

Japan Gastroenterological Endoscopy Society Guidelines Regarding Conflicts of Interest in Medical Research

The Japan Gastroenterological Endoscopy Society (JGES), originally established as the Japan Study Group of Gastroscopy in 1951, marked its 50th anniversary in 2008 and now has over 32,000 members. The goals of the JGES are to promote fundamental and clinical research in the field of Gastroenterological Endoscopy and to contribute to improvements in human healthcare not only in Japan, but also worldwide through extensive academic research. As a result of continued efforts, the JGES has become a Society with solid achievements and a strong reputation across a broad range of activities relating to the diagnosis, treatment, and prevention of various gastrointestinal diseases (primarily gastroenterological cancer), in addition to the development and technological advancement of endoscopic devices. Endoscopy is currently an essential component of daily medical practice and further developments of medical research led by JGES are expected in the future.

The research outcomes presented at academic meetings hosted by the JGES or in official JGES journals include medical research into the diagnosis, treatment, and prevention of various diseases, as well as research into the use of new drugs, devices, and techniques. To promote this research, joint efforts between industry (e.g. pharmaceutical or venture companies) and academia (collaborative research, funded research, transferring and assisting technology for use in clinical settings, and the funding of scholarships and study groups etc.) are of fundamental importance.

However, with greater collaboration between industry and academia in the field of medical research (including basic research, clinical research and clinical trial), it is inevitable that the involvement of public organizations (e.g. universities, research institutes, and academic societies) with specific private companies will increase. Consequently, the situation where the responsibilities of the academic institutions/organizations, whose primary responsibility is education and research, and personal profits arising from joint activities with private companies and organizations collide or conflict will inevitably arise. This situation is generally described as “conflict of interest” (COI). Appropriate management of COI is a significant challenge to overcome for any academic institution or organization to properly promote collaboration with industry. In addition, medical research differs from collaborative research in other academic fields in the sense that medical research requires the participation of both patients and healthy volunteers as research subjects. In medical research, serious COI resulting from financial and other types of support provided by private companies and organizations may lead to compromises in patient safety and

privacy. There may be serious concerns regarding human rights abuses and endangering of patient lives. Furthermore, the collaboration may result in biased research methods, data analyses, and interpretation of the outcomes. In some cases, even if the research outcome is appropriate, COI may mean that the outcome is not evaluated fairly or even that the study results are not published. However, the problems associated with COI that have surfaced in the past have been caused primarily by the management of COI, not by the existence of the COI itself. Thus, to promote appropriate collaborative research between industry and academia, many medical facilities and academic institutes both in Japan and abroad have created guidelines for the management of COI in medical research with the intention of maintaining justice and fairness in research, the transparency of academic presentations, and public confidence in the collaborative research undertaken by private companies and public organizations. Reporting the results of collaborative research publicly, with appropriate management of COI, is also essential to maintain public confidence in medical research.

In recent years, in the context of the national policy to promote a translational research from basic seeds discovery research to clinical research in each country, there is a global trend that an object of research in the management of COI has been extended to include a basic life-science research in collaboration between industry and academia, and has no longer been limited to the clinical research and clinical trial (including drug trial) on humans. With a background like that, basic researchers who conduct industry-academia joint researches with private companies, profit-oriented corporate bodies or organizations also tend to be requested to submit a self-declaration of financial COI. Therefore, JGES defines the researches from life-science research and basic medical research to clinical medical research on humans (including researches related to unmasked materials derived from humans or data with personal identifiers) and clinical trial, which are conducted in collaboration between industry and academia with the purpose of improving methods of prevention and diagnosis, better understanding of cause of disease and patient's quality of life, as medical researches, and position them as objects of COI management.

The basic stance of JGES on COI management is: 1) research institutes and researchers must accept funding (donations, research grant, funding contract, etc.), pharmaceuticals, medical devices and services in relation to medical research in collaboration between industry and academia from private companies, corporate bodies and organizations in which they have a vested interest in a fair and proper manner on the condition that medical, ethical and scientific nature of the research is guaranteed; 2) 2) specific information on the funding and other items provided must be properly managed and properly stated and published in clinical study implementation plan, CIO declaration and academic paper to ensure quality and

reliability of the research outcome; and 3) research institutes and researchers must fulfill their accountability when any question is raised by a third party.

To promote public accountability, the JGES has formulated this Guidelines Regarding Conflicts of Interest to manage its members' COI properly by disclosing any financial relationships with research sponsors based on certain requirements when members assume a position as an officer or present research findings at meetings, in publications etc.

Article 1: Purpose

As per the ethical doctrines for medical research on humans stated in the Declaration of Helsinki and the Ethical Guidelines for Clinical Studies (Ministry of Health, Labour and Welfare Notification No. 255, revised 2008), particular care should be taken when performing such research to ensure that subjects' lives and human rights are protected. Considering the social responsibility of JGES members and the high level of morality they are expected to display, the JGES has formulated the Guidelines Regarding Conflicts of Interest (COI) in Medical Research, hereafter referred to as the Guidelines. The purpose of the Guidelines is to properly promote research outcomes and related activities while maintaining neutrality and fairness and, at the same time, fulfilling our social responsibilities by contributing to advances in the prevention, diagnosis, and treatment of disease. The Guidelines contain the basic philosophy underlying COI for JGES members and request compliance by the voluntary disclosure of any COI when members participate in various events or present results related to various research activities.

Article 2: Persons Covered by the Guidelines

The Guidelines are applicable to any person listed below who may find themselves in a position of COI.

- (1) Members of the JGES
- (2) Presenters at academic meetings of the JGES (including non-members of the JGES)
- (3) Officers (President, directors, and inspectors), people in charge of academic meetings (chairperson etc.), committee chairpersons, and members of special committees or provisional working groups of the JGES
- (4) Administrative staff of the JGES
- (5) Spouses, first-degree relatives, and anyone who shares the income and wealth of the people listed in (1)–(4) above

Article 3: Activities Covered by the Guidelines

The activities of the JGES listed below are subject to the Guidelines.

- (1) Conferences and/or academic meetings (including Annual Meetings) hosted by the

JGES and its branches

- (2) The publication of in-house journals and academic books
- (3) The implementation of studies and research
- (4) Encouragement to undertake studies and bestowment of awards for research outcomes
- (5) Implementation of certified-fellow systems (i.e. certification of specialists or qualified facilities etc.)
- (6) Promotion of lifetime learning
- (7) Communication and cooperation with related academic societies
- (8) Promotion of international research partnerships
- (9) Promotion of advancement of Gastroenterological Endoscopy in the society and educate medical professionals regarding Gastroenterological Endoscopy
- (10) Any other projects necessary to achieve the purposes of the JGES

COI over the past three years is required to be disclosed in a prescribed form when engaging in any of the following activities.

- Presentation at conferences or academic meetings hosted by the JGES
- Presentation of research results in print publications, such as in-house JGES journals
- Formulation of clinical guidelines, manuals etc.
- Participation in or sitting on investigation committees, advisory committees etc. that are established on a temporary basis
- Presentation at conferences, workshops, luncheon seminars, evening seminars, etc. hosted or co-hosted by private companies, corporate bodies and profit-oriented organizations.

Article 4: Matters Requiring Disclosure

People falling into Categories (1)–(8) below shall report on their precise COI directly to the President of the JGES in case the benefits received exceed the criteria listed in the Detailed Regulations of the Guidelines. Specific steps for disclosure and publication are given in separate Detailed Regulations.

- (1) Those employed by, in a leadership position, and/or those who have an advisory role in private companies, corporate bodies, or profit-oriented organizations
- (2) Those owning stocks in private companies
- (3) Those receiving patent royalties and/or licensing fees from private companies, corporate bodies, or profit-oriented organizations
- (4) Those receiving daily allowances or honoraria (e.g. lecture fees) from private companies, corporate bodies, or profit-oriented organizations as compensation for attending (presenting or giving advice at) meetings
- (5) Those receiving manuscript fees from private companies, corporate bodies, or profit-

- oriented organizations for writing promotional materials (e.g. brochures)
- (6) Those receiving funding for medical research (drug trials, clinical trials, funded researches, collaborative researches, donations, etc.) from private companies, corporate bodies, or profit-oriented organizations
 - (7) Study groups sponsored by companies, corporate bodies, or profit-oriented organizations
 - (8) Those receiving payment of travel expenses (to participate in conferences, etc.) or other expenses or fees for anything unrelated to research, education, or medical practice from private companies, corporate bodies, or profit-oriented organizations

Article 5: Matters to be Avoided in Relation to COI

5.1 Matters people subject to the Guidelines should avoid

The publication of the results of medical research or the formulation of clinical guidelines must be undertaken on a purely scientific basis and for the benefit of the public. In publishing and interpreting the results of medical research, as well as in formulating clinical and/or treatment guidelines and manuals on a scientific basis, members of the JGES must not be influenced by the sponsors or companies that provided financial support for the study. JGES members should avoid any funding contract that may influence the results, outcomes, and publication of the medical research.

5.2 Matters people responsible for clinical trial as part of the medical research should avoid

People in charge of the planning and implementation of medical research, especially clinical trials, drug trials, etc., must be researchers who are socially evaluated as not having COI with their clients according to the criteria listed below in Items (1)–(3) and must maintain this lack of conflict after being selected as the leader of the research project.

- (1) Owning stocks in companies providing funding for medical research
- (2) In a position to receive patent royalties and/or licensing fees for products and/or techniques developed as a result of the medical research
- (3) Being employed by, in a leadership position, and/or having an advisory role in private companies or profit-oriented organizations sponsoring the medical research (excluding those with an unpaid position as a scientific advisor)

If, however, a person falls into one of the three categories listed above, he or she can still lead a medical research if he or she is indispensable to the planning and implementation of the medical research and if the medical research is of considerable social importance in the field, provided that the person's fairness, equity, and transparency in terms of both judgment and action are clearly

maintained.

Article 6: Means of Execution

6.1 Member responsibilities

When presenting the results of medical research at conferences or academic meetings, JGES members shall disclose COI related to the research in question according to the Detailed Regulations of the JGES and using a designated form. If any violations of the Guidelines occur in connection with the presentation, the Board of Directors shall request the committee that manages problems associated with COI (hereafter referred to as the COI Committee) to discuss the matter and make recommendations. The Board of Directors will then take reasonable measures based on the COI Committee's report.

6.2 Officers' responsibilities

Officers (President, directors, and inspectors), people in charge of academic meetings (chairperson etc.), committee chairpersons, and members of special committees or provisional working groups of the JGES have crucial roles in and responsibilities for all JGES activities and shall voluntarily disclose any COI (for three years prior to the year they first assumed their office) at the time they first assumed their office using a designated form (Form 3). In addition, directors are required to conduct hearings, investigations etc. to manage any COI problems that arise and to report back to the President.

6.3 Role of the COI Committee

When a serious COI arises among members or the COI voluntarily disclosed is reported by others to be questionable in relation to JGES activities, the COI Committee will conduct hearings, investigations etc. to manage the COI and will report back to the President.

6.4 Role of the Board of Directors

When a serious COI occurs among officers or when the COI voluntarily disclosed by board members renders their participation in JGES activities inappropriate, the Board of Directors may seek opinions from the COI Committee and call for remedial action in accordance with the Committee's report.

6.5 Role of people in charge of academic meetings

When the results of medical research are presented at conferences or academic meetings, the people in charge of such meetings (chairpersons etc.) shall verify

the presenters' compliance with the Guidelines and, if any violations are found, those in charge of the meeting have the right to take necessary measures, including suspending presentations, with prompt notification of the reasons to the presenter. In taking these measures, the above person in charge may seek opinions from the COI Committee, and the Board of Directors may call for remedial action in accordance with the Committee's report.

6.6 Role of the editorial board

When clinical results are published in JGES journals as original articles, reviews, clinical guidelines, editorials, or opinions, the editorial board shall request the author to disclose COI with private companies, corporate bodies or organizations in which the author has a vested interest. In particular, when publishing results of intervention study, if any support in a form of funding, drugs or devices, or labor or service is received from private companies, corporate bodies or organizations in the process of executing medical research or writing a paper, the editorial board shall have the authors clearly and properly indicate the role of each such organization to ensure transparency. In addition, the editorial board shall verify compliance with the Guidelines and, if any violations are found, may take necessary measures, including suspension of publication with prompt notification of the reasons to the authors. If violation of the Guidelines is detected after publication of the material in question, the editorial board may announce that fact in the journal under the name of the Editor-in-Chief. When taking these measures, the Editor-in-Chief may seek opinions from the COI Committee and may call for remedial action in accordance with the Committee's report.

6.7 Others

Other chairpersons and members of committees involved in JGES activities shall verify their compliance with the Guidelines and, if there are any violations, may take prompt remedial action. They may seek opinions on these measures from the COI Committee, and the Board of Directors may call for remedial action in accordance with the Committee's report.

Article 7: Actions in Case of Guideline Violations and Accountability

7.1 Actions to be taken against violators of the Guidelines

The Board of Directors of the JGES has the authority to discuss any violations of the Guidelines according to separate rules. If the violation of the Guidelines is deemed to be crucial after the opinions of the COI Committee, Ethics Committee,

and any other relevant committees have been sought, the matter shall be discussed at a Board of Directors meeting and the board members shall take punitive actions depending on the degree of the violation.

7.2 Filing of complaints

The person who is the object of the accusation may file a complaint against the JGES. When such complaints are received, the President of the JGES is required to set up an administrative review board (interim advisory committee), refer the complaint for examination, discuss the report of the review board at a Board of Directors meeting, and notify the complainant of the results.

7.3 Accountability

When the JGES discovers significant violation of the Guidelines in the results of medical research presented at JGES-related meetings etc., the JGES is required to fulfill its accountability obligations after discussion of the matter at the Board of Directors meeting.

Article 8: Coordination with Related Societies

The JGES works closely with many other internist and surgical societies and offers or participates in a forum to exchange information regarding any amendments to these Guidelines or the formulation of the Detailed Regulations.

Article 9: Implementation of Detailed Regulations

The JGES may implement Detailed Regulations for the execution of the Guidelines, if necessary.

Article 10: Amendments to the Guidelines

The Guidelines shall be reviewed periodically and amended if necessary to take into account societal changes, amendments to Acts related to collaborations between industry and academia, and changes in medical treatments and/or research.

Supplementary Provisions

The Guidelines will come into effect on March 1, 2012.

Partial amendments: Made on October 1, 2013

Partial amendments: Made on September 17, 2015

Partial amendments: Made on June 27, 2017

The Japan Gastroenterological Endoscopy Society (JGES) has formulated Guidelines Regarding Conflicts of Interest in Medical Research to appropriately manage members' conflicts of interest (COI) arising from involvement in a collaboration between industry and academia to undertake medical research. The Guidelines intend to show JGES members the basic philosophy of COI and require them to voluntarily disclose any COI when making presentations at JGES conferences or academic meetings.

JGES establishes detailed regulations necessary for the execution of the Guidelines, in accordance with the aims of the Guidelines, to fulfill its responsibility to ensure the fairness of the process and research outcome and to enhance ethical transparency and integrity of JGES's activities, as follows.

Article 1: Disclosure of COI at JGES Conferences or Academic Meetings

- 1.1 Any presenter or speaker at conferences and academic meetings held by the JGES (including Annual Meetings, lecture presentations, and seminars) or by its branches (including Annual Branch Meetings and seminars) shall voluntarily disclose the existence or nonexistence of any financial relationship and/or COI for three years prior to the year of Abstract registration with companies and profit-oriented organizations in connection with the medical research presented, regardless of whether they are a member of the JGES or not, at the time of Abstract registration using Form 1. This disclosure extends to the presenter's spouse, first-degree relatives, and anyone who shares his/her income and wealth. The head presenter including co-presenter shall disclose any COI at the beginning of his/her presentation or on the slide profiling the presenters involved in the study using Form 1-A (if he/she has any COI to disclose) or Form 1-B (if he/she has no COI to disclose). Alternatively, for poster presentations, any COI shall be disclosed at the bottom of the poster using Form 1-C.
- 1.2 "Private companies, corporate bodies and profit-oriented organizations that are related to the medical research" refers to the following private companies, corporate bodies and organizations.
 - (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 patents 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

1.3 “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, to better understand disease etiology and conditions, to enhance the quality of life of patients, and that in which the study subjects are human. Clinical research in which the study subjects are human includes research that uses anthropogenically derived material and data that can identify a specific individual. Whether a certain material falls under a material or data that can identify a specific individual shall be determined in accordance with the Ethical Guidelines for Clinical Studies in Which the Study Subjects are Human" published (in December 2014) by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare.

Article 2: Criteria for the Disclosure of COI

The criteria and monetary values for the disclosure of COI are as follows.

- (1) (1) When the compensation for a leadership position and/or an advisory role in one 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 royalty and/or licensing fees for one patent and/or license from one private company, corporate body or organization one million yen or more per year
- (4) When the daily allowance or honoraria (e.g. lecture fees) paid for compensation for on duty hours and labor to attend (or present at or provide advice at) meetings paid by one private company, corporate body or organization is five hundred thousand yen or more per year
- (5) When the total of manuscript fees for writing brochures, etc. paid by one private company, corporate body or organization is five hundred thousand yen or more per year

- (6) When the total research funding (including funding for collaborative research, funded research and drug trial) actually allocated to medical research paid by one private company, corporate body or organization in one million yen or more per year
- (7) When the total of contributions for scholarships provided by one private company, corporate body or organization actually allocated to a presenter, his/her department (including course and class), or a representative of his/her laboratory 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
- (9) When the total amount paid by one private company, corporate body or organization for travel, gift or anything 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" as stated in (1) of Criteria for Disclosure above refers to the case where a researcher affiliated with a research institute assumes a position as an officer or an 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 at a single occasion upon request of a private company, payment made in relation to such advice shall be disclosed as "daily allowance and honoraria paid by private companies, corporate bodies, or profit-oriented organizations for compensation for on-duty hours and labor to attend (or present at or provide advice at) meetings" under (4) of Criterion for Disclosure.

Furthermore, as for the cases of (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. The amount in each criterion for research funds and scholarships provided by a company or organization shall be the amount of funds which the disclosing party may substantially make a decision on how to use, and it is clearly indicated that the total annual amount actually allocated by the head of affiliated research institute is the amount required to be disclosed.

Among the above items to be disclosed, parties to accept donations to fund scholarships from a company or organization are divided mainly into two, a head of an organization (principal or director of hospital) or a head of a course/class. In the former case, donations tend to be considered as not related to the individual researcher, but if such scholarships are delivered to individual presenter, or to his/her department (course or class) or laboratory from a private company, corporate body or organization through the head of the organization, the amount of such donations should be disclosed.

Also, financial supports (funded research and research grant) from a private company through non-profit corporate body (such as NPO) or public-interest corporate body (such as foundation) is likely to raise question, and thus should be voluntarily disclosed. The higher the amount of financial support, the more people tend to receive an impression that objectivity and fairness of research results are impaired, so in case the indirect research supports from related private company are envisioned, it is desirable to voluntarily disclose his/her COI in order to prevent any doubt or question from society.

Article 3: Publication of Disclosed Information in Journals, Including Official JGES Journals

To meet the requirements of the Author Guidelines, all authors who publish their articles (e.g. review or original articles) in in-house JGES journals (*Digestive Endoscopy* and *Gastroenterological Endoscopy*), regardless of whether they are a member of the JGES or not, are required to report any COI with a private company, corporate body or organization prescribed in Article 1.2 of these Detailed Regulations for three years prior to the year of submission of article up to the time of acceptance of publication for each author to the JGES administrative office in advance if the authors have economic ties with such private company, corporate body or organization that is related to the content of the published articles using Form 2-A “Disclosed Potential Conflict of Interest” (JGES Conflict of Interest Disclosure Statement) or Form 2-B “*Gastroenterological Endoscopy*: disclosure statement of COI”). A statement of “Disclosed Potential Conflict of Interest” will be published at the end of the article or immediately before the Acknowledgments or References. If authors do not have any COI, the phrase “No potential conflicts of interest were disclosed.” shall be published at the same place. COI to be disclosed when submitting an article for publication is as prescribed in Article 4 (Matters Requiring Disclosure) of the Guidelines Regarding Conflicts of Interest in Medical Research. The criteria for disclosure are prescribed in Article 2 of these Detailed Regulations. Any article published in a JGES publication other than *Digestive Endoscopy* shall also conform to these Detailed Regulations. Any “Disclosed Potential Conflict of Interest” reported by presenters will not be disclosed to the referees. As to *Digestive Endoscopy*, however, many of the submitted articles are written by overseas researchers (non-members) with different systems of industry-academia collaboration from country to country, so matters including 1) scope of subjects to disclose COI, 2) items to be disclosed, 3) evaluation method for disclosure and 4) ways to take measures, shall be defined in the COI disclosure policy of the journal separately.

Article 4: Submission of COI Statements by officers, chairpersons, and committee members

- 4.1 Officers (President, board members, and inspectors), councilors, people in charge of academic meetings (conferences, seminars, lecture meetings hosted by branches and annexed workshops), committee chairpersons of all committees, Editors-in-Chief of in-house journals, members of pharmaceutical and healthcare committees, guideline committees, academic workshops, award selection committees, and ethics committees, and administrative staff of the JGES are required to voluntarily submit their COI statement for each year for three years prior to the year they first assumed their office, as prescribed in Article 4 of the Guidelines Regarding Conflicts of Interest in Medical Research, to the Board of Directors when they first assumed their office and annually thereafter. However, submission is not needed if any COI have already been reported to the board. Disclosure of COI is limited to private companies, corporate bodies and organizations related to JGES projects.
- 4.2 COI to be disclosed in Form 3 are as prescribed in Article 4 of the Guidelines Regarding Conflicts of Interest in Medical Research. The criteria or monetary values for each matter to be disclosed or published are as prescribed in Article 2 of the Detailed Regulations of the Guidelines. People who come into office shall disclose any COI for each year for three years prior to the year they first assumed their office and report applicable segment of amount and the period of time over which the funds were received for each item using Form 3. During their service to the JGES, officers are required to disclose any newly occurring COI within 8 weeks of its occurrence using Form 3.

Article 5: Handling of COI Disclosure Statements

- 5.1 Any COI Disclosure Statements submitted at the time of registration of Abstracts for conferences and/or academic meetings or at the time of submission of manuscripts to JGES journals shall be kept on file for 2 years after their submission under strict supervision of the President at the JGES administrative office. Similarly, documents concerning COI information of officers whose term has expired and committee members for whom cancellation of appointment has become final shall be kept on file for 2 years after the expiration of their term or cancellation of their appointment under the strict supervision of the President at the JGES administrative office. After 2 years, these statements will be promptly deleted or destroyed under the supervision of the President. However, in cases in which a director deems that the deletion or destruction of specific statements is not appropriate, the deletion or destruction of COI information may be withheld

for a predetermined period of time. COI information of the chairpersons of academic meetings (conferences, seminars, lecture meetings hosted by branches and annexed workshops) shall be treated in the same manner as that of JGES officers.

- 5.2 The JGES directors and related officers, following these Detailed Regulations, may use the COI information submitted from time to time, if they need to make a decision on whether or not COI exists or the level of COI and/or if the JGES needs to manage the situation or take measures based on such decision. However, such access shall be limited to the extent necessary to achieve the purpose of using such information, and such information shall not be disclosed to any person other than those to whom the information needs to be disclosed for the aforementioned purpose.
- 5.3 In principle, COI information will not be disclosed, except for the events defined in Article 5.2. However, COI information that is related to the activities of the JGES (including annexed subcommittees) and regular or temporary meetings may be disclosed or published within or outside the JGES after deliberations at a Board of Directors meeting to the extent necessary, if required for JGES to fulfill social and ethical accountability. The decision to disclose relevant information may be delegated to specific board members who are responsible for these issues after consultation with the COI Committee or the Ethics Committee. In such cases, the person whose COI will be disclosed or published has the right to state his/her opinion to the Board of Directors or specific board members to whom decision-making is delegated, except in the case where disclosure or publication is urgently needed and there is no time to hear opinions.
- 5.4 When nonmembers request disclosure of COI for specific members with proper justification (including legal demands), the matter shall be sent to the COI Committee to handle appropriately, protecting members' personal information, after consultation with the President.
- If the COI committee determines that the matter cannot be handled by the committee, the president shall promptly appoint several members of JGES and at least one outside expert as members of a new COI Investigation Committee. The newly appointed COI Investigation Committee must hold a meeting within 30 days after the disclosure request and submit recommendations as expeditiously as practicable.

Article 6: The COI Committee

The JGES shall set up a COI Committee comprised of several society members nominated by the President and at least one nonmember, and the chairperson of the

Committee shall be selected from among the members. Members of the COI Committee are obliged to maintain confidentiality regarding any information gleaned through the course of the Committee's activities. The COI Committee shall, in cooperation with board members and members of the Ethics Committee, manage COI and handle any violation in accordance with the COI policy and these Detailed Regulations to preclude potentially serious COI problems for members. Article 5 shall apply to the reporting and handling of COI information for members of the COI Committee.

Article 7: Actions Against Violators

- 7.1 When any doubts or matters related to social and ethical issues are raised concerning the COI Disclosure Statements submitted by authors to all in-house journals (*Digestive Endoscopy* and *Gastroenterological Endoscopy*) or by presenters at JGES conferences and/or academic meetings, the JGES shall take appropriate measures after sufficient investigation and a hearing conducted by the COI Committee to ensure that the JGES fulfills its social accountability. If the COI is serious enough that it is impossible to achieve proper social accountability, the President may take any measures deemed necessary, such as banning of the planned presentation and/or publication following deliberation by the Board of Directors based on a recommendation from the COI Committee. In addition, when doubts are raised regarding past presentations or publications, the President will investigate the matter and will take any measures necessary, including withdrawal of the presentations or articles concerned. In cases in which the violation seriously undermines the public's trust in the JGES, membership of the JGES may be suspended, as allowed in the JGES constitution.
- 7.2 If a problem arises concerning the COI disclosure of JGES officers, chairpersons of various committees, or committee members, including their candidates who are required to disclose any COI, the chairperson of the COI Committee shall report the issue to the President in writing. The President shall promptly convene a Board of Directors meeting so that the Board can decide whether to accept or deny the allegation. If the allegation is accepted, the officers or candidates for the positions in question shall immediately resign their position; in the case of other committee members, the committee may withdraw their appointment after consultation with other committee members and candidates.

Article 8: Petition of Objection

8.1 Filing a Petition of Objection

A person who was notified of the decision on the actions to be taken against a violation of the COI Guidelines in relation to the presentation at JGES projects

(such as in-house JGES journals and academic meetings) under Article 7.1 or an officer who was requested to resign his/her position or a candidate whose appointment was cancelled under Article 7.2 may, if he/she disagrees with the decision, request a review by submitting a written petition of objection and request for review to the President of the JGES via the JGES administrative office within 7 days of receipt of the notice of decision of the Board of Director. A concrete counterargument/opinion against the reason for the decision presented in writing by the President shall be stated in a concise manner in the request for review. In this case, the person may present relevant information in writing supporting his/her objection, in addition to the information disclosed to the President.

8.2 Procedure for review of objection

- (1) Upon receipt of a request for review 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 members. Members of the Ethics Committee may not serve as the chairperson of the Review Committee. The Review Committee shall meet to review the objection filed within 30 days of the receipt of the request for review.
- (2) The Review Committee may consult with the chairperson of the Ethics Committee and undertake additional hearings with the person who has filed the objection, if necessary.
- (3) The Review Committee shall complete a report regarding the objection filed and submit it to the President within 1 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 filed objection is final.

Article 9: Amendment of the Detailed Regulations

- (1) Partial changes to these Detailed Regulations are expected in the future in response to future societal factors or changes in the laws concerning collaborations between industry and academia. The Ethics Committee may conduct a review of these Detailed Regulations and, according to resolutions made by the Board of Directors, these Detailed Regulations may be changed accordingly.
- (2) As a general rule, these Detailed Regulations shall be reviewed every few years to adapt these Detailed Regulations to changes in societal factors, revisions to or the establishment of laws and regulations concerning collaborations between industry and

academia, and changes in various conditions for biomedical and/or medical research.

Supplementary Provisions

These Detailed Regulations shall come into effect on March 1, 2012.

Partial amendments: Made on October 1, 2013

Partial amendments: Made on April 21, 2015.

Partial amendments: Made on September 17, 2015.

Partial amendments: Made on June 27, 2017.