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The Japanese Circulation Society

Bylaws Concerning Policy of Conflict of Interest in Medical Research

The Japanese Circulation Society (hereafter referred to as "the Society") was established in 1935. The purpose of the Society is to advance and improve research on cardiology and thereby to contribute to academic development by presenting and communicating scientific principles and applied research on cardiology, as well as exchanging knowledge and providing information.

The Society has developed the "Policy of Conflict of Interest (hereafter referred to as "COI") in Medical Research", in cooperation with 15 other societies related to internal medicine (The Japanese Society of Internal Medicine, The Japanese Society of Gastroenterology, The Japan Society of Hepatology, The Japan Endocrine Society, The Japan Diabetes Society, Japanese Society of Nephrology, The Japanese Respiratory Society, The Japanese Society of Hematology, Japanese Society of Neurology, Japanese Society of Allergology, Japan College of Rheumatology, The Japan Association for Infectious Diseases, The Japan Geriatrics Society, Japanese Society of Medical Oncology, Japan Gastroenterological Endoscopy Society).

For the fair management of COI involving the members, the "Bylaws concerning Policy of Conflict of Interest in Medical Research" shall be set forth as follows.

Article 1 (Declaration of COI matters at conferences of the Society)

Paragraph 1.

When a presenter, whether a member or non-member, gives a presentation or lecture on clinical research at a conference organized by the Society (Annual Scientific Meeting/Basic Research Forum), public lecture, or local scientific meeting organized by local branch of the Society, the primary presenter, and co-presenters, spouse, first-degree relative, or anyone with whom the presenter shares a living, shall self-declare on Form 1 the COI status in relation to that presentation, with respect to financial relationships with "companies, corporations, or for-profit organizations related to medical research" for the past 3 years at the time of abstract submission.

The primary presenter shall disclose the relevant COI status using Form 1-A at the beginning of presentation slides (or following the slide introducing the abstract, presenter, etc.) or using Form 1-B at the end of the poster. For company-sponsored or co-sponsored lecture meetings, etc., the chairperson should also disclose the COI status in the same manner as the presenter.

Paragraph 2

The term “companies, corporations or for-profit organizations related to medical research” as defined in the preceding paragraph shall mean companies, corporations or for-profit organizations related to medical research that have the following relationships with respect to medical research:

- (1) A company, corporation or for-profit organization that requests the medical research to be undertaken or collaborates in it (regardless of compensation received)
- (2) A company, corporation or for-profit organization that shares the rights to the medical research, including any patent rights in connection with treatments, drugs, or equipment evaluated in the study
- (3) A company, corporation or for-profit organization that provides drugs or equipment used in the medical study without charge or at a reduced price
- (4) A company, corporation or for-profit organization that provides financial support for or donates funding to the medical study
- (5) A company, corporation or for-profit organization that provides unapproved drugs or medical equipment for the medical study
- (6) A company, corporation or for-profit organization that endows a course or program.

Paragraph 3

“Medical research related to the presentation” refers to basic and/or clinical research conducted with the aim of improving disease prevention, diagnosis, and treatment methods and a better understanding of the disease etiology and conditions or enhancing the quality of life of patients and that are subject to an ethical review. Medical research in which the study subjects are human includes research that uses anthropogenically derived specimens and data that can identify a specific individual as defined in the Ethical Guidelines for Medical and Health Research Involving Human Subjects (published on December 22, 2014) published by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare.

Article 2 (Criteria for self-reported COI disclosure)

The subjects shall be the individual reporting person, the research institution to which the reporting person belongs, or the head of the research institution or department with which the reporting person has had a relationship as a joint or shared researcher in the past, or is currently in such a relationship. The COI of an individual reporter shall be reported according to the prescribed form (JSIM Form 3-A, B) when the amount exceeds the disclosure standard amount in the following items (1) to (9).

Regarding the amounts that require COI disclosure, criteria have been set for each item requiring disclosure as follows:

- (1) For directors and advisors of companies, corporations, or for-profit organizations related to medical research

(hereinafter referred to as "companies, corporations, or organizations"), the amount of remuneration from one company, organization, or for-profit organization is 1 million yen or more per year.

(2) For shareholdings, when the total annual profit (sum of dividends and profits from the sale of shares) from shares in one company is 1,000,000 yen or more, or when 5% or more of all such shares are owned by the company.

(3) For patent royalties from a company, corporation, or organization, when the annual royalty fee for a single right is 1,000,000 yen or more.

(4) For daily allowances (e.g., lecture fees) paid by a company, corporation, or organization for time and effort spent by the researcher in attending (presenting at) a conference, if the annual lecture fees from a single company, corporation, or organization total 500,000 yen or more.

(5) For manuscript fees paid by a company, corporation, or organization for writing pamphlets, etc., if the annual manuscript fees from a single company, corporation, or organization total 500,000 yen or more.

(6) For research expenses provided by a company, corporation, or organization, if the total amount paid by a single company, corporation, or organization for medical research (contracted research expenses, joint research expenses, etc.) is 1,000,000 yen or more per year.

(7) For scholarship (incentive) donations provided by a company, corporation, or organization, if the total amount paid from one company, corporation, or organization to an individual filer or a representative of the department (course, field) or laboratory to which the filer belongs is 1,000,000 yen or more per year.

(8) When the declarant and others are affiliated with an endowed chair provided by a company, corporation, or organization.

(9) For other donations such as travel or gifts that are not directly related to the research, if the total amount received from a single company, corporation, or organization is 50,000 yen or more per year.

Disclosure criterion (1), "Directors and advisors of companies, corporations, or for-profit organizations" refers to cases where a researcher belonging to a research institution assumes a directorship or advisory position at a specific company and receives remuneration for regular and continuous engagement under a contract. The provision of advice, etc. on a single occasion at the request of the counterparty company should be reported as disclosure criterion (4) "Compensation paid by a company, corporation, or organization for time and effort spent by the researcher in attending meetings (presentations, advice, etc.), including daily allowances (e.g., lecture fees).

In cases (6) and (7), it is necessary to report when research expenses, scholarship donations, etc. are provided to the individual presenter or moderator, or to the department (course, field) or laboratory to which the presenter or moderator belongs, from companies, corporations, or organizations with which there are COI relationships to be disclosed, related to the presentation of research results. In addition, it is clearly indicated that the standard amount for judgment concerning research expenses and donations provided by companies, is the amount of money for which the declarant can practically determine the use, and that the annual total

amount actually allocated by the head of the research institution is to be declared. The specific method of disclosure and publication of the contents of the report will follow the prescribed form.

As an institutional COI, when the disclosing party is currently or was in the past in a relationship of joint researcher or co-researcher with the research institute to which the disclosing party belongs or was the chief of the research institute or department of such institute (university, hospital, faculty, or center) and is deemed likely to have an influence on the Society activities in which the disclosing party is involved, the COI must be disclosed in accordance with the JSIM designated form (Form 3-C) for the following matters.

Regarding the amounts that require COI disclosure, criteria have been set for each item requiring disclosure as follows:

- (1) When the total contract-based funding (including funding for collaborative research, funded research, and clinical trials) for medical research, which the disclosing party may substantially decide on how to use, provided by one company, corporation, or organization is ten million yen or more per year.
- (2) When the total contributions provided by one company, corporation, or organization to a disclosing party, to the affiliate institute or department to which the disclosing party belongs, or to the chief of such an institute or department, which the disclosing party may substantially decide on how to use, is two million yen or more per year.
- (3) When the research institute or department to which the disclosing party belongs or the head thereof (in a joint researcher or coresearcher relationship within the past three years) owns shares (at least 5% of the total shares of a company) or patent royalties, or has investments in a venture company, include such as institutional COI.

Article 3 (COI Disclosure in official journals)

All authors who intend to publish manuscripts (such as reviews or original articles) in the official journals of the Society (Circulation Journal, Circulation Reports, scientific papers, and other publications), that have a financial relationship with "companies, corporations, or for-profit organizations" as defined in Article 1, Paragraph 2 of these Bylaws within the past three years from the time of submission in accordance with the "Conflicts of Interest (COIs)" stipulated in the Instructions to Authors, shall disclose the COI status or submit a "Form 2: Conflict of Interest Disclosure Statement" to the Society Office in advance.

For medical research conducted under contract with a company, the role and involvement of the funding source (corporate parties) in planning, protocol development, implementation, monitoring, auditing, data tabulation, statistical analysis, data interpretation, manuscript preparation, and review must be clearly described in the "Role of the funding source" or "Acknowledgements" section of the relevant paper.

In addition, from the perspective of authorship, the role and contribution of individual authors in the process from the planning of the research to the publication of the paper should be clearly stated as "Contributors".

The corresponding author is required to submit a COI status declaration form from all authors of the relevant paper together, and to take responsibility for the contents of the declaration form.

The "Disclosed Potential Conflict of Interest" will be listed at the end of the article, before Acknowledgments or References. If there is no prescribed COI status, a statement such as "The authors declare that there are no conflicts of interest." will be stated.

The COI status to be disclosed at the time of submission should be self-reported as stipulated in Article 2 (Criteria for self-reported COI disclosure) of these Bylaws. The same shall apply to publications other than the Circulation Journal and Circulation Reports. The "Disclosed Potential Conflict of Interest" reported by the corresponding author will not be disclosed to the reviewers of the paper. For the English-language journals Circulation Journal and Circulation Reports, the COI declaration should be included in the Instructions to Authors prepared in accordance with International Committee for Medical Journal Editors (ICMJE).

Article 4 (Publication of Items Notified by the Committee for Formulation of Clinical Practice Guidelines and Treatment Guidelines, etc.)

In the event that the chairperson and members of a committee involved in the formulation of guidelines and policies have financial relationships with "companies, corporations, or for-profit organizations" as stipulated in Article 1, Paragraph 2 of these Bylaws, they must submit a "COI self-disclosure form for officers, etc. (Form 3)" for the past 3 years at the time of taking office. The information must be disclosed in Tables 1 and 2 in the relevant clinical practice guideline. Committee members whose COI self-disclosure exceeds any of the threshold amounts shown in Table 3 may participate in deliberations but do not have the right to vote. However, if the president (or chairperson) determines that they are irreplaceable, they may have voting rights. Candidates for committee members who have a COI that substantially exceeds the standard amount must voluntarily decline to assume the position. If the company, organization, or for-profit organization is not related to the subject matter of the relevant guidelines, the COI Committee will determine whether the candidate can assume the position. The standard amount is in accordance with the "Guidance on Eligibility Criteria for Participation in the Formulation of Clinical Practice Guidelines" of the Japanese Association of Medical Sciences.

Table 1. Examples of COI disclosure statements by participants in clinical practice guideline formulation

COI disclosure of clinical practice guideline formulation committee participants

Participant (Affiliation, Title)	(1) Advisor	(2) Shareholdings /profits	(3) Patent royalties	(4) Lecturer fees	(5) Manuscript fees	(6) Research expenses	(7) Endowment	(8) Endowed chairs	(9) Others
Tokyo Hanako X Univ. Y Dept. Professor		A Pharm		B Pharm D Pharm	A Pharm	C Pharm	B Pharm E Pharm		
Tokyo Taro T Univ. U Dept. Associate Professor		A Pharm		B Pharm D Pharm	A Pharm H Pharm	C Pharm		G Pharm	

COI disclosure of clinical practice guideline formulation committee and systematic review team participants

Participant (Affiliation, Title)	(1) Advisor	(2) Shareholdings /profits	(3) Patent royalties	(4) Lecturer fee	(5) Manuscript fees	(6) Research expenses	(7) Endowment	(8) Endowed chairs	(9) Others
Osaka Umeko M Hosp. N Dept. Director				C Pharm D Pharm C Pharm	H Pharm E Pharm	B Pharm			
Osaka Jiro O Univ. P Dept. Professor				A Pharm A Pharm F Pharm	B Pharm C Pharm B Pharm	B Pharm	G Pharm H Pharm		

Guidance on Eligibility Criteria for Participation in the Formulation of Clinical Practice Guidelines of The Japanese Association of Medical Sciences 2017

Table 2. COI disclosures related to the formulation of clinical practice guidelines (examples)

1) Names of companies that provided funds (e.g., donations) in relation to the subcommittee's business activities
A Pharm. B Pharm. C Pharm. D Pharm. E Pharm. F Pharm.
2) Names of companies that provided funds in relation to the formulation of clinical practice guidelines
C Pharm. E Pharm. F Pharm.

Table 3. Standard amount of voting rights of participants in the formulation of clinical practice guidelines

Individual COI of Clinical Practice guideline participants			
4. Lecturer fees	5. Fees for writing brochures, etc.	6. Research expenses received from external sources	7. Scholarship endowment
2 million yen	2 million yen	20 million yen	10 million yen

Article 5 (Submission of COI reports by officers, chairpersons, committee chairs, committee members, etc.)

Paragraph 1.

Officers (directors and auditors) of the Society, presidents of academic meetings, presidents of local meetings hosted by chapters, president of BCVR, all chairpersons of various committees (including subcommittees and review committees), Ethics Committee, Medical Safety Subcommittee, Ethics Review Committee, Conflict of Interests Committee, Disciplinary Committee, Scientific Committee (including Guidelines Subcommittee and other subcommittees and review committees) , Editorial Committee, Scientific Session Steering Committee (including subcommittees and breakout sessions), Basic Cardiovascular Research (BCVR) Subcommittee, Health Insurance Committee, Postgraduate Education/Emergency and Critical Care Committee, members of the Postgraduate Education Subcommittee, and administrative staff of the Society must disclose the COI status for the past three years from the year prior to their appointment to the Board of Directors according to the prescribed Form 3 at the time of new appointment, and annually after appointment.

However, this shall not be required if a COI self-disclosure form has already been submitted. Also, the scope of the COI self-disclosure shall be limited to those related to private companies, corporate bodies, and organizations related to the business conducted by the Society.

Paragraph 2.

With regard to the COI status to be described in Form 3, self-reports should be made on the items specified in IV. of the " Bylaws Concerning Policy of Conflict of Interest in Medical Research " as to what should be reported. The amount required to be self-reported for each item to be disclosed and made public shall be the standard amount stipulated in Article 2, and the classification of the amount of money for each item shall be clearly

indicated according to Form 3. Form 3 should be filled in for the past three years at the time of assumption of office, and the period of calculation should be clearly indicated. However, in the event of the occurrence of a new COI situation during their term of office, officers, etc. shall be obliged to report it using Form 3 within 8 weeks.

Article 6 Handling of COI Self-Disclosure Form

Paragraph 1

COI self-disclosure forms submitted at abstract registration for presentations at academic conferences and at submission of articles for contribution to the official journals of the Society must be stored under lock and key in a corporate office and under the Director General's supervision for up to three years. Similarly, documents containing COI information on the officers and committee members who have completed their term of office and on individuals whose appointment as an officer or committee member has been rescinded must also be stored under lock and key in a corporate office and under the Director General's supervision for up to two years after the expiration of the final term of office or the date of rescission. After the passage of three years, the documents will promptly be deleted or disposed of under the Director General's supervision, provided, however, that if the Board of Directors recognizes that deletion or disposal of disclosed COI information on certain individuals would not be appropriate, the deletion or disposal of that information may be suspended for a necessary period to be determined by the Board of Directors.

Paragraph 2

In accordance with these Bylaws, the directors and related officers of the Society may use the COI information of the individual concerned at any time when determining the existence or non-existence and degree of COI status of the individual concerned based on the submitted self-report, and when taking management and measures in accordance with that determination by this association. However, it shall not exceed the limit necessary for the purpose of use, and shall not be disclosed to persons other than those to whom disclosure is necessary in light of the above-mentioned purpose of use.

Paragraph 3

With the exception of the provisions of Article 5, Paragraph 2, COI information will not, in principle, be made public. However, if disclosure of COI information is necessary for the Society to fulfill its social and ethical accountability in relation to the activities of the Society, its committees (including standing subcommittees affiliated with the committees), and its provisional committees, such information may be disclosed or made public within and outside the Society to the extent necessary following the deliberation of the Board of Directors. Notwithstanding the foregoing, the Society may ask a director who is dealing with the issue concerned to decide, with advice from the COI Committee and the Ethics Committee, on whether to make the information public. In the latter case, the individual to whom the COI information pertains may state his

or her opinions to the Board of Directors or the Director entrusted with the decision, except where the urgency of disclosing the information or making the information public precludes the possibility of listening to the opinions of the individual concerned.

Paragraph 4

If a request from a non-member is made for disclosure of COI information of a specified member (including statutory requests) on reasonable grounds, the Representative Director will refer the matter to the Committee on COI, which will appropriately deal with the matter, taking into consideration the principle of the protection of personal information. If it is recognized that the matter in question is beyond the Committee on COI's capacity to handle, a COI Investigation Committee shall be established and consulted, consisting of a few members and one or more external committee members appointed by the Representative Director. The COI investigation committee shall convene a meeting within 30 days of receipt of the request for disclosure and make its report as soon as possible.

Article 7 (Institutional COI Management for the Society)

It has been reported that in the process of conducting and publishing the results of medical research, especially clinical research involving human subjects, or in the process of formulating guidelines for medical treatment, if senior executives (representative directors, board members, etc.) are related to the researchers in question as mentors, colleagues, friends, relatives, etc., they may be directly or indirectly affected by institutional COI. For example, if an academic society or its senior executives receive a large endowment from a specific company, or if they hold shares or royalties in a specific company, it may be difficult to ensure fairness, objectivity, and independence in COI evaluations and ethical aspects of research results, publications, and the formulation of medical guidelines under such circumstances. The representative director of the Society should manage the total number and total amount of payments from companies, corporate organizations, and for-profit organizations to the association itself (including the holding of regional meetings) in units of fiscal years for (1) research grants, joint research, and commissioned projects, (2) donations, and (3) income from academic meetings (company-related seminars, symposiums, etc.). The total number and total amount of each of these must be managed centrally by each company and disclosed appropriately as institutional COI.

Article 8 (Committee on Conflict of Interest)

The COI Committee shall be composed of a few members of the Society and one or more external committee members appointed by the Representative Director, and a chairperson shall be elected by mutual election of the committee members. The COI Committee shall, in cooperation with the Board of Directors and the Ethics Committee, manage the COI situation of members to prevent it from developing into a serious situation and deal with any violations, as stipulated in the COI Policy and these Bylaws. The provisions of Article 5 shall apply with necessary modifications to the reporting of COI matters and the handling of COI information by the

Committee members.

Article 9 (Measures against violators)

Paragraph 1

If any doubt or social or ethical problem arises with regard to the self-reported COI disclosure statement submitted by authors who make presentations in the official journals of the Society (Circulation Journal, collection of scientific papers), etc., or by persons scheduled to make presentations at academic meetings of the Society, local academic meetings hosted by branches, etc., in order to achieve social accountability, the COI Committee will take appropriate measures after conducting thorough investigations and hearings. If there is a serious COI situation and accountability cannot be fulfilled, the Representative Director may consult with the Ethics Committee and, based on its report and after deliberation by the Board of Directors, take measures such as suspending the conference presentation or publication of a paper by the person scheduled to make such presentation. If a question or other problem arises after a publication has already been made, the facts will be investigated, and if there is a violation, measures such as withdrawal of the published paper will be taken, and if the nature of the violation seriously undermines the social credibility of the Society, measures will be taken against membership and so on, in accordance with the Constitution of the Society.

Paragraph 2

If it is pointed out that there is a problem with the self-disclosure COI report of a director, committee chairperson, committee member required to submit the report, or a candidate to any of the above offices, submitted before or after his or her appointment, the Chairperson of the Committee on Conflict of Interest will report the allegation to the Director General in writing. The Director General must promptly hold a meeting of the Board of Directors, and the Board of Directors must decide whether to confirm or reject the allegation. If the allegation is confirmed, the director or committee member concerned must resign from office. The Director General may rescind an appointment awarded to the candidate concerned as director or committee member.

Article 10 (objections)

Section 1: Filing an objection

The person who received notice of an action taken in response to a violation in relation to a presentation as part of the Society's activities (journal or conference) in accordance with Article 8.1, the director who will retire or the candidate for whom the appointment will be withdrawn in accordance with the provisions of Article 8.2 may file an objection concerning the action to be taken and request a review by submitting an objection and request for review to the Secretariat to the president within seven days from the receipt of the notice of the decision by the Board of Directors if they have an objection to the decision. The request for review shall include a brief and specific counterargument and opinion against the reason for

withdrawal indicated in writing by the chairperson. In that case, in addition to the information disclosed to the chairperson, related information that forms the basis of the reason for the objection may be presented in writing.

Section 2: Procedure for review of the objection

(1) Upon receipt of a petition of objection, the president shall promptly set up an Objection Review Committee (hereinafter referred to as the "Review Committee"). The Review Committee shall consist of a few directors appointed by the president, a few councilors and one or more external member. The chairperson of the Review Committee shall be elected by mutual vote of the Committee members. Members of the COI Committee may not serve as members of the Review Committee. The Review Committee shall meet to review the objection within 30 days of the receipt of the petition of objection.

(2) The Review Committee may consult with the chairperson of the Ethics Committee concerning the objection and undertake additional hearings with the person who filed the objection if necessary.

(3) The Review Committee shall complete a report regarding the objection and submit it to the president within one month of the first review meeting of the Review Committee unless there are special circumstances justifying a delay of the report.

(4) The decision of the Review Committee regarding the objection shall be final.

Article 11 (Education and Training on Research Ethics and Publication Ethics)

The President of the Society shall ensure that members and other relevant persons, including members of the Editorial Board, Ethics Committee, Conflict of Interest Committee, and members involved in the formulation of medical practice guidelines, have opportunities to receive continuing education and training in bioethics, research ethics, COI management, publication ethics, and related laws and regulations. For this purpose, candidates for Board Certified Physician and Board Certified Fellow shall be required to attend ethics education and training program as a condition for eligibility to apply for certification or renewal of certification.

Article 12 (Amendment of Bylaws)

It is assumed that social factors and future amendments of laws and regulations on university-industry partnership will necessitate partial revisions of these Bylaws. A COI committee will hold deliberations on the revision of the Bylaws and may revise the Bylaws following the resolution of the Board of Directors.

Supplementary Provisions

Article 1 (Effective Date)

The Bylaws shall be implemented experimentally from August 5, 2011 (the day after the end of the Annual Scientific Meeting), and shall be fully implemented from March 2013 (77th Annual Scientific Meeting).

The Bylaws, after partial revision, shall go into effect on December 3, 2021 (the day after the end of the 3rd

meeting of the Board of Directors in fiscal year 2021).

Article 2 (Amendment of Bylaws)

In principle, the Bylaws shall be reviewed generally every few years, in order to be able to adapt to social factors, amendment of laws related to university-industry partnership, and changes in conditions surrounding medical and clinical research.

Article 3 (Special rule applied to Society officers)

The Bylaws shall apply to reports by those who have already been appointed as officers in the Society at the time of execution of the Bylaws.