

# Guidelines for Conflict of Interest (COI) in Medical Research

Conflict of Interest (COI) Committee,  
The Japan Neurosurgical Society (JNS)

## I. Purpose

Many of the medical research articles presented at academic societies or in publications such as journals involve pharmaceuticals, medical devices, and related technology. Research and development is often conducted through industrial and academic collaboration. Although medical research involving such collaboration is extremely important to medical science progress, it may also attract the public interest by producing academic benefits for society and private interests, including money, position, and the rights and interests acquired through such collaboration. Conflicts of interest (COIs) may thus occur where interests conflict an individual researcher, for example. Serious COIs may even distort research methods, data analysis, or the interpretation of results, or produce research results that lack neutrality and fairness, however reasonable they may appear. Medical research requires that COI problems involving clinical research be handled carefully to ensure ethical and scientific validity while protecting study subjects' human rights, lives, and safety.

The Japan Neurosurgical Society (JNS) recognizes that actively promoting medical research is its social responsibility and that, in doing so, *Guidelines for COI in Medical Research* must clarify corporate policy on COI to JNS members.

The purpose of these Guidelines is to fulfill corporate social responsibility for helping promote the prevention, diagnosis, and treatment of neurological disease through appropriately presenting and disseminating research results through appropriate JNS management of COI status of members while ensuring justice, neutrality, and fairness in medical research involving industrial and academic collaboration.

These Guidelines provide the basic COI principles for JNS members and the JNS requires that members involved in activities conducted by the JNS comply with these Guidelines as specified below.

These Guidelines describe the core of JNS COI management. For concepts and other details of COI, see the Japanese Association of Medical Science website:

<http://jams.med.or.jp/guideline/index.html>.

## II. Scope

The Guidelines apply to the following in which COI status may occur:

- (1) JNS directors, auditors, and delegates
- (2) All JNS members in addition to the above officials
- (3) Nonmembers making presentations at scientific annual meetings and scientific branch meetings held by the JNS and who present articles in the JNS journal of *Neurologia medico-chirurgica*
- (4) JNS clerical staff

### **III. Applications**

The Guidelines apply to all activities involving the JNS, particularly researchers making academic presentations at scientific annual meetings, scientific branch meetings, and lectures held by the JNS, as well as researchers who present articles in the JNS journal, who are required to ensure any medical research presented complies with Guidelines. Compliance with the Guidelines is also required of, among others, lecturers speaking to JNS members or giving lectures open to the general public because of the potentially great impact of such lectures on society.

### **IV. Matters Disclosed and Published**

Matters related to the above persons fall under items (1) through (6), below, and to their spouses, first-degree relatives, and any others with whom the above persons share income and property falling under items (1) through (3), below. Such persons have the obligation to disclose the exact status of COI through self-reporting based on the criteria in *Bylaws on COI in Medical Research*, specified separately. Those making such reports assume responsibility for the content of such reports:

- (1) Employment/Leadership position/Advisory role
- (2) Stock ownership or options
- (3) Patent royalties/licensing fees
- (4) Honoraria (e.g. lecture fees)
- (5) Fees for promotional materials (e.g. manuscript fee)
- (6) Research funding

### **V. COI Status and Situations to Be Avoided**

#### **1. Situations that all specified persons must avoid**

Publication of medical research results must be based on scientific judgment and the public interest. No publication related to activities by the JNS should be adversely affected by the arbitrary intent of research-funding parties or specific companies regarding the determination of whether medical research results must be presented at academic societies or published in articles or contents including results of medical research and the interpretation thereof, and no agreements should be concluded making influence unavoidable.

#### **2. Situations to be avoided by those conducting clinical research**

When conducting clinical research (including clinical studies and trials), researchers must avoid the following COI status:

- (1) Receipt of considerations for mediating for or introducing clinical study subjects
- (2) Receipt of considerations for accumulating study subjects within a given period
- (3) Receipt of performance remuneration for particular research results
- (4) Conclusion of agreements enabling funding parties or companies to influence determinations on academic presentations of research results or articles

#### **3. Situations to be avoided by clinical research investigators**

Taking the post of chief researcher of a clinical research project (including clinical

studies and trials) or the post of principal investigator impacting on research plans and/or implementation, provided that no investigator at each site for a multicenter clinical research falls under these posts. Such posts should be assumed by researchers not covered by the COI status below. Such researchers and/or principal investigators must avoid such COI status even after assuming such posts:

- (1) Holding stocks of companies entrusting clinical research
- (2) Acquiring patent fees and rights of products and/or technology resulting from clinical research
- (3) Assuming positions of officials, directors, or advisors (excluding those of unpaid scientific advisors) of companies entrusting clinical research

Researchers falling under items (1) through (3) above may, subject to review by the COI Committee of the JNS, assume the post of chief researcher or principal investigator of clinical research if such researchers are vital to planning and implementing clinical research and such clinical research is highly significant.

## **VI. Enforcement Procedures**

### **1. COI Committee role**

The JNS has established the COI Committee to respond to questions and requests from members about potential COI status; to manage, investigate, and review COI; and to propose improvements and conduct educational activities.

### **2. JNS member roles**

JNS members presenting medical research results are obligated to appropriately disclose COI status associated with implementation of such research. Disclosure follows the specific procedures in *JNS Bylaws on COI in Medical Research*. The COI Committee reviews situations inconsistent with the Guidelines and reports review results to the Board of Directors (BOD).

### **3. Roles of officials**

JNS officials (i.e., directors, auditors, and delegates) are obliged to make self-reports on assuming these posts, because these officials assume important roles and responsibilities for all JNS-related projects. Self-reports are made following the specific procedures provided by the *JNS Bylaws on COI in Medical Research*.

Regarding agreements with other companies or organizations made in the performance of JNS projects, officials shall not agree to terms or conditions restricting the fairness or neutrality of research activities and presentations related to such projects.

If serious COI status occurs in JNS project performance by officials or if the BOD deems self-reports on COI to be improper, the BOD may submit such issues to the COI Committee and give instructions on improvements based on the COI Committee report.

Persons chairing scientific annual meetings and scientific branch meetings may check that research results to be presented at academic meetings follow the Guidelines and may suspend presentations of subjects inconsistent with the Guidelines. These actions are reviewed by the COI Committee as necessary and decided by chairs based on reports by the COI Committee.

#### **4. Roles of the Editorial Committee for official journal**

The Editorial Committee may check that contributed articles follow the Guidelines and that articles are consistent with the Guidelines. The Editorial Committee may suspend the appearance of such articles in the journal. For inconsistencies with the Guidelines in articles already appearing in the journal, the Editorial Committee may make public announcements to this effect in publications in the name of the Editor-in-Chief. Such actions are reviewed by the COI Committee as necessary and decided by the Editor-in-Chief based on reports by the COI Committee.

#### **5. Roles of other JNS committees**

Other JNS committees check that the performance of JNS projects involving JNS committees follows the Guidelines. In situations inconsistent with the Guidelines, committees must promptly consider improvements for such situations. These actions are reviewed by the COI Committee as necessary and decided by JNS committee chairs based on reports by the COI Committee.

### **VII. Actions Against Violators**

#### **1. Actions against violators**

The COI Committee is authorized to review acts violating the Guidelines and to report results of reviews to the BOD. For acts deemed to be in material noncompliance, the BOD will act as specified in the *Bylaws on COI in Medical Research* based on the degree of noncompliance.

#### **2. Objections**

Individuals subject to the above committee actions may object to the JNS. If the JNS receives an objection, the Provisional Review Board specified in the *Bylaws on COI in Medical Research* will consider the objection.

#### **3. Accountability**

If the JNS deems that a material violation of compliance with the Guidelines has occurred in medical research in JNS projects, the JNS pursues accountability by publishing information to this effect after discussions in the COI Committee and the BOD.

### **VIII. Retention and Management of COI Self-Report Forms and Disclosed COI Information**

The COI Self-Report Form and disclosed COI information are retained and managed strictly as private information by the JNS Office under the director as manager based on the *Bylaws on COI in Medical Research*.

### **IX. Regulations for Guideline Management**

The JNS establishes the *Bylaws on COI in Medical Research* required to actually manage the Guidelines.

## **X. Dates of Enforcement and Revision Procedures**

The Guidelines may require specific modifications due to social effects and changes in laws and regulations on industrial and academic collaboration. The COI Committee, as a rule, reviews the Guidelines biennially and may revise the Guidelines by a resolution of the BOD.

### **Supplementary Provisions**

1. The Guidelines go into force on and after January 1, 2012.