

Japan Radiological Society Guidelines on Management of Conflicts of Interest in Clinical Research

I. Purpose of formulation of guidelines

The Japan Radiological Society was established with the aim of contributing to the development of academic scholarship through the promotion of radiology and collaboration with other linked fields of research. In order to achieve this aim, it engages in (1) the hosting of scholarly gatherings such as conferences, study meetings, lecture meetings and short courses, (2) the publication of materials including the *Japanese Journal of Radiology*, and (3) other necessary activities. Much of the research presented in the publications and academic meetings of the Japan Radiological Society relates to radiodiagnosis (such as nuclear medicine), radiation therapy and interventional radiology, including a large number of clinical studies that evaluate and verify new drugs, medical equipment and medical techniques. Furthermore, studies involving research and development in industry-university partnerships are not uncommon.

Clinical research undertaken through industry-university collaboration provides a return to society of the benefits (public profit), as well as financial rewards and ownership rights (private profit). However, conflicts of interest (COI) may arise among individual researchers when dealing with these differing types of profit. The Japan Radiological Society promotes clinical research that is based on guarantees of fairness in industry-university collaborative research and development, but given the current situation of industry-university links, recognizes that cases of conflicts of interest are inevitable. When such cases are inappropriate, interpretation of research results and content of academic society guidelines run the risk of being distorted. On the other hand, there may also be cases where correct internal and external evaluations of conflicts of interest are not made, even though research results are appropriate. Therefore, the Japan Radiological Society has decided to present clear guidelines on conflicts of interest for the purpose of appropriately evaluating and interpreting issues that commonly cause concern.

II. Target group

The Society Guidelines apply to the following groups who may be subject to situations involving conflicts of interest.

1. Members of the Japan Radiological Society
2. Presenters at conferences held by the Japan Radiological Society
3. Members of the Japan Radiological Society Board of Directors, committees, working groups, annual meetings and so on

III. Target activities

The Society Guidelines apply to all activities in which the Japan Radiological Society is engaged. In particular, strict compliance with Society Guidelines will be required for all clinical research undertaken by researchers presenting at Japan Radiological Society annual meetings, symposia and lecture meetings, as well as researchers publishing in the journal, papers or other publications of the Japan Radiological Society.

IV. Establishment of a Conflicts of Interest Committee

A Conflicts of Interest Committee will be established to implement preventive measures both to ensure that conflicts of interest among target groups do not escalate to serious problems, and to deal with violators. The Conflicts of Interest Committee will collaborate with the Board of Directors, in accordance with the Society Guidelines and bylaws. 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.

V. Required disclosure items

Members of target groups who fall into one of the categories (1) to (7) below, exceeding the standards specified separately, have a duty to disclose their situation accurately through

self-declaration, using the appropriate Conflicts of Interest form. Additionally, members of target groups whose spouses, first-degree relatives or partners who share income or assets fall into one of the categories (1) to (3) below, exceeding the standards specified separately, have a duty to disclose the situation accurately to the Society. Self-declaration and declared content are the sole responsibility of the individual making the declaration. Specific methods of disclosure are determined in individual bylaws depending on activities covered.

1. Position as a board member or advisor of a company or profit-making organization
2. Owner of equity such as stock
3. Royalties or licensing fees from a company or profit-making organization
4. Payment from a company or profit-making organization for time and work (e.g., honorarium for a lecture) or attendance at meetings (presentations)
5. Payment from a company or profit-making organization for time and work for the writing of articles or similar for publications such as pamphlets
6. Research funding provided by a company or profit-making organization
7. Other remuneration (travel not directly related to research, presents etc.)

VI. Avoidance of conflicts of interest situations

1) Situations that should be avoided by all target groups

The publication of clinical research results should be based purely on scientific judgment and public benefit. Members of the Japan Radiological Society should not be influenced by the arbitrary intentions of companies or providers of clinical research funding when deciding whether to present clinical research results at meetings or through papers, or about the essential content of presentations, that is, clinical research results and their interpretation. They must not sign contracts that put them in a position in which they cannot escape the influence of companies and providers of funding for clinical research.

2) Situations that should be avoided by principal investigators of clinical research

In order to ensure no conflicts of interest, principal investigators who have the authority to decide the planning and implementation of clinical research (including clinical studies and clinical trials) must both meet the following criteria for selection and avoid entering into these situations after selection.

1. Owning stock of the company that commissions the clinical research

2. Obtaining patent rights or royalties from the products or techniques that result from the clinical research
3. Holding a position as a board member, director or advisor (with the exception of an unpaid scientific advisor) in the company or profit-making organization that commissions the clinical research

However, even if the researcher does fall into categories (1) to (3) above, they may still assume the role of principal investigator, providing that permission for the clinical research has been obtained from the Board of Directors after deliberation by the Conflict of Interests Committee, and that the researcher is essential to the planning and implementation of clinical research that is extremely significant on an international level. In this case, a post-study review will also be conducted by the Conflicts of Interest Committee to ensure that the planning, implementation and presentation of the clinical research was conducted appropriately.

VII. Implementation method

1) Role of Society members

Members of the Society who present results of clinical research at annual meetings and so on have a duty to give full disclosure concerning any situation of conflicts of interest encountered during their research. Disclosure should be provided on the designated form as specified in the bylaws. Situations conflicting with the Society Guidelines should be debated by the Conflict of Interests Committee and reported to the Board of Directors.

2) Role of executives

The President, Directors and Inspector of the Japan Radiological Society each play a substantial role and share responsibility for all activities related to the Society. They are required to submit a Conflicts of Interest Self-Declaration Form concerning any conflicts related to Society activities when they assume office. The heads of the organizing committees of the Annual Meeting and the Autumn Assembly, as well as members of the Conflicts of Interest Committee, are subject to the same duty.

In the execution of all activities of the Japan Radiological Society by the President, Directors and Auditor, if a serious situation of conflicts of interest arises, or if a self-declaration of conflicts of interest is found to be inappropriate, the Board of Directors can submit the issue to

the Conflicts of Interest Committee and implement measures for improvement based on its recommendations. In the organization of events by the heads of the organizing committee of the Annual Meeting and Autumn Assembly, if a serious conflicts of interest situation arises, or if a self-declaration of conflicts of interest is found to be inappropriate, the issue will be submitted to the Conflicts of Interests Committee and measures for improvement will be implemented based on its recommendations.

The chairman and members of the Program Committee of annual meetings and Program Reviewers should ensure that the content of clinical research that is to be presented is in accordance with the Society Guidelines. In cases where the content does not conform to Society Guidelines, the presentation can be blocked. In this case, the potential presenter should be informed of the reason as soon as possible. These measures should be discussed by the Conflicts of Interest Committee and implemented based on their recommendation, after approval by the Board of Directors.

The Publications Committee should ensure that the content of clinical research that is submitted for publication in the *Japanese Journal of Radiology* or other publications of the Japan Radiological Society is in accordance with Society Guidelines. In cases where the content does not conform to Society Guidelines, the publication can be blocked. In this case, the author who has submitted the paper should be informed of the reason as soon as possible. In cases where a violation of the Society Guidelines is discovered after publication, a declaration to this effect may be made in the name of the chairperson of the Publications Committee in the same publication or others. These measures should be discussed by the Conflicts of Interest Committee and implemented based on their recommendation, after approval by the Board of Directors.

Other committee chairpersons and members should verify that implementation of the Society activities in which they are involved is conducted in accordance with Society Guidelines. They should also prepare remedial measures that can be implemented to improve the situation swiftly if violations of Society Guidelines emerge. These measures should be discussed by the Conflicts of Interest Committee and implemented based on their recommendation, after approval by the Board of Directors.

3) Statement of objection

Individuals who have received notice of improvement instructions or measures blocking presentation/publication in accordance with items 1) and 2) above may submit a statement of objection to the Japan Radiological Society. If the Japan Radiological Society receives a

statement of objection, it must promptly examine the issue again in the Conflicts of Interest Committee, discuss it among the Board of Directors, and inform the complainant of the outcome.

VIII. Measures to deal with violators of the Guidelines and accountability

1) Measures to deal with violators of the Guidelines

The Board of Directors of the Japan Radiological Society has the authority to deliberate violations of Society Guidelines in line with the separately specified bylaws and, if this results in judgment that a major breach of adherence to Society Guidelines has been committed, the following measures can be taken for a specific period of time, according to the severity of the breach:

1. Violator is prohibited from presenting at all conferences hosted by the Japan Radiological Society
2. Violator is prohibited from publishing in publications of the Japan Radiological Society
3. Violator is prohibited from assuming a position as head of annual meetings of the Japan Radiological Society
4. Violator is prohibited from participating on the Board of Directors or in committees and working groups of the Japan Radiological Society
5. Violator is expelled as a delegate of the Japan Radiological Society, or prohibited from becoming a delegate
6. Violator is expelled as a member of the Japan Radiological Society, or prohibited from becoming a member

2) Statement of objection

The individual against whom sanctions have been imposed may submit a statement of objection to the Japan Radiological Society. When received, the issue must be reexamined by the Conflicts of Interest Committee and discussed by the Board of Directors of the Japan Radiological Society, and the complainant must be informed of the outcome.

3) Accountability

If it is judged that a major breach of adherence to Society Guidelines has been committed in the

presentation of clinical research, public accountability will be taken following deliberation by the Conflicts of Interest Committee and the Board of Directors.

IX. Enactment of bylaws

The Japan Radiological Society may enact bylaws as necessary to manage the implementation of the Society Guidelines.

X. Date of enforcement and methods of amendment

The Society Guidelines have been in effect since April 2010. The Guidelines may need to be altered in response to individual cases or changes in law related to social factors or industry-university collaboration. The Ethics Committee of the Board of Directors may debate and revise Society Guidelines following resolutions from the Board of Directors, Delegates' Committee and Annual Meeting.