

The Japanese Society of Gastroenterology (JSGE)  
Policy on Conflict of Interest in Clinical Research

The Japanese Society of Gastroenterology (JSGE) was established in December 1898 as the Research Group for Gastrointestinal Diseases. The society's name was subsequently changed to The Gastro-enterological Society of Japan in March 1902 and to the current name of the Japanese Society of Gastroenterology in May 1964. The main objective of the JSGE is to encourage and promote basic and clinical research on digestive organs and their diseases, thereby furthering development of gastroenterology and contributing to human welfare. Specifically, JSGE's activities include organizing academic conferences for research presentation and discussion on the diseases of the digestive system, publishing journals, organizing educational lectures on diagnosis and treatment of the diseases of the digestive system, running and holding courses and lectures for training of gastroenterologists, supporting gastroenterologic research, holding symposiums and issuing publications with the purpose of raising public interest in the diseases of the digestive system, designating educational hospitals and conducting certification exams for certification of gastroenterologists, and providing international cooperation to the World Gastroenterology Organization (WGO).

Many research results presented or published at JSGE-sponsored academic lectures or in JSGE's publications derive from clinical research on diagnosis, treatment, and prevention of various diseases and clinical research using new drugs, medical devices and techniques. Meanwhile, an important foundation for promotion of such clinical research is provided through university-industry partnership activities (joint research, commissioned research, technology transfer and guidance, scholarship grants, and endowed chairs) with pharmaceutical companies and venture businesses, among others.

The more active the university-industry partnership activities become in promoting clinical research, the deeper the involvement of public entities, such as universities, research institutes, and academic societies, in the activities of specific companies. As a result, a clash or conflict inevitably and unavoidably occurs between academic institutions and societies' educational and research responsibilities and the personal interest gained from university-industry partnership activities. This resultant state is called "conflict of interest (COI)." In promoting university-industry partnership, an important challenge for academic institutions and societies is to overcome conflict of interest and to organizationally and appropriately manage such states of conflict of interest. Moreover, unlike university-industry partnership in other fields of research, clinical research essentially requires participation of healthy individuals as well as

patients as subjects. For those engaged in clinical research, the greater the conflict of interest with companies or other organizations providing funding or other benefits, the more likely it is for the human rights and personal safety of the subjects to be violated and the research methods, data analysis, and interpretation of the results to be warped. There is also the possibility for legitimate research results to be undervalued or go unpublished. It has been pointed out, however, that the problem with many past COI cases lay not with the state of conflict of interest arising from university-industry partnership, but with inappropriate management of conflict of interest. In recent years, many medical institutions and academic societies, both domestic and abroad, are drawing up COI policies in clinical research, to ensure fairness and equity in clinical research and maintain transparency and social reliability of the research results presented at academic societies, while promoting university-industry partnership in clinical research, in an effort to give back legitimate research results to society through appropriate COI management.

To appropriately manage the states of conflict of interest of its members and fulfill its accountability to society, JSGE drew up a COI policy that requires its members who are in a state of conflict of interest with their sponsors regarding their presentation or publication in JSGE projects to disclose, under certain conditions, the economic relations they have with their sponsors.

### I. Objective

Ethical principles regarding medical research on humans are described in the Declaration of Helsinki and the Japanese Ministry of Health, Labour and Welfare's Ethical Guidelines on Clinical Research (notice no. 255, revised 2008), which call for particular care in the protection of the subjects' human rights and lives and for the safe conduct of research.

Considering that JSGE is required to fulfill its social responsibility and maintain a high level of ethical standards in all of its activities, JSGE drew up the Policy on Conflict of Interest in Clinical Research (hereafter called the "Policy"). The Policy's objectives are to secure neutrality and impartiality in the presentation and publication of research results by appropriately managing the states of conflict of interest of JSGE members and to fulfill JSGE's social responsibility by appropriately promoting activities for disseminating research results and contributing to the progress of prevention, diagnosis, and treatment of diseases. The Policy, therefore, makes the basic principles on conflict of interest clearly known to JSGE members, and requires the members making presentation or publication in various JSGE projects to voluntarily and

appropriately disclose their state of conflict of interest and to abide by the Policy.

## II. Persons covered by the Policy

The Policy applies to the following persons to whom a state of conflict of interest may arise:

- (1) JSGE members
- (2) Persons making presentations at the JSGE's academic lectures, etc.
- (3) JSGE's board members (President, Directors and Auditors), organizers of academic lectures, etc. (chairs, etc.), chairs of various committees, members of specific committees, and members of nonpermanent working groups
- (4) JSGE's administrative staffs
- (5) Spouses, first-degree relatives, and all persons sharing the incomes and properties of any person mentioned above from (1) to (4)

## III. Activities covered by the Policy

The Policy applies to all activities of JSGE, including, without limitation:

- (1) Organization of academic lectures (including annual general assemblies), academic lectures organized by JSGE branches, etc.
- (2) Publication of JSGE journals, scientific books, etc.
- (3) Research, surveys, and investigations
- (4) Encouragement of research and commendation of research achievements
- (5) Administration of the certification system for gastroenterologists (certification of gastroenterologists and accreditation of hospitals, etc.)
- (6) Promotion of lifelong learning activities
- (7) Communication and cooperation with related academic societies
- (8) Promotion of international research cooperation
- (9) Any other activities required for the achievement of the JSGE's objectives

Compliance to the Policy is particularly required in carrying out the following activities:

1. Making presentations at academic lectures organized by the JSGE (such lectures hereafter called the "lectures, etc.")
2. Publishing articles in JSGE journals and other publications
3. Preparation of medical guidelines and manuals
4. Work carried out by provisionally set up investigative committees and advisory committees

#### IV. Matters for disclosure

If a person covered by the Policy corresponds to any one of (1) to (9) below in excess of the threshold set in the Detailed Regulations on the Policy on Conflict of Interest in Clinical Research, that person must notify the President of JSGE by providing accurate information of the situation. The specific methods of disclosure and announcement are set down in the Detailed Regulations.

- (1) Appointment as a board member, advisor, employee of a company, corporate organization, or for-profit organization
- (2) Ownership of corporate stocks
- (3) Patent royalties received from a company, corporate organization, or for-profit organization
- (4) Per diem (honoraria, etc.) paid by a company, corporate organization, or for-profit organization for the time and energy spent by a researcher to attend or give a presentation at a meeting
- (5) Fees paid by a company, corporate organization, or for-profit organization for writing a pamphlet, etc.
- (6) Grants for clinical research (clinical trials, clinical tests, etc.) from a company, corporate organization, or for-profit organization
- (7) Research grants (commissioned research, joint research, donations, etc.) from a company, corporate organization, or for-profit organization
- (8) Endowed chair from a company, corporate organization, or for-profit organization
- (9) Free trips and other gifts unrelated to research, education, and healthcare that are provided by a company, corporate organization, or for-profit organization

#### V. Matters to be avoided in relation to the state of conflict of interest

##### 1. Matters to be avoided by all persons covered by the Policy

Activities such as publication of research results and preparation of medical guidelines should be based purely on scientific evidence and judgment or carried out in the interest of the public. In publishing clinical research results and interpretations and preparing medical guidelines and manuals (diagnosis, treatment) based on scientific evidence obtained from clinical research, JSGE members must not be influenced by the arbitrary objectives of the person or company funding the clinical research, nor must they enter into an agreement with the provider of funding that will make such influence unavoidable.

##### 2. Matters to be avoided by principal investigators

The principal investigator with rights to make decisions on the planning and implementation of clinical research (including clinical trials and tests) should be selected from among researchers socially recognized as not being in a state of material conflict of interest in relation to each of the items shown below (in other words, involvement with the sponsor is relatively small). This condition concerning directorship should be maintained even after the selection of a principal investigator.

- (1) Ownership of shares of stock of the company requesting the clinical research to be performed
- (2) Acquisition of patent royalties or patents over products or technology resulting from the clinical research
- (3) Holding the position of board member of or advisor to the company or for-profit organization requesting the clinical research to be performed (excluding scientific advisor providing advice for free)

However, if the talent of a researcher corresponding to any one of (1) to (3) above plays an important role in the planning and implementation of the clinical research and, at the same time, the clinical research has an extremely significant meaning medically, the researcher may be appointed as the principal investigator of the clinical research, provided that equity, fairness, and transparency of the principal investigator's judgment and of the measures adopted by the principal investigator can clearly be ensured.

## VI. Method of conduct

### 1. Responsibilities of JSGE members

JSGE members making presentations of clinical research results at academic lectures, etc. must appropriately disclose, at the time of the presentation and in accordance with the Detailed Regulations using the prescribed forms, the state of conflict of interest related to the implementation of the research. If, in relation to the presentation of the research, etc., it is pointed out that the Policy has been violated, the JSGE board will refer the matter to the committee with jurisdiction over conflict of interest (hereafter called the "COI committee") for deliberation and will, based on the report of the COI committee, take reasonable steps.

### 2. Responsibilities of JSGE board members, etc.

JSGE's board members (President, Directors and Auditors), organizers of academic lectures (chairs, etc.), chairs of various committees, members of specific committees, and members of working groups are vested with important roles and responsibilities concerning all activities of the JSGE. As such, they will voluntarily report conflict of

interest they may have in relation to the activities of JSGE at the time of their appointment to their respective posts using a prescribed form. If, after appointment, a state of conflict of interest that did not exist before arises, they will make necessary changes to the prior report in accordance with regulations.

### 3. Role of the COI committee

If a state of material conflict of interest arises to a JSGE member in relation to any activities of the JSGE or if a JSGE member's voluntary disclosure of conflict of interest is inaccurate, the COI committee will notify the JSGE member concerned and provide necessary guidance. If it is pointed out that there are uncertain points in the contents of the voluntary disclosure of conflict of interest, the COI committee will make an inquiry by holding a hearing, etc. to appropriately manage the state of conflict of interest of the JSGE member concerned, and report its findings to the President of JSGE.

### 4. Role of the JSGE board

If a state of material conflict of interest arises in the execution of any activities of JSGE by JSGE board member, etc. or if the JSGE board recognizes any voluntary disclosure of conflict of interest to be inappropriate, the JSGE board may refer the matter to the COI committee and, based on the report of the COI committee, instruct steps to be taken to remedy the situation.

### 5. Role of the organizer of academic lecture

When presentations of the results of clinical research are to be made, the organizer of the academic lecture (chair, etc.) will check that the presentations are given in compliance with the Policy and may take steps to disallow presentations that run counter to the Policy. In the latter case, the organizer will promptly notify the presenter concerned to that effect and provide reasons for the decision. The organizer may refer such cases to the COI committee, and based on the report of the COI committee, the JSGE board may instruct steps to be taken to remedy the situation.

### 6. Role of the editorial committee

In case where originally authored articles on research results, reviews, medical guidelines, edited articles, opinions, etc. are to be published in JSGE journals and other publications, the JSGE journal editorial committee will check that such a publication is in compliance with the Policy and may take steps to disallow publication of materials that run counter to the Policy. In the latter case, the editorial committee will promptly notify the contributor concerned to that effect and provide reasons for the decision. If, after publication of certain material, it becomes apparent that the material had actually violated the Policy, the editorial committee may make that fact public in the publication concerned in the name of the editorial committee chair. In such a case, the editorial

committee chair may refer the matter to the COI committee and, based on the report of the COI committee, instruct steps to be taken to remedy the situation.

#### 7. Others

The chairs and members of other JSGE committees will verify that the JSGE activities they are respectively involved in are being carried out in accordance with the Policy, and if any violation of the Policy occurs in relation to the activities, they will promptly consider measures to remedy the situation. They may also refer such cases to the COI committee, and based on the report of the COI committee, the JSGE board may determine steps to be taken to remedy the situation.

### VII. Measures against transgressors and accountability

#### 1. Measures against transgressors

Based on the rules provided for separately, the JSGE board reserves the right to deliberate on acts of violation of the Policy. If the JSGE board decides, after first referring a case to the COI committee, ethics committee, and/or any other committee concerned and receiving their reports on the case and having deliberated on the case, that the case corresponds to a material breach of the Policy, the JSGE board may take steps to impose penalties, etc. in accordance with the degree of the breach.

#### 2. Filing of an objection

The individual subject to the penalties, etc. may file an objection to JSGE. In case where such a filing is made, the President of the JSGE will promptly establish a committee for the review of the objection (a provisional advisory committee) and refer the case to the committee for deliberation. The JSGE board will then deliberate on the committee's report and notify the results of the deliberation to the individual filing the objection.

#### 3. Accountability

If the JSGE determines that the results of clinical research presented at a venue to which the JSGE is directly concerned with do constitute a material breach of the Policy, the JSGE board will deliberate on the matter, and JSGE must take steps to fulfill its accountability to society.

### VIII. Cooperation with related scientific societies

JSGE will work closely with many related academic societies in the fields of internal medicine and surgery, and hold consultations with them to exchange information on the revision the Policy and on the Detailed Regulations.

#### IX. Establishment of detailed regulations

JSGE may set down detailed regulations necessary for the actual implementation of the Policy.

#### X. Revision of the Policy

The Policy is subject to regular reviews and revisions to accommodate various social factors, revision or establishment of laws and regulations on university-industry partnership, and various requirements in relation to healthcare and research.

#### XI. Date of enforcement

The Policy will take effect on a trial basis for a period of two years starting on January 1, 2011, and will enter into full force and effect on January 1, 2013.