Conflict of Interest Policy in Cancer Research

Version 1 (September, 2014)
Version 2 (October, 2016)

Conflict of Interest Committee, Japanese Cancer Association

Japanese Cancer Association (JCA) has applied the conflict of interest policy that was originally established by the Japan Society of Clinical Oncology (JSCO) and the Japanese Society of Medical Oncology (JSMO), with necessary modifications and with the approval of those two organizations since April 2008. In 2011, the policy was amended to include in the scope of the Association’s conflict of interest reporting not only clinical research performed in industry-academic collaboration but also basic research. Meanwhile, the Japanese Association of Medical Sciences revised the “Guidelines for COI Management in Medical Research” (first edition in February 2011) in 2014. Based on these backgrounds, the current policy has been prepared by amending the aforementioned JSCO-JSMO joint policy from the Association’s own viewpoint in consideration of the revised guidelines of the Japanese Association of Medical Sciences.

Foreword

The purpose of JCA is to contribute to the development of cancer research and to the public well-being. The research presented via the JCA’s academic conferences and publications includes cancer biology, diagnostics, therapeutics, and other areas that are highly specialized and closely related to one another. In order to promote such research in a unified manner and contribute to the improvement of cancer prevention, diagnosis, and treatment, collaboration between academia (including research institutes as well as universities) and industry (including medical and pharmaceutical manufacturers, business ventures, and other for-profit corporations) is effective. The necessity and importance of such collaboration is increasing every day.
In some cases, industry-academic collaborative cancer research entails benefits to society (public interest) from the fruits of discharging academic and ethical responsibility, as well as money, status, rights, and other benefits (private interest) acquired attendant on industry-academic collaboration. When these two types of benefit are in conflict within an individual researcher, it is called a “conflict of interest.” In cancer research, a researcher who has invented a diagnostic or therapeutic method frequently becomes involved in the commercialization of that method by a for-profit corporation. The occurrence of conflicts of interest is unavoidable, and this in itself is not a problem. Nevertheless, in cases of serious conflicts of interest, the researcher may be greatly influenced by personal gains, and the risk of distortion of research methods, data analysis or result interpretation arises. A situation may also occur whereby fair assessment is not made, even though research findings are appropriate. When research findings are presented at academic conferences and the like, there may be an intentional failure to disclose specific data (reporting bias). At the same time, if fairness and objectivity are not secured, even industry-academic collaboration that does not involve any serious conflict of interest may create suspicion and anxiety in society and also disadvantage the researcher.

Many academic societies in Europe and North America have established conflict of interest guidelines covering clinical research in order to ensure the appropriate conduct of industry-academic collaborative clinical research and impartiality in academic presentations. In the United States, the Sunshine Provisions of the Patient Protection and Affordable Care Act (March 2010) legally require pharmaceutical and medical device companies to disclose all payments made to physicians and medical institutions, etc. and the content of these provisions has been available on the website since 2013. In recent years, against a backdrop of increasingly globalized research and development activities concerning the prevention, diagnosis, and treatment of cancer on the basis of Japanese, North American, and European joint research have been actively pursued, and the establishment and promotion of conflict of interest management systems in Japan have become an urgent task. Against this background, in January 2011, the Japan Pharmaceutical Manufacturers Association (JPMA) established the “Transparency Guidelines for the Relation between Corporate Activities and
Medical Institutions" and requested each company to disclose information on its website from 2013. In addition, there is an increasing awareness with regards to the public nature and transparency of the clinical trial results that are published in papers submitted to medical journals, and many medical journals adopt the common format for conflict of interest declarations that was established by the International Committee of Medical Journal Editors. In June 2010, JPMA adopted the “Joint Position on the Publication of Clinical Trial Results in the Scientific Literature” together with the International Federation of Pharmaceutical Manufacturers and Associations, the European Federation of Pharmaceutical Industries and Associations, and the Pharmaceutical Research and Manufacturers of America.

The Association, due to the nature of its activities, has many members who belong to a corporation and has a good basis for industry-academic collaboration. It is important to conduct research actively after having clearly indicated conflict of interest policy to members and ensured fairness in important industry-academic collaborative research and development projects.

I. Purpose of Guideline Establishment

JCA, in view of the fact that social responsibility and high ethical standards are required in its activities, hereby establishes the Conflict of Interest Policy in Cancer Research (hereinafter abbreviated as the “Policy”). The purpose of the Policy is for JCA to ensure that the presentation and dissemination of research findings, and activities to raise public awareness of research findings, are appropriately conducted in circumstances where neutrality and impartiality are maintained by means of appropriate management of conflicts of interest of the covered individuals specified by JCA in II. below, as well as to discharge social responsibility by contributing to the advancement of the prevention, diagnosis, and treatment of cancer.

As has been mentioned in the Helsinki Declaration (World Medical Association, revised in 2000) and the Ethical Guidelines for Clinical Studies (Ministry of Health, Labour and Welfare Notification No.255, 2003), medical research differs greatly from research in other academic fields in that, as the research subjects
are human beings, special consideration to protect the rights and lives of subjects and safely conduct research is required. The nature of research must not be distorted by researchers’ conflicts of interest and the like. In addition, with the recent world trend that promotes translational research from basic research to clinical practices in a unified manner, the scope of conflict of interest management is expanding to include not only clinical research and studies (including clinical trials) but also industry-academic collaborative research on basic life science. Therefore, JCA includes basic research, clinical research, and clinical studies (including clinical trials) in the scope of conflict of interest management.

The crux of the Policy is to indicate the basic concepts of conflict of interest to people participating in JCA's undertakings in order to advance the fair and smooth promotion of industry-academic collaboration. In addition, the Policy aims to prevent serious conflicts of interest, any improper acts associated with such conflicts of interest, and also suspicions or groundless criticism in society. JCA will require its members and the covered individuals specified below to observe the Policy.

II. Covered Individuals

The Policy applies to all of the following covered individuals for whom a conflict of interest may arise.

(1) Members of JCA
(2) Persons who make presentations at JCA's academic conferences
(3) Persons who present papers in JCA's journal “Cancer Science,” etc.
(4) Officers of JCA (directors, auditors, and committee chairpersons)
(5) Members of the Ethics Committee and the Conflict of Interest Committee of JCA
(6) Editors and associate editors of JCA's journal “Cancer Science”
(7) President and administrative manager of JCA's Annual Meetings as well as program committee chairperson
(8) Spouses and relatives in the first degree of the individuals listed in (1) through (7) above, or other persons who share income or property with such
III. Covered Activities

The Policy applies to activities in all undertakings concerned with JCA. In particular, observance of the Policy for all basic and clinical cancer research is required of persons who make presentations at any Annual Meeting, conference, symposium, or open lecture for the general public, etc. that is sponsored or co-sponsored by JCA (hereinafter “Academic Conferences, etc.”) or who publish presentations in JCA's bulletin “Cancer Science,” etc. Especially rigorous observance of the Policy is required of lecturers who conduct educational lectures (including luncheon seminars) for JCA members or who conduct open lectures for the general public in view of the powerful social influence of these undertakings.

IV. Matters Requiring Declaration and Disclosure

1) Common Matters Requiring Declaration and Disclosure

If any of items (1) to (7) below exceeds separately stipulated criteria with respect to a covered individual who is an officer of JCA, member of the Ethics Committee or the Conflict of Interest Committee, editor or associate editor of Cancer Science, president, administrative manager, or program committee chairperson of an Annual Meeting, lead presenter or responsible researcher at an Academic Conference, etc., or author of a paper submitted to Cancer Science, etc. (hereinafter an “Individual Required to Make a Declaration”), such an individual shall have the obligation to accurately declare or disclose by self-declaration the circumstances of the conflict of interest in accordance with the prescribed form. In addition, if any of items (1) to (3) below exceeds separately stipulated criteria with respect to a spouse or a relative in the first degree of the Individual Required to Make a Declaration, or any other person who shares income or property with such an individual, the Individual Required to Make a Declaration shall have the
obligation to report the exact circumstances to JCA. Even if no item exceeds the separately stipulated criteria, such a matter must be declared and disclosed. The declarer himself/herself shall bear responsibility for the self-declaration and the declared content. Specific standards of declaration and disclosure are separately stipulated in the “Japanese Cancer Association (JCA) Detailed Regulations on the Handling of Conflict of Interest” (hereinafter the “Detailed Regulations”) according to the covered activity.

(1) Position as an officer or advisor (including consultant) of a company or for-profit organization
(2) Ownership of share or stock options
(3) Patent royalties or licensing fees from a company or for-profit organization
(4) Daily allowances (lecture fees or fees for the chairperson or the moderator) from a company or for-profit organization paid as compensation for the time or labor of a researcher engaged for conference attendance (for a presentation or serving as the chairperson or the moderator)
(5) Manuscript fees paid by a company or for-profit organization as compensation for writing for a pamphlet or other publication
(6) Research funding (contract research funds, endowments, private research funder grants, etc.), endowed chairs, and researcher-employment costs provided by a company or for-profit organization
(7) Other remuneration (travel expenses, gifts, or other in-kind payments not directly related to research)

2) Officers and Employees of a Company or For-profit Organization (Including Those Dispatched to Other Institutions)
When any officer or employee of a company or for-profit organization (including researchers dispatched to other institutions, research students, adult graduate students, postdoctoral fellows, and part-time lecturers) makes a presentation on research findings or submits a paper, the name of the company or organization shall be clearly indicated.
V. Matters to Be Avoided

1) Matters to Be Avoided by All Covered Individuals

Presentation or publication of research findings should be on the basis of purely scientific grounds and judgment or the public interest. All covered individuals to whom the Policy applies must not be influenced by the arbitrary judgment of a company or entity providing funding for research in decisions whether to present research findings at conferences or in research papers or the publication content, namely the research findings or their interpretation, and must not enter into any contracts under which such influence cannot be avoided.

2) Matters to Be Avoided by Research Principal Investigators and Responsible Researcher

Persons who have none of the following conflicts of interest should be selected as principal investigators or responsible researchers who have the right of decision over the planning and conduct of clinical research (including clinical studies and trials). These conflicts of interest should also be avoided after selection.

(1) Ownership of share (including stock options) in a company sponsoring the clinical research

(2) Acquisition of royalties or patent rights for products or technologies obtained from the clinical research findings

(3) Position as an officer, board member, or advisor, etc. of a company or for-profit organization sponsoring the clinical research (except as an unremunerated scientific advisor)

(4) Receipt from a company or for-profit organization sponsoring the clinical research of endowments in amounts that cannot be accounted for and that significantly exceed the actual cost of the research, or execution of the contract research agreement, etc.

(5) Receipt, from a company or for-profit organization sponsoring the clinical research, of money or gifts other than the legitimate compensation paid for the time or labor required for the research
(6) Receipt of services (data management, statistical analysis, writing of papers, etc.) provided by a company that may affect the research findings

(7) Acceptance of a research collaborator (regular employee) from a company whose interests (sales promotion, etc.) may be directly related to the research findings

It is provided, however, that it in the case where an individual is essential to the planning and conduct of the clinical research concerned and the clinical research is extremely significant from a social perspective, it is possible for even a person to whom items (1), (2), (3), (6), and (7) above apply to serve as a principal investigator or responsible researcher for the clinical research concerned, provided that the impartiality and fairness of such a person’s judgment and measures are clearly secured.

VI. Method of Enforcement

1) Self-declaration of Officers, etc.
JCA’s officers (directors, auditors, and committee chairpersons); members of the Ethics Committee or the Conflict of Interest Committee; editors or associate editors of Cancer Science; and the presidents, administrative managers, or program committee chairpersons of Annual Meetings have important roles and responsibilities for all undertakings and activities concerning JCA, and they have the obligation to make self-declarations concerning conflicts of interest in connection with said undertakings by means of the prescribed form before they assume office. The declaration shall be made using the prescribed form in accordance with the Detailed Regulations.

2) Self-declaration of the Lead Presenter and the responsible researcher at an Academic Conference, etc.
The lead presenter making a presentation on research findings at an Academic Conference, etc. and the responsible researcher have the obligation to accurately declare and disclose the circumstances of any conflict of interest
relating to the implementation of the research concerned, whether or not they are members of JCA. Declaration and disclosure shall be made by the prescribed method in accordance with the Detailed Regulations.

3) Self-declarations of Authors of Papers Submitted to Cancer Science, etc.
The author of a paper on research findings which is submitted to Cancer Science, etc. has the obligation to accurately declare and disclose the circumstances of any conflict of interest relating to the implementation of the research concerned, whether or not the author is a member of JCA. Declaration and disclosure shall be made by the prescribed method in accordance with the Detailed Regulations.

4) The Role of Officers
If a serious conflict of interest has occurred in an officer in the execution of any business of JCA or if there is any doubt about the self-declaration on conflict of interest made by a member or covered individual, the Board of Directors may refer the matter to the Conflict of Interest Committee and, if necessary, the Ethics Committee (hereinafter the “Committee with Jurisdiction”) and prescribe remedial measures on the basis of the findings.

When research findings are presented at JCA’s Academic Conferences, etc., program committee chairpersons, committee members, and reviewers verify that the content of the presentations are in accordance with the Policy, and may prohibit presentations about subjects that violate the Policy. In such cases, they promptly notify the individuals planning the presentation to that effect and provide reasons. These measures are discussed by the Committee with Jurisdiction and implemented following approval of the Board of Directors on the basis of the findings.

When research findings are presented in Cancer Science, editors and associate editors of Cancer Science verify that the content of the presentation is in accordance with the Policy and may prohibit presentations about subjects that violate the Policy. In such cases, they promptly notify the individuals planning the presentations to that effect and provide reasons. These measures are discussed by the Committee with Jurisdiction and implemented following approval of the Board of Directors on the basis of the findings.
Other committee chairpersons and members verify that the content of JCA’s undertakings with which they are involved is in accordance with the Policy and promptly consider remedial measures in cases of activities that violate the Policy. These measures are discussed by the Committee with Jurisdiction of JCA in question and implemented following approval of the Board of Directors on the basis of the findings.

5) Confidential Obligations of the Parties Concerned
Members of the Committee with Jurisdiction and other parties concerned who access the declared information on conflicts of interest (JCA’s clerical staff in charge, editors, associate editors, and the editorial office members of Cancer Science, companies providing management services for the Academic Conferences, etc.) have confidentiality obligations for such information permanently.

6) Filing of Objections
A person who has been subject to remediation instructions or prohibition in accordance with 1) to 4) above may file an objection to JCA. When JCA has received an objection, the Committee with Jurisdiction promptly discusses the matter and notifies the objecting individual of its findings following consultation with the Board of Directors.
VII. Measures Against Guideline Violators and Accountability

1) Measures against Guideline Violators
The Board of Directors of JCA have the authority to deliberate actions that violate the Policy as per regulations that JCA separately sets down and, when as the result of deliberation the Board of Directors of JCA has judged that an action falls under the category of a serious breach of the Policy, the Board may take one or more of the following measures for a fixed period of time in accordance with the seriousness of the breach.

(1) Prohibition from presenting at all conferences held by JCA
(2) Prohibition from publication of papers and articles in JCA's publications and website, etc.
(3) Prohibition from serving as president of JCA's Annual Meetings
(4) Prohibition from participation in JCA's boards of directors, committees, or working groups
(5) Expulsion from JCA's Council or prohibition from becoming a councilor
(6) Expulsion from JCA or prohibition from becoming a member

2) Filing of Objections
The individual subject to measures may file an objection to JCA. When JCA has received an objection, the Committee with Jurisdiction conscientiously reexamines the matter and notifies the individual subject to measures of its findings following consultation with the Board of Directors.

3) Accountability
When JCA has judged there has been a serious violation of compliance with the Policy in research findings presented at a venue in which JCA is involved, JCA will discharge its accountability to society following discussion by the Committee with Jurisdiction and Board of Directors.
VIII. Establishment of Detailed Regulations

JCA can establish necessary detailed regulations for the actual implementation of the Policy taking into consideration the independence and special characteristics.

IX. Date of Enforcement and Method of Amendment

The Policy comes into effect on September 28, 2014. The need to amend the Policy due to individual cases arising from social influences or laws concerning industry-academic collaboration is anticipated. In principle, the Conflict of Interest Committee may discuss and amend the Policy by means of resolutions of the Boards of Directors and Councils.