

Detailed Enforcement Regulations on Conflicts of Interest (COI) of the Japan Society of Ningen Dock and Preventive Medical Care

Article 1 (Presentations at conferences held by the Japan Society of Ningen Dock and Preventive Medical Care including science meetings)

Paragraph 1 (Scope of disclosure)

Conflict of Interest (hereinafter referred to as “COI”) situations that first authors are obligated to disclose are limited to matters pertaining to companies and groups related to the presentations, which include the relationships as follows.

1. Relationships where research on preventive medicine and Ningen Dock health checkup was requested or jointly conducted (regardless of being paid or unpaid)
2. Relationships where any patents or other rights are shared in relation to examination and test devices to be evaluated for research on preventive medicine and Ningen Dock health checkup
3. Relationships where examination devices used for research on preventive medicine and Ningen Dock health checkup are provided for free or at favorable prices
4. Relationships where grants and donations are made for research on preventive medicine and Ningen Dock health checkup
5. Relationships where unapproved devices including testing devices are provided for research on preventive medicine and Ningen Dock health checkup
6. Relationships where endowed chairs are sponsored

Paragraph 2 (Disclosure method)

(Disclosure method)

To self-report a COI situation when giving a speech or presenting research, the items defined in “5. Extent and contents of disclosure” in the Conflicts of Interest (COI) Guidelines shall be disclosed on the first slide of the presentation materials or at the end of posters based on Forms 1-A and 1-B “Conflict of Interest (COI) Self-declaration Form for First Authors”. COI situations required to be disclosed are those that occurred in the last one year between January 1 and December 31. However, items that require self-declaration are limited to those with the following amounts arising.

1. Remuneration as a board member, honorary advisor, employee and other: When the remuneration amount given in a year by a company or group is one million yen or more
2. Equity holding: When one million yen or more is given a year (the sum of dividends and profit on sales) from a company by holding its equity or when one has 5% or more of the entire equity of the company
3. Royalty payments from companies and groups: When one million yen or more is given a year per patent

4. Per-diem allowance paid for time and work that the researcher spent on attending (making a presentation at) a conference and manuscript fees paid for writings such as brochures by companies or groups: When a half million yen or more is given a year from a company or group
5. Research funds provided by companies or profit-oriented organizations (e.g. clinical trial, contracted research, joint research): When the total amount paid by a company or group is 2 million yen or more a year
6. Scholarship funds provided by companies or groups: When the total amount paid by a company or group to the applicant or the representative of the department, division (course and areas) or laboratory where the applicant belongs is 2 million yen or more a year
7. When the applicant belongs to endowed chairs provided by the companies and groups
8. Other remunerations (e.g. travel and gifts, which are not directly related to research): When the remuneration amount given in a year by a company or group is fifty thousand yen or more

Article 2 (Publication in academic journals including “Ningen Dock”, an academic journal from the Japan Society of Ningen Dock and Preventive Medical Care)

Paragraph 1 (Scope of disclosure)

COI situations that all authors are obligated to disclose are limited to matters pertaining to companies and groups related to the publication, which include relationships specified in Article 1, Paragraph 1.

Paragraph 2 (Disclosure method)

The first authors of the publication in academic journals including “Ningen Dock”, an academic journal from the Japan Society of Ningen Dock and Preventive Medical Care, must declare the COI situation at the time of publication using “Conflict of Interest (COI) Self-declaration Form (Form 3)” specified in the contribution rules. The COI situation shall be printed at the end of the paper right before the References. If no COI situation needs to be declared, a statement that “The authors declare no conflict of interest.” must be inserted in the same part. The COI situations that must be declared at the time of publication are defined in the COI guidelines, which must be self-reported. The amounts defined for each item which need to be self-reported are the same amounts defined in Article 1, Paragraph 2. COI situations required to be disclosed are those that occurred in the last one year from the time of the publication of the paper. Submitted COI situations are not disclosed to the reviewers of the paper.

Article 3 (Board members)

Paragraph 1 (Scope of disclosure)

COI situations (COI information) that the board members including the president, vice presidents,

directors, president of science meetings, auditors, chairperson of the Additional Committee, chairpersons and members of other committees and subcommittees must disclose are limited to matters pertaining to companies and groups related to the business performed by the Japan Society of Ningen Dock and Preventive Medical Care.

Paragraph 2 (Disclosure method)

The board members specified above shall submit their own “Conflict of Interest (COI) Self-declaration Form for Board Members (Form 2)” defined in the COI guidelines for self-declaration when they are newly appointed and every year after the first year of their appointment. The amounts defined for each item which need to be self-reported are the same amounts defined in Article 1, Paragraph 2. Form 2 must include their COI situations for one year with the period when the amounts were accumulated. When a new COI situation occurs during their appointment term, board members are required to report it within two months using Form 1.

Article 4 (Handling of COI self-declaration from board members)

Paragraph 1

Form 2 submitted based on the Detailed Enforcement Regulations on COI (hereinafter referred to as “the Detailed Regulations”) and the COI situation disclosed within are stored and maintained at the secretariat of the Japan Society of Ningen Dock and Preventive Medical Care in strict confidence as personal information according to laws and regulations placing the president as the manager. COI information shall be always available for the Basic Issues Study Committee, executive board, and Ethics Subcommittee to fulfill their responsibilities defined in the COI guidelines. Their use of the information shall include the disclosure of the applicant’s COI information to the necessary extent within the organization or to society after having been discussed in the Ethics Subcommittee and being approved by the Basic Issues Study Committee and executive board when any questions or social or legal problems arise.

Form 2 documents shall be retained two (2) years after the termination of the board members’ and committee members’ term of office and thereafter shall be destroyed under the supervision of the president. However, if any questions or social or legal problems arise concerning the applicant in the Form 2 retention period, the disposal of Form 2 can be suspended according to the resolution of the Basic Issues Study Committee and executive board.

Paragraph 2

The Basic Issues Study Committee, executive board, and Ethics Subcommittee of the Organization determine whether the individual is in a COI situation and, if so, what the conflict degree is based on the self-declaration form submitted as defined in the Detailed Regulations. When they perform

management and take measures according to the determination of the Organization, they shall be allowed to access the COI information of the individual as needed. However, they must not exceed the amount necessary to accomplish the purpose of use and not disclose the information to others except for those who require information disclosure in light of achieving the above purpose of use.

Paragraph 3

In principle, COI information is not published except in the case of Article 4, Paragraph 2. COI information may be disclosed or published within or outside the organization to the extent required after a discussion between the Basic Issues Study Committee and executive board when it is necessary to fulfill social and moral accountabilities as the Japan Society of Ningen Dock and Preventive Medical Care concerning the activities of the organization and committee.

In this case, the parties concerned with the COI information to be published or disclosed are allowed to express their opinion to the Basic Issues Study Committee and executive board. However, this shall not apply when the COI information must be disclosed or published urgently and the committee and executive board do not have time to listen to their opinion.

Paragraph 4

If a request is made to disclose information on a specific member (including a legal claim) by a non-member, the Ethics Subcommittee shall handle the request along with the appropriate confidentiality to protect the privacy based on a request from the president of the executive board, if there is a reason deemed to be reasonable. The Ethics Subcommittee shall hold a committee meeting within 30 days after receiving the written disclosure and respond to the request as soon as possible.

Article 5 (COI committee)

The Ethics Subcommittee shall cooperate with the Basic Issues Study Committee and executive board, perform management, and respond to the violation of the COI policy and detailed regulations in order to prevent the members' COI situation from becoming a serious issue. Regarding the committee's reports on COI matters and handling of COI information, Article 4 shall apply *mutatis mutandis*.

Article 6 (Measures for offenders)

Paragraph 1

If any questions or social or legal problems arise concerning the COI self-declared information submitted by a contributor or presenter to the Organization's academic journal "Ningen Dock" and science meetings, the Ethics Subcommittee takes appropriate measures to fulfill the social responsibility as the Japan Society of Ningen Dock and Preventive Medical Care, after conducting a sufficient investigation and

interviews.

If there is a serious COI situation and the Organization is not able to fulfill their accountability, the president of the executive board consults with the Ethics Subcommittee. The Basic Issues Study Committee and executive board conduct deliberation based on their report and they may suspend the presentation at academic conferences or publication of research results of the person who planned to do so.

If a problem including questions arise after a presentation has been made, the president shall examine the matters and if there is any violation of the COI policy and regulations, he/she shall take measures by suspending the publication, for example. If it significantly impairs the Organization's credibility, the president shall take measures against their membership, for example, according to the Organization's constitution.

Paragraph 2

If it is pointed out that there is an issue with the COI situation declared by the board member of the Organization including committee members or their candidates, who are obligated to self-declare their COI situation, before or after being appointed, the chairperson of the Ethics Subcommittee must report the issue to the president of the executive board in a written format. Then, the president of the executive board must immediately hold a Basic Issues Study Committee meeting and determine the results. Then, the executive board must discuss whether they will adopt or reject what was pointed out.

If it was adopted, the board member or the candidate shall resign. Other committee members may recall his/her appointment.

Article 7 (Motion for complaint)

Paragraph 1 (Request for complaint investigation)

The person who has received a notice to take measures against the violation of a presentation, such as at conferences that the Organization holds (e.g. academic journal "Ningen Dock" and science meetings), according to Article 6, Paragraph 1, and the board member or the candidate who's dismissal has been demanded according to Article 6, Paragraph 2, may make a claim for a review within 7 days from the day when he/she was notified of the result by submitting a request for complaint review to the president of the executive board if he/she is dissatisfied with the determination.

The request shall include a succinct but concrete counterargument and counter-opinion against the reason for the determination provide by the chairperson of the Ethics Subcommittee in a written format. In this case, they can include information disclosed to the Ethics Subcommittee as well as related information that is to be grounds for an objection.

Paragraph 2 (Complaint review procedures)

1. When the president of the executive board receives a request for a complaint review, he/she must set up a complaint review committee (hereinafter referred to as “the Review Committee”) in an immediate manner. The committee consists of a few numbers of members of the Organization who are designated by the president of the executive board and one or more external members. The committee chair is chosen by the members. The members of the Ethics Subcommittee may not be members of the Review Committee. The Review Committee shall hold a committee meeting within 30 days from the day when they received the request for complaint review to perform the review.
2. Unless specific circumstances exist, the Review Committee shall make a report and submit it to the president of the executive board within a month from the date when the first committee meeting on the review was held.
3. The review will be finalized with the determination of the Review Committee.

Article 8 (Change in the detailed regulations)

It is expected that the detailed regulations will require partial changes according to individual cases due to social factors and in order to adapt to changes and the development of laws on industry collaboration. The Basic Issues Study Committee may apply changes after discussing about the review of the detailed regulations and obtaining the determination between the Basic Issues Study Committee and executive board member.

Article 9 (Supplementary Provision)

The detailed regulations come into effect on June 28, 2012.