The Physiological Society of Japan Bylaws Concerning the Conflict of Interest Policy for Collaborative Medical Research between Academia and Industry

To support further advances in medical technology, collaboration between academia and industry in medical research has become increasingly common. Universities, national institutes, and scientific societies, including the Physiological Society of Japan (hereafter referred to as the Society), feel increasingly compelled to become involved in collaborative activities with certain industries. As academia becomes more deeply involved in profit-related activities with for-profit organizations, individual researchers will inevitably develop conflicts of interests (COIs), and academia must make greater efforts to honor social responsibilities regarding education and research. Each potential COI must be appropriately managed by academia and by our Society and other medical societies, so that members of our Society are able to perform education and research in a transparent and ethical manner. Accordingly, the Society has established a COI policy and Bylaws to manage COIs, based on the guidelines of the Japanese Association of Medical Sciences.

Article 1. Self-reports on COI disclosure

The persons and their activities and status that require COI disclosure are described in Section II of the principal COI Guidelines of the Society. Such COIs must be disclosed through the self-reports of the persons involved.

Article 2. Submission of COI disclosure statement by officers, chairpersons, and committee members of the Society

1. Among the persons described in Article 1, those requiring special COI management by the Society include: (1) the Officers of the Society (president, directors, auditors), (2) chairpersons of current and upcoming academic conferences, (3) chairpersons of committees, (4) members of the COI committee, (5) members of the Editorial Board of the Journal of Physiological Sciences, and (6) members of the Publications and Public Relations committee.
2. Before assuming their position the above persons should submit a COI disclosure statement to the Society office about their COI status during the previous 12 months.

3. If persons’ COI status has changed after they assumed their position, they should self-report their new COI status in Japanese using Form 1.

**Article 3. Disclosure on submission to official journals of the Society**

All authors who intend to publish manuscripts (e.g., review articles and original research manuscripts) in the official journal of the Society (*Nihon Seirigaku Zasshi*) must report, in advance, to the secretariat of the Society using Form 2 (The Physiological Society COI Disclosure Statement) any financial relationship with commercial entities specified in Article 1, Section 2, of the Bylaws, regarding the subjects or materials discussed in the paper, within the previous 12 months. This disclosure will appear at the end of the manuscript, before the Acknowledgement and References. If there is no such relationship, the statement “No potential conflicts of interest are disclosed” will appear in the same position. The COI status must be clearly disclosed at the time of article submission, according to Article IV (“Matters to be disclosed”) of the Conflict of Interest Policy in Medical Research. The criteria are governed by Article 2. Publication in the journal issued by the Society shall conform to the above rules. The COI policy of the *Journal of Physiological Sciences* is described on its Website.

**Article 4. Disclosure of COI in conferences of the Society**

1. If a member or nonmember of the Society plans to give a lecture or presentation on his/her medical research at a conference organized by the Society (including annual meetings, local meetings, and other events), all authors are required to report any financial relationship with any commercial entities or for-profit organizations related to the medical research within the previous 12 months, using Form 1, at the time of abstract submission. The conference office will announce how the COI status should be submitted to the conference office.

2. The presenting author should disclose and self-report applicable COI using Form 3 at the beginning of presentation (on a slide immediately following the slide showing the presentation’s title and the authors’ names) or on the poster. The Society will not keep the presentation slides.
Article 5. Handling of the self-reported COI disclosure statement

1. If necessary, the Self-reported COI Disclosure Statements, submitted under Articles 2 to 4, shall be reviewed by the COI committee as soon as possible. The statements under Articles 2 to 4 will be kept confidentially at incorporated offices under the supervision of the president for 2 years from the submission.

2. The COI committee reports its review on the COI status to the president of the Society. If the COI committee judges that the disclosure contains serious problems, they may make recommendations to solve the problem.

Article 6. Disciplinary actions to be taken in case of violation

If questions or social or ethical problems arise in relation to a self-reported COI disclosure statement submitted by authors, the COI committee will perform a thorough investigation, including interviews of the authors. If a serious violation of the COI policy is confirmed, the Ethics Committee will recommend the Officers of the Society to take measures, such as forbidding such presentations or publications, after discussion with the Board of Directors, based on the recommendation of the committee(s).

Article 7. Objections to the disciplinary actions

1. Those who are judged to have violated the COI policies of the Society may request that the decision be reconsidered. When the president receives such a request, the president will form an investigation committee.

2. The investigation committee shall consist of members of the Society designated by the president. The members of the investigation committee exclude those of the COI Committee. The chairperson of the investigation committee shall be chosen by the members of the committee. The investigation committee shall hold a meeting and discuss the matter within 30 days from the receipt of the reconsideration request.

3. The Investigation Committee shall submit a report regarding the reconsideration to the president within 1 month from the first meeting, except for special occasions.

Article 8. Criteria for self-reported COI disclosure

All COIs must be reported if the amount exceeds the levels specified below.
1) Employment or administrative position, or advisory role in business enterprises, 
for-profit corporate organizations, or commercial entities that are related to 
medical research (hereafter referred to as “Commercial Entity”), if compensation 
from a single Commercial Entity exceeds one million yen or its equivalent amount per year.

2) Stock ownership or options, if profit (total of dividend and gain on sales) of at least one million yen or its equivalent amount from stocks of one Commercial Entity per year, or ownership of 5% or more of total shares

3) Patent royalties from the Commercial Entity, if the royalty fee exceeds one million yen or its equivalent amount per year

4) Honoraria (e.g., lecture fees) paid from one Commercial Entity, for the time or labor or both of an investigator who attended or made presentations at meetings, if exceeding 500,000 yen or its equivalent amount per year.

5) Manuscript fees for promotional materials (e.g., brochures) paid by one Commercial Entity, if exceeding 500,000 yen or its equivalent amount per year.

6) Research funds paid for medical research (e.g., funded research, collaborative research) paid by one commercial entity, if exceeding two million yen or its equivalent amount per year.

7) Subsidy or donation to the head of a department to which the individual belongs received from one Commercial Entity, if exceeding two million yen or its equivalent amount per year.

8) Endowed departments provided by a Commercial Entity, if the recipient participates in such a department.

9) Others benefits, including trips, travel, or gifts, that are not directly related to research, provided by one Commercial Entity, if exceeding 50,000 yen or its equivalent amount per year. Items 6 and 7 shall be reported, only if funds are provided by a Commercial Entity to a presenting author, or department to which the presenting author belongs, regarding the presentation of research activities benefitting from such funding at academic meetings.

Article 9. Cooperative actions between the COI committee and other committees
To carry out these guidelines, the COI committee will make coordinated actions with other committees of the Society and the Society office.

**Article 10. Modification to the Bylaws**

The Bylaws are expected to be reviewed regularly and modified as necessary to adapt to social conditions and changes in laws related to industrial-academic collaboration. Modifications of the Bylaws will be approved by the Administrative Committee and the Board of Directors.

**Supplementary Provisions**

*Article 1. Effective date*

The Bylaws will be implemented experimentally from April 1, 2013.

*Article 2. Periodical Reviews on the Bylaws*

The first 2 years are regarded as a trial period, after which the Bylaws will be implemented officially. After the trial period, the Bylaws shall be reviewed generally every 2 years.

*Article 3. Special rule applied to the Officers of the Society*

The Bylaws shall apply to reports by those who hold official posts in the Society at the time of execution of the Bylaws.