**The Principal Guidelines Concerning Conflict of Interest in Medical Research of the Physiological Society of Japan**

**Introduction**

Japan has pursued a national strategy of strengthening collaborative medical research between academia and industry with the aim of establishing a national basis of creative science and technology. The Science and Technology Basic Law was enacted in 1995 and was followed by the Science and Technology Plan in 1996. Medicine has made remarkable advances from the late 20th century through the 21st century. Medical research has shifted its focus from individual bodies to organs, cells, and molecules and has progressed further to examine the relationship between genetic abnormalities and diseases and to the development of regenerative medicine. The results of this research are being used to clarify unexplained pathological conditions, to develop new drugs, and to establish prophylactic and therapeutic approaches based on entirely new concepts. For Japanese citizens to enjoy safe, secure, and comfortable lives, we must return the achievements of medical research to society and to patients and be aware of the importance of revitalizing education, research, and the economy.

Medical research results presented at academic conferences organized under the auspices of the Physiological Society of Japan (hereafter referred to as “the Society”) or appearing in the Society’s publications come from a variety of studies supporting the development of prophylactic, diagnostic, and therapeutic approaches to various diseases using newly developed drugs, medical equipment, and technologies. Collaboration between academia and industry, including pharmaceutical companies and venture organizations (such as collaborative research, funded research, technology transfer and training, scholarship, contributions, and endowed departments) serves as a major basic mechanism for promoting these endeavors.

As public organizations, such as universities, research institutions, and academic societies, collaborate more closely with industry, they become ever more deeply involved with the activities of commercial entities. Therefore, the responsibilities of academic institutions and societies engaged in education and research inevitably come into conflict with the interests of individuals involved in industrial-academic collaboration. Therefore, to appropriately promote collaborative activities between industry and academia, this conflict of interest (COI) must be properly managed by academic institutions and societies. As the COI with commercial entities, which provide financial or material support, becomes greater, the likelihood increases that the rights of human research subjects will be violated, that their safety will be endangered, and that research methods, data analysis, and interpretation of results will be biased. Another possibility is that research will be unfairly judged or go unpublished, despite its results being accurate. Previous cases of industrial-academic collaboration suggest, however, that the problem lies in the management of COI, not in COI itself. Therefore, to properly promote medical research through industrial-academic collaboration; to maintain social trust, the integrity of medical research, and the transparency of presentations at academic societies; and to return the benefits of medical research to society; many medical institutions and academic societies, both inside and outside Japan, have recently been developing appropriate policies for managing COI in medical research.

The Society is also committed to properly managing COI issues involving our members by ensuring the disclosure of financial relationships with sponsors that may affect the subject matter or materials discussed in research presented at our conferences or appearing in our publications, under certain conditions, to fulfill our responsibility t o the public, and develop a COI policy that will benefit the Society.

**I. Objectives**

Regarding ethical principles for medical research involving human subjects, as stated in the “Declaration of Helsinki” and “Ethical Guidelines for Clinical Studies” (Public Notice of the Ministry of Health, Labour and Welfare No. 255, amended in 2008), special consideration should be taken to protect the human rights and the lives of subjects and to conduct research safely.

The Society, therefore, has established a Policy for COI in Medical Research (hereafter referred to as “the Policy”), in consideration of the high levels of social responsibility and moral commitment demanded of our activities. The objectives of the Policy are to properly promote research activities and presentations, including dissemination and increased awareness of the results of research, through the management of COI involving members in an appropriate manner, while maintaining neutrality and fairness and fulfilling our social responsibility by contributing to developments in medical research. Therefore, the Policy explains the principal concept of COI to our members and requires them to voluntarily and appropriately disclose any COI and to comply with the Policy when participating in various events, including making presentations.

**II. Persons to whom the Policy applies**

The Policy applies to the following persons, who may be involved in COI:

1. The persons who require 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) the Editorial Board of the *Journal of Physiological Sciences*, and (6) members of the committee of Publications and Public Relations.
2. Spouses and first-degree relatives of and persons who share income or property with any person to whom 1) may apply
3. All authors, including nonmembers, who make presentations at academic conferences and other events of the Society
4. All authors, including nonmembers, who submit articles to the journals of the Society

**III. Activities to which the Policy applies**

The Policy shall be applied to all activities conducted by the Society.

1. Academic conferences (including annual meetings) and local chapter conferences
2. Official journals and publications
3. The Website of the Society
4. Other events necessary to achieve the Objectives

Particular compliance with the Policy shall be required in the following events:

1. Presentations at academic conferences (hereafter referred to as “Conferences”) organized by the Society, including luncheon seminars
2. Publications, such as official journals (*Nihon Seirigaku* *Zasshi* and the *Journal of the Physiological Sciences*)

**IV. Matters to be reported**

If an individual member receives benefits, such as those listed in 1) to 9) below, and if amounts in such cases exceeds the limits specified in the Bylaws, he or she shall report the circumstances of the situation in detail to the president of the Society. The method of disclosure shall be set forth in the Bylaws.

1. Employment, administrative position (directors, presidents), and advisory roles in business enterprises, for-profit corporate organizations, or commercial entities
2. Stock ownership and options
3. Patent royalties and licensing fees from business enterprises, for-profit corporate organizations, or commercial entities
4. Honoraria (e.g., lecture fees) paid by business enterprises, for-profit corporate organizations, or commercial entities, for the time and labor of an investigator who attended or made a presentation at a meeting
5. Manuscript fees for promotional materials (e.g., brochures) paid by business enterprises, for-profit corporate organizations, or commercial entities.
6. Funding for medical research (e.g., clinical trials and clinical studies) provided by business enterprises, for-profit corporate organizations, or commercial entities
7. Research funding (e.g., funded research, collaborative research, and donations) provided by business enterprises, for-profit corporate organizations, or commercial entities
8. Endowed departments sponsored by business enterprises, for-profit corporate organizations, or commercial entities
9. Others (e.g., travel fees for participating in conferences, gifts)

**V. Situations to be avoided concerning COI**

1. *COI situations to be avoided by all involved*

Publication of medical research results shall be based purely on scientific evidence and judgment and should be for the common good. Members of the Society must not be influenced or manipulated by providers of funds for medical research or conclude any contract that makes such influence unavoidable, with regard to the topic of or results described in a manuscript, including the research results and their interpretation.

1. *COI situations to be avoided by medical research administrators*

Administrators of planning and conducting medical research (including medical studies and medical trials) should be investigators who are publicly recognized as not having any significant COI (i.e., having little relationship with a sponsor) regarding the conditions listed below. These conditions shall be adhered to even after the person assumes the administrative position.

1. Ownership of stock of the sponsoring company
2. Patent royalties or licensing fees of products or technology obtained from medical research
3. Employment, administrative position, or advisory role in business enterprises, for-profit corporate organizations, or commercial entities that sponsor the medical research (except for serving as a scientific advisor without receiving compensation).
4. *Investigations on COI situations*

Investigators to whom the above conditions 1) to 3) apply can be appointed as a principal investigator responsible for medical research projects, if he or she is essential for planning or conducting the research and if such medical research has a medically significant implication, and as long as the fairness and transparency of his or her judgment and actions are clearly assured.

**VI. Implementation method**

1. *Responsibilities of the members of the Society*

When presenting medical research results at Conferences, members of the Society must disclose, at the beginning of the presentation, any COI in accordance with the Bylaws of the Society. If such a COI is against the Policy in relation to the research presentation, the Board of Directors shall refer the matter to the committee in charge of COI (hereafter referred to as the “COI Committee”) and take appropriate actions according to the committee recommendations.

1. *Responsibilities of Officers*

Officers of the Society (president, directors, and auditors), persons presiding over Conferences (e.g., chairpersons), chairpersons of committees, members of special committees, and members of working groups have important roles and are responsible for all of the various activities related to the Society. Accordingly, they are obliged to report any and all COIs concerning such activities using the appropriate form at the time he or she assumes the position. If another COI arises after this time, the member shall report that COI in accordance with the rules.

1. *Roles of members of the COI Committee*

The COI Committee must investigate cases in which a member may possibly be involved in a major COI or in which there is doubt concerning the veracity of a self-reported COI. The committee must hold hearings to manage a COI problem involving any member and must report the results to the president of the relevant society.

1. *Roles of the Board of Directors*

If a major COI arises regarding the Society in relation to the members or their self-reported COI, the Board of Directors shall refer the matter to the COI Committee and order remedial actions based on the recommendation of the committee.

1. *Roles of persons in charge of a Conference*

When research results of concern are presented at a Conference, those in charge of the Conference (e.g., conference chairpersons) shall verify that such a presentation is in accordance with the Policy, and if it is not, they should take appropriate actions, including cancelling the presentation. In such cases, the presenter should be immediately informed about the cancellation and the reasons for it. In such circumstances, the persons in charge shall refer the matter to the COI Committee and may order remedial actions according to the recommendation of the committee.

1. *Roles of the editorial committee*

If research manuscripts, review articles, practice guidelines, articles, or opinions are to be published in official journals, the editorial committee of these journals shall verify that the publication is in accordance with the Policy, and if not, the committee should take appropriate actions, including cancelling publication. Accordingly, the author should immediately be informed of the cancellation and the reasons for it. If the policy violation is found only after the article is published, the committee may make an official announcement, in the name of the editor-in-chief, regarding the matter. In the execution of such actions, the editor-in-chief shall refer to the COI Committee and may order remedial actions according to the recommendation of the committee.

1. *Others*

Other committee chairpersons and members of committees shall verify that activities related to the Society are carried out is in accordance with the Policy, and if the activities are not in accordance with the Policy, appropriate actions to deal with the matter shall be considered. The committee may refer to the COI Committee regarding such actions and order remedial actions according to the recommendation of the committee.

**VII. Violation of Policy and Accountability**

* 1. *Violation of Policy*

The Board of Directors of the Society is authorized to make decisions regarding behavior that possibly violates the Policy, according to the appropriate rules. They shall refer the possible Policy violation to the Ethics Committee (or any other appropriate committee), discuss the matter on the basis of the recommendation of the relevant committee, and if a major violation is confirmed, take the following actions against the violator, all or in part, for a certain period, depending on the severity of the violation.

1. Prohibit from making presentations at any conferences organized by the Society
2. Prohibit from publishing articles in publications issued by the Society
3. Prohibit from acting as a chairperson of conferences organized by the Society
4. Prohibit from becoming a member of the Board of Directors, committees, or working groups of the Society
5. Dismiss as, or prohibit from becoming, a councilor of the Society
6. Suspend membership, strike from the rolls of the Society, and reject any membership application
   1. *Statement of Objections to Sanctions*

Persons who are subject to sanctions may explain their objections to the Society. If the president of the Society accepts the objections, he or she shall immediately set up a deliberation committee (interim advisory committee), refer the matter to the committee, and, after discussing the matter at the board meeting based on the recommendation of the committee, report the results to the person who made the objection.

* 1. *Accountability*

If a major violation of the Policy regarding research results presented at places related to the Society is confirmed, the Society shall immediately explain its responsibility to the public after discussing the violation at a board meeting.

**VIII. Development of Bylaws**

The Societies shall develop Bylaws necessary to execute the Policy.

**IX. Modification of the Policy**

The Policy shall be regularly reviewed and modified to adapt to social conditions, amendment and establishment of laws related to industrial-academic collaboration, and conditions associated with medical research.

**XI. Effective date**

The policy shall become effective on April 1, 2013.