

Policy of Conflict of Interest in Clinical Research

The Japan Society of Hepatology

Academic-industrial collaboration has been assigned as a national strategy to assist in establishing Japan as a nation based on the creativity of science and technology. In order to comply with this strategy, the Science and Technology Basic Law was enacted in 1995, followed by the launch of the Science and Technology Basic Plan in 1996. Development of medicine and medical care from late 20th century to the early 21st century has been remarkable. Focus of medical research has shifted from individual human bodies to organs, cells, and molecules, finding the relationship between genetic abnormalities and diseases, implementing regenerative medicine, further studying unexplained pathological conditions, discovering new drugs, and developing prevention and treatment techniques based on totally new concepts. Returning such achievements in medical research to the public and patients is extremely important for citizens of Japan to lead safe, secure and comfortable lives. It also has profound significance in promoting the activation of education and research, and the revitalization of the economy.

The Japan Society of Hepatology contributes to Japan's academic development through its mission to further and publish research achievements on hepatology by making reports, transmitting information and exchanging knowledge on hepatology. More specifically, the Society promotes and provides academic conferences on hepatology, journals published both in Japanese and English including research on diagnosis of liver diseases, educational lectures on medical treatment, training and lectures for medical specialists, research grants for researchers in hepatology and liver diseases, open lectures and publication for the purpose of raising public interest in liver diseases, designates hospitals as educational hospitals and certifies qualified hepatologists.

The research achievements presented at academic conferences or in publications organized by the Society include clinical research on the development of diagnosis, treatment, and prevention of hepatic diseases, and clinical research using new drugs, medical equipment and techniques. The wide range of research presented by the Society can be conducted through collaboration between industry, such as pharmaceutical and venture companies, and academia (for example, joint research programs, contract education programs, technology transfer and guidance, scholarship contributions, and endowed courses).

The more widespread clinical research conducted in collaboration with industry becomes, the more deeply academia such as universities, research institutions, and academic organizations, which are public organizations, becomes involved in the activities of specific firms. Subsequently, responsibility for education and research held by such academic

organizations and societies inevitably and unavoidably conflicts and contradicts with interests of individuals associated with the industry. Such a state is called “conflict of interest” (hereafter referred to as COI). In their role as organizations promoting academic-industrial collaboration, it has become critical for academic organizations and societies to properly manage COI. Unlike academic-industrial collaborative research in different areas, clinical research depends upon the participation of patients and healthy volunteers as subjects of research. We concern that the more entwined clinical research with industry become, the more conflict of interest status might possibly endanger human rights and the safety and security of subjects. We also worry that research method, data analysis, or interpretation of results could be distorted and that even valid research outcome couldn't be evaluated fairly and therefore couldn't be published if they contain COI.

Many of the past cases revealed that the problem did not lie in the conflict of interest status associated with academic-industrial collaboration itself, but in the lack of appropriate management of it. Recently, both in Japan and overseas, many medical institutions and academic organizations have developed COI policies regarding clinical research in order to promote the research through academic-industrial collaboration, maintaining objectivity, transparency in conference presentation, and social trust. The Society hereby establish its COI policy to accomplish accountability to the public.

I. Objectives

The ethical principle for medical research in human subjects has been already declared 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), in which it is said that special consideration should be paid to conduct research safely in order to secure human rights and the lives of subjects.

The Society enacts this “Policy of Conflict of Interest (COI) in Clinical Research” (hereafter, referred to as the Policy) to accomplish transparency of their aims of social responsibility. The objectives of the Policy are to properly promote presentation of research achievements and associated activities while ensuring neutrality and objectivity when contributing to the progress of prevention, diagnosis and treatment of diseases. The Policy reveals the basic concept of COI to the members of the Society and requires them to disclose their own COI status in an accurate manner by self-declaration when participating in society activities, such as presentations.

II. Subjects

The policy applies to individuals who fall into any of the following categories which may involve a COI:

1. Member of the Society
2. Presenter at academic conferences and associated activities organized by the Society
3. Board Members of the Society (director general, directors, and supervisors), persons responsible for academic conferences (chairpersons, etc.), persons responsible for public open lectures, chairpersons of various committees, special committee members (Committee of Exploring Best Practice, Finance Committee, Editorial Committee for journals in Japanese/English, Ethics Committee, COI committee, etc.), members of a temporary working group.
4. Administrative staff of the Society
5. Spouses and immediate family, or those who share income or property with any person who applies to any of 1 to 4 above.

III. Activities included in COI circumstances

The policy applies to all activities conducted by the Society conducts, such as:

1. Holding research meetings, academic lectures, and other events on hepatology;
2. Publishing the journals;
3. Liaison and corporation with related academic organizations in Japan and abroad;
4. Any other activities necessary for achieving the objectives of the Society.

Persons in charge of the following activities need to fully comply with the Policy:

- i. Presentation at academic conferences etc. of the Society;
- ii. Publications such as journals of the Society;
- iii. Development of practice guidelines, manuals, etc;
- iv. Working for a temporary investigation or advisory committee.

IV. Matters to be declared

Any individuals who have benefitted from any of the following circumstances should declare their status to the director general of the Society, if the benefit they receive exceeds the limitations, if any, defined by bylaws. The bylaws would also define how the declared matters should be disclosed.

1. Acceptance of a position as executive, adviser, or employee of business enterprise, corporation, organization, or for-profit entity;
2. Stock ownership;
3. Patent royalties from enterprises, corporations or entities;
4. Honoraria (e.g. lecture fees) paid by business enterprises, corporation, organization, or for-profit entity to a researcher for labor contributions for conference

participation or presentation;

5. Manuscript fees for brochures, subscriptions, etc. paid by enterprises, corporations or entities;
6. Clinical research funding (e.g. clinical trial, clinical investigation) offered by business enterprises, corporation organization, or for-profit entity
7. Research funding (e.g. contract research programs, joint research program, Scholarship contributions) offered by business enterprises, corporation organization, or for-profit entity
8. Chair courses provided by business enterprises, corporation organization, or for-profit entity
9. Travel expense or gifts, which are not related to research, training, or medical practice, provided by business enterprises, corporation organization, or for-profit entity

V. Matters to be avoided regarding a conflict of interest status

1. The intention of publication of clinical research results and development of clinical guidelines should be conducted based purely on scientific evidence and judgment, or for public interest. Members of the Society should not be influenced by sponsors of the clinical research or arbitrary intention of business enterprises concerning the content of publication such as the result of clinical research and its interpretation, producing clinical guidelines or manuals. Members should not make a contract with a sponsor or business entity if such influence cannot be avoided.
2. A research administrator in a position having rights on planning and conducting clinical research (including clinical trial, clinical investigation) is required to be a researcher evaluated not to be found participating in the following circumstances. After being selected as the administrator, the researcher may not change their circumstances to include any of the following:
 - i. Owning stock of a company requesting a clinical research
 - ii. Obtaining products, patent royalties, patent ownership, etc. as the result of the clinical research
 - iii. Accepting a position of executive, member of the board members, adviser, etc. of a corporation organization, or for-profit entity requesting the clinical research

If the circumstances of a potential researcher match any of i. to iii. above, they may accept the position of a lead principal investigator if they are indispensable for planning and conducting the clinical research, and if the clinical research has extremely valuable medical

significance.

VI. Method of Implementation

Under any of the following circumstances, whereby any document or activity is found to be contrary to the Policy, the Board of Directors may refer the issue to the committee that administers COI (hereafter, referred to as the COI Committee), to deliberate the issue and take appropriate measures, including remedial action, based on their recommendations.

1. Obligation of the members

When making a presentation on clinical research achievements at academic lectures or events, the members of the Society must disclose any COI concerning the clinical research in the stipulated form complying with bylaws of the Society.

2. Obligation of board members, directors and members of committees

Board members of the Society (director general, directors, and supervisors), persons responsible for academic lectures (chairpersons, etc.), chairpersons of various committees, special committee members, and members of working groups are responsible for all activities related to the Society. They are obliged to submit self-declaration on their COI concerning the activities in a stipulated form at the time of accepting to any of the Society or the Society affiliated positions. In the event that a COI arises after having been awarded the positions, they must amend their initial self-declaration using the stipulated form.

3. Role of COI Committee

When a member of the Society gets involved in gross conflict of interest status in any activities conducted by the Society, or when the self-declaration on COI is found incorrect, the COI Committee shall notify the member of the fact and provide proper guidance to the member. In the event that a question arises in connection with a self-declaration on COI, the COI Committee shall investigate the issue by holding a hearing in order to manage the member's conflict of interest status and report of the result of the investigation to the director general of the Society.

4. Role of Board of Directors

When the Board of Directors gets involved in a gross conflict of interest circumstance regarding any activities conducted by the Society, or when the self-declaration on COI is found incorrect, the Board of Directors will refer the issue to the COI Committee.

5. Role of Persons Responsible for Academic Lectures

A person responsible for academic conferences (chairpersons, etc.) must

confirm whether a presentation on clinical research achievements at the conference complies with the Policy, and in the event any presentation is found to be against the Policy, the responsible person may take actions such as prohibiting the presentation. In such cases, the responsible person must promptly inform the proposed presentation speaker that they are prohibited to present their findings at the conference with the reasons why such a decision was made.

6. Role of the Editorial Committee

When manuscripts, reviews, practice guidelines, editorial notes, comments, or other such documents concerning clinical research are to be presented in publications such as academic journals, the Editorial Committee for journals may verify that the contents of the publication complies with the Policy. In the event that it is found that such findings are against the Policy, the Editorial Committee may take actions to halt the publication or any other action deemed necessary. In such cases, the Editorial Committee must promptly inform the author that their article will not be published and the reasons why such a decision has been made. If an article is found to be against the Policy after publication, the Editorial Committee may publicly announce regarding the matter under the name of the editor-in-chief of the publication. At this time, the editor-in-chief may refer to the COI Committee concerning the matter.

7. Others

Other committee leaders and members must verify that activities of the Society they are involved in comply with the Policy. In the event that it is found such activities are against the Policy, the person must promptly examine how the activity can be remedied.

VII. Measures for Violation and Accountability

1. Measures for Violation

The Board of Directors of the Society is authorized to deliberate regarding violations against the Policy as specified in VI. 4. in this Policy. After referring to and receiving a report from the COI Committee, and examining the matter, if the Board of Directors judges the matter falls into gross default, it may take action such as imposing penalty in accordance with the level of the default.

2. Statement of Objection

The person who is placed on the penalty may make a statement of objection to the Society. When the director general receives the statement, he must promptly establish an Appeal Examination Committee (interim advisory committee) to examine the matter and to report the result to the Board of Directors. Upon discussion of the report, the Board of Directors must

notify the person who stated the objection of the conclusion of discussion.

3. Accountability

When the Society detects gross violation against the Policy concerning any clinical research achievements having been presented at a Society event, after discussion between the Board of Directors, the Society must acknowledge and explain its responsibility to the public.

VIII. Cooperation with Other Societies

The Society will join the COI Policy Council that is composed of the 14-Internal Medicine-related Societies (Japanese Society of Internal Medicine, Japanese Society of Gastroenterology, Japan Society of Hepatology, Japanese Circulation Society, Japan Endocrine Society, Japan Diabetes Society, Japanese Society of Nephrology, Japanese Respiratory Society, Japanese Society of Hematology, Japanese Society of Neurology, Japanese Society of Allergology, Japan College of Rheumatology, Japanese Association for Infectious Diseases, and Japan Geriatrics Society), and work in close cooperation with related societies, such as the American Gastroenterological Association, , exchanging information regarding bylaws or revision of the Policy or having other necessary discussions.

IX. Establishing Bylaws

The Society may establish bylaws necessary for actual operation of the Policy.

X. Revising the Policy

The Policy may be regularly reviewed and revised to adapt to social conditions, amendments of laws related to academic-industrial collaboration, and changes in conditions surrounding medical and clinical research.

XI. Effective Date

The Policy will be implemented provisionally on June 4, 2012 (the day after the Annual Meeting), and will take complete effect on April 1, 2013.