

The Japanese Society of Gastroenterological Surgery (JSGS)

Policy on Conflict of Interest

Introduction

Many research results presented or published at academic meetings or in publications derive from various research on new medical devices, drugs, and technologies leading to patents, and such research is conducted through academic-industrial partnerships. Research involving academic-industrial partnerships often yields not only public profits (those made by fulfilling academic and ethical responsibilities and applied to society) but also personal profits (including money, status, and interests gained from academic-industrial partnerships). Conflict of interest is a situation in which a researcher is affected by these two incompatible interests.

Conflict of interest is inevitable in our society where academic-industrial collaboration research is recommended, and some legal restrictions have been imposed on certain activities. However, a state of conflict of interest may occur in activities not governed by such legal restrictions.

A serious state of conflict of interest could affect research methods and data analysis and interfere with the evaluation of research results. On the other hand, there is a possibility for legitimate research results to be undervalued if conflict of interest is not disclosed. Therefore, it is important to clarify a policy on conflict of interest while promoting academic-industrial partnerships in research.

I. Objective

The purpose of this Policy is to make the basic principles on conflict of interest clearly known to members of the Japanese Society of Gastroenterological Surgery (hereinafter referred to as the “JSGS”) and to require the members participating and making presentations in JSGS projects to voluntarily and appropriately disclose their state of conflict of interest.

II. Matters covered by the Policy

The Policy applies only to “personal conflict of interest” which is a situation where a researcher receives a salary etc. paid by an organization other than the one he/she belongs to for research activities. Specifically, “personal conflict of interest” includes situations where a researcher receives compensations paid in exchange for services (lecture fees and honorariums etc.), accepts matters related to academic-industrial partnership activities (acceptance of sponsored research, guest researchers, and postdoctoral fellows; acceptance of research grant; trials/analyses sponsored; and provision of equipment etc.), or owns stocks and intellectual property rights (patent,

copyright, and royalty paid for the patent and copyright etc.).

III. Persons covered by the Policy

The Policy applies to the following persons.

- 1) JSGS members
- 2) Persons making presentations at the JSGS
- 3) JSGS's board members and members of committees

IV. Activities covered by the Policy

The Policy applies to activities, such as making presentations at the JSGS's academic meetings or lectures etc. and publishing articles in JSGS journals, research papers, and books etc.

V. Matters for disclosure

A state of conflict of interest shall be disclosed voluntarily by using a specified form if you, your spouse, or first-degree relative living in the same house engages in the activities covered by the Policy and receives an amount exceeding the standards specified separately in one or more of the following 7 items. The person who made the disclosure shall be responsible for the self-disclosure and the information included in the disclosure.

1. Appointment as an executive or adviser of a company or profit-making organization
2. Ownership of stocks
3. Patent royalty paid by a company or profit-making organization
4. Per diem (lecture fees etc.) paid by a company or profit-making organization to a researcher for his/her time and effort.
5. Fees for writing a pamphlet etc., paid by a company or profit-making organization
6. Research funds provided by a company or profit-making organization
7. Other rewards (including travel expenses and gifts not related to research activity)

VI. COI Management

Information obtained in the activities of the ethics committee etc. shall not be disclosed with no justifiable reason for proper protection of personal information and information on research or technologies.

VII. Measures against transgressors

1. The board reserves the right to deliberate on acts of violation of the Policy.
2. If an act of violation of the Policy is recognized, the case is referred to the ethics committee for evaluation and to the board for deliberation. If the case is judged to be a

material breach of the Policy, penalties may be imposed in accordance with the degree of the breach.

3. Filing of an objection

The individual subject to the penalties in Section VII 2, may file an objection to the JS GS. If the JS GS accepts an objection, the committee with jurisdiction shall review it, and the result will be sent to the individual filing the objection following the deliberation of the board.

4. Accountability

The JS GS shall fulfill its accountability to the society following the deliberation of the committee and the board regarding the research presented by the individual.

VIII. Establishment of detailed regulations

The JS GS may establish detailed regulations necessary to implement the Policy.

IX. Date of enforcement and revision methods

The Policy shall be implemented on April 13, 2010. It is expected that partial modifications to the Policy will be required to accommodate various factors, such as revision of laws and regulations etc. The ethics committee may deliberate and revise the Policy following the deliberation of the board.

Detailed Regulations for Enforcement of the Policy on Conflict of Interest in Clinical Research in Gastroenterological Surgery

Article 1. Presentation at the academic meetings of the Japanese Society of Gastroenterological Surgery (hereinafter referred to as the “JSGS”)

(Scope of disclosure)

The disclosure which has to be made by a first presenter is limited to states of conflict of interest with the companies or profit-making organizations that are related to the contents of the presentation.

(At the time of abstract registration)

A presenter making a presentation at the JSGS’s academic meetings or lectures etc. must report the existence or nonexistence of a state of conflict of interest that the presenter has had in the last one year at the time for applying for the presentation or at the time of abstract registration by using a specified form (Form 1).

(At the time of presentation)

The state of conflict of interest reported at the time of abstract registration must be disclosed in the slide of the presentation or at the end of a poster. The amount requiring voluntary disclosure is set for each item of disclosure as follows.

1. Appointment as an executive or adviser of a company or profit-making organization: An annual compensation of one million yen or more from one company or organization.
 2. Ownership of stocks: An annual profit (an aggregate of dividends and capital gain) from one company’s stock of one million yen or more, or ownership of 5% or more of all shares of the company’s stock.
 3. Patent royalty paid by a company or profit-making organization: An annual royalty payment of one million yen or more for use of one patent.
 4. Per diem (lecture fees etc.) paid by a company or profit-making organization for the time and effort spent by a researcher to attend (or give a presentation) at a meeting: A total amount of 500,000 yen or more of lecture fees paid by one company or organization in a year.
 5. Fees paid by a company or profit-making organization for writing a pamphlet, etc.: A total amount of 500,000 yen or more in fees received from one company or organization in a year.
 6. Research funds provided by a company or profit-making organization: A total amount of two million yen or more in funds awarded for a clinical research in a year.
- Scholarship grants (incentive donations): A total amount of two million yen or more in

grants awarded by one company or organization in a year to a representative researcher.

7. Other rewards (including travel expenses and gifts not related to research activities):
A total amount of 50,000 yen or more provided from one company or organization in a year.

Article 2. Publication in JSGS journals etc.

(Scope of disclosure)

The disclosure which has to be made by an author is limited to states of conflict of interest with the companies or profit-making organizations that are related to the contents of the contribution.

(At the time of contributing)

All authors publishing their work in the Japanese Journal of Gastroenterological Surgery etc. must report a state of conflict of interest at the time of contributing their work by using a form (Form 1) specified in the contribution regulations. The threshold regarding the amount to be disclosed for each item will be pursuant to the provisions of Article 1 of these Detailed Regulations. The authors must disclose a state of conflict of interest that the authors have had during the period from one year prior to the time of submitting their work to the time of submitting their work. The provisions of this Article are also applicable to publication in JSGS journals other than the Japanese Journal of Gastroenterological Surgery, and the voluntary disclosure must be made by using the same form.

Article 3 Board members and specific committee members

(Specific committees)

In these Detailed Regulations, “specific committees” mean Journal Editorial Committee, Education Committee, Health insurance Treatment Committee, Ethics Committee, and Academic Committee.

(Scope of disclosure)

The disclosure which has to be made by the board members and specific committee members is limited to states of conflict of interest with the companies or profit-making organizations that are related to the activities of the JSGS.

(At the time of appointment)

The JSGS board members and specific committee members must disclose a state of conflict of interest at the time of their appointment and at each year after their appointment by submitting a COI self-disclosure form for the board members and

specific committee members (Form 2). The states of conflict of interest voluntarily disclosed in Form 2 are those indicated in “V. Matters for disclosure” in the JS GS’s Policy on Conflict of Interest. The threshold regarding the amount to be voluntarily disclosed for each item will be pursuant to the provisions of Article 1 of these Detailed Regulations. The amount which covers a period of one year is to be entered for each item, and the calculation period shall be clearly indicated. At the time of appointment, the JS GS board members and specific committee members must report a state of conflict of interest that they have had in the last two years prior to their appointment. In this case, two COI self-disclosure forms must be prepared for submission; one for the period from two years prior to their appointment to one year prior to their appointment, and the other for the period from one year prior to their appointment to the time of their appointment.

Article 4. Handling of COI Self-Disclosure Forms for the Board Members and Specific Committee Members

COI self-disclosure forms submitted to the JS GS in accordance with these Detailed Regulations and the states of conflict of interest (COI information) disclosed in the forms must be stored as personal information under lock and key in a corporate office and under the President’s supervision. COI information may be used by the board and specific committees from time to time to handle requirements specified in the Policy. If any question or social and legal issues arise regarding the state of conflict of interest of the person who made the disclosure, such COI information may be disclosed or made public within and outside the JS GS to the extent necessary following the deliberation of the ethics committee and approval of the board. The COI self-disclosure forms submitted by the board members and specific committee members must be stored for up to two years after the completion of their term of office. After the passage of two years, the forms will be disposed under the President’s supervision. However, if any question or social and legal issues arise regarding the person who made the disclosure during the storage period, the disposal of the forms may be suspended by a resolution of the board.

Supplementary Provisions

The Detailed Enforcement Regulations will take effect on April 13, 2010.

(Form 1)

COI Self-Disclosure Form for the First Presenter (Author)

Name of First Presenter (Author):

	Amount	Applicability	If applicable, company name etc.
Position as executive or adviser	1,000,000 yen or more	Yes / No	
Stocks	Profit of 1,000,000 yen or more / ownership of 5% or more of total shares	Yes / No	
Patent royalties	1,000,000 yen or more	Yes / No	
Lecture fees	500,000 yen or more	Yes / No	
Manuscript fees etc.	500,000 yen or more	Yes / No	
Research funds	2,000,000 yen or more	Yes / No	
Other rewards	50,000 yen or more	Yes / No	

(Form 2)

**COI Self-Disclosure Form for the Board Members and Specific Committee
Members**

(Calculation Period: to)

(For official use only) Receipt No.:

Date of receipt (/ /):

To: The President of the Japanese Society of Gastroenterological Surgery

Name of the reporter:

Department (institution, class room / medical department):

Position in the JSGS:

Committee the reporter belongs to in the JSGS: _____ committee member

A. Matters for Disclosure for the Reporter

1. Position and compensation for an executive or adviser of a company or profit-making organization (an annual compensation of one million yen or more from one company or organization)	Yes / No (please circle which applies) Company / organization name (if yes): Position (executive or adviser etc.): Amount of compensation:
2. Ownership of stocks and profits from the stocks (an annual profit from one company's stock of one million yen or more, or ownership of 5% or more of all shares of the company's stock)	Yes / No (please circle which applies) Company name (if yes): Number of shares owned: Share price at the time of disclosure (per share): Profit from the stocks in the last one year:
3. Patent royalty paid by a company or profit-making organization (an annual royalty payment of one million yen or more for use of one patent)	Yes / No (please circle which applies) Company / organization name (if yes): Name of patent: Patent royalty:
4. Per diem (lecture fees etc.) paid by a company or profit-making organization for the time and effort spent by a researcher to attend (or give a presentation) at a meeting (a total amount of 500,000 yen or more of lecture fees paid by one company or organization in a year)	Yes / No (please circle which applies) Company / organization name (if yes): Amount of lecture fees etc.:
5. Fees paid by a company or profit-making organization for writing a pamphlet etc. (a total amount of 500,000 yen or more in fees received from one company or organization in a year)	Yes / No (please circle which applies) Company / organization name (if yes): Amount of manuscript fees:
6. Research funds provided by a company or profit-making organization (a total amount of two million yen or more in funds awarded for a clinical research in a year)	Yes / No (please circle which applies) Company / organization name (if yes): Research title: Research funds: Compensation received by the reporter:
7. Other rewards (including travel expenses and gifts not related to research activities) (a total amount of 50,000 yen or more provided from one company or organization in a year)	Yes / No (please circle which applies) Company / organization name (if yes): Detail of rewards: Amount of rewards:

B. Matters for Disclosure for the Spouse, First-Degree Relatives, or all Persons Sharing the Incomes and Properties of the Reporter

Name of the person affected (relationship to the reporter):

1. Position and compensation for an executive or adviser of a company or profit-making organization (an annual compensation of one million yen or more from one company or organization)	Yes / No (please circle which applies) Company / organization name (if yes): Position (executive or adviser etc.): Amount of compensation:
2. Ownership of stocks and profits from the stocks (an annual profit from one company's stock of one million yen or more, or ownership of 5% or more of all shares of the company's stock)	Yes / No (please circle which applies) Company name (if yes): Number of shares owned: Share price at the time of disclosure (per share): Profit from the stocks in the last one year:
3. Patent royalty paid by a company or profit-making organization (an annual royalty payment of one million yen or more for use of one patent)	Yes / No (please circle which applies) Company / organization name (if yes): Name of patent: Patent royalty:

Declaration: I declare that to the best of my knowledge the state of conflict of interest reported above is true and complete, and there is no other conflict of interest that interferes with my work within the Japanese Society of Gastroenterological Surgery. I approve the disclosure of this report in response to a request issued by a social or judicial institution.

Date of disclosure (/ /):

Signature of the reporter: