

## The Japan Endocrine Society Bylaws Concerning Conflict of Interest Policy in Clinical Research

The Japan Endocrine Society (JES) (hereafter referred to as “the Society”) was established in 1925. The Society aims to promote the spread of endocrinology through research presentations related to basic and applied endocrinology, exchange of knowledge, and collaboration among members, and thereby to contribute to academic development in this country and improve the welfare of humankind.

The Society has developed a policy concerning Conflict of Interest (hereafter referred to as “COI”) in clinical research, in cooperation with 13 other societies related to internal medicine (The Japanese Society of Internal Medicine, The Japanese Society of Gastroenterology, The Japanese Society of Hepatology, The Japanese Circulation Society, The Japan Diabetes Society, The Japanese Society of Nephrology, The Japanese Respiratory Society, The Japanese Society of Hematology, Societas Neurologica Japonica, The Japan Society of Allergology, The Japan College of Rheumatology, The Japan Association for Infectious Diseases, the Japan Geriatrics Society). For the fair management of COI involving the members, the Bylaws concerning Conflict of Interest Policy in Clinical Research shall be set forth as follows.

### Article 1 (Disclosure of COI in conferences of the Society)

1. If a member or non-member presenter will make presentations or lecture on his/her clinical research at a conference organized by the Society (including annual meetings, JES Summer Seminar on Endocrinology & Metabolism, JES Clinical Update on Endocrinology & Metabolism, et al.), public forum, or local/branch chapter conference, the presenting author is required to report any financial relationship between s/he, his/her spouse, first-degree relatives, or anyone living with the presenter, and any commercial entities or for-profit organizations related to the clinical research within the previous 12 months, using Form 1, at the time of abstract submission. The presenting author shall disclose applicable COI at the beginning of presentation slides (the slide after the title of presentation and the name of presenters) using Form 1-A, or at the end of a poster using Form 1-B.
2. “Business enterprises, for-profit corporate organizations, and commercial entities related to clinical research” are defined as follows.
  - (1) Sponsors of clinical research, or organizations who jointly conduct clinical research, regardless of whether funded or non-funded.
  - (2) Organizations sharing the rights including patent rights regarding treatment methods, drugs and/or equipment that are evaluated in clinical research.
  - (3) Organizations providing drugs and/or equipment for clinical research gratis or at an

advantageous price.

- (4) Organizations funding or contributing financially to clinical research.
  - (5) Organizations providing unapproved drug and/or equipment for clinical research.
  - (6) Sponsors of endowed departments.
3. “Clinical research” related to the subject of presentation shall be defined as medical research involving human beings with an aim to improve prevention, diagnosis and treatment methods, understand pathogenesis and pathology, and enhance quality of life of patients. Medical research involving human subjects includes research on human-derived specimens and/or data that can identify individuals. Whether the specimens or data can identify individuals or not shall be decided according to the Ethical Guidelines for Clinical Research (Ministry of Labor, Health, and Welfare of Japan).

#### Article 2 (Criteria for self-reported COI disclosure)

All COIs must be reported if the amount exceeds the criteria specified below.

- (1) Employment or administrative position, or advisory role in business enterprises, for-profit corporate organizations, or commercial entities that are related to clinical research (hereafter referred to as “Commercial Entity”), if compensation from a single Commercial Entity exceeds 1,000,000 yen per year.
- (2) Stock ownership or options, if profit (total of dividend and gain on sales) of at least 1,000,000 yen from stocks of one Commercial Entity per year, or ownership of 5% or more of total shares.
- (3) Patent royalties from one Commercial Entity, if the royalty fee exceeds 1,000,000 yen per year.
- (4) Honoraria (e.g. lecture fees) paid from one Commercial Entity, for the time and/or labor of an investigator who attended or made presentations at meetings, if exceeding 500,000 yen per year.
- (5) Manuscript fees for promotional materials (e.g. brochures) paid by one Commercial Entity, if exceeding 500,000 yen per year.
- (6) Research funds paid for clinical research (e.g. funded research, collaborative research) paid by one Commercial Entity, if exceeding 2,000,000 yen per year.
- (7) Subsidy or donation to an individual or a head of department to which the individual belongs received from one Commercial Entity, if exceeding 2,000,000 yen per year.
- (8) Endowed departments provided by a Commercial Entity, if the recipient participates in such a department.
- (9) Others including trips, travel, or gifts, which are not directly related to research, provided by one Commercial Entity, if exceeding 50,000 yen per year.

Items 6 and 7 shall be reported, only if funds are provided by a Commercial Entity to a presenting author, or department to which the presenting author belongs, regarding the presentation of research activities benefitting from such funding at academic meetings.

#### Article 3 (Disclosure in official journals)

All authors who intend to publish manuscripts (e.g. review articles, original research manuscripts) in the official journals of the Society (Endocrine Journal) must report any financial relationship with a Commercial Entity specified in Article 1, Section 2 of the Bylaws, regarding the subjects or materials discussed in the paper, within the previous 12 months, using Form 2 (Endocrine Journal Conflict of Interest Disclosure Statement) to the secretariat of the Society in advance. This disclosure will appear at the end of the manuscript, before the Acknowledgement or References. If there is no such relationship, the statement “No potential conflicts of interest were disclosed” will appear in the same position. COI status must be clearly disclosed at the time of article submission, according to Article IV “Matters to be reported” of the Policy of Conflict of Interest in Clinical Research. The criteria are governed by Article 2. Publication in Journals issued by the Society other than Endocrine Journal shall conform to the above rules. Note that “Disclosed Potential Conflict of Interest” shall not be disclosed to referees to whom the manuscript is sent for review.

#### Article 4 (Submission of COI Disclosure Statement by officers, chairpersons, and members of committees)

1. Officers of the Society (Chair of the Board of Directors, Directors, Auditors, Advisors), Presidents of academic conferences (annual meetings, JES Summer Seminar on Endocrinology & Metabolism, JES Clinical Update on Endocrinology & Metabolism, local/branch chapter conferences, et al.), chairpersons of various committees, members of special committees (conference organization committees, continuing medical education committees, editorial boards, committees for the development of practice guidelines, Ethics & COI committee ), members of temporal working groups and small committees shall self-report their COI status within the previous 12 months before assuming the position, according to Article IV “Matters to be reported” in the Policy of Conflict of Interest in Clinical Research, using Form 3, at the time of and every year after assuming the position, to the Board of Directors. Disclosure is not necessary if a self-reported COI disclosure statement has already been submitted. Note that the disclosure of COI shall be limited to those associated with Commercial Entity related to the activities of the Society.
2. Items to be disclosed in Form 3 are defined in Article IV “Matters to be reported” in the Policy of Conflict of Interest in Clinical Research. Criteria for disclosure shall refer to Article 2, and the amount shall be clearly stated for each item to be disclosed in Form 3. COI status within the

previous 12 months before assuming the position shall be reported in Form 3 together with the period of having such status. If any additional COI occurs during the period of service, the recipients shall be responsible for reporting such status within eight weeks, using Form 3.

#### Article 5 (Handling of the self-reported COI disclosure statement)

1. The self-reported COI Disclosure Statement, which is submitted at the time of abstract submission for a conference presentation or at the time of manuscript submission to the journal of the Society, shall be kept confidentially at an incorporated office under the supervision of the Chair of the Board of Directors for two years from the submission. Similarly, COI documents related to those who served out terms as an officer or who received a notice of removal from the position as a member of committee shall be kept confidentially at an incorporated office under the supervision of the Chair of the Board of Directors for two years from the date of termination of the term or removal from the position. COI documents shall be deleted or disposed of promptly after two years of storage, under the supervision of the Chair of the Board of Directors. If the Board of Directors has decided that the deletion or disposal of the document is inappropriate, the deletion or disposal of such document shall be postponed for a set period of time. COI information related to the President (including the next President), Presidents of academic conferences, and members of academic conference organization committees shall be treated in the same manner.
2. The directors and related officers of the Society shall judge whether an individual is subject to COI regulations and the extent of COI based on the submitted self-reported COI disclosure statement and according to Bylaws. If they take measures or actions as a society based on the judgment, they shall use the COI information of such a person as needed. They shall not, however, use such information unnecessarily nor disclose the information to any persons other than those who need to be informed for the above purposes.
3. In general, COI shall be not disclosed, except in occasions specified in Article 5, Section 2. COI may be disclosed or publicly announced, to the extent necessary to achieve, as a society, social and ethical accountability associated with the activities of the Society, committees (including a standing subcommittee under a large committee), and temporary committees, after discussion at a board meeting. The Society may not prevent a director who is specifically in charge of the issue from making the decision for disclosure or public announcement based on the advice from the Ethics & COI Committee. In this case, any persons involved in COI that is to be disclosed or publicly announced may express his/her opinion to the Board of Directors or a director who is asked to make such decision, unless the disclosure or public announcement is in an emergency, and there is no time for discussion.
4. If disclosure of any COI of a certain member is requested (including requested legally) by a non-member, and if reason(s) for such a request seems reasonable, COI Committee shall take

appropriate actions following a recommendation by the Chair of the Board of Directors based on a private information protection policy. If the COI Committee decides that they cannot handle the issue, the disclosure shall be discussed at a COI Investigation Committee, which consists of some members of the Society designated by the Chair of the Board of Directors and at least one non-member of the Society. The COI Investigation Committee shall meet within 30 days from the receipt of a disclosure request and report their decision as soon as practicable.

#### Article 6 (Ethics & COI Committee)

The chairperson and vice-chairperson of the Ethics & COI committee shall be designated by the Chair of the Board of Directors. The Committee shall consist of some members of the Society and at least one non-member of the Society, designated by the chairperson. The members of the Ethics & COI Committee shall be confirmed by the Board of Directors. They strictly protect the confidentiality of all COI information regarding the members of the Society that they obtained. The Ethics & COI Committee, in collaboration with the Board of Directors, shall make protective efforts to prevent serious compromise of the COI status of the members, and take actions toward any violations, according to the COI Policy and the Bylaws. Rules set forth in Article 5 shall be applied to the COI report involving members and the handling of COI information.

#### Article 7 (Measures to be taken in case of Violation)

1. If questions or social or ethical problems arise in relation to a self-reported COI disclosure statement submitted by authors intending to publish their findings in the official journals of the Society (Endocrine Journal) or to present at a conference organized by the Society, the Ethics & COI Committee shall take appropriate measures in order to achieve social accountability based on sufficient investigations and interviews. If a serious COI is confirmed, and cannot be accounted for, the Chair of the Board of Directors may refer the matter to the Ethics & COI Committee, and take measures, such as forbidding such presentations or publications, after discussion with the Board of Directors, based on the recommendation of the committee(s). If questions arise after a presentation or publication, the Chair of the Board of Directors shall conduct factual investigation. If any violation is confirmed, the Chair of the Board of Directors should take measures such as retraction of the published manuscript. Should the social reputation of the Society be severely damaged by the violation, the Chair of the Board of Directors should take measures regarding membership of the person(s) concerned, according to the Statute of the Society.
2. If any problem is indicated regarding COI reported before or after the appointment or nomination of officers of the Society, chairpersons of committees, or committee members, the COI Committee shall make a report in writing to the Chair of the Board of Directors. The Chair of the

Board of Directors shall call for a board meeting without delay, and decide whether the problem indicated is valid or not. If it is valid, the officers shall resign, the members of committees shall be dismissed after the discussion with such members, and candidates shall withdraw his/her candidacy.

#### Article 8 (Objections to punishment)

##### 1. Objection statements

Those who are punished for violations regarding presentations or publications related to the Society (e.g. official journals, academic conferences), in accordance with Article 7, Section 1, or those who are required to resign their official posts or dismissed as a member of committee in accordance with Article 7, Section 2, may request reconsideration of the decision within seven days after they receive the notice from the Board of Directors, by sending a request form to the Chair of the Board of Directors addressed to the Secretariat, if they have objections to the punishment. The request for reconsideration should include specific and brief objections to the reasons for dismissal given by the chairperson. In this case, information disclosed to the chairperson as well as related information supporting their objections should be provided in the written statement.

##### 2. Review procedures concerning statement of objections to punishment

1. If a request to reconsider a reprimand or punishment is received, the Chair of the Board of Directors shall forthwith set up an investigation committee (hereafter referred to as the “Investigation Committee”). The Investigation Committee shall consist of a few members of the Society and at least one person who is not a member of the Society, designated by the Chair of the Board of Directors. The chairperson of the committee shall be chosen by the members of the committee. The members of COI Committee cannot concurrently serve as members of the Investigation Committee. The Investigation Committee shall hold the meeting and discuss the matter within 30 days from the receipt of the request of reconsideration.
2. The Investigation Committee may interview the chairperson of the Ethics & COI Committee in relation to the statement of objections, in addition to the person who requested the reconsideration.
3. The Investigation Committee shall draw up and submit a report regarding the reconsideration to the Chair of the Board of Directors within one month from the first meeting except for special occasions.
4. The decision by the Investigation Committee is final.

#### Article 9 (Modification to the Bylaws)

The Bylaws are expected to need partial modification to adapt to social conditions and changes in laws related to industrial-academic collaboration. The Ethics & COI Committee may discuss the

review of the Bylaws, and a decision to modify them if so decided by the Ethics & CIO Committee and the Board of Directors.

## Supplementary provisions

### Article 1 (Effective Date)

The Bylaws will be implemented experimentally from April 1, 2011 for a period of 2 (two) years and will become completely effective after that.

### Article 2 (Modification to the Bylaws)

The Bylaws shall be reviewed generally every few years, in order to be able to adapt to social conditions, amendment of laws related to industrial-academic collaboration, and changes in conditions surrounding medical and clinical research.

### Article 3 (Special rule applied to Society officers)

The Bylaws shall apply to reports by those who have official posts in the Society at the time of execution of the Bylaws.