

## **Japan Radiology Society bylaws concerning management of conflicts of interest in clinical research**

### **Article 1: Conflicts of interest at presentations given by members of the Society at annual meetings, etc.**

#### Section 1: Extent of disclosure

The duty of the lead presenter or relevant responsible clinical research presenters, their spouses, first degree relatives, or partners who share income or assets, to disclose conflicts of interest is limited to cases involving companies or profit-making organizations that are linked to the content of the presentation.

#### Section 2: At the time of submission of abstract

When presenters give presentations or lectures at Society events including annual meetings, symposia, lecture meetings or public speeches, and the lead presenter or relevant responsible clinical research presenters have conflicts of interest related to the content of their presentation, a declaration of the content in accordance with Form 1, “Conflicts of Interest Self-Declaration Form,” should be submitted by post to the organizers of the event. However, this only applies to conflicts of interest arising in the previous year or in the academic year preceding the submission of the presentation topic and abstract. Form 1 is governed by Section V (Necessary disclosure items) of the “Japan Radiological Society Guidelines on Management of Conflicts of Interest in Clinical Research” (referred to hereafter as the “Society Guidelines”). If the lead presenter and relevant responsible clinical research presenters have no conflicts of interest concerning the content of presentation, this does not need to be reported upon submission of the abstract.

#### Section 3: At the time of presentation

At the time of the presentation, the lead presenter and relevant responsible clinical research presenters should declare the existence of conflicts of interest as defined by Article 1 Section 1 and Section 4 of these bylaws, and disclose the content of the same in a presentation slide or display as instructed by the event organizer, in accordance with guidance from the Conflicts of Interest Committee. Disclosure is required for the previous year or the past academic year.

#### Section 4: Sums of money for which self-declaration is required

The amount of money for which self-declaration is required for each item to be disclosed is as follows:

1. Annual remuneration of over 1 million yen from a company or profit-making organization in which the individual serves as a committee member, advisor or employee.
2. Ownership of equity with profit (shares, sum total of sales profit) of over 1 million yen on stocks of a single company in one year, or possession of at least 5% of total equity
3. Royalties of over 1 million yen from one patent from companies and profit-making organizations
4. Payments made from companies or profit-making organizations to researchers for time and work (e.g., honorarium for a lecture), attendance at meetings (presentations), or writing of articles or similar for publications such as pamphlets, if total income from one company or organization exceeds 1 million yen in one year
5. Involvement in clinical research (clinical trials) funded by a company or profit-making organization
6. Research funding (entrusted research, collaborative research, donations, etc.) provided by companies or profit-making organizations, if the total amount paid in one year from one company or organization exceeds 2 million yen
7. Other remuneration (e.g., travel not directly related to research, gifts) worth at least 50,000 yen in one year from one company or profit-making organization

#### Section 5: Review and record of review

Organizers of events such as annual meetings, symposia and lecture meetings should review all “Conflicts of Interest Self-Declaration” forms submitted by presenters. If serious conflicts of interest arise, cases can be referred to review by the Conflicts of Interest Committee.

Organizers of events such as annual meetings, symposia and lecture meetings should rigorously manage and preserve a hard copy of all reviews for their records.

**Article 2: Conflicts of interest in papers presented by members of the Society in Society publications, etc.**

Section 1: Extent of disclosure

The duty of member authors, their spouses, first degree relatives, or partners who share income or assets, to disclose conflicts of interest is limited to cases involving companies or profit-making organizations that are linked to the content of the paper.

Section 2: At the time of submission

Contributing authors to the journal of the Society, the *Japanese Journal of Radiology*, are required to declare conflicts of interest in accordance with Article 2 Section 1 and Section 3 of these bylaws, using the “Conflicts of Interest Self-Declaration of Authors” form (Form 2) as specified in the submission regulations at the time of submission. Form 2 should be clearly labeled at the end of the paper, directly before the references. If there are no conflicts of interest according to the regulations, this should be indicated in the same place with a statement to the effect that, “No potential conflicts of interest were disclosed”. Conflicts of interest which need to be self-declared at the time of submission are specified in Section V, “Necessary disclosure items” of the Society Guidelines. Disclosure is required for conflicts of interest existing in the previous year or the academic year preceding the submission of the paper. For publication in Society-related publications other than the *Japanese Journal of Radiology*, the same guidelines and submission format for self-declaration should be followed.

Section 3: Sums of money for which self-declaration is required

The amount of money for which self-declaration is required for each item to be disclosed is the same as specified in Article 1 Section 3 of the bylaws.

Section 4: Review and record of review

Editors of the Society’s journal, the *Japanese Journal of Radiology* should review all “Conflicts of Interest Self-Declaration” forms submitted by authors. If serious conflicts of interest arise, cases can be referred to review by the Conflicts of Interest Committee.

Editors of the Society’s journal, the *Japanese Journal of Radiology* should rigorously manage and preserve a hard copy of all reviews for their records.

### **Article 3: Conflicts of interest of executives**

#### Section 1: Extent of disclosure

The duty of executives (President, Directors, Inspector), annual meeting presidents and Conflicts of Interest committee members, their spouses, first degree relatives, or partners who share income or assets, to disclose conflicts of interest is limited to cases involving companies or profit-making organizations that are linked to the activities undertaken by the Society.

#### Section 2: At time of appointment to office

Executives and committee members specified above should submit a “Conflicts of Interest Self-Declaration of Executives” form (Form 3) upon assuming office and annually thereafter. Conflicts of interest to be disclosed in Form 3 through self-declaration are specified in Section V, “Necessary disclosure items” of the Society Guidelines. Activities undertaken over a 1 year period should be detailed on Form 3, and the period covered by calculations should be clearly specified.

### **Article 4: Self-declaration concerning conflicts of interest of executives (duty of confidentiality)**

Copies of Form 3 submitted to the Society as required by these bylaws, as well as information concerning conflicts of interest contained in these forms, shall be retained by the President of the Society in the head office, and shall be managed and kept in strict compliance with legal requirements as personal information. Information regarding conflicts of interest may be used as required by the Board of Directors and the Conflicts of Interest Committee in order to handle items defined in Society Guidelines. If doubt or a social or legal problem arises pertaining to conflicts of interest of an individual who has self-declared, information concerning the conflicts of interest will be discussed by the Conflicts of Interest Committee and may, upon approval by the Board of Directors, be made known to members of the Society or the wider public, depending on the extent necessary. Form 3 will be kept on record until 2 years after the end of the period of office of the executive member or Conflicts of Interest committee member, and will then be disposed of under the supervision of the Society President. However, in cases where there is doubt or a social or legal problem pertaining to the individual who has self-declared, the Board of Directors may decide to postpone the disposal of Form 3.

## **Article 5: Conflicts of interest committee**

The Conflicts of Interest Committee will be composed of a small number of directors and delegates appointed by the Board of Directors, as well as at least one external committee member. A chairperson will be elected from among the members. The Conflict of Interests Committee works with the Board of Directors in accordance with the regulations laid down in the Society Guidelines and bylaws, taking preventive measures both to ensure that conflicts of interest among members do not escalate to serious problems, and to deal with violators. The provision in Article 4 applies to declaration of conflicts of interest from committee members and treatment of the relevant information.

## **Article 6: Measures for dealing with violators**

Section 1: If doubts or social or moral problems arise concerning self-declaration of conflicts of interest submitted by authors of papers in the Society's *Japanese Journal of Radiology* or by the main presenters or relatives at the Society's annual meetings and other meetings, the Conflicts of Interest Committee will examine the issue in depth, conduct hearings and take reasonable measures to deal with the issue, in order to fulfill the duty of the Society to be socially accountable. In serious cases of conflicts of interest where accountability cannot be assured, the President may consult an Ethics Committee and, based on their response and debate among members of the Board of Directors, may take measures such as prohibiting conference presentations or publications by the individual concerned. If doubts arise after publication or presentation, the facts should be investigated, and measures such as repealing the publication or presentation should be examined. If the Society risks losing substantial social credibility, suspension of Society activities or rescinding of membership are possible.

Section 2: If it is decided that there is a problem with the conflicts of interest declared by executive members, committee chairs, and committee members who have a duty to declare such conflicts of interest and credentials before and after assuming office, the Chairperson of the Conflicts of Interest Committee should notify the Society President in writing, the President should call a Board of Directors meeting as soon as possible, and the Board of Directors should decide whether or not to recognize the issue as a problem. If the issue is recognized as such, executive or candidate members should resign from office or candidacy, and members of other

committees may be asked to withdraw from office after discussion with relevant committee members and member candidates.

## **Article 7: Statement of objection**

### Section 1: Claim of statement of objection

Individuals who have received a notice of measures related to violations concerning a presentation (Society publication, lecture meeting etc.) forming part of the Society's activities as defined in Article 6 Section 1, or those who have received notice of removal or withdrawal from office, as defined in Article 6 Section 2, and who are dissatisfied with this result, have the right to request a review of the case by submitting a statement of objection to the head office addressed to the Society President within 7 days of receiving notice of results of the Board of Directors decision. The request for a review should include a clear, concise summary of specific counter-arguments and alternative opinions concerning the reasons for repeal given in writing by the committee chairman. In this case, relevant grounds for dissenting reasons may be provided in addition to the information disclosed to the committee chairman.

### Section 2: Procedure for statement of objection requesting a review

1. If a statement of objection requesting a review is received, the Society President must immediately establish a Statement of Objection Review Committee (referred to hereafter as Review Committee). The Review Committee will be composed of a small number of directors and Advisory Committee appointed by the President, together with at least one external member. The chairperson of the committee will be selected from among the members. Members of the Conflicts of Interest Committee cannot serve as members of the Review Committee. The Review Committee will hold a meeting and make a decision within 30 days of receiving the statement of objection requesting a review.
2. The Review Committee will directly hear the opinions of the chairpersons of the Ethics and Conflicts of Interest Committees, and of the individual who submitted the statement of objection. However, if attendance at the hearing is not possible within the prescribed time frame, this procedure is not applicable.
3. Providing no exceptional circumstances, the Review Committee will summarize and submit to the Society President their review in response to the statement of objection within 1 month of the first meeting of the Review Committee.

### Section 3: Decision on final course of action

The decision of the Review Committee on the statement of objection raised in response to the measures decided by the Board of Directors is final.

### **Article 8: Revisions of bylaws**

It is likely that these bylaws may need to be changed in part in response to individual cases or changes in law related to social factors or industry-university collaboration. The Board of Directors may debate revisions of Society Guidelines and make changes following resolutions by the Board of Directors and the General Committee.

### **Supplementary provisions**

#### Article 1 (Date of enforcement)

These bylaws came into effect on 11 April 2010.

#### Article 2 (Revision of bylaws)

In principle, these bylaws will be revised 2 years after the date of enforcement to ensure that they are compatible with legal changes and revisions related to social factors and industry-university collaboration, and with changes in various conditions surrounding medical and clinical research.

#### Article 3 (Special provision concerning application to executive members and others in office)

Individuals who already hold positions such as executive members of the Society at the time of enforcement of these bylaws should immediately take any necessary action to apply these bylaws, such as filing reports.