

Guidelines for Conflict of Interest Issues Related to Clinical Studies in Thoracic Surgery

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Guidelines for Conflict of Interest Issues Related to Clinical Studies in Thoracic Surgery

Conflict of Interest Committee, The Japanese Association for Thoracic Surgery

Introduction

The Japanese Association for Thoracic Surgery 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 Association for Thoracic Surgery 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 Association for Thoracic Surgery 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 Association for Thoracic Surgery, 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 Association for Thoracic Surgery, 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 Association for Thoracic Surgery
- ii. Employees of the Japanese Association for Thoracic Surgery Secretariat
- iii. Any individual making a presentation to the Japanese Association for Thoracic Surgery
- iv. Any individual attending a board meeting, committee or working party of the Japanese Association for Thoracic Surgery

III. Activities covered by the COI Guidelines

The COI Guidelines shall apply to any and all activities involving the Japanese Association for Thoracic Surgery. In particular, researchers making a presentation at an academic conference, symposium, or lecture meeting of the Japanese Association for Thoracic Surgery or publishing

research in the journal, publications, or books of the Japanese Association for Thoracic Surgery 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 Association for Thoracic Surgery 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 Association for Thoracic Surgery (JATS) 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 JATS members

When presenting the results of a clinical study at an academic gathering, JATS 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 JATS committee responsible for conflicts of interest (hereinafter “the competent committee”) will deliberate on the matter and then report to the JATS board of directors.

2) Role of JATS executives Committee for Scientific Affairs

The JATS 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 JATS, 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 JATS executive in any activity of the JATS, or if the conflict of interest self-assessment of a JATS executive (director, president or inspector) is recognized to be inappropriate, the JATS 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 JATS event, the JATS 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 JATS board, based on the response of the committee.

When the results of a clinical study are presented in a publication of the JATS, 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 JATS board, based on the response of the committee.

The chairpersons and members of the other committees verify that the JATS 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 JATS 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 JATS. After the JATS accepts such an appeal, the matter is promptly reassessed by the competent committee, and after consultation with the JATS 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 JATS 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 JATS
- (2) Prohibition from publication of papers in all publications of the JATS
- (3) Prohibition from appointment as congress president or congress president-elect of academic gatherings of the JATS
- (4) Prohibition from participation in the board or any committee or working group of the JATS
- (5) Expulsion from positions as a councilor of the JATS or prohibition from becoming a councilor of the JATS
- (6) Expulsion from JATS membership or prohibition from becoming a JATS member

2) Appeals

Any person against whom action is taken for violation of these guidelines may make an appeal to the JATS. When the JATS accepts such an appeal, the matter is fairly reassessed by the competent committee, and after consultation with the JATS board, the individual making the appeal is informed of the result of the reassessment.

3) Accountability

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

VIII. Enactment of supplement

The JATS 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 JATS.

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 JATS is able to amend these guidelines through a resolution of the JATS board.

Supplementary Provisions

1. These guidelines take effect on April 1, 2011

Supplementary Rules to the Guidelines for Conflict of Interest Issues Related to Clinical Studies in Thoracic Surgery

The Japanese Association for Thoracic Surgery

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 Thoracic Surgery (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 JATS)

(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 JATS 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 JATS 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 JATS 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 JATS publications other than “General Thoracic and Cardiovascular Surgery”, COI self-declarations must be submitted in the same format.

No. 4 (JATS 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 JATS.

(At the time of appointment)

All executives of the JATS 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 JATS 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 JATS.

No. 7 (Enforcement date and amendment procedures)

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

Supplementary Provisions

1. These supplements take effect on April 1, 2011.
2. These supplements were revised as of September 8, 2011.

(Form1)

Principal Presenter/Author Conflict of Interest Self-Declaration Form

Name of
Presenter /author

	Amount	Applicability	Name of company etc. if applicable
Executive/advisor	>1 million yen	Yes No	
Stocks	>1 million yen profit /shareholding >5%	Yes No	
Patent royalties	>1 million yen	Yes No	
Lecture fees, etc.	>1 million yen	Yes No	
Manuscript fees, etc.	>1 million yen	Yes No	
Research expenses	>2 million yen	Yes No	

General Thoracic and Cardiovascular Surgery Conflict of Interest Disclosure Statement

Manuscript Title: _____

**Each author is required to complete and return this form to the corresponding author.
(Please do not send to the General Thoracic and Cardiovascular Surgery office)**

When submitting a manuscript to *General Thoracic and Cardiovascular Surgery*, all authors are required to disclose any financial relationship with a biotechnology manufacturer, a pharmaceutical company, or other commercial entity that has an interest in the subject matter or materials discussed in the manuscript. The matters requiring disclosure are outlined in “Guidelines for Conflict of Interest Issues Related to Clinical Studies of Thoracic Surgery” (<http://jats-e.umin.jp/journal/pdf/jatscoi.pdf>).

In a manuscript submitted to *General Thoracic and Cardiovascular Surgery*, all disclosures should be inserted by the corresponding author in the “Conflict of Interest” before the reference list, as shown in the following example. The Conflict of Interest statement should list each author separately by name:

Conflict of Interest Statement

A (author name) serves as a consultant to Z (entity name); B’s spouse is chairman of Y; C received a research grant from X; D received lecture fees from V; E holds a patent on U; F has been reimbursed by T for attending several conferences; G received honoraria for writing promotional material for S; H has no conflict of interest.

If you, your spouse, or other immediate family member has any of the listed relationships with a commercial entity that has an interest in the subject matter in your manuscript, please refer to the JATS's definition for conflicts of interest which must be disclosed (<http://jats-e.umin.jp/journal/pdf/jatscoi.pdf>). And then, check the appropriate "Yes" box below and provide details. If the listed relationship does not apply to you or your family member, check the appropriate "No" box.

Categories	No	Yes (Give names of authors and entities)	
1. Employment/Leadership position/ Advisory role			
2. Stock ownership			
3. Patent royalties/licensing fees			
4. Honoraria (e.g. lecture fees)			
5. Fees for promotional materials (e.g. manuscript fees)			
6. Research funding			

Signature: _____

Date: _____

All of the forms from each author need to be uploaded online and submitted with the manuscript at the time of submission by the corresponding author.

Executive Conflict of Interest Self-Declaration Form
(Calculation period: April 1, 2012 – March 31, 2013)

To the President, The Japanese Association for Thoracic Surgery Mr. Ryuzo Sakata

Name of declarer:

Affiliation (Institution/class/clinical dept.):

(Please circle the applicable option.)

Titles at JATS: Director Inspector Committee chairperson

Congress president Congress president-elect

Designated committees: Editorial Committee Committee for Policy Review

Committee for Scientific Affairs Committee for Health Insurance Affairs

Committee on Ethics and Safety Conflict of Interest Committee

A. Items concerned directly with the declarer

1. Have you served as executive or adviser of a company or commercial organization? If

so ,how much compensation did you receive for this? (Yes• No)

(State all instances of receiving 1 million yen or more in compensation from a single
Company /organization.)

	Company/Organization name	Role (e.g. executive, adviser)	Amount range
1			
2			
3			

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;

(3) 5.01 million yen or more

2. Do you own any stocks and have you earned any profit from this stock (in the past 1 year)?

(Yes • No)

(State all cases of earning 1 million yen or more in profit within a 1-year period from the stock of a single company, or of owning 5% or more of the outstanding stock of a company.)

	Company name	No. of shares held	Stock value at time of declaration (price per share)	Amount range
1				
2				

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01to 5.00 million yen;

(3) 5.01 million yen or more

3. Have you received payment for patent royalties/licensing fees from any company or commercial organization? (Yes • No)

(State all cases of receiving 1 million yen or more in patient royalties/licensing fees within 1- year period for a single patent)

	Company/Organization name	Patent name	Amount range
1			
2			

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;

(3) 5.01 million yen or more

4. Have you received any money from a company or commercial organization for attendance (presentation) at conferences, as a daily allowance (e.g. lecture fees) to cover time and effort (at researcher rates)? (Yes • No)

(State all instances of receiving a total of 1 million or more in lecture fees within 1-year period from a single company/organization.)

	Company/Organization name	Amount range
1		
2		
3		

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;
(3) 5.01 million yen or more

5. Have you been paid manuscript fees by a company or commercial organization for writing a brochure or other kind of publication? (Yes • No)

(State all instances of receiving a total of 1 million or more in manuscript fees within 1-year period from a single company/organization.)

	Company/Organization name	Amount range
1		
2		

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;
(3) 5.01 million yen or more

6. Have you received any research funds from a company or commercial organization? (Yes · No)

(Disclose details of any clinical trial for which you were paid a total of 2 million yen or more a year and any scholarship (incentive) endowment through which you were paid 2 million yen or more a year by a company or commercial organization as the sole recipient) (For the amount range, please state the total sum received from the company or commercial organization, without subtracting administrative expenses.)

	Company/Organization name	Research funds range	Amount range
1			
2			
3			

Research funds range: (1) Clinical trial; (2) Industry-academia collaborative research;
 (3) Contract research; (4) Scholarship (incentive) endowment

Amount range: (1) 2.01 to 5.00 million yen; (2) 5.01 to 20.00 million yen;
 (3) 20.01 million yen or more

B. Spouse/partner, family or any first-degree relation to the declarer, or anyone else with whom the declarer shares income or assets

Name of applicable person (relationship to declarer):

1. Have you served as executive or adviser of a company or commercial organization? If so, how much compensation did you receive for this? (Yes· No)

(State all instances of receiving 1 million yen or more in compensation from a single Company /organization.)

	Company/Organization name	Role (e.g., executive, adviser)	Amount range
1			
2			
3			

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;
(3) 5.01 million yen or more

2. Do you own any stocks and have you earned any profit from this stock (in the past 1 year?) (Yes· No)

(State all cases of earning 1 million yen or more in profit within a 1-year period from the stock of a single company of owning 5% or more of the outstanding stock of a company.)

	Company name	No. of shares held	Stock value at time of declaration (price per share)	Amount range
1				
2				

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01 to 5.00 million yen;
(3) 5.01 million yen or more

3. Have you received payment for patent royalties/licensing fees from any company or commercial organization? (□Yes· □No)

(State all cases pf receiving 1 million yen or more in patent royalties/licensing fees within 1-year period for a single patent.)

	Company/Organization name	Patent name	Amount range
1			
2			

Amount range: (1) 1.01 to 3.00 million yen; (2) 3.01to 5.99 million yen;

(3) 5.01 million yen or more

Oath: I hereby declare that the above statements regarding my conflicts of interest are true and correct. There is absolutely no other conflict of interest that may impinge on the proper execution of my responsibility to the Japanese Association for Thoracic Surgery.

I hereby consent to the public disclosure of the details contained in this declaration if necessitated by reason of the public interest or legal dispute.

Date _____ (dd) _____ (mm) _____ (yy)

Signature

Reception No:

4. Q&A About the Supplement to the Guidelines for Conflict of Interest Issues related to Clinical Studies of Thoracic Surgery

Q1. What do we need to do specifically when giving a presentation at the JATS?

A1. Currently, for all presentations given at JATS, the principal presenter/author needs to disclose their COIs. Disclosure is limited to COIs connected with the topics of the presentation. When we were formulating this supplement, we considered requesting that all presenters, including joint presenters, disclose their COIs in relation to the applicable topics, but to avoid overburdening these other presenters, we decided to limit the obligation of reporting to the principal presenter for now. Note that in surgery-related clinical studies, merely giving a presentation at an academic gathering is not recognized as scientifically rigorous—i.e., it is important to also publish a paper on the subject in a scientific journal. Accordingly, the findings of surgery-related clinical studies of substantial clinical impact will certainly be submitted for publication as a paper. At this stage, we are making it obligatory that relevant conflicts of interest are disclosed by all co-authors—not only the principal author.

Q2. Over what period of time is it necessary to consider COIs when completing a self-declaration as a presenter at the JATS? (Related to Supplement No. 1)

A2. If, for example, you are doing the presentation registration on the day of May20, then you need to self-declare all applicable COIs that were in effect at any time since May 21 of the previous year. This means that if the presentation is to be held on October 10, you will need to report on COIs in effect between May 21 of the previous year and October 10 of the current year—a period of approximately 1 year and5 months. The reasoning behind this period is to ensure that presenters report on any new COIs that might arise between the time of registration and the time of the presentation.

Q3. How do we need to fill in Form 2 when submitting a manuscript for publication in General Thoracic and Cardiovascular Surgery?

A3. In the case of manuscript submission, all the authors, including co-authors, are obligated to disclose their COIs, limited to matters concerning the topics of the applicable paper. It is important to note that not only the authors themselves need to declare their COIs, but so do their spouses/partners, any first-degree relations, and anyone with whom they share income or assets. Note that international journals based in Europe and United States also require spouses/partners

to declare any COIs, and therefore Surgery Today is merely complying with accepted international practice.

Q4. Over what period of time is it necessary to disclose COIs when submitting a manuscript for publication in General Thoracic and Cardiovascular Surgery?

A4. If, for example, the date of submission is June 10, you need to self-declare all applicable COIs that were in effect at any time since June 11 of the previous year. If a paper then needs to be revised, you will need to self-declare COIs that were in effect at any time between June 11 of the previous year and the date on which the final version of the paper is submitted, while revising the self-declaration as necessary.

Q5. Judging by these guidelines and the associated supplements, the JATS is accumulating a very large quantity of personal data. I wonder if the JATS will be able to manage all this data properly. In addition, in the event that it is necessary for information to be publicly disclosed, how does the JATS intend to handle this necessity?

A5. The COI information for conference presenters is used only to provide relevant COI statements on slides or posters at the time of presentations—after which it has served its purpose. That is, the JATS does not store or manage this COI information beyond this purpose. Even in the case of papers submitted to General Thoracic and Cardiovascular Surgery or other JATS publications, the COI information of authors is used only to provide a relevant statement in the publication. The only COI data we keep for any length of time are copies of Form 3 filled in by several dozen serving JATS executives, and even these forms are only retained until two years after the term of service. The Conflict of Interest Committee and Board of the JATS will deliberate carefully to ensure that only the minimum necessary information is released.