

Bylaws on Conflict of Interest in Clinical Studies at the Japanese Society of Intervention Radiology

Section 1: Conflict of Interest When a Member of the JSIR Makes a Presentation at an Academic Group Meeting, etc. in Which the JSIR is Involved

Clause 1: Scope of Disclosure

Conflict of Interest (COI) situations that must be disclosed by a head lecturer and a primary investigator of a clinical study, and their spouse, relatives in the first degree, or other people who share income and assets with them shall be limited to those related to a private company/legal entity or a for-profit group that is involved in the presentation.

Clause 2: At the Time of Submitting Abstract

In a case that a lecturer makes a presentation or a lecture at an academic group meeting, symposium, a lecture meeting, or a civil public lecture held by the JSIR, and that the head lecturer or the primary investigator of the clinical study has a COI situation related to such presentation or lecture, such person shall submit the details of his/her COI situation pursuant to the Form 1 “Self-Reporting on COI of Researcher” to a sponsor of such academic group meeting, symposium, or lecture by post. Provided, however, this provision shall only apply to the cases where the COI situation exists in the previous fiscal year (or calendar year) or the past twelve months before applying the lecture subject or submitting the abstract. Form 1 shall be the one defined in “V. Matters to be Disclosed and Announced” in the “Guidelines of Conflict of Interest in Clinical Studies by cof Intervention Radiology” (hereinafter referred to the “Guidelines”). If the head lecturer and the primary investigator of the clinical study have no COI situation related to the presentation or the lecture, they are not required to report such effect when submitting the abstract.

Clause 3: At the Time of Presentation

The following shall be disclosed in a method indicated by the conference organizer who is instructed from the COI Committee, in a presentation slide or an exhibition poster: Whether there is any COI situation that should be disclosed by the head lecturer and the primary investigator of clinical study at the time of the presentation or the lecture pursuant to Section 1, Clause 1 to 4, and, if any, the details of such COI situation. COI situations that need to be disclosed shall be those occurred in the last fiscal year (calendar year) or the last 12 months.

Clause 4: Amount Subject to Self-Reporting

Matters that should be disclosed by each applicable person shall be prescribed as follows, such as the amount subject to self-reporting:

1. As for an officer, advisor, or employee of a private company/legal entity or a for-profit group, reporting is required if the annual compensation from a single company/group exceeds one million yen;
2. As for holding equities, reporting is required if an annual profit of shares of a single company (aggregate of dividends and capital gains) exceeds one million yen, or a

- person holds 5% or more of the total equities of one company;
3. As for royalty from a private company/legal entity or a for-profit group, reporting is required if the annual amount of a single royalty exceeds one million yen;
 4. As for a per diem (such as a lecture fee) that is paid by a private company/legal entity or a for-profit group for the time and efforts provided by a researcher for attending a meeting (or making a presentation), or a manuscript fee for a pamphlet, reporting is required if the annual total payment from a single private company/legal entity or a for-profit group exceeds one million yen;
 5. Reporting is required if a researcher participates in a clinical study (clinical trial) sponsored by a private company/legal entity or a for-profit group as a representative;
 6. As for a research fee provided by a private company/legal entity or a for-profit group (commissioned research, joint research, donation, etc.), reporting is required if the total annual payment by a single private company/legal entity or a for-profit group exceeds two million yen;
 7. As for a scholarship (incentive) donation provided by a private company/legal entity or a for-profit group, reporting is required if the annual total payment from a single private company/legal entity or a for-profit group to the reporting person or the section the reporting person belongs to or a representative of the section (such as an academic course and a scientific field) exceeds two million yen;
 8. Reporting is required if a reporting person belongs to an academic course donated by a private company/legal entity or a for-profit group; and
 9. As for other compensations (such as gifts and travel expenses that are not directly related to the research), reporting is required if the annual compensation received from a single private company/legal entity or a for-profit group exceeds 50,000 yen.

Clause 5 Review and Record of Review

A conference organizer of academic group meeting, symposium, and lecture shall review the “Self-Reporting on COI of Researcher” submitted by a presenter. If it is found that a serious COI situation exists, the conference organizer may ask the COI Committee for review.

A conference organizer of academic group meeting, symposium, and lecture shall strictly maintain and manage the record of review with a paper media.

Section 2: COI When a JSIR Member Publish a Paper on a Publication the JSIR is Involved in

Clause 1: Scope of Disclosure

COI situations that must be disclosed by all the authors, their spouse, relatives in the first degree, or other people who share income and assets with them shall be limited to those related to a private company/legal entity or a for-profit group that has a relationship with the paper.

Clause 2: At the Time of Posting

An author who publishes a paper on the JSIR official journal must clarify his/her COI

situation as prescribed in Section 2, Clause 1 and 3 of the Bylaws in the “COI Reporting Form” (Form 1) as prescribed in the Publication Rules at the time of publishing the paper. Form 1 shall be shown at the end of the paper, in References, and immediately before the “Literature” section. If no COI situation subject to reporting exists, a text like “No COI situation that should be reported exists in this research” shall be inserted and clearly indicated in the above-mentioned position. COI situations that are subject to self-reporting at the time of publishing shall be those prescribed in “V. Matters to be Disclosed and Announced” in the Guidelines. Matters that should be reported shall be those occurred in the previous fiscal year (or calendar year) or the last 12 months from the date when the paper is published. When publishing a paper on a publication other than the JSIR official journal that is issued by a related academic conference, a form similar to the Form 1 should be used for self-reporting.

Clause 3: Amount Subject to Self-Reporting

The amount that should be disclosed by each applicable person in a self-reporting form shall be the same as those prescribed in the Section 1, Clause 4.

Clause 4: Review and Review Record

An editor of the JSIR official journal shall review the Self-Reporting on COI of Researcher submitted by an author. If it is found that a serious COI situation exists, the editor may ask the COI Committee for review.

The editor of the JSIR official journal shall strictly maintain and manage the record of review with a paper media.

Section 3: Conflict of Interest for Officers

Clause 1: Scope of Disclosure and Public Announcement

COI situations that that must be disclosed by officers of the JSIR (chief governor, governor or auditor), chairs of various committees, members of the Editorial Committee, the Ethical Committee, and COI Committee, members of a temporary committee that seems to play an important role in activities of the JSIR, a chair of an academic group meeting, and their spouse, relatives in the first degree, and other people who share income and assets of the above-mentioned people shall be limited to those related to a private company/legal entity or a for-profit group that is involved in the business conducted by the JSIR. The people mentioned above must make a revised report within six weeks when a COI situation newly occurs after assuming the position.

Clause 2: At the Time of Assuming the Position

The above-mentioned officers and members shall submit the “Self -Reporting on COI of Officers” (Form 2) at the time when it newly assumes the position and in every year. COI situations that must be disclosed and announced in self-reporting shall be those prescribed in “V. Matters to be Disclosed and Announced”. Form 2 must include the COI situations occurred in a full year and clearly indicate the reporting period.

Section 4: Handling of Self-Reporting on COI of Officers (Confidentiality)

Form 2 submitted pursuant to the Bylaws, and the COI situation disclosed therein (COI Information) shall be managed at the JSIR Secretariat by the chief governor as a manager, and strictly maintained and managed as personal information pursuant to applicable laws and regulations. The COI Information may be used by the board of governors and the COI Committee from time to time for processing matters prescribed in the Guidelines. The COI Information shall be used when any doubt arises or a social/legal issue occurs on the COI situation of the reporters, and a necessary part of such COI Information may be disclosed within the JSIR or to the society after making a discussion at the COI Committee and obtaining approval from the board of governors. The retention period of Form 2 shall be two years after the end of last term of officer or a member of the COI Committee, and Form 2 shall be disposed thereafter under supervision by chief governor. Provided, however, if any doubt arises or a social/legal issue occurs on the person who submitted the Form 2 during the retention period thereof, disposal of Form 2 may be suspended by the resolution at the board of governors.

Section 5: Conflict of Interest Committee

The COI Committee shall consist of a few governors and delegates and at least one external member who are appointed by the board of governors. The Committee chair shall be mutually elected among the members. The COI Committee shall cooperate with the board of governors to manage matters for the purpose of preventing any COI situation held by the JSIR members from becoming a serious event, and decide on disposition for people who breach the Guidelines, pursuant to the Guidelines and the Bylaws. The provisions in Section 4 shall apply mutatis mutandis to reporting of COI situation of the Committee Members and handling of the COI Information.

Section 6: Actions against Breaching People

Clause 1: If any doubt arises or a social/moral issue occurs on the COI situation that is self-reported by an author who published a paper on the JSIR official journal and a head lecturer of academic group meeting held by the JSIR, the JSIR shall take an appropriate action such as full examination and hearing by the COI Committee for fulfilling the social accountability of the JSIR. If a serious COI situation exists and the JSIR cannot assume its accountability, the chief governor shall consult with the Ethical Committee. Then, the board of governors shall discuss it based on a report submitted by the Ethical Committee, and may take an action such as suspension of presentation at an academic conference or publishing of papers by such person. If any doubt arises on the presentation or paper that has already been presented or published, the JSIR shall investigate all the facts, and consider taking an action such as withdrawing the publication if any breach is found. If the finding materially impedes the social credibility of the JSIR, the JSIR may suspend the activities of such person at the JSIR or invalidate the membership of such person.

Clause 2: If it is pointed out that any COI issue exists that has been reported by the officers, chairs of various committees, and the members who have the COI self-

reporting obligation, and candidates thereof before or after assuming the position, the chair of the COI Committee shall report it in writing to the chief governor who must immediately hold a meeting of the board of governors to make a resolution whether the JSIR accepts the existence of such issue or not. If the JSIR accepts the existence of COI, the officer or a candidate of the officer subject to such COI issue shall resign. For other committee members and candidates subject to such COI issue, the JSIR shall discuss with such person and may withdraw an appointment as a member.

Section 7: Filing of Complaints

Clause 1: Claim for Complaint Filing

If a person who receives a notice of actions against breach of the Guidelines on its publication (on the official journal) or presentation (at an academic lecture) pursuant to Section 6, Clause 1, and a person who resigns from the position of the officer or a candidate who receives a notice to withdraw an appointment as a committee member pursuant to Section 6, Clause 2 has complaints on the disposition determined by the JSIR, such person may ask for review by submitting a request for complaint review to the JSIR Secretariat with attention to the chief governor within seven days from the date when such person receives the notice of the resolution at the board of governors. The request for review shall briefly include a specific counterargument and objections against the reason for withdrawal indicated by the committee chair. In such a case, such person may show related information that can be a basis of claiming objections in addition to the information disclosed to the committee chair.

Clause 2: Procedures of Complaint Review

1. When the JSIR receives a request for complaint review, the chief governor must immediately establish the Complaint Review Committee (hereinafter referred to as the "Review Committee") The Review Committee shall consist of a few governors and delegates, and at least one external member, and the chair shall be mutually elected among the members. No members of the COI committee can also be a member of the Review Committee. The Review Committee shall hold a meeting and conduct a review within 30 days from the date when the request for review is received.
2. The Review Committee shall directly hear opinions from the chairs of the Ethical Committee and the COI Committee and the person who made such request on the filed complaints. Provided, however, this provision shall not apply if the above-mentioned persons do not attend the hearing determined by the Review Committee.
3. Unless any special situation exists, the Review Committee shall make its report on the filed complaint within one month from the first meeting of the Committee about the review, and submit the report to the chief governor.

Clause 3: Decision of the Final Disposition

The decision made by the Review Committee shall be final and non-contestable for any complaints about disposition made by the board of governors.

Section 8: Modification of Bylaws

It is expected that the Bylaws need to be partly modified depending on individual cases due to changes in social factors and laws and regulations related to the industry-university collaboration. The board of governors may discuss and review the Guidelines for modification, and modify it with a resolution at the Ethical Committee and the board of governors.

Supplementary Provisions

Article 1 Enforcement Date

The Bylaws shall be enforced on March 1, 2014.

Article 2 Modification of Bylaws

The Bylaws shall be reviewed after two years from the enforcement date in principle to fit for changes in and development of social factors and laws and regulations on the industry-university collaboration, and changes of various conditions surrounding medical treatment and clinical studies. When reviewing the Bylaws, the “The guidelines concerning COI management of medical research” published by the Japanese Association of Medical Sciences, etc. shall be referred to.

Article 3 Special Rules Regarding the Application to Officers, etc.

A person who has already been an officer of the JSIR at the time when the Bylaws are enforced shall immediately make a necessary report as prescribed herein pursuant to the Bylaws.