

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

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1. Guidelines for Conflict of Interest Issues related to Clinical Studies of Surgery

Clinical Studies Promotion Committee, Japan Surgical Society

Introduction

The Japan Surgical Society 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.

Research presented in the academic conferences and publications of the Japan Surgical Society includes many clinical studies on patients that have focused on the standardization of treatments as well as the use of new drugs, medical equipment and technology. A significant number 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 this collaborative clinical research is increasing on a daily basis.

Collaborative clinical research by academia and industry may in some cases 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 legal restrictions have therefore been implemented for specific instances.

However, the possibility remains that COI issues will occur with regard to activities that fall outside of what is regulated by law. In serious cases, COI 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, the evaluation may not be conducted in a fair and reasonable manner. To ensure fairness in collaborative clinical research between academia and industry, as well as fairness in conference presentation, many academic societies in Europe and the United States have determined set of COI guidelines for clinical research. In recent years, research and development related to the prevention, diagnosis and treatment of surgical diseases have actively been conducted and an urgent need for the establishment of COI guidelines has arisen in Japan. The Japan Surgical Society 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 subjects of research are humans—this is something already 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 needs to be given to the protection of human rights and the lives of subjects, in addition to the safe implementation of research.

The Japan Surgical Society 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), in view of the high ethical standards and social responsibility required in its activities. The Japan Surgical Society, through the appropriate management of COI issues of its members, aims to promote the presentation of research findings as well as the 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 basic philosophy of the Society toward COI for its members and to enable researchers participating and making presentations in the Society's activities to appropriately declare their COI. All Japan Surgical Society members 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 Japan Surgical Society
- ii. Employees of the Japan Surgical Society Secretariat
- iii. Any individual making a presentation to the Japan Surgical Society
- iv. Any individual attending a Japan Surgical Society Board Meeting, Committee or Working Party.

III. Activities covered by the COI Guidelines

The COI Guidelines shall apply to any and all activities involving the Japan Surgical Society. In particular, researchers making a presentation at an academic conference, symposium, or lecture meeting of the Japan Surgical Society or publishing research in the journal, publications, or books of the Japan Surgical Society 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 Japan Surgical Society

or an open lecture for the general public must pay particular attention to the COI Guidelines, due to the large social impact.

IV. Items for Disclosure

In the event that a subject exceeds the criteria defined separately with regard to any of the descriptions listed i. through to vii. below, the subject is required to accurately disclose their COI according to a specified format. Furthermore, in the event that the spouse or any relation in the first degree of a subject or individual who shares income and assets with the subject exceeds criteria defined separately with regard to any of the descriptions listed i. through to iii., the subject is required to accurately inform the Society of their 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 efforts 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
- vii. Any other remuneration (gifts, travel expenses, etc. not directly related to research)

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 Japan Surgical Society (JSS) should not be influenced by any intention or motive that a person or company financing the clinical study may have, nor should they enter into any agreements or contracts that make such influence unavoidable.

2) What the 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 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 JSS members

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

2) Role of JSS executives

The JSS president, directors, auditors, committee chairpersons, congress president, congress president-elect, and the Japanese journal editing committee, the English journal editing committee, the scientific committee, the clinical study promotion committee, the insured medical care committee, the ethics committee, and the conflict of interest committee have an important role and duty with regard to all activities concerning the JSS, 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 JSS executive in any activity of the JSS, or if the conflict of interest self-assessment of a JSS executive (director, president or auditor) is recognized to be inappropriate, the JSS board of directors will question the competent committee, and then, based on its response, provide instructions on appropriate improvement measures.

When the results of a clinical study are presented at a JSS event, the JSS 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 JSS board, based on the response of the committee.

When the results of a clinical study are presented in a publication of the JSS, the Japanese journal editing committee and English journal editing committee verify 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 be immediately informed of the decision and 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 editing committee. Note that the action taken in such cases is first discussed by the competent committee and implemented only after approval by the JSS board, based on the response of the committee.

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

2) Appeals

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

3) Accountability

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

VIII. Enactment of supplement

The JSS 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 JSS.

IX. Enforcement date 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 clinical study promotion committee of the JSS is able to amend these guidelines through resolutions of the JSS board.

X. Partial revision of the “Guidelines on Conflict of Interest in Clinical Studies of Cancer”

The JSS guidelines described herein were created with reference to “Guidelines on Conflict of Interest in Clinical Studies of Cancer,” formulated jointly by the Japan Society of Clinical Oncology and the Japanese Society of Medical Oncology. With the approval of these two societies, the guidelines were slightly modified to suit the needs of the JSS.

Supplementary Provisions

1. These guidelines take effect on April 1, 2009

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

I. Q&A about the purpose of guideline implementation

Q1. I understand that conflict of interest (hereinafter “COI”) matters are essentially handled by the institute/hospital to which a researcher belongs. Therefore, what kind of conflict of interest is the Japan Surgical Society (hereinafter “JSS”) dealing with? (Related to Guidelines I - III)

A1. JSS members typically conduct clinical studies at the institute/hospital they belong to, and then publish the results of the study through the JSS. Please note that there are two steps here—conducting the study and publishing the results—and therefore COI needs to be disclosed not only in connection with the research institute/hospital, but also to the JSS.

It is recommended that research institutes/hospitals implement a COI management system, under which all researchers involved in a particular clinical study submit a COI self-assessment to the head of the institute/hospital whenever they submit a study implementation plan (“Guidelines on Formulation of Conflict of Interest Policies for Clinical Research,” Working Group on Ethics and Conflict of Interest in Clinical Research, Ministry of Education, Culture, Sports, Science and Technology).

On the other hand, the “Guidelines for Conflict of Interest Issues related to Clinical Studies of Surgery” (hereinafter “the/these guidelines”) developed by the JSS obligate all persons involved in any activity performed in the name of the JSS to disclose and publicly declare any potential COI by means of a self-assessment, for the purpose of preserving the public standing and ethical integrity of all persons connected with the JSS.

In other words, all potential conflicts of interest relating to the topics of presentations or

research papers about clinical studies in surgery must be disclosed to the JSS by means of self-declaration. Furthermore, all members—not just the chairperson—of designated committees (Japanese Publication Editing Committee, English Publication Editing Committee, Scientific Committee, Clinical Study Promotion Committee, Insured Medical Care Committee, Ethics Committee, and Conflict of Interest Committee, as defined in “Guidelines for Conflict of Interest Issues related to Clinical Studies of Surgery - Supplement No. 3”) are obligated to disclose and publicly declare the details of any potential conflicts of interest.

Q2. Does compliance with these guidelines and supplement mean that legal liability will be avoided?

A2. These guidelines and the supplement to them are strictly for the purpose of preserving the ethical integrity of the JSS—compliance with these guidelines does not in any way obviate legal liability. Furthermore, legal liability may also apply in relation to the truth of information provided in COI assessments, to any undeclared COI, or to any problem arising even after the end of the data retention period. Please understand that, as a general statement, the guidelines, rules, and supplement of the JSS do not have the authority to override higher-order “statutory laws.”

II. Q&A about the subjects of COI guidelines

Q3. The guidelines specify that reporting should extend to COI involving a spouse/partner, family and any first-degree relation, and anyone with whom income or assets are shared.

What happens, though, if someone in this category refuses to disclose and publicly declare pertinent information? (Related to Guidelines II and IV)

A3. It is generally accepted that the COI of a spouse/partner can have a strong influence on the potential COI of the principal individual in question. Clearly, it is not uncommon for a family member to be involved in the startup or operation of a venture business in a relevant field. Although individuals presenting studies through the JSS are not requested to disclose the COI of their spouse/partner, all JSS executives are required to include these other people in their COI disclosures. The purpose of this is to avoid subjecting the reporting individual to social sanctions arising from a failure to report the COI of a spouse/partner. Try to persuade the spouse/partner or other applicable person that this requirement is based on the need to protect the reporting individual. The JSS is not in a position to speak directly to the spouse/partner. However, if the conflict of interest of a spouse/partner were to lead to a serious consequence, or to an issue of public interest or legal dispute, the Society would, unfortunately, not be able to protect the applicable reporting individual from public censure for failing to disclose such information in a self-declaration. In addition, the JSS is also obligated to treat such an individual as a violator of the guidelines, and to take appropriate punitive action, as defined in these guidelines.

III. Q&A about the activities covered by the COI guidelines

Q4. In addition to conference presentations, submission of papers, and the delivery of public lectures, what other activities of the JSS do these guidelines apply to?

A4. Making recommendations to bodies, such as the Japan Medical Association and the Ministry of Health, Labour and Welfare, responding to questions from these bodies, conferring awards and honors for outstanding achievements, and developing guidelines for medical care. Although these activities are performed in the name of the JSS, the development of recommendations and inquiry responses, the selection of award recipients, and the development of medical care guidelines are in fact carried out by individual JSS directors or members, so it is necessary for these people to make COI disclosures.

IV. Q&A about items for disclosure

Q5. What is the difference between disclosure and public declaration?

A5. In these guidelines “disclosure” is defined as the presentation of applicable information to the JSS secretariat, directors, councilors, members of working group committee, members, JSS conference participants, or JSS journal readers, whereas “public declaration” is defined as the presentation of applicable information to external people with no connection to the JSS or to the general public. The handling of information provided in self-declarations, in terms of the extent of disclosure and how far it is publicly declared, depends on the presenting individual and the activity in question.

The extent of self-declarations in conference presentations and journal submissions is limited to relationships between companies and organizations connected with the applicable presentation or paper and the individual making the presentation or submitting the paper. In addition, the act of submitting a self-declaration itself is considered to be disclosure.

JSS executives are required to submit more detailed self-declarations of COI. In addition, JSS

executives are obligated to report any COI of any first-degree relation and anyone else with whom they share income or assets. These self-declarations are disclosed to the JSS, but before submission, the individual in question must consent to the publication of COI information. However, there is no assumption that the actual publication of all information provided in self-declarations should be permissible under personal data protection laws. In the event that information needs to be publicly released as a result of a matter of public interest or a legal dispute, the JSS Conflict of Interest Committee will discuss the issue and the JSS board will decide on the extent to which public disclosure is necessary. The necessary information will then be released.

Q6. I work for a company in an executive role. Do I need to submit a conflict of interest report? (Relates to IV-i)

A6. In the case that you earn money working as an executive or advisor for a company that develops or sells anti-cancer drugs or medical instruments, you would need to declare the amount of compensation you receive from that company. On the other hand, suppose you worked for a pharmaceutical company that is not engaged in the development or sale of drugs used in surgical treatments, such as cancer treatment drugs or antibiotics. Then, despite the fact that you might earn money as an executive or adviser of the company, you do not need to make a COI report.

Q7. Is the need to declare stock ownership and other kinds of compensation limited to companies or organizations connected to the clinical study? (Related to Guidelines IV-ii, vii)

A7. COI declarations are required only in relation to companies and organizations connected with the applicable clinical study for individuals making a presentation at a JSS conference or submitting a paper to a JSS journal. Executives of the JSS, however, must submit self-declarations only in relation to any company or organization connected to the activities of the

JSS.

Q8. I assigned the patent rights for a particular item of medical equipment to a company for the sum of 10 million yen. As I understand it, since this money does not correspond to a patent royalty payment, I do not need to submit a conflict of interest report. Am I correct?

(Relates to IV-iii of these guidelines)

A8. Reporting the assignment of patent rights is required, as described in item IV-(3) of these guidelines.

Q9. I own 200,000 yen worth of stock in a pharmaceutical company. I also received payment of 70,000 yen for giving a lecture at a seminar organized by the company the other day. Do I have to report these payments in my self-declaration? Furthermore, do I have to make a report each time that I earn money like this? (Relates to IV-ii, iv of these guidelines)

A9. The particular time periods, reporting methods, and minimum amounts for which COI reporting is necessary vary according to the activity and the individual presenting the information. Details are specified in the supplement to these guidelines. Generally, reports are made at the time of making a conference presentation or at the time of submitting a paper for publication. JSS executives, however, must submit self-declarations at the time of their appointment and once a year thereafter. As specified in the supplement, reporting on stocks is required if 1 million yen or more is earned from stocks within a 1-year period, while the reporting of lecture fees is required if 1 million yen or more within a 1-year period is earned this way from any single company.

Q10. I received over 1 million yen in manuscript fees from a publishing company that has no

ties to any pharmaceutical company. Do I need to report this? (Relates to IV-v of the guidelines)

A10. Manuscript fees need to be reported in the case that the source of the manuscript fee payments is a pharmaceutical company, medical equipment manufacturer, or the like. Even when manuscript fees are paid by the publisher, if the publication in question is effectively sponsored by a pharmaceutical company or the like, such that the payment can be considered to originate from the company, then reporting is necessary.

Q11. A certain medical equipment manufacturer made a contribution of 2 million yen as a scholarship endowment to the municipal hospital at which I work, and I am the doctor in charge of the research conducted using the scholarship funds. In practice, the scholarship money is used impartially to cover research expenses for the entire hospital. Do I need to disclose or publicly declare this kind of scholarship endowment as a potential COI? (Related to IV-vi of these guidelines)

A11. If any payment, even a scholarship endowment, conforms to the definition of item IV-vi of these guidelines, and the amount is 2 million yen or more from a single company within a 1-year period, then the doctor who is responsible for the research must declare the payment in their COI information. However, as stated in the supplement to the guidelines, when making a conference presentation or paper submission through the JSS, if the topic of the presentation or paper is unconnected with the company or organization that paid the scholarship endowment, then there is no need for disclosure. Note, though, that since JSS executives are obligated to disclose or publicly declare potential COI in greater detail, they must include such payments in their self-assessments.

Q12. Under an agreement at the institute I work for, 10% of money received from companies as scholarship donations or for clinical tests is deducted as an administrative expense

according to the institute's accounting procedures. For this reason, even when a company gives a scholarship endowment of 3 million yen, for example, only 2.7 million yen of this can be used for research. In such a case, would it be OK for me to report the amount as 2.7 million yen? (Related to IV-vi of the guidelines, and Form 3)

A12. The reported amount should be that before the administrative expenses of your institute are deducted. In other words, please report the full amount paid by the company. In your example, the reported amount should be 3 million yen.

Q13. The guidelines state that we are obligated to report "any other compensation not directly related to research." Would this include, for example, winning an overseas trip on a television quiz program sponsored by a pharmaceutical company? (Related to item IV-vii of these guidelines)

A13. Anything won in a quiz or a lottery would be classified as a giveaway, not as compensation. Reporting is obligatory for "compensation", where "compensation" is considered to be something paid in exchange for some kind of effort. Accordingly, a giveaway would not be subject to COI reporting. As an example corresponding to item IV-vii of these guidelines, suppose there is a certain doctor that frequently prescribes a particular medication, and for this reason the company that sells that medication decides to express its gratitude to the doctor by giving him a USB flash drive. Extreme cases of this kind of thing might constitute bribery and be punishable by law, but do not fall under these guidelines. Therefore, item vii was added for the purpose of covering exchanges not covered by items i to vi, but that may still represent a significant COI. The supplement specifies that any compensation received from a company or organization amounting to 50,000 yen or more must be reported.

V. Q&A about avoiding conflicts of interest

Q14. In many cases, endowed chairs are operated using the endowment funds provided by a company. Is it necessary for the professors and staff of an endowed chair to avoid all COI issues specified under “What all individuals subject to these guidelines must avoid”?

A14. Since endowed courses represent a significant risk of serious COI, these guidelines certainly apply in such cases.

Q15. In relation to COI avoidance, doesn't the exception to COI reporting—“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”—weaken the principles of these guidelines?

A15. The aim of these guidelines is not to deny that researchers have COIs, or to prevent researchers with strong COI from conducting clinical studies. It is a fact that researchers who perform more meaningful and valuable clinical studies in terms of social benefit also tend to face stronger COI. We believe that providing the above exception is important for opening up a way for exceptionally qualified researchers to get involved in clinical studies. The American Society of Clinical Oncology (ASCO) includes the same exception in its COI policy. Some people are of the opinion that a third-party review should be necessary before a researcher can qualify for this exception and be appointed as a trial director. While the JSS is in a position to manage COI issues concerning its own activities, it would be going beyond the scope of its jurisdiction if it tried to control the clinical studies conducted by every hospital and institute. On matters arising outside the jurisdiction of the JSS, these guidelines serve only to express the views of the JSS.

Q16. According to “What the trial directors of clinical study trial directors must avoid,” acquisition or earning of patent fees or patent rights should be avoided. However, while not included under the protocol, in the case that an extremely valuable finding is made (falling outside the scope of the rights of a company), or in the case that a doctor generates intellectual property rights in an independently conducted clinical study, is it still necessary to renounce these patent fees and rights?

A16. It is basically understood that obtaining findings or intellectual property rights that fall outside the scope of the rights of a company and the fair supervision by a trial director of an applicable clinical study are virtually mutually exclusive. A simple way to avoid abandoning these rights is to resign as trial director.

Q17. I am the head of the surgery department of a private hospital that is cooperating in a clinical study in which a total of 10 hospitals are participating, and I have been asked to serve as the doctor in charge of this clinical study at our hospital. However, I am also a director of the company that manufactures and sells the medication used in this clinical study, receiving 5 million yen a year in compensation for this role. Should I be disqualified from serving as the doctor in charge of the study at my hospital due to my conflict of interest?

A17. The case of doctors in charge of a multicenter clinical study at a particular hospital is not covered in item V of these guidelines, so there is nothing to prevent this head of the surgery department from becoming the doctor in charge of the study for the applicable hospital. However, if the conflict of interest committee or ethics committee of that hospital were to decide that it was inappropriate for the head of the surgery department to become the doctor in charge of the clinical trial, then we believe that such a decision would take precedence over our guidelines.

VI. Q&A about implementation methods

Q18. I would like to give a presentation at the Japan Surgical Society on the topic of medical equipment using pigs. According to these guidelines, would I have to disclose potential COIs?

A18. Since these guidelines apply to “clinical studies”, for now COI does not need to be disclosed in relation to research presentations that only make use of cultured cells or animal experiments. However, COIs can arise in all kinds of research—not only “clinical studies of surgery”—so in the future it is quite possible that the scope of research covered by the guidelines will increase.

Q19. Is it necessary to make the same kind of COI disclosures when making presentations at conferences other than those of the JSS?

A19. COI disclosures when making presentations at a conference of other societies will be defined by the particular society; the present guidelines do not apply in such cases.

IX. Q&A about enforcement date and amendment procedures

Q20. These guidelines came into effect on April 1, 2009, so any breach of the guidelines occurring after this day will be immediately subjected to action. Is that correct? (Related to items VII and IX)

A20. Yes. The guidelines took effect on April 1, 2009. However, in order to give sufficient notice about the guidelines, no punitive action will be taken for a period of 2 years, other than to caution and advise individuals who are committing a violation. In addition, these violations will be anonymously presented as case studies in the journal of the JSS and on the JSS

website, to help promote awareness about the guidelines. Real action in response to breaches of the guidelines are expected to be implemented starting with any cases occurring after April 2011.

3. Supplement to Guidelines for Conflict of Interest Issues related to Clinical Studies of Surgery

No. 1 (Presentations at academic gatherings of the JSS)

(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)

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

(When making presentations)

Any matter defined under IV. Items for Disclosure in “Guidelines for Conflict of Interest Issues related to Clinical Studies of Surgery” (hereinafter “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 need to be disclosed. The monetary amount for which self-reporting is necessary for a particular disclosure matter is defined as;

(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
- (7) Receiving 50,000 yen or more worth of compensation within a 1-year period from a single company or organization for any other purpose (not directly related to research, e.g., travel expenses, gifts)

No. 2 (Presentation in the JSS 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 JSS bulletin, “Surgery Today” or the “Journal of Japan Surgical Society” of the JSS 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 indicated 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 JSS publications other than “Surgery Today” and the “Online Journal”, COI self-declarations must be submitted in the same format.

No. 3 (JSS executives)

(Designated committees)

This supplement applies to the following designated committees: Japanese Journal Editing Committee; English Journal Editing Committee; Scientific Committee; Clinical Study Promotion Committee; Insured Medical Care Committee; Ethics Committee; 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 JSS.

(At the time of appointment)

All executives of the JSS 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 a year prior to the 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. 4 (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 that part of the information from the Conflict of Interest Statement needed for the matter at hand will be disclosed, either only 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. 5 (Enforcement date and amendment procedures)

The clinical study promotion committee of the JSS is able to amend these supplements through a resolution of the JSS board.

No. 6 (Partial revision of the “JSCO Detailed Enforcement Regulations for Guidelines on Conflict of Interest in Clinical Studies of Cancer”)

These supplements were created with reference to “JSCO Detailed Enforcement Regulations for Guidelines on Conflict of Interest in Clinical Studies of Cancer,” formulated jointly by the Japan Society of Clinical Oncology and the Japanese Society of Medical Oncology. With the approval of these two societies, the guidelines were slightly modified to suit the needs of the JSS.

Supplementary Provisions

1. These supplements take effect on April 1, 2009.
2. These supplements were revised as of September 14, 2009.

(Form 1)

Principal Presenter/Author Conflict of Interest Self-Declaration Form (draft)

Name of
presenter/author

	Amount	Applicability	Name of company, etc. if applicable
Executive/adviser	≥ 1 million yen	Yes No	
Stocks	≥ 1 million yen profit /shareholding $\geq 5\%$	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	\geq million yen	Yes No	
Other compensation	$\geq 50,000$ yen	Yes No	

Surgery Today

Conflict of Interest Disclosure Statement

Manuscript No.

Manuscript Title:

Each author is required to complete and return this form to the corresponding author.

(Please do not send to the Surgery Today office)

When submitting a manuscript to Surgery Today, 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 Surgery". (<http://www.jssoc.or.jp/english/journal/surgerytoday/COICSS.pdf>)

When your manuscript is accepted for publication, all of the disclosures will appear in your article as "Conflict of Interest Statement" in Surgery Today as follows.

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 it to the JSS's definition for conflict of interest which must be disclosed (<http://www.jssoc.or.jp/english/journal/surgerytoday/COICSS.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 fee)			
6. Research funding			
7. Others (e.g. trips, travel, or gifts)			

Print name: _____

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, 2008 – March 31, 2009)

To the President, Japan Surgical Society Mr. Susumu Satomi

Name of declarer: _____

Affiliation (Institution/class/clinical dept.): _____

(Please circle the applicable option.)

Titles at JSS: Director Auditor Committee chairperson Congress president
 Congress president-elect

Designated committees: Japanese Publication Editing Committee
 English Publication Editing Committee Scientific committee
 Clinical Study Promotion Committee Insured Medical Care Committee
 Ethics Committee 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) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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 patent royalties/licensing fees within a 1-year period for a single patent.)

	Company/Organization name	Patent name	Amount range
1			
2			

Amount range: (1) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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 a 1-year period from a single company/organization.)

	Company/Organization name	Amount range
1		
2		
3		

Amount range: (1) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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 a 1-year period from a single company/organization.)

	Company/Organization name	Amount range
1		
2		

Amount range: (1) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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) 2.00 to 4.99 million yen; (2) 5.00 to 19.99 million yen; (3) 20.00 million yen or more

7. Have you received any other kind of compensation (not directly related to research, e.g., trips, gifts)?

Yes • No

(State all instances of receiving 50,000 yen or more within a 1-year period from a single company/organization.)

	Company/Organization name	Details of compensation	Amount range
1			
2			
3			

Amount range: (1) 50 to 199.9 thousand yen; (2) 200 to 499.9 thousand yen; (3) 500.0 thousand 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) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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 patent royalties/licensing fees within a 1-year period for a single patent.)

	Company/Organization name	Patent name	Amount range
1			
2			

Amount range: (1) 1.00 to 2.99 million yen; (2) 3.00 to 4.99 million yen; (3) 5.00 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 Japan Surgical Society. 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: _____

(Exhibit)

Name of declarer: _____

< Items to declare >

1. Have you served as executive or adviser of a company or commercial organization? If so, how much compensation did you receive for this?
2. Do you own any stocks and have you earned any profit from this stock (in the past 1 year)?
3. Have you received payment for patent royalties/licensing fees from any company or commercial organization?
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)?
5. Have you been paid manuscript fees by a company or commercial organization for writing a brochure or other kind of publication?
6. Have you received any research funds from a company or commercial organization?
7. Have you received any other kind of compensation (not directly related to research, e.g., trips, gifts)?

Declarer (A·B)	Declaration number	Company/Organization name	Application (e.g. position, name of patent, type of research funds) *In the case of 2, specify the number of stocks owned and stock prices	Amount range (Please refer to each item)

* Please make extra copies of this form if you need more space.

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

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

(Relates to Supplement No. 1)

A1. Currently, for all presentations given at JSS, 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. An example is shown below.

Principal Presenter/Author Conflict of Interest Self-Assessment Form (example)

Name of
principal
presenter/author Taro Geka

	Amount	Applicability	Name of company, etc. if applicable
Executive/adviser	≥1 million yen	Yes No	Hoshiguchi Pharmaceuticals
Stocks	≥1 million yen profit /shareholding ≥ 5%	Yes No	AB Pharmaceuticals
Patent royalties	≥1 million yen	Yes No	
Lecture fees, etc.	≥1 million yen	Yes No	Hoshiguchi Pharmaceuticals
Manuscript fees, etc.	≥1 million yen	Yes No	Hoshiguchi Pharmaceuticals
Research expenses	≥2 million yen	Yes No	AB Pharmaceuticals
Other compensation	≥50,000 yen	Yes No	

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

A2. If, for example, you are doing the presentation registration on the day of January 20, then you need to self-declare all applicable COIs that were in effect at any time since January 21 of the previous year. This means that if the presentation is to be held on April 20, you will need to report on COIs in effect between January 21 of the previous year and April 20 of the current year—a period of approximately 1 year and 3 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 *Surgery Today*? (Relates to Supplement No. 2)

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. An example of a completed Form 2 is shown below (Form 2). 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.

Surgery Today

Conflict of Interest Disclosure Statement

Manuscript No. ST□2009□XXXX□Co

Manuscript Title: ××××××××

Each author is required to complete and return this form to the corresponding author.

(Please do not send to the Surgery Today office)

When submitting a manuscript to Surgery Today, 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 Surgery”. (http://www.jssoc.or.jp/english/journal/surgerytoday_COICSS.pdf)

When your manuscript will be accepted for publication, all of the disclosures will appear in your article as “Conflict of Interest Statement” in Surgery Today as follows.

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 it to the JSS's definition for conflict of interest which must be disclosed

(<http://www.jssoc.or.jp/english/journal/surgerytoday/COICSS.pdf>).

Thereafter, 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		✓	XXXX YYYY , ABCD Company , Co . LTD
4. Honoraria (e.g. lecture fees)	✓		
5. Fees for promotional materials (e.g. manuscript fee)	✓		
6. Research funding		✓	XXXX YYYY , EFGH Health , Co . LTD
7. Others (e.g. trips, travel, or gifts)	✓		

Print name: XXXX YYYY

Signature: ○○○○ _____

Date: January 1, _____

2009 _____

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.

Q4. Over what period of time is it necessary to disclose COIs when submitting a manuscript for publication in *Surgery Today*? (Relates to Supplement No. 2)

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 JSS is accumulating a very large quantity of personal data. I wonder if the JSS 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 JSS intend to handle this necessity? (Related to Supplement No. 4)

A5. In accordance with Supplement Nos. 1 and 2, this COI information for conference presenters is only 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 JSS does not store or manage this COI information beyond this purpose. Even in the case

of papers submitted to Surgery Today or other JSS 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 JSS executives, and even these forms are only retained until two years after the term of service. It is true that when submitting a COI self-declaration form (Form 3), presenters/authors must consent to public disclosure of any information therein. In practice, however, as clearly explained in Supplement No. 4, in the event that it is necessary to divulge information to a third party, the Conflict of Interest Committee and Board of the JSS will deliberate carefully to ensure that only the minimum necessary information is released. (Form 3)