

The Japan Society for Transplantation Guidelines on Conflicts of Interest

Introduction

The Japan Society for Transplantation aims to improve, develop academic research and popularize academic knowledge in medical transplantation, as well as increasing communications with relevant overseas academic societies.

Many of the research projects presented in the academic meetings and printed publications of the Japan Society for Transplantation are clinical research using new technology that could lead to development of new medical devices and new drugs as well as patent applications, and the Japan Society for Transplantation strongly desires to proceed with research and development under an academic-industrial alliance and make proactive contributions to society by returning the outcomes to the clinical practice sites.

In clinical research under an academic-industrial alliance, along with the return of the outcomes obtained by carrying out the academic and ethical responsibilities to society (public benefit), the Japan Society for Transplantation and its administrators and members (hereinafter referred to as “members, etc.”) may obtain money, positions, rights, etc. (private benefit) from the academic-industrial alliance. The condition under which such public benefit and private benefit arise in one researcher personally is called a “conflict of interest” (hereinafter abbreviated as “COI”). It is unavoidable for the COI state to arise in the current complicated social structures and diversified organizational styles, and certain activities are legally regulated. However, the COI state may also arise outside of the legal regulations.

When the COI state is serious, the research methodology, data analysis and interpretation of results may be distorted. On the other hand, when COI is not disclosed, even appropriate research results may not be appreciated fairly. It is therefore important to proactively promote clinical research under an academic-industrial alliance by maintaining the fairness of medical transplantation-related research, securing the safety of the subject(s), maintaining the confidence of society in the members, and assuring fairness in publication, etc. The guidelines for controlling COI in clinical research are enacted in this regard.

I. Objective

As mentioned already in the “Helsinki Declaration”, “Ethical Guidelines for Medical and Biological Research Involving Human Subjects” (revised on March 27, 2023), and “Japanese Association of Medical Science COI management guideline 2022” (revised in 2022), special considerations are required to conduct clinical research safely while protecting the rights, life and health of the subject(s).

The Japan Society for Transplantation enacts the “Japan Society for Transplantation

Guidelines on Conflicts of Interest” (hereinafter referred to as “the present Guidelines”) in light of the fact that social responsibility and high morality are required in the activities of the Japan Society for Transplantation. The objectives are to make the members, etc. of the Japan Society for Transplantation promote in an appropriate manner the presentation of research results and popularization/enlightenment thereof while maintaining neutrality and fairness by controlling appropriately the COI states of members, etc. and to carry out their social responsibilities by contributing to the progress of prevention, diagnosis and treatment of disease related to medical transplantation.

The present Guidelines aim to improve transparency in the programs and research by showing the basic concept about COI to the members of the Japan Society for Transplantation and making them disclose appropriately the COI state by means of self-reporting on presentations made in programs held by the Japan Society for Transplantation.

II. Target persons

The present Guidelines shall be applied to the following persons in whom the COI state may possibly arise.

- (i) Members of the Japan Society for Transplantation
- (ii) Secretariat personnel of the Japan Society for Transplantation
- (iii) Persons making presentations at the programs of the Japan Society for Transplantation
- (iv) Persons making presentations in printed publications such as the journal of the society, “Transplantation”
- (v) Persons (other than the members of the Japan Society for Transplantation) participating in Management Board or COI Committee meetings

III. Target activities

The present Guidelines shall be applied to all programs and activities carried out by the Japan Society for Transplantation.

- (i) Holding academic lecture sessions, etc.
- (ii) Issuance of the journal of the society, “Transplantation”, and academic books, etc.
- (iii) Execution of research and surveys
- (iv) Research encouragement and research achievement commendation
- (v) Certification of specialist physicians
- (vi) Communication and collaboration with relevant academic organizations
- (vii) Promotion of international research collaboration
- (viii) Other programs necessary for achieving the objectives

Compliance with the present Guidelines is particularly necessary in the following activities.

- (i) Presentation at the academic lecture sessions held by the Japan Society for Transplantation
- (ii) Presentation in printed publications such as the journal of the society, “Transplantation”
- (iii) Enactment of treatment guidelines, manuals, etc.
- (iv) Temporarily established operations in the investigation committee or advisory committee, etc.

IV. Items to be disclosed/released

On carrying out the target activities, each target person and his/her spouse and relation in the first degree, research institution/division shall be obligated to disclose the COI status by means of self-reporting, using the defined form for the following items shown in (i) – (ix) below in a case applicable to the standards specified separately. The reporter himself/herself shall be responsible for the self-reporting and reported contents.

- (i) Board member or advisor of a business enterprise or profit-oriented organization
- (ii) Holding the stocks (including a right to purchase stocks as option)
- (iii) Patent royalty paid by a business enterprise or profit-oriented organization
- (iv) Daily allowance (lecture fee, etc.) paid by a business enterprise or profit-oriented organization for the time and labor restricting the researcher
- (v) Manuscript fee paid by a business enterprise or profit-oriented organization for writing pamphlets, etc.
- (vi) Research fund under contract provided by a business enterprise or profit-oriented organization
- (vii) Scholarship (encouragement) donation provided by a business enterprise or profit-oriented organization
- (viii) Endowed chairs offered by companies, etc.
- (ix) Other rewards (travels, gift items, etc. having no direct relation with research)

V. Avoidance of COI state

1) What all target persons shall avoid

The results of clinical research should be published based on purely scientific judgment or public benefit. On publishing and interpreting the results of clinical research, the members, etc. of the Japan Society for Transplantation must not be influenced by the arbitrary intention of the person or business enterprise sponsoring the research.

2) What each clinical research manager shall avoid

The manager responsible for deciding the plan and conduct of clinical research (including clinical study/clinical trial) (does not apply to the principal investigator of each

medical institution in multicenter clinical research) shall be selected from among the persons who are not under the following COI states and shall likewise avoid falling into such COI states after being selected.

- (i) Holding the stocks of the business enterprise requesting the clinical research (including a right to purchase stocks as option)
- (ii) Acquisition of patent royalty or patent right for the product or technology derived from the clinical research results
- (iii) Board member, commissioner, advisor, etc. of the business enterprise or organization requesting the clinical research (except for scientific advisor receiving no payment)
- (iv) Reception of a large amount of research expenses, etc. practically from the business enterprise requesting the clinical research

However, when a researcher to which any of (i) - (iii) applies is essential to plan and conduct the clinical research concerned, and the clinical research concerned is extremely important also in an international situation, it is acceptable for such a person to become the principal investigator in the clinical research concerned after judgment by the COI Committee and the Management Board.

VI. Implementation methods

1) Role of the member

On presenting the results of clinical research at academic meetings, etc., the member of the Japan Society for Transplantation shall be obligated to appropriately disclose the COI state related to the conduct of the clinical research concerned. The disclosure shall be performed using the defined form according to the detailed rules. An event of violation of the present Guidelines shall be reviewed by the committee that exercises jurisdiction over COI (hereinafter referred to as “COI Committee”) and reported to the Management Board.

2) Role of administrator, etc.

All of the head commissioners, auditors, commissioners, committee chairpersons, chairpersons, next chairpersons and members of Specific Committee (Clinical Practice Guideline Supervisory Committee, COI Committee, Scientific Assembly Steering Committee, Journal Editorial Committee, Ethics Committee, etc.) of the Japan Society for Transplantation bear important roles and responsibilities for all programs and activities of the society, and they shall carry out self-reporting with regards to the COI status related to the programs concerned at the time of assuming the post.

When a serious COI state has arisen in execution of the program of the Japan Society for Transplantation by the administrator, etc. or the COI self-reporting of the administrator, etc. is recognized as inappropriate, the Management Board can consult the COI Committee and indicate corrective measures based on the report from the COI

Committee.

When clinical research results are presented at the meetings of the Japan Society for Transplantation, the chairperson shall check whether each presentation meets the present Guidelines and can stop the presentation violating the present Guidelines depending on the results of these checks. In such a case, the situation shall promptly be notified to the person planning to make the presentation together with the reason. The countermeasures shall be reviewed by the COI Committee and shall be executed after approval of the Management Board based on the report from the COI Committee.

When clinical research results are published in printed publications of the Japan Society for Transplantation, the Editorial Committee shall check that each article meets the present Guidelines and can stop the publication of an article violating the present Guidelines depending on the results of these checks. In such a case, the situation shall promptly be notified to the person planning to publish the article together with the reason. If violation of the present Guidelines is found after publication of the article, the Editorial Committee can disclose the situation in the printed publication concerned under the name of the chairperson of Editorial Committee. The countermeasures shall be reviewed by the COI Committee and shall be executed after approval of the Management Board based on the report from the COI Committee.

The chairpersons and members of the other committees shall check whether the society program related to each committee meets the present Guidelines and shall deliberate over improvement plans promptly in the event of violation of the present Guidelines. The countermeasures shall be reviewed by the COI Committee and shall be executed after approval of the Management Board based on the report from the COI Committee.

3) Statement of dissatisfaction

The person receiving the direction for improvement or stoppage as mentioned in 1) or 2) above can make a statement of dissatisfaction to the Japan Society for Transplantation. On receiving the statement of dissatisfaction, the Japan Society for Transplantation shall have it reviewed again by the COI Committee and notify the result to the person concerned after deliberation by the Management Board.

VII. Measures taken in relation to Guideline violators

1) The Management Board of the Japan Society for Transplantation has the right to deliberate the actions violating the present Guidelines after the review by the COI Committee and can execute all or some of the following measures for a certain term depending on the level of noncompliance when the actions are judged as applicable to serious noncompliance as a result of deliberation. However, Article 10 of the Society Constitution shall be followed for (v) and (vi) below.

- (i) Prohibition of presentation at all meetings held by the Japan Society for Transplantation

- (ii) Prohibition of publishing articles in printed publications of the Japan Society for Transplantation
- (iii) Prohibition of assuming the position of chairperson or next chairperson of the academic meeting of the Japan Society for Transplantation
- (iv) Prohibition of participating in the Management Board or each committee of the Japan Society for Transplantation
- (v) Expulsion from the board of representatives of the Japan Society for Transplantation or prohibition of becoming a representative
- (vi) Expulsion from the Japan Society for Transplantation or prohibition of becoming a member

2) Statement of dissatisfaction

The person receiving the measure as mentioned in 1) above can make statement of dissatisfaction to the Japan Society for Transplantation. On receiving the statement of dissatisfaction, the Japan Society for Transplantation shall have it reviewed again by the COI Committee and notify the result to the person concerned after deliberation by the Management Board. But, before the decision, an opportunity for an exculpatory statement must be given to the member concerned at a general assembly meeting of the representatives.

3) Accountability

When the clinical research results presented on the occasion related to the Japan Society for Transplantation are judged as seriously violating the present Guidelines, the Japan Society for Transplantation shall achieve accountability to the society after deliberation by the COI Committee and the Management Board.

VIII. Enactment of detailed rules

The Japan Society for Transplantation shall enact the detailed rules necessary to implement the present Guidelines.

IX. Date of implementation and revision method

The present Guidelines shall be implemented from March 17, 2025.

Under various situations including future revisions of the relevant laws and regulations, it may become necessary to revise the present guidelines. The COI Committee shall be able to review and revise the present guidelines depending on the decision of the Management Board.

Japan Society for Transplantation Guidelines on Conflict of Interest
Detailed Rules for Implementation

No. 1 (Presentation at academic meetings of the Japan Society for Transplantation
(hereinafter referred to as “this society”))

(Scope of disclosure)

The COI state that the first speaker is obligated to disclose is limited to the case relevant to a business enterprise or profit-oriented organization involved in the presentation contents.

(At the time of submitting the summary)

The speaker who is going to make a presentation or lecture at the academic meetings or lecture sessions of this society shall clarify the presence/absence of his /her COI state in the past three years using the predefined form (Format 1) at the time of application for presentation or at the time of submitting the summary.

(At the time of presentation)

The COI state described at the time of submitting the summary shall be disclosed at the end of the slides or posters used for presentation. The amount of money that requires self-reporting is shown below for each item to be disclosed.

- (i) In case of being a board member or adviser of a business enterprise or profit-oriented organization, when the payment from one business enterprise or organization is not less than one million yen per year, self-reporting is necessary.
- (ii) In case of holding stocks, when holding at least 5% of the entire stocks of one business enterprise, self-reporting is necessary. (This is also applicable to a right to purchase stocks as an option. In this case, when holding at least 5% of the latent stocks, self-reporting is necessary.)
- (iii) In case of receiving patent royalty from a business enterprise or profit-oriented organization, when one patent royalty is not less than one million yen per year, self-reporting is necessary.
- (iv) In case of receiving a daily allowance (lecture fee, etc.) paid by a business enterprise or profit-oriented organization for the time and labor restricting the researcher for participating in meetings (presentations), when the total lecture fee from one business enterprise or organization is not less than half million yen per year, self-reporting is necessary.

- (v) In case of receiving a manuscript fee paid by a business enterprise or profit-oriented organization for writing pamphlets, etc., when the total manuscript fee from one business enterprise or organization is not less than half million yen per year, self-reporting is necessary.
- (vi) In case of receiving research funds provided by a business enterprise or profit-oriented organization, when the total amount paid for one research project is not less than one million yen per year, self-reporting is necessary. In case of receiving a scholarship donation (encouragement donation) or endowed chair, when the total amount paid to one research representative from one business enterprise or organization is not less than one million yen per year, self-reporting is necessary.
- (vii) In case of receiving other rewards (travels, gift items, etc. having no direct relation with research), when the rewards received from one business enterprise or organization are not less than 50,000 yen per year, self-reporting is necessary.

No. 2 (Publication in journal, etc. of this society)

(Scope of disclosure)

The COI state that the author is obligated to disclose is limited to any case relevant to a business enterprise or profit-oriented organization involved in the manuscript contents.

The author who is going to publish an article in the journal “Transplantation”, etc. of this society shall clarify the COI state at the time of manuscript submission using the format specified in the manuscript submission rules. For each item to be disclosed, the amount of money that requires self-reporting shall be the same as the amount specified in Detailed Rule No. 1. The disclosure targets shall be those falling within one year before the manuscript submission. Also, for publication in printed publications of this society other than the journal “Transplantation”, self-reporting shall be carried out using the same format.

No. 3 (Head commissioner, commissioners, committee chairperson, and members of the Guideline Committee)

(Scope of disclosure/release)

The COI state that the head commissioner, commissioners, committee chairperson and members of the Guideline Committee are obligated to disclose/release is limited to any case relevant to a business enterprise or profit-oriented organization involved in the programs carried out by this society.

(At the time of assuming the post)

The head commissioner, commissioners, committee chairperson and members of the Guideline Committee of this society shall be obligated to report the COI state at the time of assuming the post and every year after assuming the post, using the “COI Self-Reporting Sheet for Administrators” (Format 2). The items specified in “IV. Items to be disclosed” of the present Guidelines shall be reported with Format 2. For each item to be disclosed/released, the amount of money that requires self-reporting shall be the same as the amount specified in Detailed Rule No. 1. The one-year-portion shall be described, and the calculation period shall be shown clearly.

No. 4 (Handling of COI Self-Reporting Sheets for head commissioner, commissioners, committee chairperson, and members of the COI Committee)

The COI Self-Reporting Sheets submitted to this society according to these detailed rules and the COI states (COI information) disclosed herein shall be strictly retained and controlled as personal information at the secretariat of this society (controlled by the head commissioner). The Management Board and the COI Committee shall be able to utilize the COI information as necessary to treat the items specified in the present Guidelines. The utilization shall include the following cases: when a case of mistrust or a social/legal problem has arisen in relation to the COI state of the individual reporter concerned, the necessary part of the COI information concerned is disclosed to the inside of this society or to the society after discussion at the COI Committee and approval of the Management Board. The COI Self-Reporting Sheets submitted shall be retained for 2 years after the end of each person’s term as head commissioner, commissioner, committee chairperson or member of the COI Committee, and thereafter shall be disposed of under the control of the head commissioner. However, if a case of mistrust or a social/legal problem has arisen in relation to the reporter concerned during the retention period, the disposal can be suspended under the decision of the Management Board.

Additional rule: These detailed rules shall be implemented from March 17, 2025