

The Japanese Society of Pediatric Hematology/Oncology
Detailed Regulations Concerning the Handling of Conflict of Interest

Conflict of Interest Committee in the Japanese Society of Pediatric Hematology/Oncology

Chapter 1 Reporting and publication of COI related to research and presentation activities

Article 1 (Reporting of COI in lecture meetings held by JSPHO)

1. An individual planning to make a presentation or give a lecture on medical research at lecture meetings (including academic conferences and educational seminars) hosted by JSPHO is required to provide a self-report of any financial relationship with companies or for-profit organizations related to the medical research to be presented; the report will cover the past year and will use a designated form, at the time of abstract submission. The report by the responsible presenter must include the COI status of those who share income and property with the responsible presenter.

The presenter will disclose applicable COI using a designated form in the first slide of the presentation (or the slide immediately after the title slide containing the name of the presenter) or at the end of a poster.

2. The "companies, corporate organizations, or for-profit organizations related to medical research" are defined as those companies and organizations with the following relationships in medical research:

- ① Requesting or jointly conducting medical research (with or without payment).
- ② Sharing rights, including patent rights, for therapies, drugs and/or devices that are evaluated in medical research.
- ③ Providing drugs and/or equipment for medical research, free of charge or at especially advantageous prices.
- ④ Funding or contributing financially to medical research.
- ⑤ Providing unapproved drugs and/or medical devices for medical research.
- ⑥ Sponsoring an endowed chair.

3. "Medical research" related to the subject of presentation is defined as investigations involving industry-academia collaborations, conducted with aims to improve prevention, diagnosis and treatment methods; to promote understanding of etiology and pathology; and to enhance patients' quality of life. It includes life science research, basic medical research, clinical research in humans (including research on human-derived samples and data that could be used to identify specific individuals), and clinical studies.

Article 2 (Standards for self-reporting of COI)

The amount of money subject to COI reporting set for each item of COI disclosure is based on the following standards:

- ① For appointment as an officer or advisor in companies, corporate organizations, or for-profit organizations (hereafter referred to as "a company or organization") related to the medical research, an annual remuneration of ¥1 million or more, from a single company or organization.
- ② For ownership of stocks, an annual profit (an aggregate of dividends and capital gain) from a single company's stock of ¥1 million or more, or ownership of 5% or more of all shares of the company's stock.

- ③ For patent royalties received from a company or organization, an annual royalty payment of ¥1 million or more for use of 1 patent.
- ④ For per diem payment made by a company or organization for expenses incurred by a researcher to attend or give a presentation at a meeting (including lecture fees), a total amount of ¥500,000 or more, received from a single company or organization in a year.
- ⑤ For payment made by a company or organization for writing a manuscript of a brochure or similar communication, a total amount of ¥500,000 or more, received from a single company or organization in a year.
- ⑥ For research funds from a company or organization, a total amount of ¥1 million or more, in funds provided by a single company or organization in a year for medical research (e.g., commissioned research funds, joint research funds).
- ⑦ For scholarship donations (incentive donations) provided by a company or organization, a total amount of ¥1 million or more in funds provided by a single company or organization in a year, to the individual filing the COI report, the division (e.g., department, field) the individual is affiliated with, or the head of a laboratory.
- ⑧ An individual filing a COI report and affiliated with an endowed chair provided by a company or organization.
- ⑨ For others including travel fees and gifts, which are not directly related to research, a total amount of ¥50,000 or more provided from a single company or organization in a year.

Reporting of Items ⑥ and ⑦ is only required, if research funds, scholarship donations, etc. are given by a company or organization involved in COI to be disclosed to a presenter, or division (department, field) or laboratory to which the presenter belongs, regarding the presentation of research results.

Article 3 (Publication of the reported matters in the JSPHO journal or other communications)

All authors publishing their work (e.g., reviews, original research articles) in the JSPHO journal (The Japanese Journal of Pediatric Hematology/Oncology), clinical practice guidelines and other communications, must, if they are in an economic relationship (regarding publication contents) with a company or organization provided for in Article 1, Paragraph 2 of the Detailed Regulations, report in advance to the Secretariat of JSPHO the COI status over the past 1 year from the time of manuscript submission; the form specified in the Guideline for Authors will be used. The disclosure report must include the COI status of those who share income and property with the author. The corresponding author must collect the written reports of COI status from all co-authors of the article, submit them together, and take responsibility for the contents. The contents of the "Conflict of Interest" will be displayed at the end of an article or before the "Acknowledgements" or "References" sections. If no COI requires disclosure, a statement such as "No conflict of interest requiring disclosure" will appear in the abovementioned areas. COI status must be self-reported at the time of manuscript submission as shown in "IV. Matters to be Reported" in the "Conflict of Interest Policies in Medical Research in the Pediatric Hematology/Oncology Field." The amount of money to be disclosed for each COI item will be pursuant to the provisions of Article 2. The provisions of this paragraph are also applicable to publication in JSPHO publications. The contents of the submitted self-report of COI will not be disclosed to the referees.

Chapter 2 Handling of COI related to activities by officers and others, in JSPHO

Article 4 (Submission of the COI report by officers, chairpersons, and committee members)

1. Officers (President, Vice President, Directors, and Auditors) of JSPHO, conference chairpersons (including the next President, and the President after the next President), chairpersons and members (including observers) of various committees, and employees of JSPHO will self-report their COI status over the past 1 year before assuming the position, according to "IV. Matters to be Reported" in the "Conflict of Interest Policies in Medical Research in the Pediatric Hematology/Oncology Field," using the designated form at the time of and every year after assuming the position, to the Board of Directors. When a self-report of COI has already been submitted, the submission of the COI report is unnecessary. Note that the self-report of COI will be limited to those associated with companies, corporate organizations, or for-profit organizations related to the projects of JSPHO.
2. The amount of money subject to the self-report of COI for each COI item to be disclosed will be pursuant to the standard amounts described in Article 2. The amount, with its account title, is to be entered for each item in the designated form, for a period of 1 year before assuming the position, and the applicable period will be clearly indicated in the form; however, JSPHO officers and others will have an obligation to report any new COI status during their tenure of office, within 8 weeks, using the designated form.

Chapter 3 Management, use, publication of COI information

Article 5 (Principles for management)

1. The self-report of COI, which is submitted at the time of abstract submission for a conference presentation or at the time of manuscript submission to the JSPHO journal, will be deemed confidential and retained at the Secretariat of JSPHO, under the supervision of the President for 2 years from the date of submission.
2. The COI information may be used by JSPHO Directors and other officers, in accordance with the provisions of the Detailed Regulations, to ascertain the existence and degree of COI for the individual, on the basis of the submitted self-report of COI and, based on that judgment, to provide management and take necessary measures as an organization. The information may only be used for these objectives and may not be disclosed to anyone other than those to whom disclosure is necessary in light of these objectives.

Article 6 (Deletion of unnecessary information)

The COI documents related to those who served out terms as an officer or those whose assigned responsibility as a committee member was determined to be withdrawn will be deemed confidential and retained at the Secretariat of JSPHO, under the supervision of the President for 2 years from the date of termination of their tenure or withdrawal of the assigned responsibility. The COI documents of the concerned member will be deleted or disposed of promptly after 2 years of retention, 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 of the reporter will be postponed for a set period of time. The COI information related to the chairpersons of academic conferences will be handled in the same manner as that for JSPHO officers.

Article 7 (Disclosure or publication of the COI information)

1. The COI information will be not disclosed in principle, except for cases specified in Article 5, Paragraph 2.

2. The COI information may be disclosed or published within and outside of JSPHO, to the extent necessary to achieve the social and ethical accountability of JSPHO, associated with the activities of JSPHO and committees, after discussion at the Board of Directors meeting.
3. In this case, any person involved in the COI information to be disclosed or published may express his/her opinion to the Board of Directors, unless the disclosure or publication is an emergency, and there is no time for discussion.
4. If disclosure of any COI information of a certain member is requested (including legal request) by a non-member, the COI Committee, after being consulted by the President, will take appropriate actions in compliance with the personal information protection policy. If the COI Committee decides that they cannot handle the issue, the President will consult the COI Investigation Committee, which comprises some JSPHO members designated by the President and one or more members from outside JSPHO. The COI Investigation Committee will meet within 30 days from the receipt of a disclosure request and report their decision as soon as possible.

Article 8 (COI Committee)

1. The COI Committee will comprise several JSPHO Directors, several councilors, and one or more members from outside JSPHO, all of whom are designated by the President.
2. A Director designated by the President through a decision at the Board of Directors meeting will assume the post of the Chairperson of the COI Committee.
3. The COI Committee, in collaboration with the Board of Directors and the Ethics Committee, will provide necessary management to prevent the COI situation of JSPHO members from becoming serious and will deal with violations, in accordance with the COI Policy and the Detailed Regulations.
4. The members of the COI Committee are obligated to maintain confidentiality of the disclosed COI information of JSPHO members.
5. Rules set forth in Article 5 will be applied to the COI reports involving members and the handling of the COI information.

Article 9 (Measures against policy violators)

1. In cases where doubts or social or ethical problems arise as to the self-report of COI submitted by an author who is expected to publish in the JSPHO journal or other publications or by a candidate presenter at an academic conference organized by JSPHO, the COI Committee will, in order that JSPHO may fulfill its social accountability, take appropriate measures based on sufficient investigation, hearing or other means. If the COI situation of an author or presenter is so serious that JSPHO is not able to fulfill its accountability, the President may consult the Ethics Committee, and after the deliberation by the Board of Directors based on the recommendation by the Ethics Committee, the President may take measures, such as cancellation of the journal publication or conference presentation by the author or presenter concerned. If doubts or other problems arise after the publication or presentation, the President may investigate the facts and, if there is any violation, take measures such as retraction of the published article. If the policy violation made by the individual may significantly damage the trust that society has in JSPHO, the President may implement measures in terms of the membership or other privileges of the individual concerned, in accordance with the bylaws of JSPHO.

2. If it is pointed out that there is a problem with the reported COI information of the JSPHO officer, the chairperson of each committee, a committee member required to submit the self-report of COI, or a candidate to any of the above positions (submitted before or after his/her assuming the position), the chairperson of the COI Committee will report the matter to the President in writing. The President must promptly hold a Board of Directors meeting, which then must decide whether to confirm or reject the matter. If the matter is confirmed, the Director must resign from office and the candidate director concerned must withdraw from the appointment. As for the other committee members, the President may withdraw the appointment through consultation with the committee member and the candidate concerned.

Article 10 (Filing of objection)

1. Individuals who have been notified of a decision to impose measures against them for violation in relation to publication or presentation in JSPHO projects (e.g., the JSPHO journal or academic conferences) in accordance with Article 9, Paragraph 1, or those who are required to resign their posts of officers or dismissed as a committee member in accordance with Article 9, Paragraph 2, may file a written claim for reconsideration addressed to the President, if they have objections to the decision. The claim must be submitted to the Secretariat of JSPHO within 7 days of the notification on the decision of the Board of Directors.

2. Any claim for reconsideration must contain brief and concrete counterarguments to the reasons of the withdrawal stated in writing by the President. In addition to the information disclosed to the President, the individual may submit in writing other related information that forms the basis of his/her counterarguments. In this case, the information is handled as COI information, if the objection is accepted.

Article 11 (Process for the examination of an objection)

1. Upon receiving a claim for reconsideration, the President must promptly establish the Objection Examination Committee (hereafter called the "Examination Committee"). The Examination Committee will comprise several JSPHO members and one or more members from outside JSPHO, all of whom are designated by the President. The committee members will elect the chairperson of the Examination Committee from among themselves. The COI Committee members may not concurrently serve as the Examination Committee members. The Examination Committee will hold its meeting to deliberate on the objection within 30 days of receipt of the written claim for reconsideration.

2. The individual who filed the objection may submit the claim within 7 days before the first committee meeting for the examination, by adding supplemental briefs and materials to the examination request form. In this case, rules set forth in Article 10, Paragraph 2, will be applied.

3. The Examination Committee may hear the opinions of the chairperson of the Ethics Committee related to the claim and the individual who filed the objection. However, it does not apply if they do not present themselves on the dates set for the hearings.

4. Except where special circumstances exist, the Examination Committee will prepare its report on the examination of the objection and submit it to the President within 1 month of the first committee meeting held for the examination.

Article 12 (Final disposition of the claim examination determined by the Examination Committee)

The decision made by the Examination Committee will be the final decision on the objection.

Article 13 (Revisions of the Detailed Regulations)

It is assumed that social factors and future amendments of laws and regulations related to industry-academia collaborations will necessitate partial revisions of the Detailed Regulations for some individual cases. The Ethics Committee will discuss proposed revisions to the Detailed Regulations and may revise the Detailed Regulations following the resolution of the Board of Directors.

Supplemental Provisions

Article 1 (Effective date)

The Detailed Regulations will be implemented experimentally from May 10, 2013 for a period of 2 years and will become completely effective after that period. During the experimental period, no punitive clauses are applicable.

Article 2 (Revision of the Detailed Regulations)

The Detailed Regulations will be reviewed every several years in principle, to accommodate social factors, preparation and revision of laws and regulations related to industry-academia partnership, and changes in conditions related to healthcare and clinical research.

Article 3 (Special provisions on the application of the Detailed Regulations on officers and others)

Individuals who have already been appointed as JSPHO officers or to other positions at the time the Detailed Regulations come into effect will be required to submit the required reports or other documents promptly, by applying the Detailed Regulations.