

The Japanese Society of Gastroenterology (JSGE)

Detailed Regulations on the Implementation of the Policy on Conflict of Interest in Medical Research

The Japanese Society of Gastroenterology (JSGE) drew up its Policy on Conflict of Interest in Medical Research to impartially manage possible states 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 equality in medical research by the JSGE and to maintain transparency and social reliability of research results presented at academic conferences, while appropriately promoting university-industry partnership in medical research. To ensure proper and smooth implementation of the Policy, the Detailed Regulations on the Implementation of the Policy on Conflict of Interest in Medical Research have been set down as follows.

Article 1. COI Disclosure at JSGE Lectures, Etc.

All presenters giving presentation or lectures on medical research at a JSGE-sponsored lecture (including annual general assemblies, annual meetings, postgraduate courses, JSGE branches' educational meetings), public lectures, regional meetings, seminars for gastroenterologists, adjunct study groups, or related study groups, 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 presenter (including the presenter's spouse, first-degree relatives, and individuals living on the same income as the presenter) has had in the previous year with companies or for-profit organizations that are related to the medical 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.

The lead presenter or the lecturer must disclose a conflict of interest requiring disclosure, including any conflict of interest requiring disclosure of any co-presenters, either in the first slide of the presentation or lecture (alternatively, in the slide following the one showing the title and name of the author/presenter/lecturer) or at the end of a poster, using Form 1-A (If there is a state of conflict of interest requiring disclosure). If the lead presenter or lecturer has no conflict of interest requiring disclosure, the individual will clearly indicate this either 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, using Form 1-A (If there is no state of conflict of interest requiring disclosure).

Article 2. 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., regardless of whether or not they are JSGE members, must, if they are in an economic relation regarding the contents of their publication with a company or organization provided for in IV. of the Policy on Conflict of Interest in Medical Research, report any state of economic conflict of interest that they have had in the last three years 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 corresponding author must collect the written disclosures on the states of conflicts of interest from all co-authors of the work and submit them. 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 Policy on Conflict of Interest in Medical Research, “V. Matters for COI disclosure and disclosure standards.” 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” submitted by the presenter will not be disclosed to the referees.

In the case of *Journal of Gastroenterology* and *Clinical Journal of Gastroenterology*, the journals receive many papers from overseas scientists (non-JSGE members) who may have different frameworks for university-industry partnership in their countries. Therefore, these journals will set their own COI guidelines that include (1) the scope of authors who must declare conflict of interest, (2) information to be declared, (3) COI assessment methods, and (4) steps taken when those guidelines have been violated.

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 3. Submission of COI Disclosure Forms by JSGE Officers, Executive Councilors, Council Members, and Committee Chairpersons and Members

Paragraph 1

JSGE’s officers (Director General, Directors and Auditors), Executive Councilors, Council Members, organizers of academic conferences (general meetings, annual meetings, postgraduate courses, regional meetings, JSGE branches’ educational meetings), chairs of public lectures, chairs of all committees, members of specific committees (Consideration Committee for Scientific and

Educational Meetings, Journal Editorial Board, Scientific Research Grant Committee, Guidelines Editorial Committee, Social Insurance Investigation Committee, Ethics Committee, Medical Malpractice Indemnity Committee, and Committee on Conflict of Interest), and administrative staffs must disclose the existence or nonexistence of a state of conflict of interest that they have had in the last three years prior to their appointment regarding “V. Matters for COI disclosure and disclosure standards” indicated in JSGE’s Policy on Conflict of Interest in Medical Research, by submitting a COI self-disclosure form (Form 3) to the Director General 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 “V. Matters for COI disclosure and disclosure standards” in the JSGE’s Policy on Conflict of Interest in Medical Research. The amount, indicated in categories, is to be entered for each item in Form 3. The disclosure should cover a period of the last three years prior to the year of appointment, and a period of the last three years for each year thereafter, in Form 3. The applicable period will also be clearly indicated in Form 3. JSGE officers, 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 4. 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 Director General’s supervision for up to two years. Similarly, documents containing COI information on JSGE officers and committee members who have completed their term of office and on individuals whose appointment as a JSGE officer or committee member has been rescinded must also be stored under lock and key in a corporate office and under the Director General’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 Director General’s supervision, provided, however, that if the Board of Directors 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 Board of Directors. The COI information on organizers of academic lectures (presidents, etc.) will be handled the same way as that of JSGE officers.

Paragraph 2

COI information may be used by JSGE 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 4, 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 Board of Directors. Notwithstanding the foregoing, the JSGE may ask a JSGE Director who is dealing with the issue concerned to decide, with advice from the Committee on Conflict of Interest 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 Board of Directors or the Director entrusted with the decision, except where the urgency of disclosing the information or making the information public precludes the possibility of listening to the opinions of the individual concerned.

Paragraph 4

If a request is made for disclosure of COI information of a specified JSGE member (including statutory requests) on reasonable grounds, the Director General of the JSGE will refer the matter to the Committee on Conflict of Interest, 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 Committee on Conflict of Interest's capacity to handle, the Director General will establish a COI investigative committee, which will consist of a JSGE 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 regarding a specified JSGE member and present its report to the Director General as soon as possible.

Article 5. Committee on Conflict of Interest

The Committee on Conflict of Interest will consist of several JSGE members, several JSGE

councilors, and a member from outside JSGE, all of whom are appointed by the Board of Directors, and the committee members will elect a chairperson 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 Board of Directors and the Ethics Committee, the Committee on Conflict of Interest 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 exacerbated 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 Committee on Conflict of Interest 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 4 will apply mutatis mutandis to the Committee on Conflict of Interest members regarding reporting of the state of conflict of interest and handling of their COI information.

Article 6. 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 Committee on Conflict of Interest 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 Director General may refer the matter to the Ethics Committee for deliberation, and based on the report of the Ethics Committee and following deliberation by the Board of Directors, the Director General 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 Director General 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 Director General may also refer the matter to the Ethics Committee for deliberation and implement necessary measures.

Paragraph 2

If it is pointed out that there is a problem with the self-disclosure COI report of a JSGE Director, committee chairperson, 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 Chairperson of the Committee on Conflict of Interest will report the allegation to the Director General in writing. The

Director General must promptly hold a meeting of the Board of Directors, and the Board of Directors must decide whether to confirm or reject the allegation. If the allegation is confirmed, the director or committee member concerned must resign from office. The Director General may rescind an appointment awarded to the candidate concerned as director or committee member.

Article 7. 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 4, Paragraph 2, as the JSGE Directors and other related officers. The Board of Directors 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 the proper procedures.

Article 8. 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 Board of Directors, will hold deliberations on the revision of the Detailed Regulations and may revise the Detailed Regulations following the resolution of the Committee on Conflict of Interest and the Board of Directors.

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 Officers, Etc.

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

Revisions

- December 21, 2012: status changed to a general incorporate foundation, Article IV, effective as of January 4, 2013
- September 6, 2013: “clinical research” amended to “medical research,” other related changes, Articles I, II, III, and IV, effective as of January 1, 2014
- September 8, 2015: revision, effective as of January 1, 2016
- December 22, 2016: revision, effective as of January 1, 2017
- September 12, 2017: revision, effective as of January 1, 2018
- December 27, 2017: revision, effective as of January 1, 2018
- October 5, 2020: partial revision, effective as of January 1, 2021