

Conflicts of Interest (COI) Guidelines of the Japan Society of Ningen Dock and Preventive Medical Care

1. Introduction

The aim of the Japan Society of Ningen Dock and Preventive Medical Care (hereinafter referred to as “the Organization”) is to contribute to increasing the nation’s health by pursuing academic promotion, enhancing the welfare of senior citizens and improving the welfare of workers through studies and research of areas related to preventive medicine including the Ningen Dock health checkup, dissemination of knowledge, enlightenment activities and holding of science meetings. In areas like preventive medicine, there is strong demand for actively contributing to the society by returning the research results back to today’s Ningen Dock health checkup field while carrying out research in collaboration with industries. The Organization thinks that the members must fulfill their social accountability by, based on certain requirements, disclosing financial relationships with the sponsors with which they have a conflict of interest (hereinafter referred to as “COI”), for example, through presentations under their business operations to their members. These guidelines are policies that the Organization has established to handle COI matters related to all activities of the Organization and their members (hereinafter referred to as “member”) from the Organization’s standpoint in a fair, appropriate and prompt manner.

2. Objectives

If a member personally obtains financial benefit from a specific company, it may raise social suspicions that “the research theme is set for the profit of the company, which may be lacking in the significance of academic research” or “the research collects data that is profitable to the company, which may impair research objectivity.” Regarding the publication of research attainment and enlightenment activities within the Organization, in order to ensure their social credibility, the Organization shall fulfill its social accountability by having individuals voluntarily disclose COI (Self-declaration) based on the Organization’s standard (detailed enforcement regulations) and maintaining neutrality and transparency.

3. Intended audience

The guidelines are applied to the following people who have possibilities to be in COI situations.

- (i) Members of the Organization
- (ii) Secretariat members of the Organization
- (iii) Those who make presentations on science meetings and publications in the academic journal “Ningen Dock”
- (iv) Members of the board, committees and subcommittees of the Organization

4. Intended activities

The guidelines are applicable to all the activities that the Organization is involved with, specifically

to science meetings and lectures held by the Organization, training sessions and workshops, and research funded by the Organization. Also, committees which make publications and create guidelines in the academic journal of the Organization are required to comply with the guidelines.

5. Extent and contents of disclosure

Those intended audience members who himself/herself receives or has more than the amounts in the criteria separately defined for the following items from i) to viii) shall disclose the accurate information for their COI situation by self-declaring using the designated form. Also, if the relative of the first degree or whose living expenses are shared with the intended audience member receives or has more than the amounts in the criteria separately defined for the following items from i) to viii), then the accurate information shall be disclosed to the Organization.

The declarant shall be responsible for the self-declared information. Detailed disclosure and the procedures are separately defined in the detailed regulations based on each activity.

- (i) Board members, honorary advisories, employees of companies or profit-oriented groups
- (ii) Equity holding (e.g. shares, investment, employee stock option, beneficiary right)
- (iii) Royalty payments from companies or profit-oriented groups
- (iv) Per-diem allowance paid for time and work that the researcher spent on attending (making a presentation at) a conference or manuscript fees paid for writings such as brochures by companies or profit-oriented groups
- (v) Research funds provided by companies or profit-oriented groups (e.g. clinical trial, contracted research, joint research)
- (vi) Scholarship funds provided by companies or profit-oriented groups
- (vii) Endowed chairs provided by companies or profit-oriented groups
- (viii) Other remunerations (e.g. travel fees and gifts, which are not directly related to health checkup and research)

6. Avoidance of COI situation

The results as well as their publication and interpretation of the research for preventive medicine and the Ningen Dock health checkup must be developed and made genuinely based on scientific judgments or public interest. They cannot be influenced by the arbitrary intention of the investors or investor companies of the research.

Also, those who are not in the following COI situations shall be selected as directors of the research initiated by the Organization on preventive medicine and the Ningen Dock health checkup. Those who are selected as directors must avoid these COI situations.

- (i) Equity holding of the companies' which are related to preventive medicine and Ningen Dock health checkup research
- (ii) Acquisition of patent rights and fees from products and technologies benefited by research on preventive medicine and Ningen Dock health checkup

(iii) Board member, chairperson, advisor (except for unpaid scientific advisors) of profit-oriented groups from companies related to preventive medicine and Ningen Dock health checkup research
However, a researcher to whom the above i) to iii) are applicable but who is indispensable in planning and implementing the preventive medicine and Ningen Dock health checkup research, and where the relevant research has a great significance internationally, is allowed to be appointed as the director.

7. Disclosure method

(i) Responsibilities of the members

When a member presents the results of the preventive medicine and Ningen Dock health checkup research at an academic conference, he/she shall disclose his/her COI situation concerning the research in a proper manner using the designated form (Form 1-A, 1-B) in accordance with the detailed regulations of the Organization. If it is pointed out that there is a breach of the guidelines in relation to the presentation of the research, the Basic Issues Study Committee and executive board call on the committee with jurisdiction over COI, the Ethics Subcommittee of the Japan Society of Ningen Dock and Preventive Medical Care (hereinafter referred as “the Ethics Subcommittee”) to hold a deliberation and take appropriate measures based on their report.

(ii) Responsibilities of the board members

The board members (chairperson, chairpersons, directors and auditors) of the Organization, presidents of science meetings, chairpersons of committees, and members of specific committees and subcommittees which, for example, develop guidelines have significant roles and responsibilities for all business activities related to the Organization. They shall self-declare their COI situation concerning the business using the designated form (Form 2) at the time of their appointment. Also, if a COI situation occurs after their appointments, an amendment shall be declared based on the regulations.

(iii) Roles of the Ethics Subcommittee

In any business carried out by the Organization where a serious COI situation arises or it is pointed out that the self-declared COI is not appropriate and is questionable, the Ethics Subcommittee shall conduct an inspection such as an interview to manage the member’s COI situation, and report the results to the chairperson.

(iv) Roles of the Basic Issues Study Committee and executive board

In business carried out by board members where a serious COI situation arises or the Basic Issues Study Committee and executive board admitted that the self-declared COI is not appropriate, they can consult with the Ethics Subcommittee and indicate remedial actions based on the report provided by the subcommittee.

(v) Roles of the presidents of science meetings

When research results on preventive medicine and Ningen Dock health checkup are presented in a science meeting, the president of the meeting examines whether the presentation is in line with the

guidelines and, if the subject violates the guidelines, can take measures by suspending it, for example. In this case, he/she shall inform the presenter to be with the reasons in an immediate manner. When taking these measures, he/she can consult with the Ethics Subcommittee and indicate remedial actions based on the report provided by the subcommittee.

(vi) Roles of the Editorial Committee

When original papers, reviews, medical guidelines, editorial matters, and opinions of research results are published in a journal such as academic journals, the Editorial Committee of the journal examines whether they are in line with the guideline and can take measures by, for example, suspending their posts if they violate the guidelines. In this case, the committee shall inform the paper's contributor with the reasons in an immediate manner. If a violation is found after publication, the committee can announce it in the journal under the name of the chairperson of the committee. When taking these measures, he/she can consult with the Ethics Subcommittee and indicate remedial actions based on the report provided by the subcommittee.

(vii) Others

In any of the Organization's businesses that other committees' chairpersons and members get involved with, they shall examine whether such business implementations are in line with the guidelines and, if a violation occurs, develop remedial actions in an immediate manner. In the course of the development, they can consult with the Ethics Subcommittee and Basic Issues Study Committee and the executive board can indicate remedial actions based on the report provided by the subcommittee.

8. Measures and accountabilities against those who violated the guidelines

(1) Measures against those who violated the guidelines

A separately defined rule specifies that the Basic Issues Study Committee and executive board have the right to deliberate on actions that violated these guidelines. It also specifies that they can take the following measures in whole or in part for a certain period depending on the degree of the violation when they determined that there is a serious guideline violation based on the result of the deliberation and report provided by the Ethical Subcommittee, which they consulted with.

- (i) Prohibits making presentations at any lecture meetings and workshops held by the Organization
- (ii) Prohibits posting papers to the Organization's publications such as the academic journal
- (iii) Prohibits being appointed as the president of the science meetings of the Organization
- (iv) Prohibits participating in the executive board, committees, and subcommittees
- (v) Dismisses from employment at the Organization or prohibits being its employee
- (vi) Suspends the Organization's membership, expels or prohibits being a member

(2) Motion for complaint

Those for whom such measures were applied can file a complaint against the Organization. If the chairperson of the Organization accepts it, the complaint is referred to the complaint deliberation committee, which will be immediately set up, and the results shall be notified to the person who filed

the complaint after the report has been deliberated by the Basic Issues Study Committee and executive board.

(3) Accountability

If the Organization determines there is a serious violation of the guidelines of the research results on preventive medicine and Ningen Dock health checkup, they must fulfill their accountability to society in an immediate manner through discussion between the Basic Issues Study Committee and executive board.

9. Institution of detailed regulations

The Organization may institute detailed regulations necessary to keep the guidelines in place.

10. Revision of the guidelines

The guidelines may be reviewed and revised on a regular basis due to social factors and in order to adapt to changes and the development of laws on industry collaboration and conditions associated with preventive medicine and Ningen Dock health checkup and their research.

11. Date of enforcement

These guidelines come into effect on June 28, 2012.