Conflict of Interest Guidelines of the Japan Society of Perinatal and Neonatal Medicine

Introduction
The activities of the general incorporated association Japan Society of Perinatal and Neonatal Medicine (hereinafter called “JSPNM”) are aimed at contributing to mankind and society through stimulating progression and advances in perinatal medicine and neonatal medicine. To this end, the JSPNM has been engaged in organizing educational activities for its members, arranging opportunities for members to present their research results, etc., organizing educational campaigns to citizens, etc.

The studies presented at/in professional meetings, publications, etc., of the JSPNM pertain to new knowledge/new findings, clinical research for standardization of treatments in the fields of perinatal/neonatal medicine, clinical research on new drugs/medical devices/technologies, and research & development through industry-academia linkage. The outcomes of these actions are urgently needed and highly important, because they are later reflected in the clinical practice of perinatal and neonatal medicine.

In studies conducted via industry-academia linkage, the outcomes of fulfillment of the academic and ethical responsibilities can yield two types of benefit: (1) benefits for the public (utilization of the outcome by the society) and (2) private benefits (private acquisition of money, social status, interests, rights, etc., arising from the studies). If a researcher derives both forms of benefit, he/she is considered to have a conflict of interest (COI). If the conflict of interest is serious, it can cause biases in the study method, data analysis or interpretation of the results. Even when the results of a study are rational, fair evaluation of the results is not always made. The JSPNM considers it essential to present clear guidelines on COI to its members, so that fair research, investigation and development capable of contributing to advances in perinatal/neonatal medicine can be ensured and active research and activities/businesses of the JSPNM can be facilitated.

1. Objectives of preparing the Guidelines
In view of the social responsibilities and high degree of ethical consideration required for its activities, the JSPNM has prepared Guidelines on Conflict of Interest (hereinafter called “the Guidelines”). The objective of the Guidelines is to ensure appropriate management of COI so that the activities within the framework of the major businesses of the JSPNM can be
promoted properly while maintaining neutrality and fairness, and the JSPNM can fulfill its social responsibilities through contribution to advances in perinatal/neonatal medicine. The Guidelines represent the fundamental views of the JSPNM over COI and require members of the JSPNM to disclose any COI when making presentations related to the activities/businesses of the JSPNM.

2. Members covered by the Guidelines
The Guidelines cover members of the JSPNM listed below.
(1) Members submitting articles for publication in the journals, publications, etc., of the JSPNM.
(2) Members making presentations at the professional meetings of the JSPNM.
(3) Officers of the JSPNM

3. Activities covered by the Guidelines
The Guidelines are applied to activities undertaken within the framework of the major businesses of the JSPNM. JSPNM members, particularly those who make presentations at professional meetings or seminars or submit articles for publication in publications (journals, etc.) of the JSPNM are required to comply with the Guidelines. Members who provide educational lectures to other members or provide open lectures or the like to citizens are required to take particular care to ensure compliance with the Guidelines in view of the notably large social impacts of such activities.

4. Information to be disclosed/made public
If a member falls under or exceeds any of the criteria specified in the Conflict of Interest Guidelines Detailed Rules (“Detailed Rules”) in terms of the items (1) through (7) listed below, he/she is required to accurately disclose the COI by means of a self-report in the prescribed format. Such a member is required to take responsibility for making a self-report and for the information contained in the self-report. The concrete method for disclosure/making public is set forth in the Detailed Rules, corresponding to the nature of the activities concerned.
(1) Serving as an officer or advisor of an enterprise or a for-profit corporation or involvement in a university course donated by such an enterprise/corporation;
(2) Possessing stocks of an enterprise related to the study;
(3) Receiving patent royalty from an enterprise/corporation related to the study;
(4) Receiving daily allowance (lecture fee, etc.) covering the time/labor needed for participation (presentation) in/at the meeting paid by an enterprise/corporation related to the study;
(5) Receiving a reward for the preparation of leaflets, etc., from an enterprise/corporation related to the study;
(6) Study expenses paid by an enterprise/corporation related to the study;
(7) Other rewards (tours, gifts, etc. having no direct relationship to the study)

5. Avoidance of COI

1) What should the members covered by the Guidelines avoid

The results of a study should be published purely on the basis of scientific judgments and public benefits. When a judgment is made about the essential contents of a planned presentation (results of a study, selection and interpretation of the study results, etc.) at a professional meeting or in a journal, the members should ensure that the decision is not affected by the arbitrary intention of the sponsor/enterprise and that no contract inevitably involving such an influence is concluded.

2) What should members responsible for a clinical study or a committee avoid

Members having the authority to plan and implement a clinical study (including a clinical trial), excluding members serving as the Principal Investigator at a given study center during a multicenter clinical study, and members serving as the chairmen of committees in charge of surveys should be appointed from among those who do not fall under any of the following COI statuses and should avoid entering any of these COI statuses after appointment.

(1) Possession of stock of an enterprise sponsoring the clinical study;
(2) Getting patent royalty/right for the products/technologies arising from the clinical study;
(3) Serving as an officer, member of the Board of Directors or advisor for an enterprise or for-profit corporation sponsoring the study (excluding assuming the office of unpaid academic advisor).

6. Disclosure of COI

1) Responsibility of the members
When a member presents his/her study results at professional meetings or in publications or the like of the JSPNM, he/she is required to issue an appropriate statement disclosing his/her COI. The disclosure should be made in the format set forth in the Detailed Rules. If the planned presentation involves departure or violation from/of the Guidelines, the member needs to report it to the Scientific Committee Chairman if the presentation is planned to be made at a periodical professional meeting of the JSPNM, to the Perinatal Medicine Symposium Management Committee if the presentation is planned at a perinatal medicine symposium, and to the Publication/Editorial Committee if the presentation is planned in a publication. The committee receiving such information shall review the planned presentation and report its judgment to the Board of Directors.

2) Responsibility of officers or the like
The offices or the like of the JSPNM have large roles and responsibilities in the businesses and activities of the JSPNM and are required to make a self-report about COI in the businesses concerned using the prescribed format when they assume office. The Chairman of the Conflict of Interest Sub-committee shall review the self-report submitted and report the judgment to the Board of Directors. In the event of any serious conflict of interest arising during the pursuit of the businesses of the JSPNM by any officer or the like, the Board of Directors shall seek the advice of the Ethics Committee and suggest measures for resolution, etc., on the basis of the reply from the Ethics Committee.

7. Prohibition from presentation
When a plan for presentation of clinical study results (in paper form, presentation at meetings, etc.) violating the Guidelines has been submitted to the JSPNM Journal Editorial Committee, organizer of the professional meeting, etc., the presentation may be banned by the Publication/Editorial Committee, the Scientific Committee or the Perinatal Medicine Symposium Management Committee. The judgment about such prohibition shall be made by the respective committee, and the decision shall be reported to the Board of Directors. The decision can be implemented after the decision of the committee reported to the Board of Directors is approved by the Board of Directors.

8. Actions to be taken on members who have violated the Guidelines and social accountability of such conduct
1) Actions on members who have violated the Guidelines

The Scientific Committee, the Perinatal Medicine Symposium Management Committee, the Publication/Editorial Committee and the Ethics Committee are entitled to review possible violations of the Guidelines. If the results of the review lead to the judgment that there has been a serious failure by any member, officer or the like to comply with the Guidelines, these committees can advise the Board of Directors as to the application of the actions listed below, in whole or in part, for a period considered appropriate for the extent of non-compliance. Each committee can implement the actions concerned after obtaining the approval of the Board of Directors.

(1) Prohibition of presentation at professional meetings sponsored by the JSPNM
(2) Prohibition of publication of manuscripts in journals, publications, etc., of the JSPNM.
(3) Prohibition of assuming the office of a chairperson at professional meetings of the JSPNM
(4) Prohibition from attending meetings of the Board of Directors and committees of the JSPNM
(5) Actions pursuant to the Rules on Disciplinary Measures of the JSPNM

2) Appealing of decisions

A member who has been informed as to the action taken on him/her can appeal to the JSPNM if unsatisfied with the decision. If the JSPNM accepts such an appeal, the Ethics Committee is required to review the case faithfully. The decision made by the committee shall be notified to the appellant after verification by the Board of Directors.

3) Social accountability

If the Board of Directors has judged that there has been serious violation of the Guidelines in a clinical study or survey presented in a professional meeting, journal, publication, etc., of the JSPNM, the findings needs to be published in the journal, publication, etc., to fulfill the responsibility of explanation to the society.

9. Detailed rules

The JSPNM can set forth detailed rules needed for practical implementation of the Guidelines.

10. Modification of the Guidelines
Any modification of the Guidelines is proposed by the Ethics Committee and shall be reported to the General Conference after a decision at the Board of Directors.

11. Supplementary rules
The Guidelines are effective from July 11, 2011.
Detailed Rules for the Japan Society of Perinatal and Neonatal Medicine Conflict of Interest Guidelines

( Objectives )
Article 1 These detailed rules set forth a concrete way for implementing Conflict of Interest Guidelines (hereinafter called “the Guidelines”) of the Japan Society of Perinatal and Neonatal Medicine (hereinafter “JSPNM”) to ensure compliance of the members with the Guidelines.

(Activity and Amounts to Be Reported)
Article 2 The activities, amounts, etc., which require reporting, are set forth below.
(1) Annual rewards amounting to one million Yen or more from a single enterprise/corporation to a member serving as an officer or advisor of an enterprise or a for-profit corporation or belonging to the university course donated by such an enterprise/corporation;
(2) Annual profits (total of dividends and bond sales) amounting to one million Yen or more from the stocks of a single enterprise related to the study, or possession of 5% or more of the total stock of the enterprise;
(3) Receiving annual royalty amounting to one million Yen or more per single patent right from an enterprise/corporation related to the study;
(4) Receiving a daily allowance (lecture fee, etc.) amounting to 500,000 Yen or more in a year covering the time/labor needed for participation (presentation) in/at the meeting from an enterprise/corporation related to the study;
(5) Receiving a reward for the preparation of leaflets, etc., amounting to 500,000 Yen or more in a year from an enterprise/corporation related to the study;
(6) Study expenses amounting to two million Yen or more in a year paid by an enterprise/corporation related to the study or scholarship (promotional) award amounting to two million Yen or more in a year paid to a single research representative from a single enterprise/corporation related to the study;
(7) Other rewards (tours, gifts, etc., having no direct relationship to the study) amounting to 50,000 Yen or more in a year paid by a single enterprise/corporation.
(Studies Requiring Reporting and Disclosure of Conflict of Interest)

Article 3 Studies which require reporting and disclosure of conflict of interest at the time of presentation are confined to “clinical studies.” “Clinical studies” here refers to “medical studies in human subjects aimed at improving the methods of disease prevention, diagnosis and treatment during healthcare, facilitating understanding of the cause and features of disease and improving the quality of life of patients,” as defined in the government’s “Ethical Guidelines on Clinical Studies,” including clinical trials.

(Reporting of Conflict of Interest at the Time of Presentation at Professional Meetings or the Like of the JSPNM)

Article 4
1. When a presentation/lecture is delivered at a professional meeting, seminar, open seminar for citizens or the like of the JSPNM, the lead presenter and the study representative are required to disclose their conflict of interest in the enterprise or for-profit corporation related to the study in accordance with the provisions of Article 2.
2. When a presentation is made at a professional meeting or the like of the JSPNM, the presenter is required to disclose conflict of interest at the time of registering the presentation title or submitting the abstract of presentation, using the format, “Conflict of Interest Self-Report by Presenter (Format 1),” set forth in the rules for presentation.
   (1) The conflict of interest disclosed at the time of presentation must satisfy the provision “4. Information to be disclosed/made public” of the Guidelines.
   (2) The period requiring disclosure of conflict of interest spans from one year before submission of the abstract to the time of presentation.
   (3) The last part of the slides or posters presented must state that any conflict of interest has been declared using the format, “Conflict of Interest Self-Report by Presenter.”

(Reporting on Conflict of Interest at the Time of Publication in Journals or the Like the JSPNM)

Article 5
1. When a member publishes his/her paper in a journal or other publication of the JSPNM, he/she is required to disclose his/her conflict of interest in the enterprise or for-profit corporation related to the study in accordance with the provisions of Article 2.
2. When a presentation is made in a journal or other publication of the JSPNM, the author is required to disclose his/her conflict of interest at the time of submission of the manuscript using the format, “Conflict of Interest Self-Report by Presenter/Author,” set forth in the rules for contribution.

(1) The conflict of interest disclosed at the time of contribution must satisfy the provision “4. Information to be disclosed/made public” of the Guidelines.

(2) The period requiring disclosure of conflict of interest spans from one year before submission of the manuscript to the time of submission.

(3) The “Conflict of Interest Self-Report by Presenter/Author” submitted shall not, as a rule, be disclosed to the manuscript reviewer.

(4) The manuscript is required to state at the end that disclosure has been made using the format, “Conflict of Interest Self-Report by Presenter/Author.”

(Reporting Conflict of Interest by Officers or the Like)

Article 6

1. The officers or the like in the Detailed Rules encompass the officers set forth in Article 19 of the Enforcement Rules for the Articles of Incorporation and the chairman of each of the Publication/Editorial Committee, the Scientific Committee, the Ethics Committee and the Perinatal Medicine Symposium Management Committee among the committees set forth in Article 26 of the Enforcement Rules for the Articles of Incorporation.

2. The officers or the like and the chairperson for the current professional meeting and the next professional meeting set forth in the preceding paragraph of this article are required to disclose their conflict of interest with each enterprise/for-profit corporation related to the businesses of the JSPNM.

3. The officers or the like of JSPNM are required to submit the “Conflict of Interest Self-Report by Officers or the Like (Format 2)” at the time of assuming their office and at intervals of one year thereafter. In the event of a new conflict of interest developing while he/she is still in office, the officer or the like is required to report it within 8 weeks after the occurrence using the format, “Conflict of Interest Self-Report by Officers or the Like.”

(1) The conflict of interest disclosed at the time that the relevant person assumes office must be self-reported by the officer in compliance with provision “4. Information to be disclosed/made public” of the Guidelines.
(2) The “Conflict of Interest Self-Report by Officers or the Like” must cover the latest one-year period (calendar year), with specification of the covering period.

(3) If a member plays the role of two or more officers or the like concurrently, the “Conflict of Interest Self-Report by Officers or the Like” must cover the period dating back to 2 years before assumption of the first officer role. This provision does not apply to cases where a member of the Board of Directors is appointed as the chairman of one or more committees in accordance with Article 29 of the Enforcement Rules for the Articles of Incorporation.

(Treatment of Conflict of Interest Self-Report)

Article 7

1. The “Conflict of Interest Self-Report by Presenter” (“Conflict of Interest Self-Report by Presenter/Author”) and the “Conflict of Interest Self-Report by Officers or the Like” submitted to the JSPNM in accordance with the Detailed Rules, as well as the information on conflict of interest disclosed in these reports (hereinafter called “conflict of interest information”) must be strictly stored and managed as personal information by the Secretariat of the JSPNM, with the President serving as the Administrator.

2. The Board of Directors and the Ethics Committee may utilize the conflict of interest information to process matters set forth in the Guidelines with the permission of the President.

3. The utilization stated in the preceding paragraph includes disclosure of the necessary part of the conflict of interest information concerned to the JSPNM or to the society after review by the Ethics Committee and approval of the Board of Directors if a question or a social/legal issue has arisen concerning the conflict of interest information of a self-reporter.

4. The storage period for the “Conflict of Interest Self-Report by Presenter” (“Conflict of Interest Self-Report by Presenter/Author”) and the “Conflict of Interest Self-Report by Officers or the Like” mentioned in Paragraph 1 is 2 years after presentation at a professional meeting or in a publication or 2 years after expiration of the term of the officer or the like. After that period, the self-report is discarded under the supervision of the President. If a question or a social/legal issue has arisen concerning the conflict of interest information during the storage period, it is allowed, under the decision of the Board of Directors, to reserve the discarding of the “Conflict of Interest Self-Report by Presenter” (“Conflict of Interest Self-Report by Presenter/Author”) or the “Conflict of Interest Self-Report by Officers or the Like” carrying the conflict of interest information concerned.
(Actions on Members who Have Violated the Detailed Rules)

Article 8 The actions on members who have violated the Detailed Rules shall be taken in accordance with the Guidelines.

(Modification of Detailed Rules)

Article 9 The Detailed Rules may be modified if proposed by the Ethics Committee and approved by the Board of Directors.

Supplementary Rules

1. The Detailed Rules are effective from July 11, 2011.

2. Format 1 “Conflict of Interest Self-Report by Presenter” (“Conflict of Interest Self-Report by Presenter/Author”) and Format 2 “Conflict of Interest Self-Report by Officers or the Like” related to the Detailed Rules are given below.

Format 1: Conflict of Interest Self-Report by Presenter (Conflict of Interest Self-Report by Presenter/Author)

Format 2: Conflict of Interest Self-Report by Officers or the Like