

Japan Gastroenterological Endoscopy Society
Detailed Rules Regarding Conflicts of Interest (COI) in Medical Research

The Japan Gastroenterological Endoscopy Society has formulated the Guidelines Regarding Conflicts of Interest (COI) in Medical Research given the necessity as an organization to appropriately manage conflicts of interest (hereinafter “COI”) arising in relation to a person’s deep involvement in collaborative activities between industry and academia for all medical research. The Guidelines set forth the basic concept of COI to JGES members and others, and the COI status needs to be declared when participating in JGES activities and making presentations.

In accordance with this intent and based on the duty to maintain fairness in the processes and outcomes of medical research with the aim of increasing ethical transparency and reliability in JGES activities, the detailed rules necessary for the actual implementation of the Guidelines shall be set forth as follows.

I. (COI declaration for JGES conferences)

I. 1

Regardless of whether a person is JGES member or not, when making a presentation or giving a lecture on medical research at a conference hosted by the JGES (annual general meeting, academic meeting, or seminar) or an academic conference hosted by a JGES branch (branch regular meeting or seminar), all presenters (including all spouses, relatives in the first degree, and persons with whom the presenter shares income and assets) must, at the time of the presentation, make a declaration using Form 1 concerning the COI regarding the financial relationships with private companies, corporate bodies, or for-profit organizations involved in the medical research (hereinafter “Private Company, Corporate Body, or Organization”) for the three years prior to the year before registration of the abstract.

The lead presenter and co-presenters shall make a COI declaration on Form 1-A if there are any COI to disclose and on Form 1-B if there are no COI to disclose in the first slide of the presentation or a slide following the slide that introduces the subject and presenters. Also, in the case of a poster session, use the designated Form 1-C to disclose any COI at the end in the poster.

In the case of a luncheon seminar, evening seminar, or a study group or lecture hosted or co-hosted by a private company or a for-profit organization, the chairperson/moderator must, using slides similar to those for the lecturers, disclose and read out loud to the audience the names of the relevant private companies and organizations. When there are many private companies to be disclosed, an appropriate response must be made by disclosing them on a slide using a different projector.

I. 2

"Private companies, corporate bodies, and for-profit organizations that are related to the medical research" refer to the following private companies, corporate bodies, and organizations that have the

following relationship with medical research.

- (1) A private company, corporate body, or organization that requests the medical research to be undertaken or collaborates in it (regardless of compensation received)
- (2) A private company, corporate body, or organization that shares the rights to the medical research, including any patent rights in connection with treatments, drugs, or equipment evaluated in the study
- (3) A private company, corporate body, or organization that provides drugs or equipment used in the medical study without charge or at a reduced price
- (4) A private company, corporate body, or organization that provides financial support for or donates funding to the medical study
- (5) A private company, corporate body, or organization that provides unapproved drugs or medical equipment for the medical study
- (6) A private company, corporate body, or organization that sponsors study groups

I. 3

“Medical research related to the presentation” refers to basic and/or clinical research conducted with the aim of improving disease prevention, diagnosis, and treatment methods and a better understanding of the disease etiology and conditions or enhancing the quality of life of patients and that are subject to an ethical review. Medical research in which the study subjects are human includes research that uses anthropogenically derived specimens and data that can identify a specific individual as defined in the Ethical Guidelines for Medical and Health Research Involving Human Subjects (published on December 22, 2014) published by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare.

II. COI Declaration Items and Disclosure Criteria

Regarding the amounts that require COI disclosure, criteria have been set for each item requiring disclosure as follows:

- (1) When the compensation for a leadership position and/or an advisory role in one private company, corporate body, or for-profit organization (hereinafter referred to as “private company, corporate body, or organization”) involved in medical research is one million yen or more per year
- (2) When the profit from stocks (total dividend and gain-on-sale) in one private company is one million yen or more per year, or when the ratio of stocks held is 5% or more of all shares in one private company
- (3) When patent royalties and/or licensing fees for one patent and/or license from one private company, corporate body, or organization are one million yen or more per year
- (4) When the daily allowance or honoraria (e.g. lecture fees) paid as compensation for the hours detained or labor for attending (or presenting at or providing advice at) meetings by one private company, corporate body, or organization is five hundred thousand yen or more per year

- (5) When the total manuscript fee for writing brochures or other publications paid by one private company, corporate body, or organization is five hundred thousand yen or more per year
- (6) When the total contract-based research funding (including funding for collaborative research, funded research, and drug trials) for medical research that the disclosing party may substantially make a decision on how to use paid by one private company, corporate body, or organization is one million yen or more per year
- (7) When the total of contributions for scholarships provided by one private company, corporate body, or organization to a disclosing party, course/class, or laboratory that the disclosing party may substantially make a decision on how to use is one million yen or more per year
- (8) When a presenter belongs to a study group sponsored by a private company, corporate body, or organization; provided, however, that when the total contributions that the disclosing party may substantially make a decision on how to use is one million yen or more per year
- (9) When the total amount paid by one private company, corporate body, or organization for travel, gifts or anything directly unrelated to research is fifty thousand yen or more per year

"A leadership position, and/or an advisory role in one private company, corporate body, or organization" stated in (1) of the Disclosure Criteria above refers to the case where a researcher affiliated with a research institute assumes a position as an officer or advisor of a specific private company and performs duties on a regular and continuous basis under contract and receives compensation therefor. When a researcher provides advice on a single occasion upon request from a private company, payment made in relation to such advice shall be disclosed as the "daily allowance and honoraria paid by private companies, corporate bodies, or for-profit organizations for compensation for hours detained or labor for attending (or presenting at or providing advice at) meetings" under (4) of the Disclosure Criteria. Furthermore, in cases (6) and (7), all disclosing parties are required to disclose research funds and scholarships provided by a relevant company or organization to their departments (courses and classes) or laboratories. It is clearly indicated that the amount in each criterion for research funds and scholarships provided by a company or organization shall be the amount of funds that the disclosing party may substantially make a decision on how to use. Regarding the specific method for disclosure and publication, the provisions in the designated form must be followed.

As an institutional COI, when the disclosing party is currently or was in the past in a relationship of joint researcher or co-researcher with the research institute to which the disclosing party belongs or the chief of the research institute or department of such institute (university, hospital, faculty, or center) and it is deemed likely to have an influence on the JGES activities in which the disclosing party is involved, the COI must be disclosed in accordance with the designated form (Form 3-C) for the following matters. Regarding the amounts that require COI disclosure, criteria have been set for each item requiring disclosure as follows:

- (1) When the total contract based research funding (including funding for collaborative research, funded research, and drug trials) for medical research that the disclosing party may substantially make a decision on how to use paid by one private company, corporate body, or organization is ten

million yen or more per year

(2) When the total contributions provided by one private company, corporate body, or organization to a disclosing party, the affiliate institute or department to which the disclosing party belongs or chief of such institute or department for which the disclosing party may substantially make a decision on how to use is two million yen or more per year

(3) When there are any shares (at least 5% of the total shares) owned by the research institute or department to which the disclosing party belongs or the head thereof (in a joint researcher or co-researcher relationship within the past three years), patent royalties, or investment in a venture company, include such as institutional COI

III. Public Announcement of the Notification Items in JGES Journals, Clinical Practice Guidelines, and Treatment Guidelines

III. 1

When the authors who publish an article (review, original paper, etc.) in a JGES journal (an English journal or a Japanese journal), regardless of whether a member or not, have a financial relationship with a Private Company, Corporate Body, or Organization set forth in I. 2 of these Detailed Rules, the authors must notify the JGES administrative office in advance of the COI of each author for the three years prior to the year before publication of the article and up to the time when the article was accepted using the Disclosed Potential Conflict of Interest (Form 2-A JGES Conflict of Interest Disclosure Statement) or Form 2-B (*Gastroenterological Endoscopy*: COI Declaration) stipulated in the Contribution Rules. The details of the Disclosed Potential Conflict of Interest will be included either at the end of the article or before the Acknowledgments or References. When there is no relevant COI, a phrase such as “No Potential conflicts of interest were disclosed” will be included in the abovementioned parts of the journal. The COI to be declared when submitting an article shall be those set forth in IV of the Guidelines Regarding Conflicts of Interest (COI) in Medical Research. ("Private companies, corporate bodies, and for-profit organizations that are related to the medical research" refer to the following private companies, corporate bodies, and organizations that have the following relationship with medical research.) The amount requiring COI disclosure for each matter shall be as set forth in Article II. This shall also apply to JGES publications other than an English journal.

In the case of an English journal, since there are a large number of articles submitted by researchers from abroad (non-members) and the framework of collaborations between industry and academia differ in each country, matters, such as (i) the scope of people required to make a declaration, (ii) matters to declare, (iii) assessment method for the declaration, and (iv) actions to be taken shall be separately stipulated in the Journal COI Guidelines.

III. 2

In addition to the COI of all committee members involved in the creation of the guidelines, the COI when formulating the Clinical Practice Guidelines must also be disclosed individually in the Clinical

Practice Guidelines. A member who has an amount exceeding the criteria amount for each item indicated in VIII. 7 Table 3 of the Guidelines Regarding Conflicts of Interest (COI) in Medical Research may participate in reviews but should not have voting rights unless it is difficult to name a replacement. In the event a candidate committee member has a COI that largely exceeds the criteria amount, the person must voluntarily withdraw as a candidate.

IV. Submission of a COI Declaration by the Board of Directors, Chairpersons, and Committee Members

IV. 1

The JGES Board of Directors (president, director, auditor), councilor, chairperson of the academic conferences (general meeting, academic seminar, focused seminar for post graduates, branch regular meeting, branch seminar, academic conference hosted by a branch, accompanying study session), chairperson of each committee; all members of specific committees, such as the General Affairs Committee, Finance Committee, Ethics Committee, Conflicts of Interest Committee, Academic Committee, Committee for the Formulation of Clinical Practice Guidelines, Japanese Journal Editors Committee (including peer reviewers), English Journal (Digestive Endoscopy) Editorial Board, English Journal (DEN Open) Editorial Board, Pharmaceuticals and Social Insurance Committee, Sakita Award and Niwa Award Selection Committee, JGES Award Selection Committee, Board of Directors Selection Committee, Medical Safety Committee; all members of the working groups within the specific committees, as well as all JGES employees, must submit a COI declaration form to the Board of Directors at the time of appointment and every year thereafter in accordance with the designated Form 3 on the status of COI during the three years prior to the year before taking office concerning the matters to be declared as stipulated in IV of the Guidelines Regarding Conflicts of Interest (COI) in Medical Research. However, this shall not be required if a COI declaration form has already been submitted. Also, the scope of the COI declaration shall be limited to those related to private companies, corporate bodies, and organizations related to the JGES activities.

IV. 2

Regarding the COI in Form 3, a declaration shall be made for items set forth in IV of the Guidelines Regarding Conflicts of Interest (COI) in Medical Research. ("Private companies, corporate bodies, and for-profit organizations that are related to the medical research" refer to the following private companies, corporate bodies, and organizations that have the following relationship with medical research.) Regarding the amounts that require COI disclosure, criteria have been set for each item requiring disclosure in II; enter the amount category for each item during the three years prior to the year before taking office in Form 3 and state the calculation period. However, in the event a new COI occurs to a member of the Board of Directors during the term of office, the member shall be required to report the COI using Form 3 within eight weeks from its occurrence.

V. Handling of COI Declarations

V. 1

The COI declaration submitted when registering the abstract for a presentation at a conference or submitting an article to a JGES journal must be strictly stored at the JGES office under the control of the president for two years from the date of submission. Similarly, the documents containing COI information for persons who have completed the term of office or withdrew from an appointment as a committee member must be strictly stored at the JGES office under the control of the president for two years from the date of expiration of the final term of office or the date of withdrawal of the appointment. Regarding persons for whom two years have passed, the documents shall be promptly deleted or discarded under the control of the president. However, in the event the directors deem it inappropriate to delete or discard the documents, the disposal of the COI information may be postponed for the period of time deemed necessary. The same handling as that of Board of Directors shall apply to COI information concerning chairperson of academic conferences (general meeting, academic seminar, academic conference hosted by a branch, accompanying study session).

V. 2

JGES directors or executives shall, in accordance with these Detailed Rules, determine the existence or degree of individual COI based on the submitted declaration. When actions will be taken or the situation will be managed in accordance with the decision as JGES, the COI information concerning the relevant individual may be used as necessary. However, such use shall not exceed the extent necessary for the purpose of use, and information may not be disclosed to persons other than those to whom the information needs to be disclosed in light of the above purpose of use.

V. 3

COI information shall be, excluding the cases in V.2, undisclosed, in principle. COI information may be disclosed or announced inside and outside of the JGES to the extent necessary following discussion at the Board of Directors when it is necessary for the purpose of fulfilling social or moral accountability as the JGES in relation to JGES activities, committee activities (including those of affiliated permanent subcommittees), or extraordinary committee activities. However, this shall not preclude the issue from being entrusted to a specific director who handles such issues and enable the director to make a decision based on advice from the Conflicts of Interest Committee or the Ethics Committee. In that case, the subject person of the COI information to be disclosed or announced may express his/her opinion to the Board of directors or the director to whom the issue is entrusted. However, this shall not apply to urgent cases where there is no time to hear the opinion before disclosure or announcement.

V. 4

In the event a non-member requests disclosure (including legal claims) designating a specific member, if there are reasonable grounds, the president shall ask the COI Committee to handle it

appropriately while protecting the personal information. However, in the event the COI Committee determines it is not possible for the committee to respond to such a request, a COI Investigation Committee that is made up of a several JGES members and at least one outside committee member who are appointed by the president shall be established and respond to the request. The COI Investigation Committee shall hold a meeting within 30 days from the receipt of the request for disclosure and issue a response as soon as possible.

VI. Conflicts of Interest Committee

The Conflicts of Interest (COI) Committee shall be made up of several JGES members and at least one outside committee member who are appointed by the president, and the chairperson shall be selected from among the committee members through election by the committee members. The members of the COI Committee are obligated to protect the confidentiality of the COI information about members learned through the course of their duties. The COI Committee shall, in cooperation with the Board of Directors and the Ethics Committee, conduct management to prevent members' COI from evolving into a serious situation and respond to violations in accordance with the Conflicts of Interest Policy and these Detailed Rules. Regarding the reporting of COI matters and handling of COI information about committee members, the provision of V shall apply with the necessary changes.

VII. Actions Against Violators

VII. 1

When there is a question or social/moral issue in relation to the COI declaration submitted by an author who will publish an article in a JGES journal (an English journal or Japanese journal) or a planned presenter at a JGES conference, after thorough investigation and hearings by the COI Committee with the aim of fulfilling social accountability as the JGES, appropriate actions shall be taken. In the event of a serious COI and it is not possible to fulfill the required accountability, the president shall seek advice from the Ethics Committee, and following a review by the Board of Directors based on the response from the Ethics Committee, actions of the suspension of the presentation at the conference or publication of the article may be taken. In the case a question or other issue arises after the presentation or publication, the president shall investigate the facts, and if there is a violation, take such action as retraction of the published article. In the event the details of the violation significantly damage the JGES's trust from society, in accordance with JGES Articles of Incorporation, action, such as revocation of membership, shall be taken.

VII. 2

Regarding the JGES Board of Directors, committee chairmen, members required to make COI declarations, and candidates for such positions, the COI Committee chairperson shall report to the president in writing if an issue is pointed out in relation to the COI matters declared before or after

taking office. Also, the president shall promptly hold a meeting of the Board of Directors and determine whether or not to approve such finding as the Board of Directors. In the event the finding is approved, if the relevant individual is a director or director candidate, the person shall immediately resign; in other cases, following discussions with the relevant committee member or candidate, the appointment may be withdrawn.

VIII. Objections

VIII. 1 Filing an objection

The person who received notice of an action taken in response to a violation in relation to a presentation as part of JGES activities (JGES journal or conference) in accordance with the provisions of VII. 1, the director who will retire or the candidate for whom the appointment will be withdrawn in accordance with the provisions of VII. 2 may file an objection concerning the action to be taken and request a review by submitting an objection and request for review to the JGES Secretariat to the president within seven days from the receipt of the notice of the decision by the Board of Directors if they have an objection to the decision. The request for review shall include a brief and specific counterargument and opinion against the reason for withdrawal indicated in writing by the chairperson. In that case, in addition to the information disclosed to the chairperson, related information that forms the basis of the reason for the objection may be presented in writing.

VIII. 2 Procedure for review of the objection

- (1) Upon receipt of a petition of objection, the president shall promptly set up an Objection Review Committee (hereinafter referred to as the "Review Committee"). The Review Committee shall comprise several JGES members nominated by the president and at least one external nonmember. The chairperson of the Review Committee shall be selected from among the members. Members of the COI Committee may not serve as members of the Review Committee. The Review Committee shall meet to review the objection within 30 days of the receipt of the petition of objection.
- (2) The Review Committee may consult with the chairperson of the Ethics Committee concerning the objection and undertake additional hearings with the person who filed the objection if necessary.
- (3) The Review Committee shall complete a report regarding the objection and submit it to the president within one month of the first review meeting of the Review Committee unless there are special circumstances justifying a delay of the report.
- (4) The decision of the Review Committee regarding the objection is final.

IX. Revision of or Changes to the Detailed Rules

- (1) These Detailed Rules are expected to require partial changes in accordance with social factors, guidelines on collaboration between industry and academia, revisions and establishment of

laws, and other conditions concerning medical treatment and research. The Conflicts of Interest Committee may review these Detailed Rules for the purpose of making changes and make changes following a resolution adopted by the Board of Directors.

- (2) These Detailed Rules may be reviewed and revised regularly based on the trends of the 16 internal medicine academic societies with the aim of conforming to the social factors, guidelines on collaboration between industry and academia, revisions and establishment of laws, and other various conditions surrounding medical treatment and medical research.

Supplementary Provisions

These Detailed Rules will come into effect on March 1, 2012.

Partial amendment: October 1, 2013

Partial amendment: April 21, 2015

Partial amendment: September 17, 2015

Partial amendment: June 27, 2017

Partial amendment: July 3, 2019

Partial amendment: May 22, 2020

Partial amendment: September 23, 2020

Partial amendment: April 12, 2021