

Conflict of Interest Policies in Medical Research in the Pediatric Hematology/Oncology Field

The Japanese Society of Pediatric Hematology/Oncology

Introduction

The Japanese Society of Pediatric Hematology/Oncology (hereinafter referred to as "JSPHO") works to contribute widely to the public welfare, by promoting improvements in the prevention, diagnosis and treatment of pediatric cancer and blood disorders in Japan, through educational activities for members of JSPHO, the presentation of research results by the members and public enlightenment activities. The majority of JSPHO members are pursuing various medical research studies, such as clinical studies to establish standard treatment for pediatric cancer patients and studies using new drugs, medical devices and technologies. Not a few of these studies conduct research and development through industry-academia collaborations.

In Japan, collaborations between industry and academia are being promoted as part of an approach toward building a nation that fosters scientific and technological creativity. To promote science and technology policies in a comprehensive and systematic manner, the "Science and Technology Basic Plan" was developed in 1996; this was followed in 2001 by the "Second Science and Technology Basic Plan" that defined a concept that forms the foundation of Japan's science and technology policy, and also established 2006 as the first year for the "Third Science and Technology Basic Plan." Thus, while various approaches are being taken as a national strategy aiming to build a nation that is creative in science and technology, industry-academia collaborations have been further strengthened, producing significant achievements in the development of science and technology.

However, in some cases, medical research involving industry-academia collaborations generates money, status and rights (private benefits), in addition to the desired feedback to society on outcomes gained via scientific and ethical responsibility (public benefits). When this occurs for an individual researcher, it is referred to as a Conflict of Interest (COI). More specifically, COI refers to a situation in which the fair and appropriate judgment required for public research may be compromised (or the perception of unfair interest as observed by a third party) by a financial interest with an external entity or person. A serious COI situation that interferes with fair and appropriate judgments may lead to practices, such as distorted research methods, data analysis or interpretation of research results in medical research; and unfair evaluation of research despite highly reliable results obtained using appropriate study methods.

In the United States and Europe, many academic societies have developed management guidelines to address COI in medical research. This has been done to promote medical research involving industry-academia collaborations in a proper manner and to ensure the fairness of presentations of research findings at academic conferences. In the United States, according to the provisions of the Sunshine Act (under the Healthcare Reform Act established in 2010), pharmaceutical- and medical device-related companies are legally obliged to disclose all payments to physicians, medical institutions, and other parties (website disclosure began in 2013). In Japan, the "Guidelines on Conflict of Interest Management in Health and Labour Sciences Research" were developed in 2008. The Guidelines provide policies for the management of COI between researchers and companies potentially having an interest, to ensure the transparency of public research. Based on this situation, the "Guidelines for the Management of COI in Medical Research" were issued by the Japan Medical Association in February 2011. The Guidelines provide a basic approach, in line with the situation of each subcommittee of the Japan Medical

Association, for the development of guidelines and their detailed regulations regarding COI in medical research.

I. Objectives

JSPHO takes its social responsibility seriously, in conducting its activities ethically, and also considers it important to actively encourage medical research by JSPHO members. Therefore, JSPHO announces "Conflict of Interest Policies in Medical Research in the Pediatric Hematology/Oncology Field" (hereinafter referred to as the "Policy"). Its objective is to provide members with clear COI policies to enable appropriate promotion of the publication of research results and their dissemination and enlightenment activities, while maintaining neutrality and fairness. This is accomplished by maintaining the fairness of research and development involving industry-academia collaborations, through appropriate management by JSPHO, of the COI situation of its members. This will eventually lead JSPHO and its members to contribute to society through their commitment to the advancement in the prevention, diagnosis and treatment of pediatric cancer and blood disorders.

II. Persons to Whom the Policy Applies

The Policy applies to the following persons, who may be involved in COI:

- ① Members of JSPHO.
- ② Those who make presentations at academic conferences, educational seminars, or other venues, for JSPHO.
- ③ Chairpersons and members (including observers) of standing committees, presidential advisory committees and disease committees, members of academic conference organization committees, and others in similar capacities.
- ④ Administrative staff of JSPHO.
- ⑤ Those who share income and property with any person(s) in categories ① to ③.

III. Activities to Whom the Policy Applies

The Policy applies to all activities conducted by JSPHO, including the following:

- ① Holding of academic conferences, educational seminars, or other such meetings.
- ② Issuance of the JSPHO journal and publications.
- ③ Implementation of research and surveys.
- ④ Incentives for research and awards research achievements.
- ⑤ Accreditation of certified physicians (e.g., pediatric hematologists/oncologists, pediatric oncology surgeons) and specialist training institutions.
- ⑥ Promotion of lifelong learning activities.
- ⑦ Liaison and collaboration with related academic societies.
- ⑧ Promotion of international research collaboration.
- ⑨ Other projects necessary to achieve objectives.

Particular compliance with the Policy is required in the following activities:

- 1) Presentations at academic conferences organized by JSPHO.
- 2) Publications by the JSPHO journal or other media.
- 3) Development of clinical practice guidelines, application for health insurance coverage, application based on public knowledge, and similar activities.
- 4) Work at temporary investigation committees, advisory committees, or other such groups.

IV. Matters to be Reported

If a person to whom the Policy applies receives benefits as an individual, such as those listed in ① to ⑨ below, exceeding the limits specified in the Detailed Regulations, she/he will report the accurate situation to the President of JSPHO. Concrete methods for disclosing and publishing the contents reported will be set forth in the Detailed Regulations.

- ① Appointment to the post of officer, advisor, employee or other position in companies, corporate organizations, or for-profit organizations.
- ② Ownership of corporate stocks.
- ③ Patent royalties and other fees from companies, corporate organizations, or for-profit organizations.
- ④ Per diem payment made by companies, corporate organizations, or for-profit organizations, for expenses incurred by a researcher to attend or give a presentation at a meeting (including lecture fees).
- ⑤ Payments made by companies, corporate organizations, or for-profit organizations, for writing a manuscript of a brochure or similar communication.
- ⑥ Medical research funds (e.g., commissioned research funds, joint research funds) provided by companies, corporate organizations, or for-profit organizations.
- ⑦ Scholarship donations (incentive donations) provided by companies, corporate organizations, or for-profit organizations.
- ⑧ Endowed chairs sponsored by companies, corporate organizations, or for-profit organizations.
- ⑨ Other rewards, such as travel fees (e.g., those for participating in academic conferences) and gifts.

V. Situations to be Avoided Concerning COI

1. Situations to be avoided by all researchers

Publication of medical research results and the development of clinical practice guidelines will be based purely on scientific judgment and should be for the benefit of the public. Members of JSPHO must not be influenced by manipulative practices of providers (including companies) of funds for medical research; nor must they conclude any contract that makes such influence unavoidable, regarding decisions to present (or not present) the research results at a conference or to publish in journals and also essential presentation details, including the research results and their interpretation.

2. Situations to be avoided by principal investigators of clinical research

Responsible researchers (excluding the investigator of each institution in multicenter clinical research) who are authorized to make decisions on planning and conducting clinical research (eg, clinical studies and clinical trials, including preclinical studies) should avoid the following situations of COI:

- ① Ownership of stock of the company sponsoring clinical research.
- ② Acquisition of patent royalties and/or patent rights of products and/or technology obtained from clinical research.
- ③ Appointment to the post of officer, Director, or advisor (except for uncompensated scientific advisors) in a company or for-profit organization sponsoring clinical research.

Researchers to whom ① to ③ apply can be appointed as the principal investigator responsible for clinical research projects, if they are indispensable in planning and/or conducting the research and as long as justice, fairness and transparency of their judgment and action are clearly assured.

VI. Implementation Methods

1. Responsibilities of JSPHO members

When presenting medical research results at academic conferences or other similar opportunities, JSPHO members must disclose any COI appropriately in the designated form, in accordance with the Detailed Regulations of JSPHO. If such a COI is indicated as being against the Policy in relation to the research presentation, the Board of Directors will consult the COI Committee and will take appropriate actions based on the recommendation by the Committee.

2. Responsibilities of officers and others

Officers (President, Vice President, Directors, and Auditors) of JSPHO, conference chairpersons (including the next President, and the President after the next President), and the chairpersons and members (including observers) of committees (standing committees, presidential advisory committee, disease committees) have an important role and are responsible for all projects and activities of JSPHO. Accordingly, each of them will make a self-report of any and all COI situations related to the projects and activities of JSPHO at the time she/he assumed the position. If another COI situation arises after assuming the position, they will submit an amended self-report in accordance with the rules.

3. Roles of the COI Committee

For all projects and activities of JSPHO, the COI Committee will investigate cases in which a serious COI situation arises with a member, or cases in which the self-report of COI is claimed to be inappropriate and doubtful, by conducting hearings in order to manage the COI situation involving the concerned member, and will report the results to the President of JSPHO.

4. Roles of the Board of Directors

If a serious COI situation arises in the conduct of a project of JSPHO by an officer, or for any inadequacy detected in the self-report of COI, the Board of Directors may consult the COI Committee and order remedial actions based on the recommendation by the Committee.

5. Roles of conference chairpersons and persons responsible for educational seminars or other sessions

Conference chairpersons and persons responsible for educational seminars or other sessions will request all presenters to comply with the Policy in their presentation and to disclose the presence or absence of COI related to the presentation. If it is found in advance that the presentation violates the Policy, they are authorized to take measures, such as cancellation of the presentation. In such case, the responsible persons are required to promptly notify the candidate presenter thereof and to explain the reason for said action. If a serious COI situation arises, or for any inadequacy detected in the self-report of COI, the responsible person may consult the COI Committee and order remedial actions based on the recommendation by the Committee.

6. Roles of the Editorial Committee

If original research articles, review articles, clinical practice guidelines, summarized articles, or opinions are to be published in the JSPHO journal or other publications, the Editorial Committee will verify that the publication is in compliance with the Policy and, if not, the Committee should take appropriate actions, including cancellation of the publication. Accordingly, the author should immediately be informed of the cancellation and the reasons for the cancellation. If any violation of the Policy is found after the publication of the paper, the Committee may make an official announcement regarding the matter in the name of the editor-in-chief in the publication. In the execution of such actions, the editor-in-chief may consult the COI Committee and order remedial actions based on the recommendation by the Committee.

7. Roles of the Clinical Research Ethics Review Committee

The Clinical Research Ethics Review Committee will verify that the research plan submitted complies with the Policy, and if not, it may request the representative of the research group to revise the research plan. Even if any violation of the Policy is found after approval of the research plan, the same action may be taken.

8. Roles of the Ethics Committee

The Ethics Committee related to COI management will determine concrete measures for violators of the COI Policy in response to a consultation by the President, taking into account the details of the violation and its impact on JSPHO; the measures determined will be reported to the President. COI management needs to be conducted at a high ethical level. Therefore, the Ethics Committee, COI Committee and Editing Committee need to exchange information and collaborate, on a routine basis, so that medical research involving industry-academia collaborations is promoted properly.

9. Others

The chairpersons and members of other committees will verify that the implementation of JSPHO projects in which they are involved complies with the Policy. If any violation of the Policy is found, they will promptly consider appropriate actions for the situation. The Board of Directors may consult the COI Committee regarding

such actions and order remedial actions based on the recommendation by the Committee.

VII. Measures Against Policy Violators and Accountability

1. Measures against policy violators

The Board of Directors of JSPHO is authorized to deliberate about violations of the Policy, according to the separately specified rules. The Board of Directors will consult the Ethics Committee, discuss the matter based on the recommendation by the Committee and, if a serious policy violation is confirmed, may take all or some of the following actions for a certain period, depending on the extent of the violation:

- ① Prohibition of presentation at any lecture meeting held by JSPHO.
- ② Prohibition of publication of papers in publications issued by JSPHO.
- ③ Prohibition of serving as a chairperson of academic conferences organized by JSPHO.
- ④ Prohibition of participation in the Board of Directors, committees, or working groups of JSPHO.
- ⑤ Dismissal from the position of JSPHO councilor or prohibition from becoming a councilor.
- ⑥ Suspension of JSPHO membership, expulsion from JSPHO, or rejection of JSPHO membership application.

If actions against policy violators are settled, such information will be provided to the President of JSPHO.

2. Filing of objection

Individuals who are subject to actions specified in the preceding section may file an objection with JSPHO. If the President of JSPHO accepts the objection, she/he will promptly set up the Objection Examination Committee (an interim advisory committee); assign the examination to the Committee and, after discussing the recommendation by the Committee at the Board of Directors meeting, notify the individual who filed the objection of the results of the deliberation.

3. Accountability

If a serious violation to the Policy regarding the research results presented at places related to JSPHO is confirmed, JSPHO must immediately be accountable to the public, after discussion at the Board of Directors meeting.

VIII. Establishment of Detailed Regulations

1. JSPHO will specify Detailed Regulations necessary to execute the Policy, separately.
2. The Detailed Regulations may be revised or abolished, after deliberations by the COI Committees and the resolution(s) made by the Board of Directors meeting.

IX. Effective Date

The Policy will become effective on May 10, 2013.

