

The Japanese Society of Gastroenterology (JSGE)

Detailed Regulations on the Policy on Conflict of Interest in Clinical Research

The Japanese Society of Gastroenterology (JSGE) drew up the Policy on Conflict of Interest in Clinical Research to impartially manage the state of conflict of interest (COI) of its members. The Policy, which is based on similar policies of the Japanese Society of Internal Medicine, Japan Surgical Society, and other related academic societies, is designed to ensure fairness and equity in clinical research at JSGE and to maintain transparency and social reliability of research results presented at academic conferences, while appropriately promoting university-industry partnership in clinical research. To ensure proper and smooth implementation of the Policy, the Detailed Regulations on the Policy on Conflict of Interest in Clinical Research have been set down as follows.

Article 1. COI Disclosure at JSGE Lectures, Etc.

Paragraph 1

Lead presenters giving a presentation or a lecture on clinical research at a JSGE-sponsored lecture (including annual general assemblies, annual meetings, postgraduate courses, JSGE branches' educational lectures), public lecture, regular branch meeting, adjunct workshop, or related workshop, must, regardless of the presenter's membership in JSGE, voluntarily report the existence or nonexistence of a state of economic conflict of interest that the lead presenter (including the lead presenter's spouse, first-degree relatives, and individuals living on the same income as the lead presenter) has had in the previous year with the companies or for-profit organizations that are related to the clinical research. The voluntary disclosure must be made at the time of abstract registration and by using Form 1, which must be submitted to the conference secretariat.

If the lead presenter or lecturer is in a state of conflict of interest requiring disclosure, the individual must disclose such a state of conflict of interest either by using Form 1-A in the first slide of the presentation or lecture (alternatively, in the slide following the one showing the title and name of presenter/lecturer) or by using Form 1-B at the end of a poster. If the lead presenter or lecturer is not in a state of conflict of interest requiring disclosure, the individual will clearly indicate it either by using Form 1-C in the first slide of the presentation or lecture (alternatively, in the slide following the one showing the title and name of presenter/lecturer) or by using Form 1-B at the end of a poster.

Paragraph 2

“Companies, corporate organizations, and for-profit organizations that are related to clinical research” will mean companies, corporate organizations, and for-profit organizations that are related to “clinical research” in any of the following capacities:

- (1) Sponsoring or jointly carrying out the clinical research (with or without payment)
- (2) Jointly owning patents, etc. in relation to therapeutics, drugs, devices, etc. that are assessed in the clinical research
- (3) Providing drugs, devices, materials, etc. that are used in the clinical research for free or at especially advantageous prices
- (4) Providing research grants, subsidies, etc. for the clinical research
- (5) Providing unapproved drugs, medical devices, etc. for the clinical research
- (6) Sponsoring an endowed chair

Paragraph 3

“Clinical research” as it relates to presentation or publication means medical research on humans conducted with the purpose of improving methods of medical prevention, diagnosis, and treatment of diseases, promoting etiological and pathological understanding, or improving the quality of life of patients. The medical research on humans includes research on human-derived samples and data that could be used to identify specific individuals. Whether samples or data can be used to identify specific individuals will be determined by the provisions of the Japanese Ministry of Health, Labour and Welfare’s Ethical Guidelines on Clinical Research.

Article 2. Threshold for COI Disclosure

The amount set for each item of COI disclosure is based on the following standards:

- (1) Concerning appointment as a board member or advisor of a company, corporate organization, or for-profit organization (hereafter collectively called “a company or organization”) that is related to clinical research, an annual compensation of ¥1 million or more from any one company or organization
- (2) Concerning ownership of corporate stocks, an annual profit (an aggregate of dividends and capital gain) from one company’s stock of ¥1 million or more, or ownership of 5% or more of all shares of the company’s stock
- (3) Concerning patent royalties received from a company or organization, an annual loyalty payment of ¥1 million or more for use of one patent
- (4) Concerning per diem (honorariums, etc.) paid by a company or organization for the time and energy spent by a researcher to attend or give a presentation at a meeting,

- a total amount of ¥1 million or more of honorariums received from one company or organization in a year
- (5) Concerning fees paid by a company or organization for writing a pamphlet, etc., a total amount of ¥1 million or more in fees received from one company or organization in a year
 - (6) Concerning research grants from a company or organization, a total amount of ¥2 million or more in grants awarded by one company or organization in a year for clinical research (commissioned research, joint research, donations, etc.)
 - (7) Concerning grants for clinical trials or scholarship grants from a company or organization, a total amount of ¥2 million or more in grants awarded by one company or organization in a year to the individual making the COI disclosure, the department (chair, field, etc.) the individual is affiliated with, or the head of a laboratory
 - (8) Concerning endowed chair from a company or organization, the individual making the COI disclosure is affiliated with the endowed chair
 - (9) Concerning free trips and other gifts unrelated to research, education, and healthcare that are provided by a company or organization, a total amount of ¥50,000 or more provided from one company or organization in a year

Article 3. Publication of Disclosed Information in JSGE Journals, Etc.

Paragraph 1

All authors publishing their work (reviews, originally authored articles, etc.) in JSGE journals (*Journal of Gastroenterology*, *Clinical Journal of Gastroenterology*, *Nihon Shokakibyō Gakkai Zasshi*), etc. must, if they are in an economic relation regarding the contents of their publication with a company or organization provided for in Article 1, Paragraph 2 of these Detailed Regulations, report a state of economic conflict of interest that they have had in the last one year retrospectively from the time of submitting their work. The disclosure is to be made as “Disclosed Potential Conflict of Interest” provided for in the contribution regulations (using Form 2-A, Self-reported Potential Conflict of Interest Disclosure Statement, or Form 2-B, Self-Disclosed COI Report), which must be submitted in advance to the conference secretariat. The contents of the “Disclosed Potential Conflict of Interest” will be displayed at the end of an article or before the “Acknowledgements” or “References.” If no conflict of interest exists that requires disclosure, a statement such as “No potential conflict of interest requiring disclosure exists” will appear in the abovementioned space. The state of conflict of interest requiring disclosure at the time of contribution is shown in the Conflict of Interest

Policy in Clinical Research, “IV. Matters To Be Reported.” The threshold regarding the amount to be disclosed for each COI item will be pursuant to the provisions of Article 2 of these Detailed Regulations. The provisions of this paragraph are also applicable to publication in JSGE publications other than the JSGE journals. The contents of the “Disclosed Potential Conflict of Interest” will not be disclosed to the referees.

Paragraph 2

For the publication of medical guidelines with which JSGE is involved editorially, the states of conflict of interest of the members of the drafting, assessment, and supervisory committees must collectively be disclosed in the publication. The disclosure will be limited to states of conflict of interest with the companies, corporate organizations, and for-profit organizations that are related to the contents of the guidelines.

Article 4. Submission of COI Disclosure Forms by JSGE Board Members, Councilors, and Committee Chairs and Members

Paragraph 1

JSGE’s board members (President, Directors and Auditors), councillors, organizers of academic conferences (general assemblies, annual meetings, postgraduate courses, JSGE branches’ educational lectures), chairs of all committees, members of specific committees (Academic Conference Committee, Journal Editorial Committee, Academic Research Grant Selection Committee, Public Service Committee, Guideline Committee, Social Insurance Review Committee, Ethics Committee, and COI Committee), and administrative staffs must disclose existence or nonexistence of a state of conflict of interest that they have had in the last one year prior to their appointment regarding “IV. Matters for disclosure” indicated in JSGE’s Policy on Conflict of Interest in Clinical Research, by submitting a COI self-disclosure form (Form 3) to the President at the time of their appointment and at each year after their appointment. If the COI self-disclosure form has already been submitted, there is no need to submit a new one. The disclosure will be limited to states of conflict of interest with the companies, corporate organizations, and for-profit organizations that are related to the activities of JSGE.

Paragraph 2

The states of conflict of interest voluntarily disclosed in Form 3 are those indicated in “IV. Matters for disclosure” in the JSGE’s Policy on Conflict of Interest in Clinical Research. The threshold regarding the amount to be voluntarily disclosed for each COI

item will be pursuant to the provisions of Article 2 of these Detailed Regulations. The amount, indicated in categories, is to be entered for each item in Form 3, which covers a period of one year prior to appointment, and the applicable period will be clearly indicated in Form 3. JSGE board members, etc., moreover, will have an obligation to report any state of conflict of interest arising anew during their tenure of office, in which case the report must be made within eight weeks of the rise of the state of conflict and by using Form 3.

Article 5. Handling of COI Self-Disclosure Form

Paragraph 1

COI self-disclosure forms submitted at abstract registration for presentations at academic conferences and at submission of articles for contribution to JSGE journals, etc. must be stored under lock and key in a corporate office and under the President's supervision for up to two years. Similarly, documents containing COI information on JSGE board and committee members who have completed their term of office and on individuals whose appointment as a JSGE board or committee member has been rescinded must also be stored under lock and key in a corporate office and under the President's supervision for up to two years after the expiration of the final term of office or the date of rescission. After the passage of two years, the documents will promptly be deleted or disposed of under the President's supervision, provided, however, that if the JSGE board recognizes that deletion or disposal of disclosed COI information on certain individuals would not be appropriate, the deletion or disposal of that information may be suspended for a necessary period to be determined by the JSGE board. The COI information on organizers of academic lectures (chairs, etc.) will be handled the same way as that of JSGE board members.

Paragraph 2

COI information may be used by JSGE board directors and other officers from time to time in accordance with the provisions of these Detailed Regulations, to judge the existence and degree of conflict of interest that an individual to whom the information pertains to has in relation to the activities of JSGE, and, based on that judgment, to provide management and take necessary steps as an organization. The information may only be used for these objectives and may not be disclosed to anyone other than to those to whom disclosure is necessary in light of carrying out these objectives (duty of confidentiality).

Paragraph 3

With the exception of the provisions of Article 5, Paragraph 2, COI information will not, in principle, be made public. However, if disclosure of COI information is necessary for JSGE to fulfill its social and moral accountability in relation to the activities of JSGE, its committees (including standing subcommittees affiliated with the committees), and its provisional committees, such information may be disclosed or made public within and outside the JSGE to the extent necessary following the deliberation of the JSGE board. Notwithstanding the foregoing, the JSGE may ask a director on JSGE board who is dealing with the issue concerned to decide, with advice from the COI committee and the ethics committee, on whether to make the information public. In the latter case, the individual to whom the COI information pertains may state his or her opinions to the JSGE board or the director entrusted with the decision, except where urgency of disclosing the information or making the information public precludes such facility for listening to the opinions of the individual concerned.

Paragraph 4

In case where a request is made for disclosure of COI information of a specified JSGE member (including statutory requests) on reasonable grounds, the President of the JSGE will refer the matter to the COI committee, which will appropriately deal with the matter, taking into consideration the principle of the protection of personal information. If it is recognized that the matter in question is beyond the COI committee's capacity to handle, the President will establish a COI investigative committee, which will consist of a JSGE board director dealing with the issue concerned, several JSGE members, and a member from outside the JSGE. The COI investigative committee will meet within 30 days of receiving a written request for the disclosure of COI information on specified JSGE member and present its report to the President as soon as possible.

Article 6. COI Committee

The COI committee will consist of several JSGE members, several JSGE councilors, and a member from outside JSGE, all of whom are appointed by the JSGE board, and the committee members will elect a chair from among themselves. The committee members are obligated to maintain confidentiality of the COI information of JSGE members that the committee members come to learn. Working in cooperation with the JSGE board and the ethics committee, the COI committee will, based on the provisions of the COI Policy and these Detailed Regulations, provide necessary management to prevent the state of conflict of interest of JSGE members from becoming serious and

deal with violations. In case where a serious state of conflict of interest arises to a JSGE member in relation to any activities of JSGE or there is inappropriate voluntary disclosure of conflict of interest by a JSGE member, the COI committee will notify to that effect to the member concerned and provide necessary guidance, such as recommending revision of the COI report. The provisions of Article 5 will apply *mutatis mutandis* to the COI committee members regarding reporting of the state of conflict of interest and handling of their COI information.

Article 7. Measures against Transgressors

Paragraph 1

In case where doubts or social or ethical problems arise as to the self-disclosed COI report submitted by an author who is expected to publish in a JSGE journal (*Journal of Gastroenterology*, *Clinical Journal of Gastroenterology*, *Nihon Shokakibyō Gakkai Zasshi*), etc. or by an individual expected to give a presentation at JSGE-sponsored lecture, etc., the COI committee will, in order that JSGE may fulfill its social accountability, take appropriate steps in response, based on sufficient investigation, hearing, etc. If the author or presenter is in such a serious state of conflict of interest that JSGE would not be able to fulfill its social accountability, the President may refer the matter to the ethics committee for deliberation, and based on the report of the ethics committee and following deliberation by the JSGE board, the President may take such steps as to prohibit the author or presenter concerned from publishing or making the presentation. If doubts or other problems arise after the publication or presentation, the President may consider taking steps to investigate the facts and if there is any violation, to retract the published article or take other necessary measures. If the act of the individual concerned may significantly damage the trust that society has in JSGE, the President may also refer the matter to the ethics committee for deliberation and implement necessary measures.

Paragraph 2

If a problem is pointed out that there is with the self-disclosure COI report of a JSGE board director, committee chair, committee member required to submit the report, or a candidate to any of the above offices, submitted before or after his or her appointment, the chair of the COI committee will report the allegation to the President in writing. The President must promptly hold a JSGE board meeting, and the JSGE board must resolve on whether to confirm or reject the allegation. If the allegation is confirmed, the director or committee member concerned will resign from office. The President may

rescind an appointment awarded to the candidate concerned as director or committee member.

Article 8. Filing of Objection

Paragraph 1: Filing of an objection

Individuals who have been notified of a decision to impose measures against them for violation in relation to presentation or publication in JSGE's projects (JSGE-sponsored lectures, JSGE journals, etc.) pursuant to Article 7, Paragraph 1, or who have been notified of a decision on their resignation as JSGE board director or committee member or rescission of their appointment as director or committee member pursuant to Article 7, Paragraph 2 may, if they feel the decision to be inappropriate, file a written claim for reconsideration addressed to the President. The claim must be submitted to the JSGE secretariat within seven days of receipt of the notification on the JSGE board's decision. It must contain brief, concrete counterarguments to the reasons stated by the committee chair in writing for the decision. In addition to the information disclosed to the committee chair, the individual may submit in writing other related information that forms the basis of the counterarguments.

Paragraph 2: Process for the review of an objection

1. Upon receiving a claim for reconsideration, the President must promptly establish a committee for the review of the objection (hereafter called the "review committee"). The review committee will consist of several JSGE members and one or more members from outside JSGE, all of whom are appointed by the President. The committee members will elect the chair of the review committee from among themselves. The members of the COI committee may not concurrently serve on the review committee. The review committee will hold its meeting to deliberate on the objection within 30 days of receipt of the written claim for reconsideration.
2. The review committee must listen to the opinions of the chair of the ethics committee related to the claim, the chair of the COI committee, and the individual filing the objection; provided, however, that they present themselves on the dates set for the hearings.
3. Except where special circumstances exist, the review committee will prepare its report on the review of the objection and submit it to the JSGE board within a month of the first committee meeting held for deliberation.
4. Based on the review committee's judgment on the objection, the JSGE board will come to a final decision on the objection.

Article 9. Measures against Violators of Duty of Confidentiality

The JSGE's administrative staff members who learn about personal COI information in the management of such information will be bound to the same duty of confidentiality provided for in Article 5, Paragraph 2, as the JSGE board directors and other related officers. The JSGE board may impose penalties, including expulsion and dismissal, on JSGE members and administrative staff members who deliberately leak COI information to any outsider without going through proper procedures.

Article 10. Revision of the Detailed Regulations

It is assumed that social factors and future amendments of laws and regulations on university-industry partnership will necessitate partial revisions of these Detailed Regulations. A COI committee for the review of the Detailed Regulations, established under the JSGE board, will hold deliberations on the revision of the Detailed Regulations and may revise the Detailed Regulations following the resolution of the COI committee and the JSGE board.

Supplementary Provisions

Article 1. Date of Enforcement

The Detailed Regulations will take effect on a trial basis for a period of two years starting on January 1, 2011, and will enter into full force and effect on January 1, 2013.

Article 2. Revision of the Detailed Regulations

To accommodate various social factors, revision or establishment of laws and regulations on university-industry partnership, and various requirements in relation to healthcare and research, the Detailed Regulations are subject to, in principle, regular reviews at intervals of several years.

Article 3. Special Provisions on the Application of the Detailed Regulations on JSGE Board Members, Etc.

The Detailed Regulations will apply *mutatis mutandis* to individuals who have already been appointed as JSGE board members, etc. at the time the Detailed Regulations enter into force. Such individuals will be required to promptly submit the required reports, etc.

Article 4. Regarding “VII. Measures against Transgressors and Accountability” of the Policy on Conflict of Interest in Clinical Research

The enforcement of the provisions of “VII. Measures against transgressors” in the Policy on Conflict of Interest in Clinical Research will be withheld for some time after the Detailed Regulations take effect on a trial basis. During this period, the JSGE board, together with the COI committee, will make efforts to explain the purpose of the provisions in question and encourage full implementation of the self-disclosed COI reporting.