Conflict of Interest Policy in Clinical Research


Introduction

In Japan, industrial-academic collaboration has been strengthened as a national strategy, with the aim of establishing a national basis of creative science and technology. In 1995, the Science and Technology Basic Law was enacted, followed by the Science and Technology Plan in 1996. Medicine has made remarkable advances from the late 20th through the 21st century. Research in the medical field has moved from individual bodies as a whole to organs, cells, and molecules, progressing further to the relationship between genetic abnormalities and diseases as well as the development of regenerative medicine. These results are also being applied to the studies of unexplained pathological conditions, new drug development, and the creation of prophylactic and therapeutic approaches based on entirely new concepts. In order for Japanese citizens to enjoy secure, safe and comfortable lives, it is extremely important not only to return the achievements of medical research to society and patients, but also to be aware of the significance of revitalization of education, research, and the economy.
Results of research presented at academic conferences or in publications organized under the auspices of the above-listed societies related to internal medicine (hereafter referred to as “the Societies”) include a variety of clinical research studies for the development of prophylactic, diagnostic, and therapeutic approaches to various diseases using newly-developed drugs, medical equipment and technologies. Collaboration between industry such as pharmaceutical companies and venture organizations and academia (such as collaborative research, funded research, technology transfer and training, scholarship and contributions, as well as endowed departments) serves as a major basicmechanism in promoting these endeavors.

With increasing clinical research in collaboration with industry, public organizations such as universities, research institutions, and academic societies become more deeply involved with the activities of commercial entities. It therefore becomes inevitable that education and research, which are the responsibilities of academic institutions and societies, conflict with the interests of individuals associated with industrial-academic collaboration. It is important such conflict of interest (COI) must be properly managed by academic institutions and societies as organizations in order to appropriately promote industrial-academic collaborative activities. Moreover, unlike in other areas of industrial-academic collaboration, participation not only by healthy members of the general population, but also patients, is essential in the medical field as subjects of clinical research. For those involved in clinical research, the deeper the level of COI with commercial entities, who are the financial or benefit provider, becomes serious, the more human rights of subjects could be violated, safety of life could be endangered, and research methods, data analysis and interpretation of results could be distorted. It is also possible that research may be unfairly evaluated or not published, even if the results are accurate. Concerning many reports on cases in the past, however, it is suggested that the
problem lies in the management of COI, not in COI itself associated with industrial-academic collaboration.

Recently, both within and outside Japan, many medical institutions and academic societies have been working on the development of appropriate COI policies in clinical research, in order to maintain clinical research honesty, transparency of presentation at academic societies, and social trust, as well as to properly promote clinical research through industrial-academic collaboration, and efforts have been made to return reasonable benefits obtained from clinical research to society through appropriate COI management.

The Societies are also committed to properly managing COIs involving our members by ensuring disclosures of financial relationships with sponsors that may have any interest in the subject matter or materials discussed in the manuscript presented or published at our events, under certain conditions, in order to fulfill our accountability to the public, and develop a COI policy that will benefit all societies.

I. Objectives

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

The Societies therefore have made a Policy of COI in Clinical Research (hereafter referred to as “the Policy”), in consideration of the high levels of social responsibility and
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 through contributions to the prevention, diagnosis and treatment of diseases in the field of internal medicine. Therefore, the Policy explains the basic concept of COI to our members, and requires them to voluntarily disclose any COI appropriately 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) Members of the Societies.
(2) Those who make presentations at academic conferences etc. of the Societies.
(3) Officers of the Societies (presidents, directors, auditors), persons in charge of academic conferences (e.g. chairpersons), chairpersons of committees, members of special committees (academic conference organization committees, editorial committees of official journals, ethics committee, medical safety committee, COI committee), members of interim working committees (subcommittees, working groups).
(4) Administrative staff of the Societies
(5) Spouses and first-degree relatives of, or those who share income or property with any person to whom (1) to (4) may apply.
III. Activities to which the Policy applies

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

(1) Academic conferences (including annual meetings) and local chapter conferences.

(2) Official journals and publications

(3) Research and studies, such as surveys

(4) Incentives for research and awards research achievements

(5) Accreditation of certified physicians and institutions

(6) Promotion of continuing medical education

(7) Liaison and collaboration with related academic societies

(8) Promotion of international research collaboration

(9) 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 Societies.

(2) Publications such as official journals

(3) Development of clinical practice guidelines and manuals

(4) Contributions to temporarily established study committees and consulting committees

IV. Matters to be reported

If an individual member receives benefits such as those listed in(1)-(9) below, and if remuneration in such cases exceeds the limits specified in the Bylaws, s/he shall report the circumstances of the situation in detail to the president of the relevant society. The method of disclosure shall be set forth in Bylaws.
(1) Employment, administrative position (directors, presidents), and/or advisory roles in business enterprises, for-profit corporate organizations, or commercial entities.

(2) Stock ownership and/or options

(3) Patent royalties, and/or 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/or 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) Clinical research funding (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 conferences, gifts)

V. Situations to be avoided concerning COI

1. COI situations to be avoided by all involved

   Publication of clinical research results and the development of clinical practice guidelines shall be based purely on scientific evidence and judgment, and should
be for the common good. Members of the Societies must not be influenced by the manipulative influences of providers of funds for clinical research, nor conclude any contract that makes such influence unavoidable, with regard to the topic of or results in the manuscript, including the research results and their interpretation, and the development of medical practice (diagnosis or treatment) guidelines based on the results of clinical research.

2. COI situations to be avoided by clinical research administrators

Administrators of planning and conducting clinical research (including clinical studies and clinical trials) should be investigators who are publicly recognized as not having any significant COI (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 sponsoring company stock
(2) Patent royalties and/or licensing fees of products and/or technology obtained from clinical research.
(3) Employment, administrative position, and/or advisory role in business enterprises, for-profit corporate organizations, or commercial entities who sponsor the clinical research (except for scientific advisories without receiving compensation).

Investigators to whom (1) to (3) apply can be appointed as principal investigator responsible of the clinical research projects, if s/he is indispensable in planning and/or conducting the research and such clinical research has a medically significant implication, and as long as fairness and transparency of his/her judgment and action are clearly assured.
VI. Implementation method

1. Responsibilities of the members of the Societies

When presenting clinical research results at Conferences, members of the Societies must disclose any COI in accordance with Bylaws of the Societies at the beginning of the presentation. If such a COI is indicated as being 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 “COI Committee”), and take appropriate actions according to the committee recommendations.

2. Responsibilities of officers

Officers of the Societies (president, directors, and auditors), persons presiding over the Conference (e.g. chairpersons), chairpersons of committees, members of special committees, and members of working groups have an important role and are responsible for all the various activities related to the Societies. Accordingly, they are obliged to report any and all COI concerning such activities using the appropriate form at the time s/he assumed the position. If another COI arises after assuming the position, the member shall report that COI in accordance to the rules.

3. Roles of the members of the COI Committee

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

4. Roles of the Board of Directors

If a major COI arises regarding the Societies related to the members, or inadequacy of 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.

5. Roles of persons in charge of the Conference

Concerning research results are presented at conferences, those in charge of the conference (conference chairperson, etc.) shall verify that such presentations are in accordance with the Policy, and if it is not, they should take appropriate actions, including cancellation of the presentation. In such cases, the presenter should then be immediately informed about the cancellation and the reasons. In such circumstances, the person in charge shall refer the matter to the COI Committee and may order remedial actions according to the recommendation of the committee.

6. 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 official journals shall verify that the publication is in accordance with the Policy, and if not, the committee should take appropriate actions, including cancellation of the publication. Accordingly, the author should immediately be informed of the cancellation with the reasons. If the policy violation to the Policy is found after the publication of the article, the committee may make an official announcement regarding the matter in the name of the editor-in-chief. 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.

7. Others

Other committee chairpersons and members of committees shall verify that the execution of activities related to the Societies is in accordance with the Policy, and if it is not, consider appropriate actions to handle the matter. 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 Societies is authorized to decide on behavior that may contravene the Policy, according to the appropriate rules. They shall refer to the Ethics Committee (or any other appropriate committee), discuss the matter based on the recommendation of the relevant committee, and if a major violation is confirmed, take the following actions, all or in part, for a certain period, depending on the degree of the violation.

(1) Prohibit from making presentations at any conferences organized by the Societies
(2) Prohibit from publishing articles in publications issued by the Societies
(3) Prohibit from acting as a chairperson of conferences organized by the Societies
(4) Prohibit from becoming a member of the Board of Directors, committees, or working groups of the Societies
(5) Dismiss as, or prohibit from becoming a councilor of the Societies
(6) Suspension of membership, struck from the rolls of the Societies, rejection of any membership application

If measures toward the person who violates the Policy are determined, such information must be provided to the president of the internal medicine society of which the person is a member.

2. Statement of Objections to Sanctions

Persons who are subject to sanctions may explain their objections to the Societies. If the president of the Societies accepts the objections, s/he 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.

3. Accountability

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

VIII. Collaboration among the 14 internal medicine societies

In order to review the Policy and exchange information regarding Bylaws, the Societies shall set up a consultative committee, representing the 14 internal medicine societies (Japanese Society of Internal Medicine, Japanese Society of Gastroenterology, Japanese Society of Hepatology, Japanese Circulation Society, Japan Endocrine Society, Japan Diabetes Society, Japanese Society of Nephrology, Japanese Respiratory Society, Japanese Society of Hematology, Societas Neurologica Japonica, Japan Society of Allergology, Japan College of Rheumatology, Japan Association for Infectious Diseases, Japan Geriatrics Society (hereafter referred to as “Consultative Committee of the 14 Internal Medicine Societies on COI Guideline Policy”) that are involved with the COI Policy in Clinical Research, and meetings shall be held as deemed necessary.

IX. Development of Bylaws

The Societies shall develop Bylaws necessary to execute the Policy.
X. 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 medicine and research.

XI. Effective date

The Policy shall become effective on April 12, 2010.

<Working group on Conflict of Interest Policy in Clinical Research>

Saburo Sone (Tokushima University)
Hiroyuki Daida (Juntendo University)
Yutaka Kogo (Asahikawa Medical College)
Hiroshi Fukui (Nara Medical University)
Takeshi Fukuda (Dokkyo Medical University)
Taira Maekawa (Kyoto University)
Nobuyuki Miyasaka (Tokyo Medical and Dental University)
Tatsuo Kuroyanagi (Kaneko & Iwamatsu Law Farm)
Tomoko Mise (University of Tokyo)