

Guidelines of Conflict of Interest in Clinical Studies by Japanese Society of Intervention Radiology

I. Purpose of Preparing the Guidelines

The Japanese Society of Intervention Radiology (JSIR) was established for the purpose of promoting the collaboration and technical development of interventional radiology and other areas related thereto, cooperating with domestic and overseas researches and studies, and rising awareness of interventional radiology among the Japanese nationals, thereby contributing to the welfare of human beings. To achieve these purposes, the JSIR has conducted the following activities: (1) Holding academic meetings, such as academic conferences, study meetings, lectures, and classes; (2) Publicizing the official journal “Interventional Radiology” and other documents related to interventional radiology, and (3) Businesses associated with or incidental to the activities mentioned in (1) or (2) that can contribute to the public interest. While studies publicly announced at an academic meeting or by a publication of the JSIR include the results of clinical studies related to interventional radiology, some of them are clinical studies evaluating and verifying new medical equipment and technologies, which are conducted by industry-university cooperation in many cases.

In the case of clinical studies conducted by industry-university cooperation, the fruitful results of the studies are not only given back to the society (public interests) but also used for generating money and rights/interests (private interest). For individual researchers, such two types of interests may cause the conflict of interest (COI). The stance of the JSIR is to promote clinical studies based on the belief that research and development conducted by industry-university cooperation should be fair and square. However, given the current situation surrounding industry-university cooperation, we cannot avoid the COI when conducting various activities in the JSIR. If the COI brings an inappropriate situation, it may distort the interpretation of the studies and the criteria included in guidelines prepared by an academic society. On the other hand, it is possible both internal and external parties may fail to properly evaluate the COI situation although the study result in itself is proper. For properly judging and solving problems that may be brought as a result of COI, the JSIR shall hereby clearly indicate the Guidelines of Conflict of Interest in Clinical Studies.

II. People Subject to the Guidelines

The Guidelines shall apply to those who are likely to face the COI as indicated below:

- (i) Members of the Japanese Society of Interventional Radiology;
- (ii) People who present their research results at a conference of the JSIR; and
- (iii) Members of the board of governors, committees, working groups, and/or meetings of academic group of the JSIR.

III. Activities Subject to the Guidelines

The Guidelines shall apply to activities in all the businesses with which the JSIR is associated or involved. In particular, researchers who make a presentation at an academic group meeting, symposium, or a lecture held by the JSIR and who publicize their research on the official journals, papers or books of the JSIR shall strictly be required to comply with the Guidelines in their clinical studies.

IV. Establishment of the Conflict of Interest Committee

The Conflict of Interest Committee (the COI Committee) shall be established to prevent any COI situation of the people subject to the Guidelines from becoming a serious event as well as to impose a disposition on people who breach the Guidelines. The COI Committee shall collaborate with the board of governors at the JSIR and conduct activities pursuant to the Guidelines and the Bylaws thereof. The COI Committee shall consist of a few governors and delegates, and at least one external member appointed by the board of governors. The Committee chair shall be mutually elected by and among the committee members.

V. Matters to be Disclosed and Announced

If any person who is subject to the Guidelines falls into any of the conditions as set forth from (i) to (ix) below and exceeds the criteria that are separately prescribed, such person is obliged to make self-reporting to disclose an exact situation of his/her COI pursuant to a pre-defined form. If a spouse or relatives in the first degree of the person subject to the Guidelines, or other people who share income and assets with such subject person fall into any of the conditions set forth from (i) to (iii) below and exceed the criteria that are separately prescribed, such person is obliged to report an exact COI situation of the above-mentioned people to the JSIR. The person who made self-reporting or a report on the COI situation of himself/herself or related parties shall be responsible for the matters contained in such report. A specific method of disclosure/announcement shall be prescribed in the Bylaws hereof depending on the types of activities.

- (i) Assuming a position as an officer or adviser of a private company/legal entity or a for-profit group;
- (ii) Holding equities (such as shares) of a counterparty of industry-university collaboration;
- (iii) Receiving a royalty from a private company/legal entity or for-profit group;
- (iv) Receiving a per diem (such as lecturer fee) from a private company/legal entity or a for-profit group for time to be taken and efforts to be made by a researcher who attended (and/or made a presentation at) a meeting;
- (v) Receiving a manuscript fee from a private company/legal entity or a for-profit group for writing an article for their leaflet;
- (vi) Receiving a research fee provided by a private company/legal entity or a for-profit group;
- (vii) Receiving scholarship or incentive donation provided by a private company/legal entity or a for-profit group;
- (viii) Receiving donation from a private company/legal entity or a for-profit group to an academic course to which the person belongs and makes self-reporting on the COI situation; and
- (ix) Receiving other compensations (such as gifts and travel expenses that are not directly related to the research activities).

VI. Avoiding COI Situations

1) Matters that should be avoided by all the people subject to the Guidelines

The JSIR believes that a result of clinical studies should be publicly announced based on a pure scientific judgment or the public interest. When a member of the JSIR makes a decision on the substantial matters of its research, such as deciding on whether it presents the result of a clinical study at a meeting or in a paper, or determining how to handle and interpret the result, the member should not be affected by an arbitrary intention of a sponsor or a partner corporation of such clinical study. The member is not allowed to execute a contract under which it cannot avoid receiving an effect from the sponsor or the partner corporation.

2) Matters that should be avoided by a primary investigator of clinical study

When electing a primary investigator who is responsible for planning and implementing a clinical study (including clinical tests and trials), a person who does not fall into any of the COI situations mentioned below should be elected. Additionally, the elected primary investigator should make efforts to avoid the COI situations mentioned below after the election.

- (i) Holding shares of a corporation that is a sponsor of the clinical study;
- (ii) Obtaining a royalty or a patent right of products/technologies generated from the result of the clinical study; and
- (iii) Assuming a position as an officer, governor, or advisor (excluding a scientific advisor without compensation) of a corporation or a for-profit group that is a sponsor of the clinical study.

Provided, however, if a researcher who falls into any of (i) to (iii) above is a staff member who is indispensable for planning and implementing the clinical study, and the clinical study has a significant value in the international society, the researcher may become a primary investigator of such clinical study after discussing at the COI Committee and obtaining approval from the board of governors. In such a case, the COI Committee shall conduct ex-post verification whether planning, implementing, and publishing of the clinical study are made properly and fairly.

VII. Implementation Method

1) Role of members

When a member of the JSIR presents the result of clinical study at an academic group meeting, etc., such member is obliged to properly disclose his/her COI situations in connection with such clinical study. The disclosure shall be made pursuant to the Bylaws and in a defined form. If any event occurs that may breach the Guidelines, such event may be reviewed by the COI Committee for escalation to the board of governors.

2) Role of officers

The chief governor, governors and auditors of the JSIR assume important roles and responsibilities for all the business activities of the JSIR. Such officers shall be obliged to make self-reporting on their COI situation related to such business activity with a pre-defined form at a time when the officer assumes his/her position. Chairs of various committees, members of the Editorial Committee, the Ethical Committee, and the COI Committee, members of a temporary committee that seems to play an important role in activities of the JSIR, the grand chair of general meetings, and the members of the COI Committee shall also assume the same obligations. The people mentioned above must make a revised report when a COI situation newly occurs after assuming the position.

If a serious COI situation occurs on the chief governor, governors, and auditors in conducting any business for the JSIR, or the board of governors' judges that self-reporting on the COI situation is inappropriate, the board of governors may commission such case to the COI Committee and instruct a corrective action based on a report submitted by the COI Committee. As for the grand chair of general meetings, if any serious COI situation occurs in holding a meeting, or self-reporting is judged inappropriate, the board of governors may commission such case to the COI Committee and instruct a corrective action based on a report submitted by the COI Committee.

When the result of clinical study is presented at an academic group meeting, the chair and members of the program committee for such academic group meeting, and members of the program peer review committee may verify whether such presentation complies with the Guidelines, and suspend the presentation if it is judged that the subject of the presentation is inconsistent with the Guidelines. In such a case, a notice with the reason for such suspension shall immediately be made to a person who expects to make the presentation. These actions shall be discussed at the COI Committee and approved by the board of governors based on a report submitted by the COI Committee before implementing them.

When the result of clinical study is to be reported in a publication issued by the JSIR such as the official JSIR journal, the Editorial Committee may verify whether the implementation of the clinical study complies with the Guidelines, and suspend the publication if the Committee judges that the implementation is inconsistent with the Guidelines. In such a case, a notice with the reason for such suspension shall immediately be made to a person who expects to publicize the paper on the result. If it is found that the implementation is inconsistent with the Guidelines after the publication is issued, the JSIR may announce such effect on the publication under the name of the chief editor. These actions shall be discussed at the COI Committee and approved by the board of governors based on the report submitted by the COI Committee before implementing them.

A chair and members of other committees shall verify whether the business of the JSIR in which they are involved is conducted pursuant to the Guidelines, and discuss corrective measures if any inconsistency with the Guidelines is found. These actions shall be discussed at the COI Committee and approved by the board of governors based on the report submitted by the COI Committee before implementing them.

3) Role of administrative staff members

Administrative staff members shall understand and conduct tasks related to COI in compliance with the Guidelines, as well as assume the confidential obligation on COI matters.

4) Filing of complaint

A person who is instructed a corrective action or suspension pursuant to 1) or 2) above may file complaints to the JSIR. When the JSIR receives such complaint from the person, the COI Committee shall immediately review the case subject to the complaint again, and notify the result to the person who filed the complaint after discussing it at the board of governors.

VIII. Actions against Guideline Breaching People and Accountability

1) Actions taken against guideline breaching person

The board of governors at the JSIR shall have the right to review actions that may breach the Guidelines pursuant to the Bylaws that are separately prescribed, and take any of the following actions if it judges that such breach is material incompliance with the Guidelines during a certain period of time depending on the

seriousness of such non-compliance:

- (i) Prohibit to make a presentation at any meeting held by the JSIR;
- (ii) Prohibit to publish a paper on any publication issued by the JSIR;
- (iii) Prohibit to assume the position as a chair of an academic group meeting held by the JSIR;
- (iv) Prohibit to participate in the board of governors, committees, and/or working groups of the JSIR;
- (v) Get expelled from the delegate members of the JSIR, or prohibit to become a delegate; and
- (vi) Get expelled from a member of the JSIR, or prohibit to become a member of the JSIR.

2) Filing of complaints

A person who receives the above actions may file complaints to the JSIR. When the JSIR receives such complaint from the person, its COI Committee shall review it again, and notify the result to the person who filed the complaint after discussing it at the board of governors.

3) Accountability

When the JSIR judges that a clinical study published in a field in which the JSIR is involved breaches the Guidelines seriously, the JSIR shall assume the accountability to the society after obtaining approval from the COI Committee and the board of governors.

IX. Establishment of Bylaws

The JSIR may establish the Bylaws of the Guidelines that are necessary for practical operation of the Guidelines.

X. Enforcement Date and Modification Method

The Guidelines shall be enforced on March 1, 2014. It is expected that the Guidelines need to be partly modified depending on individual cases due to consideration on the social impact and changes of laws related to the industry-university collaboration. The Ethical Committee of the JSIR may discuss and review the Guidelines for modification and modify it with a resolution at the board of governors or the board of delegates or the general meeting.