a study at an individual hospital in the case of a multicenter clinical study.)

- (1) Ownership of stock in a company requesting the clinical study
- (2) Acquisition of patent fees or rights for a product or technology that may be obtained from the results of the clinical study
- (3) Serving as an executive, director, or adviser to a company or commercial organization

requesting the clinical study (excluding unpaid scientific advisers)

Note that even if one of the conditions (1) to (3) applies, if the individual in question is absolutely essential to the planning and execution of a particular clinical study, and if the clinical study is of exceptional international importance, the person may be appointed as trial director for the applicable clinical study.

VI. Implementation methods

1) Role of JSAO members

When presenting the results of a clinical study at an academic gathering, JSAO members are obligated to appropriately disclose information about potential conflicts of interest in connection with the applicable study. Disclosure will be made according to the formats prescribed in the supplement. In the event that these guidelines are violated, the JSAO committee responsible for conflicts of interest (hereinafter “the competent committee”) will deliberate on the matter and then report to the JSAO board of directors.

2) Role of JSAO executives Committee for Scientific Affairs

The JSAO president, vice president, directors, inspector, committee chairpersons, congress president, congress president-elect, and the Editorial Committee, Committee for Policy Review, Committee for Scientific Affairs, Committee for Health Insurance Affairs, Committee on Ethics and Safety, and Conflict of Interest Committee have an important role and duty with regard to all activities concerning the JSAO, and on their appointment they are obligated to submit self-assessments of potential conflicts of interest concerning applicable activities, in accordance with the prescribed format.

When a serious conflict of interest arises in relation to the involvement of a JSAO executive in any activity of the JSAO, or if the conflict of interest self-assessment of a JSAO executive (director, president or inspector) is recognized to be inappropriate, the JSAO board of directors will question the competent committee, and then, based on the committee’s response, provide instructions on appropriate improvement measures.

When the results of a clinical study are presented at a JSAO event, the JSAO congress president will verify that the presentation is implemented in accordance with these guidelines. If the presentation topics violate the guidelines, the congress president has the discretionary ability to suspend the presentation. In this event, the congress president will notify the individual scheduled to make the presentation about the decision, giving reasons. Note that the action taken in such cases is first discussed by the competent committee and implemented only after approval by the JSAO board, based on the response of the committee.

When the results of a clinical study are presented in a publication of the JSAO, the journal editorial committee verifies that the presentation conforms to these guidelines. These

committees can suspend publication in the event that the guidelines are violated. In this event, the individual submitting the paper for publication will immediately be informed of the decision and given an explanation. If a guideline violation comes to light after publication of the applicable paper, the conflict of interest can be disclosed in the applicable publication under the name of the chairperson of the editorial committee. Note that the action taken in such cases is first discussed by the competent committee and implemented only after approval by the JSAO board, based on the response of the committee.

The chairpersons and members of the other committees verify that the JSAO activities in which they are involved conform to these guidelines, and in the event that a breach of the guidelines occurs they promptly examine appropriate improvement measures. Note that the action taken in such cases is discussed by the competent committee and implemented only after approval by the JSAO board, based on the response of the committee.

3) Appeals

Any persons who are instructed to improve their presentations or whose presentations are suspended, as described in items 1) or 2) above, may submit an appeal to the JSAO. After the JSAO accepts such an appeal, the matter is promptly reassessed by the competent committee, and after consultation with the JSAO board the individual making the appeal is informed of the result of reassessment.

VII. Action and accountability of guideline violators

1) Actions on guideline violators

The board of the JSAO has the authority to deliberate on behavior that is in violation of these guidelines according to separately defined rules, and if a serious noncompliance is judged to have occurred as a result of the deliberation, then one or more of the following actions may be taken for a specified period, in proportion to the severity of the noncompliance:

- (1) Prohibition from making presentations at all gatherings held by the JSAO
- (2) Prohibition from publication of papers in all publications of the JSAO
- (3) Prohibition from appointment as congress president or congress president-elect of academic gatherings of the JSAO
- (4) Prohibition from participation in the board or any committee or working group of the JSAO
- (5) Expulsion from positions as a councilor of the JSAO or prohibition from becoming a councilor of the JSAO
- (6) Expulsion from JSAO membership or prohibition from becoming a JSAO member

2) Appeals

Any person against whom action is taken for violation of these guidelines may make an appeal to the JSAO. When the JSAO accepts such an appeal, the matter is fairly reassessed by the

competent committee, and after consultation with the JSAO board, the individual making the appeal is informed of the result of the reassessment.

3) Accountability

In the event that the JSAO determines that there is a serious violation of these guidelines in relation to a clinical study presented in a forum in which the JSAO is involved, the matter is discussed by the competent committee and the JSAO board, after which the JSAO will take appropriate action to fulfill its duty of public accountability.

VIII. Enactment of supplement

The JSAO is able to enact supplements, as necessary, for ensuring the appropriate and effective operation of these guidelines, taking into account the unique and special characteristics of the JSAO.

IX. Enforcement data and amendment procedures

It is foreseen that these guidelines will need to be partly amended in accordance with individual cases, due to social changes, changes in laws relating to industry-academia collaboration, or other reasons. The Conflict of Interest Committee of the JSAO is able to amend these guidelines through a resolution of the JSAO board.

Supplementary Provisions

1. These supplements take effect on July 31, 2012.

Supplementary Rules to the Guidelines for Conflict of Interest Issues Related to Clinical Studies in Artificial Organs

The Japanese Society for Artificial Organs

No.1 (Purpose)

The purpose of these rules is to indicate specific methods of operation of the Guidelines for Conflict of Interest Issues Related to Clinical Studies in Artificial Organs (hereinafter “these guidelines”) and methods of action with respect to guideline violators in order to ensure compliance by subjects of these guidelines.

No.2 (Presentations at academic gatherings of the JSAO)

(Scope of disclosure)

The COI information that the principal presenter/author is obligated to disclose is limited to that relating to companies and commercial organizations connected with the content of the presentation.

(When submitting abstracts) At the time of submitting their presentation topics or abstract, individuals who make presentations or talks at academic gatherings, symposiums, lectures, or public lectures of the JSAO should declare whether the principal presenter/author has had any potential COI at any time in the previous 1 year.

(When making presentations) Any matter defined under IV. Items for Disclosure in these guidelines must be disclosed at the end of a presented slide or poster according to “Self-reporting of Conflicts of Interest by Presenters” (Format 1) in order to clearly provide COI information at the time of a presentation. All matters falling in time between 1 year prior to the submission of a journal abstract and the time of the presentation must be disclosed. The monetary amount for which self-reporting is necessary for a particular disclosure matter is defined as follows:

- (1) Receiving 1 million yen or more worth of compensation within a 1-year period from a particular company or other commercial organization for services rendered as an employee or consultant
- (2) Earning 1 million yen or more of profit within a 1-year period by ownership of stock in a particular company (total from dividends and share trades), or holding 5% or more of outstanding shares in a relevant company
- (3) Receiving 1 million yen or more in patent royalties or licensing fees within a 1-year period from a particular company or other commercial organization
- (4) Receiving a total of 1 million yen or more in lecture fees within a 1-year period from a particular company or commercial organization in daily allowance (e.g., lecture fees) for the time and effort spent by researchers when attending conferences (and making presentations)
- (5) Receiving a total of 1 million yen or more within a 1-year period from a particular company

or commercial organization in manuscript fees paid for writing of brochures or other publications

(6) Receiving a total of 2 million yen or more within a 1-year period from a particular company or commercial organization in research expenses, for a particular clinical study, or receiving a total of 2 million yen or more within a 1-year period from a particular company or organization, paid as a scholarship endowment (incentive endowment) to a single research representative

No. 3 (Presentation in the JSAO bulletin)

(Scope of disclosure)

The COI information that the author is obligated to disclose is limited to that relating to a company or commercial organization connected with the submitted content.

(At the time of submission)

Authors who are making presentations in the JSAO bulletin “General Thoracic and Cardiovascular Surgery” must clarify their potential COIs at the time of submitting their manuscript using Form 2, as prescribed in the submission regulations. The information provided in Form 2 is summarized as a “Conflict of Interest Statement” and printed at the end of the paper. If there is no potential COI according to the guidelines, then “The authors declare that there is no potential conflict of interest” or a similar statement will be printed at the end of the paper. The COI information to be disclosed when submitting a manuscript, in the form of a self-declaration, is defined in item IV of these guidelines, “Items for Disclosure.” For each item to be disclosed, the minimum amounts for which self-declaration is necessary are the same as those given in Supplement No. 1. Disclosure is necessary for anything occurring up to 1 year before the time of manuscript submission. In the case of JSAO publications other than “General Thoracic and Cardiovascular Surgery”, COI self-declarations must be submitted in the same format.

No. 4 (JSAO executives)

(Designated committees) Committee for Scientific Affairs;

This supplement applies to the following designated committees: Editorial Committee; Committee for Policy Review; Committee for Scientific Affairs; Committee for Health Insurance Affairs; Committee on Ethics and Safety; and Conflict of Interest Committee.

(Scope of disclosure and public declaration)

COIs that executives, committee chairpersons, congress president, congress president-elect, and members of designated committees (hereinafter “executives”) are obligated to disclose and publicly declare are limited to matters concerning companies and commercial organizations connected to the activities of the JSAO.

(At the time of appointment)

All executives of the JSAO must submit an “Executive Conflict of Interest Self-declaration Form” (Form 3) when they are first appointed, and once a year thereafter. In addition, if any

new COI should arise during a term of office, the executives are obligated to report this within 6 weeks by means of Form 3. The COI information to be disclosed and publicly declared using Form 3 is a self-declaration, as detailed in item IV of these guidelines, "Items for Disclosure." For each item to be disclosed and publicly declared, the minimum amounts for which disclosure is necessary are the same as those given in Supplement No. 1. The 1-year period for which calculations are made should be precisely specified in Form 3. The self-declaration made at the time of first appointment should include all COIs going back to 2 years before the date of appointment. In this case, the executive must fill in and submit a Form 3 for the 1-year period from 2 years prior to appointment, and a separate Form 3 for the 1-year period from 1 year prior to appointment.

Any executive who is serving in more than one position simultaneously should submit a self-declaration (Form 3) going back as far as 2 years before the earliest appointment.

No. 5 (Handling Conflict of Interest Self-reports of Employees, etc.)

COI information (Conflict of Interest Statements) submitted (in Format 3) to or disclosed to the Society in accordance with this Addendum will be stored and managed with stringent security procedures as personal information under the administrative responsibility of the President. The COI information may be used at any time by the Board of the Society or the Conflict of Interest Committee in order to carry out the items defined in these guidelines. The COI information will be used only in the event that the individual comes under suspicion, or if necessitated by a matter of public interest or a legal issue, after deliberation of the Conflict of Interest Committee and the approval of the Board of the Society. Only the information from the Conflict of Interest Statement needed for the matter at hand will be disclosed, either within the Society or to the public. This COI information (in Format 3) will be retained by the Society until 2 years after the individual's association with the company or organization in question has ended, after which the data will be deleted under the supervision of the President. If, during the period of data retention, the individual comes under suspicion or is implicated in a matter of public interest or a legal issue, the Board of the Society may resolve to suspend the destruction of the relevant data.

No. 6 (Actions on guideline violators)

The Conflict of Interest Committee of the JSAO may take the actions on guideline violators indicated in these guidelines in accordance with the severity of the violations through a resolution of the board of directors by procedures pursuant to X. Discipline No. 58 and No. 59 of the Enforcement Regulations of the Articles of Association of the JSAO.

No. 7 (Enforcement date and amendment procedures)

The Conflict of Interest Committee of the JSAO is able to amend these supplements through a resolution of the JSAO board.

Supplementary Provisions

1. These supplements take effect on October 10, 2012.