

## **Guidelines on Conflicts of Interest in JSCO/JSMO Business and Activities**

Japan Society of Clinical Oncology, Japanese Society of Medical Oncology

### **Preface**

The Japan Society of Clinical Oncology (JSCO) and Japanese Society of Medical Oncology (JSMO) aim to improve the prevention, diagnosis and treatment of cancer and contribute to the public good by providing educational activities for members, venues for member presentations of cancer study results and other research, awareness-raising activities for the general public, recommendations to government agencies, and similar benefits.

A large proportion of the research presented in JSCO/JSMO scientific conferences and publications is basic medical research that includes clinical studies done to standardize treatment methods for cancer patients, clinical studies using new drugs, medical equipment or technologies, and translational research done as a bridge to clinical medicine. Research and development done through partnerships between industry and academia are not uncommon. Cancer research done through these partnerships is continually growing in necessity and importance since it generates work products that are given back as benefits to clinical sites.

Cancer research done through partnerships between industry and academia generates work products that are obtained by satisfying scientific and ethical obligations and given back as benefits to the community (public benefits). But these partnerships can also result in the acquisition of benefits in forms such as money, status or rights (private benefits). Conflict of interest (COI) is the term used when these two types of benefits arise in an individual researcher. Since the complexity of human activities in the modern world makes it impossible to avoid generating conflicts of interest, legal restrictions have been imposed on certain activities.

However, conflicts of interest could also arise from actions not covered by legal restrictions. When these conflicts are serious, they run the risk of distorting research methods, data analysis or the interpretation of results. Another possibility is unfair evaluation of valid research findings. When educational or awareness-raising activities are done on the basis of these research findings, proper handling is needed to prevent questions arising over conflicts of interest.

So there is a need to clearly define guidelines on conflicts of interest for participants in JSCO/JSMO business or activities, and to ensure the fairness of all the business and activities done by JSCO/JSMO.

## **I. Guideline Aims**

As has been stated in the *Declaration of Helsinki*, and Japan's Clinical Trials Act and *Ethical Guidelines for Medical and Health Research Involving Human Subjects*, clinical research is very different from research done in other scientific fields. Since clinical research subjects are human, particular care is needed to conduct research safely while protecting subject lives and human rights.

Development in areas such as drug design and medical equipment is always done by way of basic medical research. Data from basic medical research is used to make decisions about continuing on to clinical research. Ensuring the reliability of basic medical research is also a critical issue affecting human lives, as specified in provisions such as the basic elements of reviews conforming to Japan's Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

The practice of cancer care involves presenting research findings, providing educational activities on the basis of these findings, creating guidelines, making recommendations to government agencies and engaging in other actions that can have a major public impact. To prevent questions over conflicts of interest from arising, proper handling is needed for these actions and all the business and activities done by JSCO/JSMO.

JSCO/JSMO have created these Guidelines on Conflicts of Interest in JSCO/JSMO Business and Activities ('the Guidelines') in light of our need to uphold our responsibility to the public and exercise high ethical standards in our business and activities. The aim of the Guidelines is to enable JSCO/JSMO to fulfill our duty to the public by properly handling conflicts of interest of our members and ourselves, and by appropriately conducting activities such as presentations of research findings, education and awareness-raising in a manner that maintains fairness and impartiality, assisting in the progress of cancer prevention, diagnosis and treatment.

Essentially, the Guidelines have been created to present JSCO/JSMO members with basic ideas on conflicts of interest, to prevent participants in JSCO/JSMO business or activities from making conflicts of interest more serious or from engaging in improper research associated with conflicts of interest, and to prevent suspicions arising in the public's mind.

JSCO/JSMO members are asked to obey the Guideline provisions that follow.

## **II. Applicable People**

The Guidelines apply to the following people who may generate a conflict of interest ('Guideline Subjects'):

1. JSCO/JSMO members
2. JSCO/JSMO staff
3. Presenters at JSCO/JSMO events
4. Attendees of JSCO/JSMO Board meetings, committee meetings or subcommittee meetings
5. Other participants in JSCO/JSMO business or activities

## **III. Applicable Activities**

The Guidelines apply to all the business and activities of JSCO/JSMO. Due to the high public impact of their activities, exceptional COI handling is required for people involved in areas such as educating JSCO/JSMO members, creating open courses, guidelines or other materials for the general public, or making recommendations to government agencies.

- (1) Presenting information such as research findings
  1. Presentations at JSCO/JSMO-hosted scientific conferences or similar events
  2. Presentations in JSCO/JSMO scientific journals, organization journals or similar publications
  3. Presentations at lectures, luncheon seminars, evening seminars or similar events hosted or cohosted by companies or for-profit organizations affiliated with JSCO/JSMO
- (2) Holding scientific conferences (including annual general meetings) or similar events
- (3) Publishing scientific organization journals or scientific books
- (4) Creating diagnostic/treatment guidelines, manuals or similar materials
- (5) Engaging in research or studies
- (6) Promoting research or providing research achievement awards
- (7) Certifying specialist physicians, supervising physicians or certified facilities
- (8) Engaging in educational seminars, courses open to the general public, or other educational, awareness-raising or publicity activities
- (9) Submitting recommendations or requests to government agencies or similar organizations
- (10) Working on organizations created on a provisional basis such as review or advisory committees
- (11) Engaging in other business or activities required for achieving objectives

While the responsibility for handling conflicts of interest in research activities lies with the researcher, JSCO/JSMO members will also refer to the Guidelines to handle conflicts of interest

in an appropriate and self-directed manner. All JSCO/JS MO members must also follow the provisions of the Guidelines to disclose COI statuses in a self-directed manner for scientific activities unrelated to the business activities of JSCO/JS MO (whether or not hosted/cohosted by a company).

#### **IV. Items for Disclosure or Public Release**

If a standard is exceeded within the separately specified time period, Guideline Subjects are obligated to make a self-declaration to disclose the precise circumstances surrounding their conflicts of interest in relation to Items (1) to (10) below that apply to themselves, following the specified format and insofar as needed for presentations at scientific conferences or the like. Moreover, if a standard is exceeded within the separately specified time period, Guideline Subjects are also obligated to make a declaration to JSCO/JS MO of the precise circumstances surrounding their conflicts of interest that apply to Items (1) to (3) below in relation to family members or others in their household who could potentially have an effect. If COI circumstances change, the declarer is personally responsible for promptly making an additional report for the original self-declaration and the information therein. The specific methods to be used for disclosure or public release are given separately, grouped by applicable activity.

- (1) Concurrently held posts as an officer or adviser of a company or for-profit organization
- (2) Stock ownership
- (3) Patent licensing fees from companies or for-profit organizations
- (4) Allowances, lecture fees or similar monies paid by companies or for-profit organizations for researcher time or labor when attending conferences (presenting, giving advice or the like)
- (5) Manuscript fees paid by companies or for-profit organizations for writing pamphlets or other publications
- (6) Research funding provided by companies or for-profit organizations (for joint research, contracted research, clinical trials or the like)
- (7) Advisory fees or remuneration paid by companies or for-profit organizations in connection with lawsuits or the like
- (8) Scholarship (subsidy) donations provided by companies or for-profit organizations
- (9) Endowed chairs provided by companies or for-profit organizations
- (10) Other remuneration (travel, gifts, or other in-kind payments not directly related to research)

The name of the company providing the funds will also be declared in the event that a research fee or donation is distributed indirectly via the head of an organization or the like, from a company

or for-profit organization to a department (course/field) or lab with which an individual is affiliated. The name of the company funding the applicable corporation will also be entered in the COI declaration in the event that researcher-led clinical research is performed after receiving financial support (contracted research fee, research grant-in-aid) from a not-for-profit organization (such as an NPO), public-interest corporation (such as an association or foundation) or similar organization.

## **V. Avoiding Conflicts of Interest**

### **1) Actions to be avoided by all Guideline Subjects**

The decision to publish research findings must be made purely on the basis of scientific factors or benefit to the public. JSCO/JSMO members must not be influenced by the self-interest of the research funding provider or company when deciding whether to present their research findings at conferences or in research papers, or when determining the basic information to present (the research findings and their interpretation). Members must avoid any contracts that would make such influence unavoidable. Researchers who accept contracts that make corporate influence unavoidable must provide and publicly release a detailed description of the role and involvement of the funding provider at the time their findings are published.

The actions below must especially be avoided when engaging in interventional studies of human subjects done through partnerships between industry and academia.

- (1) Acquiring discretionary bonuses in connection with mediation or introduction of research subjects taking part in clinical research
- (2) Acquiring discretionary bonuses for case gathering within a given time period
- (3) Receiving travel or lodging expenses from a funding provider or company for scientific conference participation unrelated to the applicable research
- (4) Acquiring discretionary performance remuneration for specific research findings

### **2) Actions to be avoided by research directors of clinical oncology research**

To be selected, research directors (other than investigators at institutions included in multifacility clinical research) with decision-making authority for planning and executing clinical research (including clinical studies and trials) must have none of the conflicts of interest below. These conflicts of interest must also be avoided after selection.

- (1) Owning the stock of the funding provider or company sponsoring the research, or taking a post as an officer or similar role at the funding provider or company sponsoring the research
- (2) Acquiring patent rights or patent fees related to drugs, treatment methods, screening methods or other elements of the research topic

- (3) Receiving money or gifts other than the legitimate remuneration corresponding to the time or labor spent on the research
- (4) Improper acts such as concealing the applicable company name in presentations of executed plans or findings when the research participants include corporate-affiliated temporary researchers, part-time instructors or adult graduate school students sent to the research institute
- (5) Conditions enabling the funding provider or company to exercise influence in relation to the gathering, storage, statistical analysis, interpretation or conclusion of the research data
- (6) Signing contracts enabling the funding provider or an interested-party company to exercise influence in relation to decisions about scientific conference presentations or paper presentations of the research findings

However, researchers who satisfy condition (1) or (2) above are permitted to be appointed as research directors when they are essential for the planning and execution of the applicable clinical research, and the research is of extremely high importance and significance. In this case, the research director must be accountable to the public for explaining information such as the method used to handle the COI, and must provide and publicly release detailed information on the role and involvement of the funding provider in the paper when the findings are published.

## **VI. Implementation Methods**

### **1) Member duties**

When presenting research findings at scientific conferences or other events, members must properly disclose any conflict of interest information related to the conduct of the research. The disclosure is made using the specified form. COIs will also be disclosed when taking part in business or activities done by JSCO/JSMO. If a contravention of the Guidelines arises, the committee in charge of conflicts of interest ('the COI Committee') will review the case, and it will then be reported to the Board of Directors. If a case is found to contravene the Guidelines and corrective action is set, the applicable member must understand the reason for it and provide their full cooperation.

### **2) Officer duties**

With important roles and duties regarding JSCO/JSMO business and activities, those in the following positions or similar positions must use the specified format to submit a COI self-declaration describing their COI status at the time they assume their post (including when reappointed): JSCO/JSMO Board chairmen/deputy chairmen, directors, auditors, Academic Conference chairmen/representatives/delegates, committee chairmen/members,

subcommittee chairmen/members and chairmen/members of Designated Committees organized when needed. COI statuses will be reviewed from the submitted COI self-declarations and will be considered when screening related committee chairmen/members. The Board of Directors is permitted to consult with the COI Committee and direct that corrective action or a similar measure be taken on the basis of the Committee's response if a serious conflict of interest arises with an officer (Board chairman/deputy chairman, director, auditor, Academic Conference chairman/representative/delegate or the like) while executing JSCO/JSMO business or activities, or if an officer's conflict of interest self-declaration is deemed improper.

When research findings are to be presented at a JSCO/JSMO event, the Board is permitted to check that the presentation will conform to the Guidelines, and to ban any presentation topics that contravene the Guidelines. In this case, the scheduled presenter will be promptly notified of the ban and the reason for it. These actions will be reviewed by the COI Committee and implemented after approval by the Board on the basis of the Committee's findings.

When research findings are to be presented in a JSCO/JSMO publication or similar work, the Board is permitted to check that the presentation will conform to the Guidelines, and to ban its publication if it contravenes the Guidelines. In this case, the scheduled paper publisher will be promptly notified of the ban and the reason for it. If a paper is found to contravene the Guidelines after publication, it will be permitted to publicly release that fact in the applicable publication or other work in the name of the Editorial Board chairman.

These actions will be reviewed by the COI Committee and implemented after approval by the Board on the basis of the Committee's findings.

JSCO/JSMO committee directors/members/staff and participants in JSCO/JSMO business or activities will check that each of the business areas or activities they are involved in conforms to the Guidelines. If a contravention to the Guidelines arises, it will be promptly reviewed by the COI Committee and handled after approval by the Board on the basis of the Committee's findings.

3) Filing objections

Anyone subjected to an action under the provisions of Item 1) or 2) above is permitted to file an objection with JSCO/JSMO. When JSCO/JSMO receives an objection, the COI Committee will promptly review the case again and notify the filer of its findings after discussing the case with the Board.

## **VII. Actions Taken Against Guideline Violators, Accountability**

1) Actions taken against Guideline violators

Under the provisions of the separate regulations specified by each Society, the JSCO/JSMO Board of Directors has the authority to review acts that violate the Guidelines. When a severe breach is deemed to have occurred after review by the COI Committee, the Board is permitted to take any of the actions below within a set time period corresponding to the severity of the breach.

- (1) Prohibiting presentations at all scientific conferences and other events held by JSCO/JSMO
  - (2) Prohibiting publication of papers in JSCO/JSMO publications
  - (3) Prohibiting appointment as chairman of JSCO/JSMO scientific conferences; revoking upcoming appointment as chairman; revoking post as chairman
  - (4) Prohibiting appointment as member of JSCO/JSMO Board of Directors, committees or subcommittees, prohibiting participation in business or activities thereof, or revoking post therein
  - (5) Prohibiting appointment or revoking post as JSCO/JSMO representative/delegate
  - (6) Revoking or prohibiting JSCO/JSMO membership
- 2) Filing objections
- Anyone subjected to an action is permitted to file an objection with JSCO/JSMO. When JSCO/JSMO receives an objection, the COI Committee will review the case again in good faith and notify the filer of its findings after discussing the case with the Board.
- 3) Accountability
- If JSCO/JSMO deems that a severe violation of the Guidelines has occurred, it will fulfill its duty of accountability to the public after discussing the case with the COI Committee and Board.

## **VIII. Dealing With COI Information**

- 1) Handling COI information
- Since it includes important personal information, COI information received from self-declarations needs to be dealt with carefully, and will be handled in a well-regimented manner by the JSCO/JSMO secretariat to ensure maintenance of confidentiality and protection of personal information.
- Declared COI information related to former officers or committee members due for removal will be stored in a well-regimented manner by the applicable secretariat under the supervision of the chairman of the Board of Directors for a set time period after the officer's final term has ended or after the date of committee member removal.
- Once the set time period has elapsed, the declared information will be promptly deleted or discarded under the supervision of the chairman of the Board. However, it is permitted to



defer the deletion or disposal of the declared COI information for a time period set as needed if the Board finds that deletion or disposal is not appropriate.

2) Using COI information

The JSCO/JSMO Board and the COI Committee are permitted to use COI information received in self-declarations at any time. However, the information will not be used any more than necessary, and will not be disclosed to anyone other than those requiring its disclosure for the specified usage objectives.

3) Responding to demands for COI disclosure or public release

If a demand for disclosure of the COI status of an officer or member is received from a member of the public (such as a media representative or civic organization), the chairman of the JSCO/JSMO Board must fulfill the duty of accountability to the member of the public making the demand. If the reason for the demand is deemed reasonable, the chairman of the JSCO/JSMO Board is permitted to consult with the COI Committee, and after receiving the Board's approval and taking adequate steps to ensure protection of personal information and privacy, the chairman is permitted to respond to the member of the public making the demand by providing information insofar as needed. If needed, it is permitted to conduct a fact-finding investigation or similar inquiry while ensuring personal information protection. In this case, it is permitted to create an investigative committee containing outside committee members (experts) if the existing members are deemed incapable of handling the investigation.

If disclosure of the COI status of a Designated Committee member, officer or JSCO/JSMO member is demanded by legal means, the Board will determine how to respond upon considering legal opinions.

## **IX. Handling Organization COIs**

An organization-wide COI status may arise for JSCO/JSMO in cases such as when a donation is received from a company or for-profit organization. Subsidies, donations and similar monies paid by companies or for-profit organizations for JSCO/JSMO business or activities will be publicly released on the websites or in other media. JSCO/JSMO will create an organization COI handling committee containing auditors and outside members, and will appropriately handle the organization-wide COIs of JSCO/JSMO.

## **X. Creating Regulations**

JSCO/JSMO is permitted to create regulations needed to implement the Guidelines in practice, taking each Society's autonomy and special characteristics into consideration.

## **XI. Amendment Method**

Factors such as public impact and amendments to laws related to partnerships between industry and academia are expected to result in the need for partial changes to the Guidelines reflecting individual cases. JSCO and JSMO are permitted to amend the Guidelines through joint discussion after each Society's decision-making body has voted for amendment.

### Supplementary Provisions

1. The Guidelines take effect on April 1, 2008.
2. The Guidelines take effect on April 1, 2010.
3. The Guidelines take effect on April 1, 2013.
4. The Guidelines take effect on February 13, 2019.