

Bylaws of Conflict of Interest in Clinical Research

Japan Society of Hepatology

The Japan Society of Hepatology has enacted the “Policy of Conflict of Interest in Clinical Research” in order to fairly manage a state of conflict of interest (COI) of the members of the Society. The Policy has been established with the aim of keeping fairness and equity in clinical research conducted by the Society, maintaining the transparency and accountability in presentations at the Society’s conferences, and promoting proper clinical research by academic-industrial collaboration, based on policies set up by related societies such as the Japanese Society of Internal Medicine and the Japanese Society of Gastroenterology, to name a few. For equitable operation of the Policy, the “Bylaws of Conflict of Interest in Clinical Research” are as follows.

Article 1 Disclosure of COI at Society events

1. When a member or non-member makes a presentation or lecture on clinical research at a conference, academic lecture (annual meeting, general assembly, meeting, or educational lecture), public open lecture, or similar event organized by the Society, upon announcing the subject of presentation, the lead presenter must disclose a COI status concerning the financial relationship between he/she, his/her spouse, immediate family, or persons who reside with the presenter, and companies or for-profit entities relating to the clinical research through the previous year at the time of submitting an abstract using FORM 1 by self-reporting.

The lead presenter will disclose the COI in the first slide to be presented (or in the 2nd slide subsequent to an introductory slide for the title of subject or introduction of the presenter) using FORM 1-A, or at the end of a poster using FORM 1-B. In the event that there is no state of COI to be disclosed, the lead presenter will indicate that fact in the first presentation slide (or in the subsequent slide to an introductory slide for the title or the presenter) using FORM 1-C, or at the end of the poster using FORM 1-B.

2. “Business enterprises, corporations, organizations, or for-profit entities related to clinical research” refer to any organization, including enterprise or entity, which has any of the following relationships concerning clinical research:

- (i) In which an organization requests clinical research, or jointly conducts the clinical research (funded or non-funded);
- (ii) In which an organization shares rights such as patent rights regarding treatment methods, drugs and equipment to be evaluated in clinical research;
- (iii) In which an organization provides drugs, equipment, or the like to be used in clinical research free of cost or at a discounted rate;

- (iv) In which an organization funds or contributes financially to clinical research;
- (v) In which an organization provides unapproved drug or medical equipment for clinical research; and/or
- (vi) In which an organization sponsors chair courses.

3. “Clinical Research” related to the subject of a presentation refers to medical research involving human subjects, which is conducted with the aim of improving methods of prevention, diagnosis and treatment of disease, understanding pathogenesis and pathology, and improving the quality of life of patients. Medical research involving human subjects will include research on human-derived specimens and/or data, which can identify individuals, subject to “the Ethical Guidelines for Clinical Research” by Ministry of Labor, Health, and Welfare of Japan.

Article 2 Article 2 Criteria for COI Self-declaration related to Articles 3 and 4 Criteria for COI self-disclosure

Financial information must be included in the COI self-disclosure if it exceeds any of the following specified financial thresholds:

- (i) Accepting a position as executive, adviser, or employee of business enterprise, corporation, organization, or for-profit entity (hereafter, referred to as enterprises, corporations or entities), if compensation from a single corporation exceeds 1,000,000 yen per year;
- (ii) Stock ownership, if profit (total dividends and capital gain) of at least 1,000,000 yen from stocks of a single corporation per year, or ownership of 5% or more of total shares is made;
- (iii) Patent royalties from enterprises, corporations or entities, if the royalty fee for a single patent exceeds 1,000,000 yen per year;
- (iv) Honoraria (e.g. lecture fees) paid from enterprises, corporations or entities, for labor contributions for conference participation or presentation, if the fee from a single corporation exceeds 1,000,000 yen per year;
- (v) Manuscript fees for brochures, subscriptions, etc. paid for by enterprises, corporations or entities, if the fee paid by a single corporation exceeds 1,000,000 yen per year;
- (vi) Research funds paid for clinical research (e.g. contract research programs, joint research programs, Scholarship Contribution) paid by enterprises, corporations or entities, if the funds paid by a single corporation exceed 2,000,000 yen per year;
- (vii) Clinical trial cost or subsidy (donation) paid by enterprises, corporations or entities, if the total cost paid to an individual who reports, or a head of department

(course, field) to which the individual belongs, from one corporation exceeds 2,000,000 yen per year;

(viii) If the recipient belongs to an Endowed department provided by enterprises, corporations or entities; or

(ix) Travel expense or gifts, which are not related to research, training, or medical practice, if total of expenses from a single enterprise, corporation or entity exceeds 50,000yen per year.

Article 3 Disclosure in official journals of the Society

1. All authors who intend to publish manuscripts (e.g. review articles, original research) in the official journals of the Society (*Kanzo*, *Hepatology Research*) must report any financial relationship, if any, with enterprises, corporations or entities specified in Article 1, Section 2 of the Bylaws, regarding the subject or material presented in the manuscript, within the previous year from the time of submission. Authors must submit a “Disclosed Potential Conflict of Interest” (FORM 2-A “Hepatology Research Conflict of Interest Disclosure Statement” or FORM 2-B Official Journal of the Japan Society of Hepatology: COI report by self-declaration) defined in the instructions for authors, to the Society’s office prior to publication. The conflicts described in the “Disclosed Potential Conflict of Interest” will appear at the end of the manuscript, before the Acknowledgement or Reference sections. If the author does not have any COI status defined, the statement “No potential conflicts of interest were disclosed” will appear. The COI status expected to be disclosed at the time of article submission is defined in Article IV “Matters to be declared” of the Policy of Conflict of Interest in Clinical Research. Article 2 defines the circumstances in which financial conflict should be disclosed. Publication in journals issued by the Society other than *Kanzo* and *Hepatology Research* are subject to the same conflict of interest conditions. “Disclosed Potential Conflict of Interest” will not be revealed to reviewers of the manuscript.

2. Society edited documents will disclose any COI of production and administrative staff, or assessment committee members, associated with enterprises, corporations or entities related to the contents of the publication.

Article 4 Submission of COI report by self-declaration by board members, directors, and members of committees

1. A COI report by self-declaration must be submitted to the Board of Directors before accepting any of the following society or society affiliated positions: officers of the Society (director general, directors, and supervisors), chairpersons of academic conferences (annual

meeting, general assembly, local chapter conferences), chairpersons of public open lectures, chairpersons of various committees, special committee members (Committee of Exploring Best Practice, Finance Committee, Editorial Committee for journals in Japanese /English, Ethics Committee, COI committee, etc.) and administrative staff of the Society. FORM 3 must be submitted at the time of acceptance of the position in order to determine whether or not any COI status has existed within the previous year, related to matters defined in Article IV “Matters to be declared” of the “Policy of Conflict of Interest in Clinical Research.” FORM 3 must also be submitted each subsequent year of employment.

2. Submission of FORM 3 is not necessary when a COI report by self-declaration has already been submitted, limited to those associated with enterprises, corporations or entities which are related to the activities of the Society.

3. If any additional COI arises during the period of service, board members are responsible to report the COI, using FORM 3, within 8 weeks after such COI status arises.

Article 5 Handling of the COI report by self-declaration

1. The COI report by self-declaration, which is submitted at the time of abstract submission for a conference presentation or at the time of manuscript submission to the journal of the Society, will be kept confidentially at an incorporated office under the supervision of the director general for 2 years from submission of the report. COI documents related to those who served out terms as an officer or who received a notice of removal from the position as a member of the committee will also be kept confidentially at an incorporated office under the supervision of the director general for 2 years from the date of termination of the term or removal from the position. COI documents will be disposed of promptly after 2 years of storage, under the supervision of the director general. If the Board of Directors has decided that the disposal of any document is inappropriate, this may be postponed for a set period of time.

2. The directors and related officers of the Society, in their role as Society representatives, may use the COI information of an individual in order to judge whether the relationship between the individual and the activities of the Society is subject to COI regulation. They will not use such information unnecessarily nor disclose the information to any persons other than those who need to be informed for the above purposes (confidentiality obligation).

3. In principle, COI information will not be disclosed, except in the case referred to in Article 5, Section 2. However, COI information may be disclosed or publicly announced, after

discussion at a board meeting, to the extent necessary to achieve social and ethical accountability associated with the activities of the Society, committees (including activities by annex standing subcommittee) and temporary committees.

The Society may not prevent a director who is specifically in charge of an issue from making the decision for disclosure or public announcement based on the advice from the COI Committee and/or Ethics Committee. In this case, any persons involved in the COI information that is to be disclosed or publicly announced may express his/her opinion to the Board of Directors or a director who is asked to make such decision, unless the disclosure or public announcement is an emergency and there is no time for discussion.

4. If disclosure of any COI of a certain member is requested (including requested legally), and if the reason(s) for such a request are reasonable, the COI Committee, upon request from the director general, will take appropriate action based on a private information protection policy. However, if the COI Committee decides that they cannot handle the issue, the director general will set up a COI Investigation Committee, that consists of a director who is specifically in charge of the issue, several Society members and at least one non-member of the Society. The COI Investigation Committee will meet within 30 days from the receipt of the disclosure request and report their decision as soon as is practicable.

Article 6 COI Committee

The COI Committee will consist of several Society members, councilors and at least one non-member of the Society, as designated by the director general. Members of the committee will elect the chairperson. The members of the COI Committee, in collaboration with the Board of Directors and the Ethics Committee, will strictly protect the confidentiality of all COI information of Society members acquired in the course of their duty. In the event that serious compromise or violation of the COI status of members was to occur, action would be taken according to the COI Policy and the Bylaws. Rules set forth in Article 5 will be applied to the reporting and handling of COI information on a member of the Committee.

Article 7 Measures to be taken for Violation

1. If questions of social or ethical violations arise in relation to a COI report by self-declaration submitted by an author intending to publish their findings in the official journals of the Society (*Kanzo, Hepatology Research*) or by a speaker intending to present at a conference organized by the Society, the COI Committee will take appropriate measures, including investigation and interviews, in order to achieve social accountability. If a serious COI was committed, the director general may refer the matter to the Ethics Committee, and take

such measures as forbidding such presentations or publications, after discussion with the Board of Directors and based on the committee's recommendation. If questions arise after a presentation or publication, investigation will be conducted, and if any violation is confirmed, measures such as retraction of the published manuscript will be discussed. Should the social reputation of the Society be severely damaged by the violation, the director general may refer the matter to the Ethics Committee and take appropriate measures.

2. If a potential violation is indicated regarding a COI reported before or after the appointment or nomination of board members of the Society, chairpersons of various committees, or committee members, those responsible to report their COI by self-declaration and their candidates, the COI Committee must inform the director general of the problem in writing. The director general will call for a board meeting immediately, and decide whether the problem indicated is valid or not. If it is decided to be valid, the board member and/or the committee member must resign, and the director general may dismiss the candidacy of the candidate board or candidate committee member.

Article 8 Appeal of the Decision

1. Objection statements

Those who are found to be in violation of COI as notified by the Board of Directors, regarding presentations or publications on behalf of the Society (e.g. official journals, academic conferences) under Article 7, Section 1, or those who are notified to resign their official posts or dismissed as a member of the committee under Article 7, Section 2, may request reconsideration of the decision by sending a request form to the director general addressed to the Society Office, within 7 days after the day on which they received the notice from the Board of Directors. The request for reconsideration should include specific and brief objections to the reasons for dismissal given by the chairperson. In this case, information disclosed to the chairperson as well as related information supporting their objections should be provided in the written statement.

2. Reconsideration procedures for statement of objections

(i) If a request for reconsideration is received, the director general will immediately set up an appeal examination committee (hereafter referred to as the "Examination Committee"). The Examination Committee, designated by the director general, will consist of several members of the Society and at least one person who is not a member of the Society. Members of the committee will elect the chairperson. The members of the COI Committee cannot concurrently serve as members of the Examination Committee. The Examination Committee will hold a meeting and discuss the matter

within 30 days from the receipt of the request of reconsideration.

(ii) The Examination Committee may interview the chairperson of the Ethics Committee and COI Committee in relation to the statement of objections, in addition to the person who requested the reconsideration. If the person appealing the decision does not appear on the date prescribed for the interview, they will not be afforded a second interview opportunity.

(iii) The Examination Committee will draw up and submit a report regarding the reconsideration to the Board of Directors within 1 month from the first meeting, with the exception of special occasions.

(iv) The Board of Directors determines the final decision based on the judging of the Examination Committee.

Article 9 Measures to be taken for violation of confidentiality obligation

All staff of the Society Office, including directors and officers, will strictly protect the confidentiality of all COI information on individuals acquired in the course of managing said information as detailed under Article 5, Section 2. The Board of Directors may impose penalties, such as expulsion or dismissal of members and/or officers of the Society who intentionally disclose COI information to an outsider without any proper procedures.

Article 10 Modification to the Bylaws

The Bylaws are expected to need partial modification to adapt to social conditions and changes in laws related to industrial-academic collaboration based on individual cases. The Ethics Committee may discuss and review the Bylaws, modified through resolution by the Board of Directors.

Supplementary provisions

Article 1 Effective Date

The Bylaws will be implemented provisionally from June 4, 2012 (the day after the Annual Meeting) for a period of 2 years and will take complete effect on April 1, 2013.

Article 2 Modification to the Bylaws

The Bylaws will be reviewed generally every few years, in order to be able to adapt to social conditions, amendments of laws related to academic-industrial collaboration, and changes in conditions surrounding medical and clinical research.

