
The Japanese Society of Hematology
Bylaws Concerning Conflict of Interest Policy in Clinical Research

Article 1 (Disclosure of COI in conferences of the Society)

If a member or non-member presenter will make presentations or lecture on his/her clinical research at a conference organized by the Society (including annual meetings, lecture meetings, and continuing medical education events), public forum, or local chapter conference, the presenting author and all co-authors are required to report any financial relationship between s/he, his/her spouse, first-degree relatives, or anyone living with the presenter and all co-authors, and any commercial entities or for-profit organizations related to the clinical research within the previous 12 months at the time of abstract submission. The presenting author shall disclose applicable COI of all authors at the beginning of presentation slides (the slide after the title of presentation and the name of presenters) using Form 1-A, 1-B, or at the end of a poster using Form 2.

“Business enterprises, for-profit corporate organizations, and commercial entities related to clinical research” are defined as follows.

- (1) Sponsors of clinical research, or organizations who jointly conduct clinical research, regardless of whether funded or non-funded.
- (2) Organizations sharing the rights including patent rights regarding treatment methods, drugs and/or equipment that are evaluated in clinical research.
- (3) Organizations providing drugs and/or equipment for clinical research gratis or at an advantageous price.
- (4) Organizations funding or contributing financially to clinical research.
- (5) Organizations providing unapproved drug and/or equipment for clinical research.
- (6) Sponsors of endowed departments.

“Clinical research” related to the subject of presentation shall be defined as medical research which includes all phases of clinical trial and pre-clinical research, involving human beings with an aim to improve prevention, diagnosis and treatment methods, understand pathogenesis and pathology, and enhance quality of life of patients. Medical research involving human subjects includes research on human-derived specimens and/or data that can identify individuals. Whether the specimens or data can identify individuals or not shall be decided according to the Ethical Guidelines for Clinical Research (Ministry of Labor, Health, and Welfare of Japan).

Article 2 (Criteria for self-reported COI disclosure)

All COIs must be reported if the amount exceeds the criteria specified below.

- (1) Employment or administrative position, or advisory role in business enterprises, for-profit corporate organizations, or commercial entities that are related to clinical research (hereafter referred to as “Commercial Entity”), if compensation from a single Commercial Entity exceeds 1,000,000 yen per year.
- (2) Stock ownership or options, if profit (total of dividend and gain on sales) of at least 1,000,000 yen from stocks of one commercial entity per year, or ownership of 5% or more of total shares.
- (3) Patent royalties from the Commercial Entity, if the royalty fee exceeds 1,000,000 yen per year.
- (4) Honoraria (e.g. lecture fees) paid from one Commercial Entity, for the time and/or labor of investigator who attended or made presentations at meetings, if exceeding 500,000 yen per year.
- (5) Manuscript fees for promotional materials (e.g. brochures) paid by one Commercial Entity, if exceeding 500,000 yen per year.
- (6) Research funds paid for clinical research (e.g. funded research, collaborative research) paid by one Commercial Entity, if exceeding 1,000,000 yen per year.
- (7) Subsidy or donation to an individual of a head of department to which the individual belongs received from one Commercial Entity, if exceeding 1,000,000 yen per year.
- (8) Endowed departments provided by a Commercial Entity, if the recipient participates in such a department.
- (9) Others including trips, travel, or gifts, which are not directly related to research, provided by one Commercial Entity, if exceeding 50,000 yen per year.

Items 6 and 7 shall be reported, only if funds are provided by a Commercial Entity to a presenting author, or department to which the presenting author belongs, regarding the presentation of research activities benefitting from such funding at academic meetings.

Article 3 (Disclosure in official journals)

All authors who intend to publish manuscripts (e.g. review articles, original research manuscripts) in the official journals of the Society (International Journal of Hematology, The Japanese Journal of Clinical Hematology) must report any financial relationship with a Commercial Entity specified in Article 1, Section 2 of the Bylaws, regarding the subjects of or materials discussed in the paper, within the previous 12 months, using Form 2-A or Form B (Conflict of Interest Disclosure Statement) to the secretariat of the Society in advance. This disclosure will appear at the end of the manuscript, before the

Acknowledgement and References. If there is no such relationship, the statement “No potential conflicts of interest are disclosed” will appear in the same position. COI status must be clearly disclosed at the time of article submission, according to Article IV “Matters to be disclosed” of the Conflict of Interest Policy in Clinical Research. The criteria are governed by Article 2. Publication in journals issued by the Society other than International Journal of Hematology and The Japanese Journal of Clinical Hematology shall conform to the above rules. Note that “Disclosed Potential Conflict of Interest” shall not be disclosed to referees to whom the manuscript is sent for review.

Article 4 (Submission of COI Disclosure Statement by officers, chairpersons, and members of committees)

Officers of the Society (president, directors, auditors), next president, chairpersons of academic conferences, chairpersons of various committees, members of special committees (conference organization committees, editorial boards, committees for the development of practice guidelines, ethics committee, COI Committee), members of working groups, employees of the Society shall self-report their COI status within the previous 12 months before assuming the position, according to Article IV “Matters to be disclosed” in the Conflict of Interest Policy in Clinical Research, using Form 3, at the time of and every year after assuming the position, to the Board of Directors. Disclosure is not necessary if a self-reported COI disclosure statement has already been submitted. Note that the disclosure of COI shall be limited to those associated with Commercial Entity related to the activities of the Society.

Items to be disclosed in Form 3 are defined in Article IV “Matters to be disclosed” in the Conflict of Interest Policy in Clinical Research. Criteria for disclosure shall refer to Article 2, and the amount shall be clearly stated for each item to be disclosed in Form 3. COI status within the previous 12 months before assuming the position shall be reported in Form 3 together with the period of having such status. If any additional COI occurs during the period of service, the recipients shall be responsible for reporting such status within 8 weeks, using Form 3.

Article 5 (Handling of the self-reported COI disclosure statement)

The Self-reported COI Disclosure Statement, which is submitted at the time of abstract submission for a conference presentation or at the time of manuscript submission to the journals of the Society, shall be kept confidentially at an incorporated office under the supervision of the president for 2 years from the submission. Similarly, 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 committee shall be kept confidentially at an incorporated office under the supervision of the president for 2 years from the date of termination of the term or removal from the position. COI documents shall be deleted or disposed of promptly after 2 years of storage, under the supervision of the president. If the Board of Directors has decided that the deletion or disposal of the document is inappropriate, the deletion or disposal of such document shall be postponed for a set period of time. COI information related to the president (including the next president), chairpersons of academic conferences, and members of academic conference organization committees shall be treated in the same manner.

The directors and related officers of the Society, shall judge whether an individual is subject to COI regulations and the extent of COI based on the submitted self-reported COI disclosure statement and according to Bylaws. If they take measures or actions as a society based on the judgment, they shall use the COI information of such person as needed. They shall not, however, use such information unnecessarily nor disclose the information to any persons other than those who need to be informed for the above purposes.

In general, COI shall be not disclosed, except in occasions specified in Article 5, Section 2. COI may be disclosed or publicly announced, to the extent necessary to achieve, as a society, social and ethical accountability associated with the activities of the Society, committees (including a standing subcommittee under a large committee), and temporary committees, after discussion at a board meeting. The Society may not prevent a director who is specifically in charge of the 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 COI 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.

If disclosure of any COI of a certain member is requested (including requested legally) by a non-member, and if reason(s) for such a request seems reasonable, COI Committee shall take appropriate actions following a recommendation by the president based on a private information protection policy. If the COI Committee decides that they cannot handle the issue, the disclosure shall be discussed at a COI Investigation Committee, which consists of some members of the Society designated by the president and at least one non-member of the Society. The COI Investigation Committee shall meet within 30 days from the receipt of a disclosure request and report their decision as soon as practicable.

Article 6 (COI Committee)

The COI Committee shall consist of some members of the Society designated by the president and at least one non-member of the Society. The chairperson of the committee shall be chosen by the members. The members of the COI Committee shall strictly protect the confidentiality of all COI information regarding the members of the Society that they obtained. The COI Committee, in collaboration with the Board of Directors, and Ethics Committee, shall make protective efforts to prevent serious compromise of the COI status of the members, and take actions toward any violations, according to the COI Policy and the Bylaws. Rules set forth in Article 5 shall be applied to the COI report involving members and the handling of COI information.

Article 7 (Measures to be taken in case of Violation)

If questions or social or ethical problems arise in relation to a self-reported COI disclosure statement submitted by authors intending to publish their findings in the official journals of the Society (Internal Medicine, The Journal of the Japanese Society of Internal Medicine) or to present at a conference organized by the Society, the COI Committee shall take appropriate measures in order to achieve social accountability based on sufficient investigations and interviews. If a serious COI is confirmed, and cannot be accounted for, the president may refer the matter to the Ethics Committee, and take measures, such as forbidding such presentations or publications, after discussion with the Board of Directors, based on the recommendation of the committee(s). If questions arise after a presentation or publication, the president shall conduct factual investigation. If any violation is confirmed, the president should take measures such as retraction of the published manuscript. Should the social reputation of the Society be severely damaged by the violation, the president should take measures regarding membership of the person(s) concerned, according to the Constitution of the Society.

If any problem is indicated regarding COI reported before or after the appointment or nomination of officers of the Society, chair persons of committees, or committee members, the COI Committee shall make a report in writing to the president. The president shall call for a board meeting without delay, and decide whether the problem indicated is valid or not. If it is valid, the officers shall resign, the members of committees shall be dismissed after the discussion with such members, and candidates shall withdraw his/her candidacy.

Article 8 (Objections to punishment)

Objection statements

Those who are punished for violations regarding presentations or publications related to the Society (e.g. official journals, academic conferences), in accordance with Article 7, Section 1, or those who are required to resign their official posts or dismissed as a member of committee in accordance with Article 7, Section 2, may request reconsideration of the decision within 7 days after they receive the notice from the Board of Directors, by sending a request form to the president addressed to the Secretarial, if they have objections to the punishment. 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.

Review procedures concerning statement of objections to punishment

1. If a request to reconsider a reprimand or punishment is received, the president shall forthwith set up an investigation committee (hereafter referred to as the "Investigation Committee"). The Investigation Committee shall consist of a few members of the Society designated by the president and at least one person who is not a member of the Society. The Chairperson of the committee shall be chosen by the members of the committee. The members of COI Committee cannot concurrently serve as members of the Investigation Committee. The investigation Committee shall hold the meeting and discuss the matter within 30 days from the receipt of the request of reconsideration.
2. The Investigation Committee may interview the chairperson of the Ethics Committee in relation to the statement of objections, in addition to the person who requested the reconsideration.
3. The Investigation Committee shall draw up and submit a report regarding the reconsideration to the president within 1 month from the first meeting except for special occasions.
4. The decision by the Investigation Committee is final.

Article 9 (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. The COI Bylaws Review Committee, which is set up under the Administrative Committee, may discuss the review of the Bylaws, and a decision to modify them if so decided by the Administrative Committee and the Board of Directors.

Article 1 (Effective Date)

The Bylaws will be implemented experimentally from March 9, 2010 and will become completely effective after that.

During the experimental period, the punitive clause stated in Article 7 shall not be applied to any case.

Article 2 (Modification to the Bylaws)

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

Article 3 (Special rule applied to Society officers)

The Bylaws shall apply to reports by those who have official posts in the Society at the time of execution of the Bylaw.