

The Japanese Circulation Society  
Regulations Concerning Conflict of Interest Policy in Clinical Research

The Japanese Circulation Society (hereinafter, “the Society”) was established in April, 1981. The Society aims to contribute to the academic development and advancement of scientific research related to circulatory medicine through presentations and communications concerning theoretical and practical research, in addition to exchange of knowledge and information.

The Society has developed a common policy concerning conflict of interest (hereinafter, “COI”) in clinical research, in cooperation with 13 other societies related to internal medicine (The Japanese Society of Internal Medicine, The Japanese Society of Gastroenterology, The Japanese Society of Hepatology, The Japan Endocrine Society, the Japan Diabetes Society, the Japanese Society of Nephrology, The Japanese Respiratory Society, the Japanese Society of Hematology, Societas Neurologica Japonica, The Japan Society of Allergology, the Japan College of Rheumatology, The Japan Association for Infectious Diseases, the Japan Geriatrics Society). In order to ensure the fair management of COI of its members, regulations concerning COI Policy in Clinical Research have been established as follows.

Article 1 (COI Disclosure at Academic Meetings)

Item 1

If the presenter, whether they be a member or not, gives presentations or lectures at a conference organized by the Society (annual academic meetings), public forums, or local or chapter meetings, the first author is required to self-disclose any COI status, including the COI status of the presenter’s spouse (partner), immediate family (first of kin), or those who are residing in the presenter’s household, and must describe the related commercial entities, foundation organizations, and any other groups related to the clinical research which aim to derive profit, within the preceding one year, using Form 1, at the time of abstract submission. The first author shall disclose applicable COI status at the beginning of the slide presentation (or on a slide following the slide showing the title of presentation and name of presenters) using Form 1-A, or at the end of a poster using Form 1-B.

## Item 2

As stated in the previous article, “businesses, organizations and for-profit groups involved in clinical research” are businesses, organizations and groups involved in research in situations defined as follows.

- (1) Sponsors of clinical research or joint clinical research, with or without recompense or remuneration.
- (2) Organizations sharing rights, such as patent rights, concerning methods of treatment, drugs and/or devices that are evaluated in clinical research.
- (3) Organizations providing drugs and/or devices for clinical research without recompense or remuneration, or providing them at a favorable price.
- (4) Organizations providing funding or donations for clinical research.
- (5) Organizations providing unapproved drug and/or medical devices for clinical research.
- (6) Sponsors of endowed departments.

## Item 3

“Clinical research” in relation to the presentation topic is defined as medical research involving human beings aimed to improve disease prevention, diagnosis and method of treatment, understand the pathology and pathogenesis, in addition to improving the patients’ quality of life. Medical research involving human subjects includes research on human-derived specimens and/or data that can identify the individual.

Whether such specimens or data are subject to the identification of individuals shall be decided according to the Ethical Guidelines for Clinical Research (Ministry of Labor, Health, and Welfare of Japan).

## Article 2 (Criteria for COI self-disclosure)

COI must be disclosed to the Society if any of the following items apply.

- (1) If you have been an officer or consultant in a business, corporation or for-profit organization, or commercial entity involved in clinical research (hereinafter, “business, organization or group”), if the remuneration from a single business, organization or group exceeds 1 million yen per year.

- (2) Concerning stock ownership or options, if the profit (total sum of the dividend or profit sales) from stocks of one business, organization or group totals more than 1 million yen per year, or if 5% or more of all stocks of the corresponding stock is owned.
- (3) Patent right fees, from a business, organization or group, of 1 million yen or more per patent fee, per year.
- (4) Remuneration for attending meetings (presentations) from businesses, organizations or groups, paid for the time and effort of the daily activity (lectures etc.) which is 500,000 yen or more from 1 organization or group per year.
- (5) Regarding manuscript fees paid for writing of pamphlets etc. by businesses, organizations and groups, 500,000 yen or more per business, organization or group, per year.
- (6) Regarding research funds for medical studies (trust research funds, joint research funds) provided by businesses, organizations and groups, an annual total of 2 million yen or more for 1 organization or group.
- (7) For scholarship funds granted by businesses, organizations and groups, an annual total of 2 million yen or more from 1 organization or group, to the individual disclosing COI or to the affiliated department of the individual disclosing COI (department, field) or to the head of the department.
- (8) If the individual disclosing COI is affiliated with the endowed department sponsored by the businesses, organizations and groups.
- (9) Concerning other travel expenses, gifts, or contributions unrelated to the research, an annual total of 50,000 yen or more by 1 business, organization or group.

However, concerning items 6 and 7, if clinical funding or scholarship funds related to the publication of research results are provided by a business, organization or group, to the first author, or his/her affiliated department or field, these must also be disclosed.

### Article 3 (Disclosure in the academic journal of the Society)

#### Item 1

All authors who will be publishing manuscripts (e.g. review articles, original research manuscripts) in the academic journal of the Society (Circulation Journal, other academic journals or publications) must disclose COI status within the preceding one year from the time of submission, using Form 2: Conflict of Interest Disclosure Statement of the “Disclosed Potential Conflict of Interest”, and submit the form to the secretariat in

advance, if there is a financial relationship with a business, organization or group specified in Article 1, Item 2 of the Regulations.

Item 2

This Disclosed Potential Conflict of Interest status mentioned in the previous item will appear at the end of the manuscript, before the Acknowledgment and Reference sections.

Item 3

If no such COI status exists as stated in Article 1 Item 2, the statement “No potential conflicts of interest are disclosed” will appear in the same space.

Item 4

COI self-disclosure must be clearly made at the time of article submission, in accordance with Article IV “Items that must be disclosed” of the Conflict of Interest Policy in Clinical Research. The criteria for self-disclosure items and amount in Article 2 of the Regulations must be followed.

Item 5

Publications in journals issued by the Society other than the Circulation Journal shall conform to the same Regulations.

Item 6

The “Disclosed Potential Conflict of Interest” form will not be disclosed to referees who review the manuscript.

Article 4 (Submission of COI Disclosure Statements by officers, chairpersons, and members of committees)

Item 1

Officers of the Society (presidents, directors), the congress chairperson of the next academic meeting, and local and chapter meetings, all committee chairpersons, committee members of the Scientific Organizing Committee, Editorial Committee, Educational Committee, Health Care Remuneration and Health Insurance Committee, Committee on Medical Safety, Committee on Medical Ethics, COI Committee,

Medical Ethics Committee, Scientific Program Committee, and other academic committees (local meeting members, all members related to the JCS Joint Working Groups for Guidelines), and employees of the Society must self-disclose their COI status within the preceding one year before appointment, using Form 3, at the time of appointment, and every year after appointment, to the Board of Directors. Disclosure is not necessary if a self-reported COI disclosure statement has already been submitted. However, COI disclosure is limited to those associated with businesses, organizations and groups which aim to derive profit, related to the activities of the Society.

#### Item 2

(1) Self-disclosure of COI status using Form 3 must follow Article IV “Items that must be disclosed” in the Conflict of Interest Policy in Clinical Research.

(2) Regarding disclosure items and the amount of money that should be notified in the self-disclosure, refer to Article 2 and fill out Form 3.

(3) COI status within the preceding one year before appointment should be disclosed using Form 3, and the total period of time having such status should also be stated. However, if any additional COI status occurs during the period of appointment, the officer shall be responsible for reporting the COI status within 8 weeks, using Form 3.

#### Article 5 (Handling of COI self-disclosure forms)

##### Item 1

COI self-disclosure forms submitted at the time of abstract for a conference presentation or at the time of manuscript submission to the journal of the Society, must be handled very carefully and securely managed by the secretariat, under the supervision of the president, for 3 years from the time of submission. Similarly, COI related documents of officers whose term has expired, or those who withdraw or terminate their commission must be kept secure and confidential by the secretariat under the supervision of the president for 3 years from the time of termination. COI related documents should be deleted or destroyed promptly after 3 years of storage, under the supervision of the president. However, if the Chairman of the Board of Directors decides that information should not be deleted or destroyed, a certain time period will be given, as necessary, to place a hold on such action.

#### Item 2

The Board of Directors and related officers of the Society, in accordance with the Regulations, will judge whether an individual is subject to COI regulations and to what extent based on the submitted COI self-disclosure form. In the event that measures need to be taken by the Society in regard to COI management, the Society will be able to access personal COI information of the member involved. However, access to this information should not be more than necessary, and information should not be disclosed to other members, or for any other purposes, other than those who are required to disclose such information.

#### Item 3

- (1) COI related information will not be disclosed, except in occasions specified in Article 5, Item 2. COI status may be disclosed or announced publicly, as necessary, if a member has a COI situation in which there is a need for the Society to take social and moral responsibility in relation to the activities of the Society, its committees (including activities of subcommittees), and ad hoc committees, after consultation at a board meeting.
- (2) Since the president specifically in charge of making the final decision for COI status disclosure or public announcement, after consultation with the COI committee, Committee on Medical Safety, Committee on Medical Ethics, the Society will not prevent this in any way. In such situations, the member involved will be given an opportunity to present their opinion to the Board of Directors or to the designated officer. However, in the case of an urgent situation leaving no time for consultation, then it will be noted as such.

#### Item 4

- (1) If disclosure of COI status of a certain member is requested (including legal requests) by a non-member, and if reason(s) for such a request seem appropriate, the COI Committee, upon request from the Chairman of the Board of Directors, will take appropriate actions after carefully considering the confidentiality of individual information and privacy of the member.
- (2) If the COI Committee decides that it is unable to respond to a situation, a discussion will be conducted by a COI Investigation Committee consisting of society members with at least one non-member, designated by the president. The COI Investigation Committee will meet within 30 days from the receipt of the request for COI disclosure and make a decision as quickly as possible.

#### Article 6 (COI Committee)

- (1) The COI Committee will consist of those members of the Society designated by the president and at least one non-member. The chairperson of the committee will be chosen from the board of directors. Members of the COI Committee must strictly ensure the confidentiality of all COI related information of the members.
- (2) The COI Committee, with the cooperation of the Board of Directors, Committee on Medical Ethics, and Committee on Medical Safety, make efforts so that COI management is conducted smoothly in accordance with the COI policy, to prevent serious situations regarding the COI status of its members.
- (3) The Board of Directors will take appropriate actions toward any violations against the COI Policy Regulations
- (4) Article 5 will be applied to COI disclosure and related information of committee members.

#### Article 7 (Handling those violating COI policy)

##### Item 1

- (1) If doubtful, or social or moral problem arises concerning COI self-disclosure of an author who intends to give a presentation at an academic conference of the society, local or chapter meetings, or publish in the official journal of the Society (Circulation Journal, other academic publications), the COI Committee, upon request by the president will conduct a thorough investigation and hearing, and will present the decision to the president
- (2) If there is a serious COI situation, the president based on the consultation with the board of directors, will take the necessary measures.

##### Item 2

If any problems arise regarding COI disclosure of officers, presidents of all committees, committee members who are subject to COI self-disclosure and potential candidates, prior to or after appointment, the president of the COI Committee will make a report in writing to the president who will take the appropriate measures.

### Article 8 (Making an Appeal)

Item 1: Making an appeal against decision on COI disclosure

In accordance with Article 7 Item 1 (1), if an appeal is made against the decision of the COI Committee, the committee, upon request of the president can conduct further investigation regarding the decision made.

### Article 9 (Changes in Regulations)

Regulations are expected to need partial modification to meet the revisions made to laws for social factors and industrial-academic cooperation. The COI Committee, may conduct a discussion on the revision of the regulations, and based on the decision of the Board of Directors, may modify the regulations.

## Appendix

### Article 1 (Effective Date)

These regulations will be implemented experimentally from August 5, 2012 (the day after the annual conference) and will become completely in effect from March 2014 (The 77<sup>th</sup> Academic Conference) thereafter.

### Article 2 (Modification of Regulations)

These regulations should, generally, be updated every few years, in order to be able to meet the revisions made to laws for social factors and industrial-academic cooperation, and various changes related to equipment, medicine, and clinical research.

### Article 3 (Special regulations applicable to officers of the Society)

Officers who are already appointed to their posts at the time of execution of these regulations, must promptly apply the regulations to the required reports.