

Hiroshima Journal of Medical Sciences Guidelines on Conflict of Interest (COI)

The following guidelines have been stipulated as set out below to present to the contributor the basic concepts of conflict of interest (hereafter COI) of the Hiroshima Journal of Medical Sciences, and to ensure that the status of COI is disclosed through appropriate self-reporting when publishing research papers. Contributors are required to comply with these guidelines.

(Declaration of COI for publication of research papers)

Contributors must self-report whether there has been any COI in the past three years concerning a financial relationship with 'corporations, corporate organisations, and for-profit organisations related to medical research' regarding publication of this manuscript.

2. ('Corporations, corporate organisations, and for-profit organisations related to medical research' are corporations, corporate organisations, and for-profit organisations with the following relationships.)

- ① Relationship of requesting or jointly implementing medical research (paid or unpaid)
- ② Relationship with shared rights including patent rights relating to the medical therapy, pharmaceutical(s), and/or medical device(s) evaluated in the medical research
- ③ Relationship of supplying the pharmaceutical(s) or equipment used in the medical research free of charge or at a particularly beneficial price
- ④ Relationship of research grants or donations for the medical research
- ⑤ Relationship of supplying unapproved pharmaceutical(s) or medical device(s) for the medical research
- ⑥ Relationship of fund provider such as an endowed department

3. (Definition of medical research)

Medical research related to the publication of research papers is basic and clinical research implemented to improve methods for the prevention, diagnosis, and treatment of disease in medical treatment, to understand the cause and pathology of diseases, and to improve patients' quality of life. It refers to research involving human subjects. Medical research involving human subjects includes research on samples derived from humans and on data that enable identifying a specific individual. Decisions on whether samples or data are applicable to samples or data that enable identifying a specific individual are based on the 'Ethical Guidelines on Clinical Research' issued by the Ministry of Health, Labour and Welfare (<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/>).

4. (Standards for COI self-reporting)

Amounts of money that require self-reported COI are as follows. Criteria are set for each item that should be disclosed.

	Items that should be disclosed	Declaration criteria
1	Executive or advisory role in corporations and for-profit organisations, and remuneration	Annual remuneration of 1,000,000 yen or more from one corporation/organisation
2	Shareholder and profits obtained from those shares (annual profit from shares)	Annual profit of 1,000,000 yen or more from the shares of one corporation or shareholder of 5% or more of total shares of one corporation
3	Remuneration paid as patent royalties from corporations or for-profit organisations	Annual income of 1,000,000 yen or more from one patent royalty/licensing fee
4	Remuneration paid by corporations or for-profit organisations as a daily allowance or lecture fees for the time and effort of the researcher for attending conferences (presentation, advice, etc.)	A total annual remuneration of 500,000 yen or more from one corporation/organisation for lecture fees
5	Manuscript fees paid by corporations or for-profit organisations to the author of pamphlets, etc.	A total annual remuneration of 500,000 yen or more from one corporation/organisation for manuscript fees
6	Contract-based research funding supplied by corporations or for-profit organisations	Actual annual allocation of 1,000,000 yen or more from one corporation/organisation in contract research funding for medical research (joint research, consignment research, clinical trials, etc.), where the person filing the declaration can substantially decide how the funding is used
7	Subsidies or donations from corporations or for-profit organisations	Actual allocation of 1,000,000 yen or more from one corporation/organisation as a donation to the individual person filing the declaration or the course or field of research to which that person belongs, where the person can substantially decide how the donation is used

8	Endowed departments by corporations	Actual allocation of 1,000,000 yen or more where the person filing the declaration can substantially decide how the donation is used
9	Other remuneration (Travel, gifts, etc. not directly related to research)	Annual payment of 50,000 yen or more from one corporation/organisation

5. (Handling of self-reported statement of COI)

When the contributor has no stipulated COI, they are to state the following on the COI Disclosure Statement form: 'None of the authors have a COI relationship with a corporation, etc. that should be declared'. That document is not disclosed to the peer reviewers.

The COI Disclosure Statement form must be carefully kept by the editorial department under the management of the Editor-in-Chief for three years after submission. After three years, the COI Disclosure Statement form is to be deleted or disposed of under the management of the Editor-in-Chief. However, when deletion or disposal is found to be inappropriate by the Editor-in-Chief/Editorial Committee, deletion or disposal of the contributor's COI information may be deferred for a set period.

The editorial department will determine whether the contributor has a COI and its extent thereof based on the submitted Disclosure Statement form, and the contributor's COI information can be used as needed. The limit required for the purpose of use shall not be exceeded, and in light of the above purpose of use, the information shall not be disclosed to persons other than those who require disclosure. COI information is in principle not disclosed.

When the Editor-in-Chief/Editorial Committee requires the COI information for social or moral accountability, the information may be disclosed or published internally or externally within the required scope through consultation between the Editorial Committee/Steering Committee.

When an external request for disclosure (including legal requests) naming the contributors is made, it may be appropriately handled if there is a valid reason for requesting disclosure after reporting the request to the Editor-in-Chief and summoning the Editorial Committee if needed, providing that personal information is protected. Requests for disclosure require as prompt a response as possible, usually within 30 days of the request (or within a corresponding timeframe if response within 30 days is impossible).

6. (Measures for persons who violate these guidelines)

If the contributor's manuscript has a serious COI, and accountability has not been fulfilled, appropriate measures may be taken, including halting publication of the submitted manuscript. If an issue arises after the article has been published, appropriate measures will be taken to promptly retract the paper, and if the contents of the violation significantly impair the social credibility of the publisher, the following measures will be taken against the contributor. The person who violated the guidelines will be notified that the measures will be implemented, and the measures will be implemented after it has been confirmed that no appeals have been filed.

- 1) Prohibition of paper submission to the Hiroshima Journal of Medical Sciences (this applies to the first author without exception and may also include the co-authors)
- 2) Withdrawal of previous paper submissions published by the Hiroshima Journal of Medical Sciences (papers by the first author)
- 3) Withdrawal of publication of the article in violation of the guidelines

7. (Appeal)

Contributors who are notified of the decision that measures will be taken against violation regarding the publication of an article in the Hiroshima Journal of Medical Sciences may submit an appeal in writing to the editorial department within ten days of receiving the notice of decision (from the date of arrival of registered mail). Contributors are to concisely state specific objections and counter opinions to the measures against violation. Any information that provides grounds for the specific objections may be submitted as an attachment. The editorial department will summon the editorial committee members under the Editor-in-Chief, convene an Editorial Committee meeting, and review the content of the appeal documents within 60 days after submission of the appeal documents. The opinion of the person submitting the appeal may be heard during the review, but this shall not be the case if the person submitting the appeal does not attend the hearing.

The content of the decision will be reported to the Steering Committee within 40 days of holding the Editorial Committee meeting. The results of no objection in the report by the Steering Committee shall be determined as the final result.

Hiroshima Journal of Medical Sciences: Self-reported Conflict of Interest (COI) Disclosure Statement

Author's name: _____

Manuscript title: _____

(All authors are required to disclose any COI within the period of three years prior to the submission of any manuscript in the subject matter of which any company, entity, or organisation has an interest)

Area	Yes or No	If Yes, list the name(s) of author(s) and corporation(s)
① Remuneration 1,000,000 yen or more annually from one corporation/organisation	Yes or No	
② Profits from shares Profit of 1,000,000 yen or more annually from the shares of one company or ownership of 5% or more of the total shares of one company	Yes or No	
③ Patent royalties/licensing fees 1,000,000 yen or more per one royalty/licensing fee annually	Yes or No	
④ Honoraria (e.g. lecture fees) Total of 1,000,000 yen or more annually from one corporation/organisation	Yes or No	
⑤ Manuscript fees 1,000,000 yen or more annually from one corporation/organisation	Yes or No	
⑥ Research funding Total of 2,000,000 yen or more annual payment to departments (department, field, or laboratory) that share research expenses from the same corporation/organisation	Yes or No	
⑦ Subsidies or Donations Total of 2,000,000 yen or more annual payment to departments (department, field, or laboratory) that share subsidies or donations from the same corporation/organisation	Yes or No	
⑧ Endowed departments by corporations (If any of the authors belong to an endowed department sponsored by any corporation entity)	Yes or No	
⑨ Travel fees, gifts not directly related to research, training, education, and treatment 50,000 yen or more annually from one corporation/organisation	Yes or No	

(This COI declaration statement form will be kept for ten years after publication of the manuscript)

(Date of Declaration) YYYY MM DD

Corresponding author's signature: _____

(Seal)