

Policy for Conflict of Interest in Epidemiological Research

1. Objective

Japan Epidemiological Association (hereafter referred to as the Association) establishes the “Policy for Conflict of Interest (COI)” (hereafter referred to as the Policy) in order to fulfill our social responsibility to promote Epidemiological research and in reaction to demands for high standard of research ethics. The Policy was designed to enable the Association to manage the members’ COI status so it may support publication, dissemination, and development of their research with impartiality and transparency. In this light, the Policy states our basic understanding of COI, and demands that members declare their COI appropriately when participating in various activities or publishing research with the Association.

2. Persons affected by the Policy

The Policy applies to all the persons listed below who may have COI.

- (1) Members of the Association
- (2) People who present at the Association’s Annual Meetings and other events
- (3) Authors submitting articles to the Association’s journals
- (4) Members in office (President, Executive Board members, Auditors, Organizer of Annual Meetings (President, etc.), Chair of Committees, Committee members, Provisional Working Groups (sub committees, working groups, etc.)
- (5) Staff members
- (6) Spouse, family members in the first degree, and/or people who share income or co-own property of those listed in (1) through (5)

3. Activities affected by the Policy

The Policy applies to all activities of the Association listed below.

- (1) Hosting Annual Meetings, seminars, or other events
- (2) Publication of journals and other academic publication
- (3) Performing research or surveys
- (4) Granting financial support or awards for research
- (5) Promotion of lifelong learning
- (6) Communication and cooperation with relating academic organizations
- (7) Promotion of international research collaboration

(8) Other projects for achievement of Association's objectives

4. What to declare

Individuals should declare (1) through (10) where they exceed the standards stated in the Bylaws. Disclosure or publication of the declaration is stated in the Bylaws.

- (1) Being employed as board member, advisor, or employee of for-profit corporate organizations
- (2) Possession of corporate bonds
- (3) Receiving patent fees from for-profit corporate organizations
- (4) Remuneration for participation or presentation at meetings of for-profit corporate organizations (includes lecture fees, etc.)
- (5) Remuneration for authoring comments on pamphlets or other publication by for-profit corporate organizations.
- (6) Research fund provided by for-profit corporate organizations (commissioned research, collaborative research etc.)
- (7) Donation provided by for-profit corporate organizations
- (8) Sponsored laboratories or departments by for-profit corporate organizations
- (9) Acceptance of personnel or loan of instruments from for-profit corporate organizations
- (10) Others (e.g. trips, travel, or gifts, which are not related to research) from for-profit corporate organizations

5. Situations to avoid in relation to COI

(1) Situations every person affected by the Policy should avoid

Publication of Epidemiological research results should be based on purely scientific evidence and decision or for the benefit of the public. Published results and their interpretation, manuals based on epidemiologic research, or proposals should not be influenced by the sponsor or corporate organizations' interests. Agreements with sponsors which prevent such impartial decision must be avoided.

(2) Situations representatives of Epidemiological research should avoid

Persons to be in position to make decisions regarding plans and execution of epidemiological research should be those who are evaluated as having no COI as noted below (or has less relations with commissioners) should be selected, and should maintain the status after selection.

- 1) Holding corporate bonds of organizations where epidemiological research is commissioned.
- 2) Acquisition of patent and patent fees through products or technology achieved

through epidemiological research

- 3) Board members and advisors (excluding unpaid scientific advisory) of for-profit organizations where epidemiological research is commissioned.

However, even when a person is affected with 1) through 3), if that person is irreplaceable for plans and execution of a certain research, and if the research has considerable importance in medical research, the person may be chosen as a representative, granted that his or her impartiality and transparency in decision and action can be secured.

6. Management of COI

(1) Responsibility of those affected

When presenting research at the Annual Meeting or other meetings, COI status must be disclosed in designated format according to the Bylaws. If the status is found to be in conflict with the Policy, the Board will decide on appropriate actions.

(2) Responsibility of the Members in Office

Members in Office (President, Executive Board Members, and Auditors), organizer of the Annual Meeting (President, etc.), chair persons and members of various committees, and staff bear important role and responsibility over all activities related to the Association. They must disclose their COI status according to the Bylaws upon assumption of office and annually thereafter.

(3) Role of the COI committee

The COI committee performs the duties below:

- 1) Answer queries and requests of persons with COI
- 2) Judgment, advisory, and guidance regarding COI status of those affected
- 3) Promoting awareness and training of research and publishing ethics, and COI management in industry-academia collaboration and activities related to planning and marketing thereof
- 4) Investigation and communication with research institutions where there are doubts in COI declaration and matters related to counsel
- 5) Review and revision of the Policy and the Bylaws

(4) Role of the Executive Board

The Executive Board will decide on appropriate actions where members of the office are found to have significant COI which interferes with the execution of the Association's activities.

(5) Role of the Organizer of Annual Meetings

Organizer of Annual Meetings (President, etc.) shall examine the research to be presented at the

meetings to ensure that they follow the Policy and to suspend those that are not in accordance with the Policy or devise other actions. The presenter must be contacted immediately with explanation of the decision when they are suspended. The organizer may inquire the Executive Board in such cases and instruct on appropriate measures according to the reply.

(6) Role of the Editorial Board

The Editorial Board shall ensure that research published in Association's journal(s) or other published material as original articles, review, editorial, or opinions are in accordance with the Policy, and withhold publication of material that do not follow the Policy or devise other action. In such cases, the relevant authors must be contacted immediately with explanation of the decision. If violation of the Policy is found after publication, the fact may be published in the relevant media in the name of the Editor in Chief. The Editor in Chief may inquire the Executive Board regarding the appropriate actions and instruct on actions according to the reply.

(7) Other

Other committee members shall ensure that relevant activities of the Association are held in accordance with the Policy and promptly plan to improve the situation when there are discrepancies. The Executive Board may instruct on improvement plans or other relevant actions.

7. Actions against violation of the Policy and accountability

(1) Actions against violation of the Policy

The Association's Executive Board may deliberate act of violation of the Policy according to the Bylaws, and if the violation is deemed significant, the Board may decide on all or some of the actions listed below.

- 1) Prohibition of presentation at Annual Meetings or any other seminars held by the Association
- 2) Prohibition of publication in the Association's journal or published material
- 3) Prohibition to become President of the Annual Meeting
- 4) Dismissal from or prohibition to assume membership of the Executive Board or committees of the Association
- 5) Dismissal from or prohibition to assume role of Auditor
- 6) Suspension or dismissal of membership or prohibition to become a member of the Association

(2) Expression of objection

Persons who have been judged as violating the Policy may express their objection against the

Association. The President shall promptly examine the objection according to the Bylaws and communicate the result to the relevant person.

(3) Accountability

Where a significant violation of the Policy is found in Epidemiological research published in relation to the Association, the Association has a responsibility to promptly discuss the matter within the Executive Board and to give an explanation to the public.

8. Training and Education on Research and Publishing Ethics

The President of the Association must ensure that members, editorial board members, ethics committee, and committees relating to COI management have the opportunity to receive continuous training on bioethics and research and publishing ethics.

9. Enactment of the Bylaws

The Association enacts Bylaws necessary for the execution of the Policy.

10. Revision of the Policy

The Policy may be revised according to changes in laws regarding industry-academia collaboration and the social situation surrounding research.

11. Date of Enforcement

The Policy is enforced starting November 7, 2014.

Annex

The Policy is enforced starting June 10, 2019.

Japan Epidemiological Association’s Bylaws for “The Policy for Conflict of Interest in Epidemiological Research”

Article 1 (Declaration of COI for Annual Meetings and other events)

Clause 1

Upon presentation of epidemiological research at Annual Meetings or other events held by the Association, whether member or non-member, all first presenters must, on behalf of all co-presenters, declare COI (i.e. financial relationship with “for-profit corporate organizations relating to the relevant epidemiological research” for the past 3 years at the time of registration of abstracts. All presenters must declare their COI status on the first presentation slide (or immediately after the title and presenters), or at the end of the poster according to [declaration format 1].

Clause 2

“For-profit corporate organizations relating to the relevant epidemiological research” shall include organizations or groups which relate to the epidemiological research in such ways as listed below.

- (1) Commissioning research or having collaborated research (whether paid or unpaid)
- (2) Co-owning patent or rights over therapy method, medicine, or instruments evaluated in the epidemiological research
- (3) Provision of medicine or instruments used in the epidemiological research for free or for especially good offer
- (4) Provision of funding or donation for the epidemiological research
- (5) Provision of medicine or medical instruments unapproved by epidemiological research
- (6) Sponsoring laboratories or departments

Article 2 (Standard of COI declaration)

COI declaration is required for items exceeding the standards listed below.

- (1) Posts such as board member, advisor or employee at for-profit organizations relating to epidemiological studies (hereafter referred to as organizations or groups) should be declared when remuneration from a single organization or group exceeds 1 million yen per year.
- (2) Possession of corporate bonds should be declared when profit (sum of dividend and selling profit) exceeds 1 million yen per year, or when more than 5% of the total bonds are held.

- (3) Patent fees from organizations or groups should be declared if fees exceed 1 million yen per year, for a single patent.
- (4) Remuneration for attendance at meetings (presentation or lectures) should be declared if the amount exceeds 500,000 yen per year from a single organization or group.
- (5) Remuneration for authoring comments on pamphlets or other publication should be declared if the amount exceeds 500,000 yen per year from a single organization or group.
- (6) Funding provided by organizations or groups should be declared if the total received amount exceeds 1 million yen per year from a single organization or group, of which the declarant is in a position to actually decide its usage.
- (7) Subsidy or donation from organizations or groups should be declared if the received amount exceeds 1 million yen per year from a single organization or group, of which the declarant is in a position to actually decide its usage.
- (8) Affiliation with a laboratory funded by organizations or groups must be declared.
- (9) Acceptance of personnel or loan of instruments from organizations or groups (worth more than 2 million yen) must be declared.
- (10) Others (e.g. trips, travel, or gifts, which are not related to research) must be declared if the total amount exceeds 50,000 yen per year from a single organization or group.

If organizations or groups with COI provided funding or donation for the first presenter as an individual or for the affiliated department (course or area) or the laboratory in relation to the research to be presented, this fact should be declared in addition to (6) and (7). Rules for articles submitted to the society journal is separately specified in Article 3, clause 2.

Article 3 (Publication of declared items in Association's journals and other published material)

Clause 1

All authors publishing research (reviews, original articles, etc.) in the Association's publications (Journal of Epidemiology, Collection of research articles, and other publication) must declare COI, in the format designated by the Association, if they have COI for the past 3

years as defined in Article 1 Clause 2 of the Bylaws. The form can be found in the instructions to authors and must be submitted to the Editorial Office in advance.

Clause 2

A declaration of COI at the time of submission to Journal of Epidemiology must be submitted to the Editorial Office according to the definition of COI in number 4 of “Policy for Conflict of Interest in Epidemiological Research” and using the ICMJE Form for Disclosure of Potential Conflicts of Interest (as published in the instructions to authors). Journal of Epidemiology will publish relevant items to be published according to the style advised by the International Committee of Medical Journal Editors (ICMJE).

Clause 3

“The Disclosure of Potential Conflicts of Interest” will not in principle be disclosed to the reviewers.

Clause 4

The contents of the “Disclosure of Potential Conflicts of Interest” will be published at the end of the article, before Acknowledgements or References.

Clause 5

If the research published in Journal of Epidemiology does not have any COI as defined in Article 1 Clause 2, the published article will contain the line “Conflict of Interest: None declared” in the same position as described in the previous clause.

Article 4 (Submission of COI declaration form for Executive Board members, Committee chair and members)

Clause 1

The Association’s members in office (President, Executive Board members, and Auditors), organizer of the Annual Meeting (President, etc.), chair and members of various committees, members of working groups, and staff must submit to the President their COI for the past 3 years including those of spouse, first degree family members, and those who share a household at the time of assumption of the role, and annually thereafter according to the designated format (COI Declaration Format 2). If the declaration has already been submitted, resubmission is not necessary. Only COIs with for-profit corporate organizations or groups that are related to the Association’s activities need to be declared.

Clause 2

- (1) The declaration form must be in accordance with items defined in number 4 in the Conflict of Interest Policy in Epidemiological Research.
- (2) Standard amount for each item to be declared are stated in Article 2, and the amount range should be clarified for each item.
- (3) The form should include total amounts for 3 years prior to the assumption of the post, and the term it covers should be clearly stated. If the affected individual encounters a new COI while in post, they are required to report them within 2 months in the same format.

Article 5 (Handling of COI declaration)

Clause 1

COI declaration forms submitted upon registration of abstracts or submission of journal articles must be kept safely in the Association's office under supervision of the President for 5 years from the day of its submission. Similarly, COI forms for Board members or Committee members who expired from office should be kept safely in the Association's office under supervision of the President for 5 years after the expiration date. Forms which have been held for 5 years shall be removed and discarded promptly under the supervision of the President. However, if the President deems it inappropriate to discard, he or she may decide on the necessary period of time to withhold the COI information.

Clause 2

The Association's Executive Board members, related members in official posts and staff may judge the existence of COI and its severity and use the COI information collected through COI declaration forms when taking appropriate actions. However, use of information must be limited to requirements of their roles, and must not be disclosed to persons other than those who need the information.

Clause 3

COI information other than cases stated in Article 5 Clause 2 is in principle public. COI information will be disclosed or published within and without the Association when it is deemed necessary in order to fulfil the Association's social and moral accountability regarding the Association's and committees' activities (including activities of subcommittees affiliated with the Association and provisional committees).

Clause 4

If a COI of a particular member is required to be disclosed (including legal request) with

substantive reason, the President will inquire with the COI committee which will reply appropriately with consideration for privacy. If the matter cannot be handled by the COI committee, the President will inquire by nominating several members from the Association and one external member to organize a COI investigation Committee. COI committee must hold a meeting within 30 days of receipt of the disclosure request and reply promptly.

Article 6 (COI committee)

The President will nominate several members of the Association and one external member to form a COI committee and the President will nominate the chair person. The COI committee will hold confidentiality obligation for the COI information acquired through the committee. The committee works to prevent COI status from becoming a serious situation and handles violation of the Policy in coordination with the Executive Board. COI declaration of the committee members and information handling will conform to Article 5.

Article 7 (Actions against violators)

Clause 1

If doubts or social and/or moral problem arise regarding COI declaration by authors of Association's journals (Journal of Epidemiology, Collection of research articles) or presenters at the Association's Annual Meetings, COI Committee will in order to fulfil the Association's social responsibility for clarification, conduct thorough investigation and interviews and report its judgment to the President. If the report judges that there is serious COI, the President will add it to the agenda for the Executive Board to discuss and decide.

Clause 2

If problems are identified in COI declaration by Board members and Committee chair or members candidates of such positions upon or after assumption of office, the COI Committee will report to the President, and the President or the Executive Board will decide on actions.

Article 8 (Expression of Objection)

Clause 1: Expression of objection regarding judgment on COI

If individuals have objections regarding the judgment made in accordance to Article 6 Clause 1(1), the person may request investigation if s/he submits an expression of objection and request for investigation within 7 days of receipt of the result. The request for investigation should include a concise and concrete argument against the measures stated in writing by the Chair of the Committee. S/he may submit documents as evidence to his or her argument in addition to information disclosed to the Chair of the Committee.

Clause 2: Procedures for investigation upon expression of objection

- (1) If an expression of objection and request for investigation is received, the President must immediately launch an “Investigation Committee in reply to expression of objection (hereafter referred to as Provisional Investigation Committee).” The Provisional Investigation Committee shall consist of several Association members nominated by the President and one external member. The chairperson will be elected by mutual vote. COI Committee members may not act as members of the Provisional Investigation Committee. The Provisional Investigation Committee must as soon as possible hold a meeting and investigate upon receipt of the objection.
- (2) If necessary, the Provisional Investigation Committee may interview the chairperson of the COI Committee and the person submitting the objection.
- (3) The Provisional Investigation Committee shall prepare and submit a reply to the President within one month after the first meeting unless there are special conditions.
- (4) The Provisional Investigation Committee’s judgment shall be the final judgment.

Article 9 (Revision of the Bylaws)

These Bylaws are assumed to require partial revision in response to individual revisions of laws relating to industry-academia collaboration and social changes surrounding the research environment. The Executive Board may discuss and review the Bylaws and make revisions after approval by the Executive Board meeting.

Supplementary rules

Article 1 (Date of Enforcement)

These Bylaws shall be enforced starting November 7, 2014.

These Bylaws shall be enforced starting June 10, 2019.

Article 2 (Revision of the Bylaws)

The Bylaws shall be in principle reviewed every several years in order to conform to changes in laws relating to industry-academia collaboration and the social changes surrounding the research environment.

Article 3 (Special rules for application to persons in office)

Those already in official posts of the Association at the time of enforcement of the Bylaws shall

be required to submit reports as required in the Bylaws.