

Organization of Japan Digestive Disease Week

Bylaws of the “Guidelines on Conflict of Interest in Medical Research”

The Organization of Japan Digestive Disease Week adopted the “Guidelines on Conflict of Interest in Medical Research” (hereinafter referred to as “the Guidelines”) in order to fairly manage conflicts of interests (COI) of JDDW officers and presenters. The Guidelines were created based on the JDDW conference guidelines to maintain the fairness and neutrality of medical research, ensure the transparency and social accountability of presentations, and promote proper collaboration on medical research between industry and academia. The Bylaws of the Guidelines on Conflict of Interest in Medical Research (hereinafter referred to as “these Bylaws”) are stipulated as follows to facilitate proper and efficient implementation of the Guidelines.

Article 1. COI Reporting by Presenters at JDDW

Clause 1

When submitting an abstract on medical research at JDDW, all presenters must disclose to the secretariat of the affiliated academic society, all financial relationships of self, a spouse, first degree relatives and other dependents with businesses or commercial enterprises associated with the medical research held over the past two years. The COI also has to be disclosed at the time of presentation using a slide or poster as per the bylaws of the affiliated academic society.

Prior to presenting or lecturing at educational lectures and other events planned by this Organization, the lead presenter or lecturer must disclose COI to this Organization using Form 1 as per reporting rules stipulated by this Organization, if a COI exists for any of presenters or lecturers, including co-presenters/co-lecturers. Similarly, the COI must be disclosed at the time of presentation as per the rules of this Organization. Presenters and lecturers must disclose such COI using Form 1-A in the first slide (that immediately after the slide that introduces the title, presenter/lecturer, etc.) of their presentations or lectures. Lead presenters must similarly disclose their COI situation using Form 1-C even if no such COI exists.

For poster presentations, COI must be disclosed using Form 1-B at the end of the presentation.

Clause 2

“Businesses, incorporated organizations or commercial enterprises associated with medical research” are any business, organization and enterprise related to medical research in any of the following ways.

- (1) Having requested or jointly implemented medical research (irrespective of whether research was financially supported or not)
- (2) Sharing patent rights or other rights for treatment methods, medicines, equipment or other material evaluated in

medical research

- (3) Having provided medicines, equipment or other material used in medical research free of charge or at special advantageous prices
- (4) Having aided, donated to or otherwise supported medical research
- (5) Having provided unapproved medicines, medical equipment or other material for medical research
- (6) Having funded pro bono courses, etc.

Clause 3

The “ medical research” related to presentations means medical research for humans implemented with the objective of improving methods for preventing, diagnosing or treating illnesses via medical care, understanding the causes and conditions of illnesses, or improving patient quality of life. Medical research for humans includes both subject-derived specimens and data that enable individuals to be identified. Whether specimens and data enable individuals to be identified or not shall be determined as per stipulations in the Ethical Guidelines for Medical and Health Research Involving Human Subjects published jointly by the Japanese Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Welfare and Labor (December 2014).

Article 2. Rules on Personal Statements on COI

Monetary amounts that must be reported in personal disclosure on COI shall be determined by the COI guidelines and bylaws of the associated JDDW member societies and participating societies. If a presentation is for an educational lecture or other event planned by JDDW, monetary amounts that must be reported shall comply with JDDW rules. JDDW stipulates the below standard amounts for matters to disclose.

- (1) For officers and advisors of businesses, incorporated organizations or commercial enterprises associated with medical research (hereinafter referred to as “businesses, incorporated organizations or commercial enterprises”), remuneration from any one business, incorporated organization or enterprise that is equal to or greater than one million JPY a year.
- (2) Regarding stock ownership, annual profit (total of dividends and profits from sales) from stock of any one company that is equal to or greater than one million JPY or constitutes a quantity equal to or greater than 5% of all concerned shares.
- (3) Patent royalties from businesses, incorporated organizations or commercial enterprises that are equal to or greater than one million JPY per year per patent.
- (4) Daily allowances (lecture fee, etc.) paid by any one business, incorporated organization or commercial enterprise to a researcher to attend (speak at) a meeting as compensation for time and labor that total or exceed five hundred thousand JPY in a year.

- (5) Manuscript fees paid by any one business, incorporated organization or commercial enterprise for contributed articles for pamphlets, etc. that total or exceed five hundred thousand JPY in a year.
- (6) Research expenses for medical research (consigned research expenses, joint research expenses, commissioned management expenses, etc.) covered by any one business, incorporated organization or commercial enterprise that total or exceed one million JPY in a year.
- (7) Scholarship donations provided by any one business, incorporated organization or commercial enterprise to the reporting individual or representative of the department (course or field) or research lab of the reporting individual that total or exceed one million JPY in a year.
- (8) Participating as organizers, presenters, or lecturers in courses sponsored by a business, incorporated organization or commercial enterprise.
- (9) Travel support or gifts unrelated to research, study or diagnosis/treatment provided by any one business, incorporated organization or commercial enterprise that total or exceed fifty thousand JPY in a year.

As for (6) and (7) above, COI disclosure is necessary if research expenses or scholarship grants were provided from a company or organization that is in a state of conflict of interest in relation to the research results of the presenter or of the department (course or field) or laboratory to which the presenter is affiliated with.

Among the above-mentioned items for disclosure, the receiving body for donations from a business, incorporated organization or commercial enterprise is generally one of either the head of the organization (head of the university or hospital), or the head of the seminar or area of specialty. In the case of the aforementioned cases, although it may be difficult to ascertain a direct relationship between an individual researcher and the donating commercial entity, in cases in which the donation made by a commercial entity via the head of the organization is provided to the presenter in question, or has been provided to the department (seminar or area of specialty) or the laboratory to which the presenter is affiliated, it is necessary to disclose the amount of the donation.

Furthermore, a matter for disclosure about which questions tend to appear is the case in which a donation from a commercial entity, etc., is made via a non-profit corporation (e.g. NPO) or a public-interest corporation (e.g. foundation), and is then used for funding and subsidy purposes (consigned research expenses, research subsidy expenses). In such cases a personal declaration is similarly required. Given the fact that the higher the subsidy provided, the greater the tendency for third parties to gain the impression that the objectivity and fairness of research results may have been lost, in cases in which it could be speculated that research support has been provided indirectly from a related commercial entity, in order to assuage concerns and questions from society it is preferable to voluntarily submit a personal statement on COI.

Article 3. Submission of Disclosure Statement on COI by Officers, Committee Chairpersons, Chairpersons of Participating Academic Societies, Etc.

Clause 1

The officers (president, directors, auditors, staff and advisors), chairpersons of standing committees (Administration & Planning Committee, Finance & Donation Committee, Academic Conference Committee, PR Committee, Conflict of Interest Committee and Integrated Program Committee) and special committees of this Organization, and the annual chairpersons and secretariats of JDDW member societies and participating societies must prepare and submit to the president of this Organization personal disclosures on COI over the past one year immediately prior to assuming their post and every year thereafter using Form 2. The chairpersons of member societies and participating societies must prepare and submit to the president of this Organization personal disclosure on COI over the past one year immediately prior to assuming their post at the time the Executive Committee is launched each year, using Form 2. Submission is unnecessary if the personal statement on COI has already been received. These personal disclosure statements on COI are limited to the relationships with businesses, incorporated organizations or commercial enterprises that are associated with projects or activities of this Organization.

Clause 2

Personal disclosure statements must report all matters stipulated in Article IV of the Guidelines as COI in Form 2. The standard amounts stipulated in Article 2 of these Bylaws apply to all disclosure requirements and must be itemized as per Form 2. The amounts for the past one year immediately prior to assuming one's post and the calculation period must be included in Form 2. Officers and others of this Organization are required to report any new COI that arises during their current term no later than eight weeks from such event, using Form 2.

Article 4. Handling of Personal Disclosure on COI

Clause 1

Personal disclosure statements on COI that are submitted at the time of abstract registration for presentation at JDDW must be retained under the strict supervision of the chairpersons of the respective societies for a period of two years. Similarly, documents with COI information on persons who have finished the terms as officer or committee chairperson of this Organization or persons whose appointment as officer or committee chairperson is withdrawn, must be retained under the strict supervision of the president of this Organization for a period of two years from the date that the final term ends or the appointment is withdrawn. In addition, personal disclosure statements that are submitted by the secretariats of JDDW must be retained under the strict supervision of the chairperson of JDDW for a period of two years after the date of retirement including incumbent periods. At the end of the two-year period, documents shall be promptly deleted and destroyed under the strict supervision of the president of this Organization. However, if document

deletion or destruction is deemed inappropriate by the president of this Organization, a necessary extension may be granted to allow deletion and destruction of the COI information of the concerned person to be kept on hold. The COI information of persons in charge of academic conferences (annual chairpersons of member societies and participating societies) shall be handled in the same way as that of officers of this Organization.

Clause 2

The directors and officers of this Organization may use as necessary the COI information as permitted by these Bylaws in order to determine the existence or degree of COI between concerned persons and activities of JDDW, manage the said information, and take necessary action based on the said determination. The COI information must not be used beyond the intended objective of use and must not be disclosed to anyone other than those who require the said information for the said objective (obligation of confidentiality).

Clause 3

With the exception of the cases described in Article 4 Clause 2, COI information shall not be disclosed in principle. COI information may within the necessary scope be disclosed and released within and outside this Organization after discussion and approval by the Board of Directors, if and when necessary towards demonstrating the social and ethical accountability of this Organization in pursuit of activities of this Organization or its committees. However, it is not precluded in this case that a special director is tasked with handling the concerned issue and bases any decisions made on the advice of the COI Committee. In such case, the concerned person whose COI information is to be disclosed or released may express his/her opinions to the Board of Directors of this Organization or the director tasked with making the said decision. This is not, however, imperative if disclosure or release is urgent and there is not adequate time to hear the opinions of the concerned person.

Clause 4

If a request for disclosure (including legal requests) is made to a specific officer, the president of this Organization shall consult the COI Committee, and given an adequate reason respond in appropriate manner while protecting the personal information of the concerned person. If deemed that the matter cannot be handled by the COI Committee, the president of this Organization shall form a COI Inquiry Commission consisting of the one special director tasked with handling the concerned issue, a few participants of this Organization and one or more outside persons. The said COI Inquiry Commission shall convene no later than thirty days from the date that the request for disclosure is received, and shall provide a response as soon as possible.

Article 5. Conflict of Interest Committee

The president of this Organization shall form a Conflict of Interest (COI) Committee consisting of a few Organization members and shall appoint a person to chair the committee. The members of the COI Committee are obliged to keep confidentiality of COI information they handle as committee members. The COI Committee shall manage, in coordination with the president of this Organization and in line with the Guidelines and these Bylaws, the COI of members so as to prevent development of serious situations, and shall deal with violations. The COI Committee shall, in the event of serious COI associated with projects or activities of this Organization or inappropriate disclosure of COI, notify the concerned person to that effect either through the associated academic society or directly, and instruct that person to take necessary action, i.e., to correct their personal disclosure statement. The reporting and handling of COI information shall comply with the stipulations of Article 4.

Article 6. Action against Violators

Clause 1

In the event that social or ethical issues are suspected or arise in the personal statement on COI submitted by a candidate presenter for JDDW, the COI Committee shall contact the associated academic society and request appropriate action to be taken in order to demonstrate the social accountability of this Organization. Moreover, the Board of Directors of this Organization may take appropriate action if acts by concerned persons significantly damage the social responsibilities of this Organization.

Clause 2

The chairperson of the COI Committee must, in the event suspicion is indicated over a personal disclosure on COI of a candidate officer or candidate committee chairperson prior to or after assuming the said post, notify the president of this Organization thereof in writing. The president of this Organization must then promptly convene the Board of Directors, which must then determine whether to acknowledge or disavow the said indication. If the said indication is acknowledged, the president must notify the parent society that nominated the said person of the issue and, after sufficient discussion with the said society, take appropriate action, i.e., demanding that the nomination be withdrawn and membership revoked.

Article 7. Petition for Appeal

Clause 1 Petition for Appeal and Review

Persons who are notified of COI violations by JDDW as per Article 6 Clause 1, and persons whose post as officer or committee chairperson or membership is revoked as per Article 6 Clause 2 may, in objection to said decision, may request a review of matters by submitting an objection and request for review to the president of this Organization via

the secretariat no later than seven days from the date that notification of the Board of Directors' decision is received. This request for review should contain a clear but concise rebuttal and opposing view to the reason for the decision elaborated in writing by the president of this Organization. The request may also specify evidence supporting the objection above and beyond the information that was disclosed to the president.

Clause 2. Appeal and Review Procedure

1. Upon receiving a request for appeal and review, the president of this Organization must promptly form a board for reviewing the petition (hereinafter referred to as "Review Board"). The Review Board shall consist of a few members and one or more outside persons appointed by the president, with a chairperson being elected from amongst these members. Members of the COI Committee may not concurrently serve on a Review Board. The Review Board shall convene and initiate their review no later than thirty days from the date that the request for review is received.
2. The Review Board may hear the opinions of the COI Committee chairperson concerned with the said petition and the petitioner. This is not, however, imperative if either party fails to appear at the hearing by the set date and time.
3. Unless special circumstances exist, the Review Board shall compile a response to the petition and submit it to the president of this Organization no later than one month from the date on which the Review Board convened the first time to initiate the review.
4. The president of this Organization shall make a final ruling based on the decision of the Review Board.

Article 8. Action against Violators of the Obligation of Confidentiality

Personnel of the secretariat of this Organization have the same obligation of confidentiality stipulated in Article 4 Clause 2 for the directors and concerned officers of this Organization with regards to COI information of individuals learned in the course of managing COI cases. The Board of Directors may punish concerned persons and secretariat personnel who deliberately release COI information to outsiders by expulsion and dismissal etc. without following proper procedure.

Article 9. Amendments to the Bylaws

These bylaws may need to be amended in part in line with social factors, amendment to laws and regulations governing cooperation between industry and academia, etc. The Board of Directors may seek the counsel of the COI Committee with regard to reviews of these Bylaws and determine amendments based on their recommendations.

Supplementary Provisions

Article 1. Date of Enforcement

These Bylaws shall come into force as of April 19, 2013.

Article 2. Amendments to These Bylaws

These Bylaws shall be reviewed, as a rule, every few years to keep pace with social factors, the establishment of or amendment to laws and regulations governing cooperation between industry and academia, and the various situations surrounding medical care and medical research.

These Bylaws shall be revised on July 28, 2015 to take effect as of January 1, 2016.

Article 3. Special Provision for Officers, etc.

Persons serving as officers or other posts of this Organization at the time these Bylaws go into force shall promptly submit reports, etc., in compliance hereto.

Article 4. Concerning “VII. Action against Violators of These Guidelines and Accountability” in the “Guidelines on Conflict of Interest in Medical Research”

The enforcement of “VII. Action against Violators of These Guidelines and Accountability” shall be temporarily deferred after the start of the trial period of the Guidelines. During this time, the Board of Directors and the COI Committee are encouraged to demonstrate the purport of this article and submit personal statements on COI in full.