

General Incorporated Association Japan Epilepsy Society

Policy of Conflict of Interest in Clinical Research

Introduction

Among the research findings presented and published in academic conferences and journals of the Japan Epilepsy Society (referred to as the Society hereinafter), many are clinical studies aiming to improve diagnosis and treatment, as well as clinical research using novel drugs, medical equipment and medical technology. A large number of these studies are promoted or sponsored by pharmaceutical companies and other industries as initiatives of academic-industrial collaboration (including collaborative research, commissioned research, technology transfer or guidance, scholarship contributions, endowed chairs). It is essential that these research findings are published with academic and ethical integrity, for the benefit of the society (public interest). On the other hand, these clinical studies based on the world trend of academic-industrial collaboration have brought a close association of the Society, which is a public body, with certain commercial activities.

As researchers become more active in fulfilling social responsibilities and engaging in academic-industrial collaboration, a state of conflict or contradiction with private interest (money, status, rights and other benefits) arises, which is termed “conflict of interest (COI)”. Appropriate management of this state of COI is important for proper promotion of academic-industrial collaboration, and to enable the Society to conduct educational, research and medical care activities with trust from the nation and the people. The participation of healthy volunteers and patients is indispensable in the conduct of a clinical study. If a serious COI state exists between the investigators conducting the clinical study and the commercial organizations or entities that sponsor funds or benefits, there is a risk that the human rights and safety of the trial subjects may be compromised, or the research methods, data analysis and interpretation of results may be distorted. Therefore appropriate management of that status of COI is necessary to prevent the researchers from being involved in a serious COI state.

The Society has established a COI policy that stipulates members to declare on a voluntary basis (transparency) the financial relations with commercial entities with which a COI relation during their presentation or publication in Society activities, and manages the state of COI of members appropriately in order to accomplish the Society’s accountability to the society.

1. Objectives

The ethical principles for medical research on human subjects have already been provided in the “Declaration of Helsinki” and “Ethical Guidelines for Clinical Studies” (Ministry of Health, Labour and Welfare Notification No. 255, amended in 2008), which demand special considerations to safeguard the human rights and the lives of the trial subjects and to conduct the research safely.

In view of the social responsibility and the high ethical standard expected of the Society in its activities, the Society has established the Policy of Conflict of Interest in Clinical Research (referred to as the Policy hereinafter). The objective of the Policy is to appropriately manage the state of COI of members of this Society so as to maintain neutrality and impartiality for appropriate promotion of transmission of research results and related dissemination and educational activities, which contributes to the progress of medical care and treatment of epilepsy. The Policy explains the fundamental concept of COI to members of the Society and stipulates them to voluntarily declare their COI status accurately when participating and presenting in various Society activities.

2. Individuals covered

This Policy applies to all persons specified below, in whom potential COI may arise:

1. Members of the Society;
2. Persons who make presentations in academic lectures held the Society;

3. Officers of the Society (President, executive committee members, auditors), persons responsible for academic meetings (including chairs of conferences, chairs of regional branches), chairs of various committees, and members of special committees (including Editorial Board, Guideline Committee, Ethical Committee, Pharmaceutical Committee, and Conflict of Interest Committee);
4. Office employees of the Society;
5. Spouses, immediate families, or persons who share income or assets with those listed in 1 to 4.

3. Activities covered

The Policy applies to all the activities conducted by this Society.

1. Convening academic meetings (including the annual conference), and academic meetings held by regional branches;
2. Publication of official journals and academic books;
3. Conducting research and surveys;
4. Incentive awards for research and prizes for research achievement;
5. Certification of specialists and facilities;
6. Promotion of continuing education activities;
7. Liaison and collaboration with related academic organizations;
8. Promotion of international research collaboration;
9. Activities necessary for achieving other objectives.

4. Matters requiring declaration

An individual should declare the exact status to the President of the Society for any of items 1 to 9 described below, when the benefits exceed the criteria provided by the Bylaws. Detailed methods of declaration are provided separately in the Bylaws.

1. Employment as officer, consultant, employee, etc. for a commercial / incorporated organization or for-profit entity;
2. Ownership of stocks of a company commercial organization;
3. Patent royalty from a commercial / incorporated organization or for-profit entity;
4. Honoraria (such as lecture fee) paid by a commercial / incorporated organization or for-profit entity as remuneration for the time and efforts of a researcher spent in participating (presenting) in a meeting;
5. Manuscript fees paid by a commercial / incorporated organization or for-profit entity for contributing to brochures and others
6. Clinical research funds (such as funds for clinical trial and clinical study) provided by a commercial / incorporated organization or for-profit entity;
7. Research funds (such as commissioned research, collaborative research, and contributions) provided by a commercial / incorporated organization or for-profit entity;
8. Endowed chairs provided by a commercial / incorporated organization or for-profit entity;
9. Other remunerations including travel expenses (such as for conference attendance) and gifts not listed above.

5. Restrictions in a COI relationship

1. Restrictions on all persons covered

Publication of clinical research findings and development of guidelines should be based purely on scientific evidence or public interest. When presenting or publishing clinical research results and their interpretations and when preparing clinical (diagnostic and treatment) guidelines and manuals based on evidence obtained from clinical studies, members of the Society shall not be influenced by the self-interest-oriented opinions of an individual or a commercial entity providing funds

for the clinical research, or enter into a contract with the fund provider by which this influence cannot be avoided.

2. Restrictions on principal investigators of clinical trials

The principal investigator who has primary responsibility for the protocol and implementation of the clinical research (including clinical study and clinical trial) should be a selected person socially accepted as having no serious COI with respect to the items described below (little association with the sponsor) and should maintain such status after being selected.

1. Owning stocks in the company sponsoring the clinical research;
2. Receiving royalties or patents of the product or technology obtained from the results of the clinical trial;
3. Holding positions such as officer, board member, and consultant of the commercial organization or for-profit entity sponsoring the clinical research (except non-paid scientific advisor).

However, a researcher who has COI as listed in 1 to 3 above may be appointed as principal investigator of the clinical research if the principal investigator is an expert indispensable in the planning and implementation of the clinical research and the research has high clinical importance, under the condition that the neutrality, impartiality and transparency of the researcher's judgments and actions can be assured explicitly.

6. Implementation

1. Responsibilities of members

When presenting the state of COI related to the research facility concerned during a presentation of clinical research findings in an academic meeting, etc., members shall appropriately disclose any COI using the form provided in the Society's Bylaws. In case of an allegation of potential violation of the Policy, the Executive Committee shall request deliberation at the committee in charge of conflict of interest (abbreviated as COI Committee hereinafter) and take appropriate action based on the decision.

2. Responsibilities of officers and others

Officers of the Society (President, executive committee members, and auditors), persons in charge of academic meetings (chairs, etc.), chairs of various committees, and members of special committees undertake important roles and responsibilities for all the activities related to the Society. At the time of appointment, they shall declare the state of COI concerning their respective activities using a predetermined form. In the event that new COI arises after appointment, they shall revise the declaration according to the regulation.

3. Responsibilities of the COI Committee

In all the activities conducted by the Society, when a member of the Society is involved in a serious state of COI or when there is allegation that the declared COI is inappropriate, the COI Committee shall investigate the issue by conducting a hearing in order to manage the member's COI state, and report the result to the President.

4. Responsibilities of the Executive Committee

When a serious state of COI arises while officers etc. implement activities of the Society, or when a declared CIO is found to be inappropriate, the Executive Committee may consult the COI Committee and instruct remedial measures etc. based on the COI committee's report.

5. Responsibilities of persons in charge of academic meetings

When clinical research findings are presented at an academic meeting, the person responsible for the academic meeting (such as the chair) should verify whether the presentations comply with the Policy. In the event that a presentation violates the Policy, actions such as prohibiting the presentation may be taken. In such case, the responsible person should promptly notify the provisional speaker to that effect, together with the reason. In taking these actions, the responsible person may consult the COI Committee and instruct remedial measures etc. based on the COI committee's report.

6. Responsibilities of Editorial Board

When original articles of research findings, reviews, clinical guidelines, editorials, and comments, are published in the official journals and other publications, the Editorial Board should verify that the publications comply with the Policy. In the event of violation of the Policy, the Editorial Board may take actions such as prohibiting the publication. In such case, the Editorial Board should promptly notify the author(s) of the submitted article to that effect, together with the reason. If an article is found to violate the Policy after publication, the Editorial Board may publicly announce this matter in the journal concerned, under the name of the Editor-in-chief. In taking these actions, the Editor-in-chief may consult the COI Committee and instruct remedial measures etc. based on the COI committee's report.

7. Others

Committee chairs and members should verify that implementation of the activities of the Society in which they are involved comply with the Policy. In the event that a violation of the Policy arises, remedial measures should be examined promptly. In taking these actions, the COI Committee may be consulted, and the Executive Committee may instruct remedial measures etc. based on the COI committee's report.

7. Penalties for violation and obligation of explanation

1. Penalties for policy violation

The Executive Committee of the Society has the authority to review an action of violation of the Policy, according to rules specified elsewhere. Upon consulting the Ethical Committee (or equivalent committee) and obtaining a response, and based on the result of deliberation at the Executive Committee, when a serious violation is judged to have taken place, the Executive Committee may impose all or part of the following penalties for a period deemed appropriate, depending on the degree of violation.

1. Prohibition from presenting at all the academic meetings held by the Society;
2. Prohibition from publishing in publications of the Society;
3. Exclusion from being appointed as chair of academic meetings of the Society;
4. Exclusion from participating in the Executive Committee and committees of the Society;
5. Dismissal or exclusion from participation as councilor of the Society;
6. Disqualification, evocation or prohibition of membership of the Society.

2. Appeal of Decision

The person imposed with penalty may appeal to the Society. When an appeal is received, the President promptly forms an appeal committee and requests a review. Upon deliberation of the report by the appeal committee, the President will notify the result to the appealing person.

3. Accountability

In the event that a serious Policy violation is judged to have taken place regarding the clinical research finding presented in a venue associated with the Society, upon prompt

deliberation at the Executive Committee, the Society must acknowledge this fact to the public to fulfill its accountability.

8. Establishment of bylaws

The Society may establish bylaws for operation and execution of this Policy.

9. Revising the Policy

The Policy may be regularly reviewed and revised to adapt to social factors, amendments of laws related to academic-industrial collaboration, and changes in conditions concerning the infrastructure, medical care and clinical research. Revision of the Policy is reported to the Executive Committee and endorsed at the General Assembly.

10. Effective date

The trial period of the Policy is from October 8, 2011 for a period of two years. The Policy will be fully effective thereafter.

General Incorporated Association Japan Epilepsy Society
Bylaws for the Policy of Conflict of Interest in Clinical Research

Purpose

The Japan Epilepsy Society (referred to as the Society hereinafter) has established the Policy of Conflict of Interest in Clinical Research. In order to manage the state of conflict of interest (COI) in a fair manner, Bylaws for the Policy of Conflict of Interest in Clinical Research are established as follows.

Article 1 (Declaration of COI)

Section 1

When presenting or lecturing on clinical research in meetings (including annual conference, regional meetings, and academic meetings) or public lectures organized by the Society, the lead presenter must, at the occasion of the presentation, declare the status of COI regarding any financial relationship with “commercial / incorporated organization or for-profit entity related to the clinical research” during the past one year, using Form 1 during abstract registration.

The lead presenter must disclose the status of COI in the first slide (or the slide following introduction of the title and presenters) using Forms 2-A or Form 2-B, or at the end of the poster using form 2-C.

Section 2

“Commercial / incorporated organization or for-profit entity with a relationship with the clinical research” is defined as a commercial / incorporated organization or for-profit entity having the following relations with the clinical research.

1. Sponsors the clinical research, or jointly conducts the research (paid or unpaid);
2. Shares rights such as patent rights related to the therapy, drug, equipment, etc. evaluated in the clinical research;
3. Provides the drug, equipment, etc. used in the clinical research, free of charge or at a special discount price;
4. Provides grant or contribution to the clinical research;
5. Provides unapproved drugs or medical device for the clinical research;
6. Sponsors endowed courses, etc.

Article 2 (Criteria for declaration of COI)

Regarding the amount that requires declaration of COI, criteria are established for each of the items requiring disclosure, as follows:

1. For appointment as officer or consultant in commercial / incorporated organization or for-profit entity related to the clinical research (referred to as company, organization or entity hereinafter), declare if the annual income from one company, organization or entity is ¥1,000,000 or more;
2. For stock ownership, declare if the annual profit (sum of dividend and capital gain) from a single company is ¥1,000,000 or more, or if owns 5% or more of the total shares;
3. For patent royalties from company, organization or entity: if the annual royalty from one patent is ¥1,000,000 or more;
4. For honoraria (such as lecture fee) paid by company, organization or entity for the time and efforts of the researcher spent in meeting participation (presentation), declare if the annual lecture fees from one company or entity total ¥500,000 or more.
5. Manuscript fees paid by company, organization or entity for contributing to brochures etc., declare if the annual manuscript fees from one company, organization or entity total ¥500,000 or more;

6. For research funds, declare if the annual amounts paid by one company or entity for a clinical research (such as commissioned research fund and collaborative research fund) total ¥2,000,000 or more;

7. For scholarship (prize) contributions provided by company, organization and entity: if the annual contributions paid by one company, organization or entity to the declarer or the representative of the declarer's affiliated department (course or specialty) or research laboratory total ¥2,000,000 or more;

8. If the declarer is affiliated with the endowed course provided by company, organization or entity;

8. For other remunerations including travel expenses and gifts not directly related to research: if the annual amounts received from one company, organization or entity total ¥50,000 or more.

However for items 6 and 7, if the lead presenter personally or the lead presenter's affiliated department (course or specialty) or research laboratory has received research funds or scholarship contributions related to the research findings from a company or entity with COI relationship that requires disclosure, then declaration is necessary.

Article 3 (Disclosure in official journals)

All authors who intend to publish articles (including reviews and original articles) in the official journals of the Society (*Tenkan Kenkyu* and *Epilepsy & Seizure*) must report to the secretariat of the journals the status of COI with any company, organization or entity with an association with the contents of publication during one year prior to the time of submission, using the "Potential Conflict of Interest Declaration Statement" (Form 3: *Tenkan Kenkyu*, Form 4: *Epilepsy & Seizure*). Regarding the COI status to be reported at the time of submission, the items provided in 4. *Matters Requiring Declaration* of "Policy of Conflict of Interest in Clinical Research" should be declared, and the amount of financial interest requiring declaration for each item of disclosure is provided in Article 2 of the Bylaws. The "Potential Conflict of Interest Declaration Statement" will not be revealed to reviewers of the manuscript.

Article 4 (Submission of declaration of COI by officers, president and committee members, etc.)

Section 1

Officers of the Society (President, executive committee members, auditors), chairs of academic meetings (including conferences), chairs of various committees, and members of special committees (including Editorial Board, Guideline Committee, Ethical Committee, Pharmaceutical Committee, Conflict of Interest Committee) must submit a declaration of COI to the Executive Committee using Form 5, regarding the status of COI during one financial year prior to the time of appointment, on items provided in 4. *Matters Requiring Declaration* of "Policy of Conflict of Interest in Clinical Research". This declaration should be submitted to the Executive Committee at the time of appointment and every year after appointment.

Section 2

Regarding the COI status to be reported in the declaration form, the items provided in 4. *Matters Requiring Declaration* of "Policy of Conflict of Interest in Clinical Research" should be declared. Referring to the standard amount of financial interest requiring declaration for each item of disclosure provided in Article 2 of the Bylaws, declaration should be made specifying the sum of financial interest for each item following the format in the declaration form. The COI during one financial year prior to the time of appointment should be reported in the declaration form. In the event that new COI arises during office, the officers etc. have the obligation to report within 8 weeks.

Article 5 (Handling of COI declaration statements)

The COI declaration forms submitted at the time of abstract submission for presentation at

a conference or at the time of manuscript submission to journals of the Society must be retained securely at the office of the Society under the supervision of the President for 2 years from the date of submission. Likewise, documents etc. with COI information related to persons who have completed their terms of office as officers or chairs of conferences and persons whose assignment as committee member has been withdrawn must also be retained securely at the office of the Society under the supervision of the President for 2 years from the date of completion of final office or withdrawal of assignment as committee member. After 2 years of retention, documents are deleted or disposed of promptly under the supervision of the President. In the case that the Executive Committee has decided that deletion or disposal is inappropriate, then deletion or disposal of the COI documentation of the declarer concerned may be postponed for a period of time deemed necessary.

Section 2

The Executive Committee members and related officers of the Society judge the presence or absence, or the degree of COI based on the declaration forms submitted, in accordance with the Bylaws. When management or actions are undertaken based on the judgment, the Society may utilize the COI information of the person concerned any time as needed.

Section 3

Except in the case of Article 5, Section 2, all COI information is in principle undisclosed. However, when there is a need for the Society to fulfill its social and ethical accountability concerning the activities of the Society and its committees, etc., COI information may be disclosed to an extent deemed necessary within or outside the Society upon deliberation at the Executive Committee. The person involved in the COI information to be disclosed or publicly announced may express his/her opinions to the Executive Committee. However, this shall not apply when there is urgency in disclosure or public announcement and no time to listen to opinions.

Section 4

In the case of a request (including a legal request) from a non-member to disclose COI information of a named member, if the request is considered reasonable and upon receiving consultation from the President, the COI Committee responds appropriately based on the principle of protection of personal information. However, if it is decided that the COI Committee cannot handle the issue, the President then sets up a COI Investigation Committee by designating several members of the Society and at least one external committee member, and conduct consultation. The COI Investigation Committee convenes a meeting within 30 days of receipt of the request for disclosure, and reports as promptly as possible.

Article 6 (Conflict of Interest Committee)

The COI Committee is composed of several members of the Society and at least one external committee member designated by the President. The chair of the Committee is elected by mutual election among the committee members. Members of the COI Committee are obliged to strictly protect the confidentiality of members' COI information acquired during their duties. In collaboration with the President and the Ethical Committee, the COI Committee manages and takes actions against violations in accordance with the Policy of Conflict of Interest in Clinical Research and the Bylaws, with the objective to prevent development of members' COI states into serious incidents.

Article 7 (Penalties for violation)

Section 1

If allegations or social /ethical problems arise in relation to a disclosed item declared by

the first author of a manuscript submitted to the official journals of the Society (*Tenkan Kenkyu* and *Epilepsy & Seizure*) or by a provisional speaker at a conference organized by the Society, the COI Committee takes appropriate measures such as thorough investigation and hearing, in order to fulfill the social accountability of the Society. In case of a serious COI that compromises the accountability of the Society, the President consults the Ethical Committee, and upon deliberation at the Executive Committee based on the Ethical Committee's report, may take measures such as prohibiting the publication or presentation by the author or presenter concerned. If issues such as allegations arise after publication, the President engages in fact finding, and if violation is confirmed, takes measures such as retraction of the published article. If the social credibility of the Society is severely damaged by the violation, the President takes measures involving membership qualification, in accordance with the Constitution of the Society.

Section 2

If potential violation is alleged regarding the COI items declared before appointment or after appointment of officers of the Society, chairs of various committees, or committee members, or nominees of the above who are required to declare COI, the COI Committee must notify the President of the problem in writing, and the President must convene an Executive Committee meeting immediately to decide whether or not to acknowledge the allegation. If the allegation is acknowledged, the involved officer or nominee of officer may be dismissed, and for other committee members, assignment may be withdrawn upon discussion with the committee member or the nominee of committee member concerned.

Article 8 (Appeal of Decision)

Section 1: Request for appeal

When a person who has been notified of penalty for violation regarding presentation or publication in Society activities (such as official journals and academic meetings) under Article 7, Section 1, or a person who is notified of dismissal as officer or withdrawal of assignment as committee member or nominee of committee member under Article 7, Section 2 objects to the decision, he/she may compose a request for appeal addressed to the President asking for review of the case, and submit the request to the secretariat of the Society within 7 days of receipt of the notification of the Executive Committee's decision. The request for review should concisely and precisely describe the opinions of rebuttal or objection to the reasons for the decision delivered by the committee chair in writing. In this case, the person may show relevant information as evidence to support the reason for objection in addition to the information disclosed to the committee chair.

Section 2: Procedures of appeal of decision

1. When receiving a request for review, the President must set up an Appeal Review Committee (referred to as Review Committee hereinafter). The Review Committee is composed of several members of the Society and at least one external committee member. The chair is elected by mutual election. A member of the COI Committee cannot serve as member of the Review Committee. The Review Committee convenes within 30 days of receipt of the request for review, and conducts the review.
2. The Review Committee may, as a necessity arises, hear the opinions of the chair of the Ethical Committee involved in the appeal and the opinions of the person who filed the appeal.
3. Except under special circumstances, the Review Committee concludes a report on the decision regarding the appeal within 30 days from the date of convention of the first review meeting, and submits to the President.
4. The decision of the Review Committee is final.

Article 9 (Revision of the Bylaws)

The Bylaws are regularly reviewed and revised as necessary. Revisions of the Bylaws are reported to the Executive Committee and endorsed at the General Assembly.

Supplemental provisions

Article 1 (Effective date)

The trial period of the Bylaws is from October 8, 2011 for a period of two years. The Bylaws will be fully effective thereafter.

Article 2 (Provision related to coverage of officials)

The Bylaws apply to persons who have been serving as officers of the Society at the time when the Bylaws are effective, who should undertake the necessary reports promptly.