

Guidelines on Conflict of Interest in Medical Research

The Japanese Society for Helicobacter Research

With the goal of contributing to society by promoting and advancing basic and clinical research in helicobacter infection, the Japanese Society for Helicobacter Research (JSHR) is engaged in such activities as holding academic conferences, lectures, and other events; publishing journals and other literature, etc.; coordinating and collaborating with other relevant academic societies in Japan and overseas; and conducting other projects, etc. that are necessary for achieving the JSHR's goal.

Research results that are shared at JSHR-hosted academic conferences and its publications, etc. include clinical and basic medical study data that assist the development of novel diagnostic, therapeutic, and preventive methods for battling helicobacter infections as well as medical research findings that are obtained using new medications, medical devices, and other types of medical technology. Therefore, such research activities include those that are based on industry-academia collaborations with pharmaceutical companies, entrepreneurial ventures, etc. (i.e., joint research, contracted research, technology transfer/technical assistance, scholarship donations, grant-funded courses, etc.), through which organizations for public interest, such as universities, research institutes and academic societies, get involved in the activities of certain business enterprises. As such academic institutions become responsible not only for providing education and conducting research but also for effectively dealing with their partners in the business world, conflicting interests may easily arise, as individuals participating in those industry-academia endeavors may be presented with opportunities to make personal gains. In these sorts of conflict of interest (COI), it is crucial for each academic institution or society to properly and systematically manage the situation, in order to appropriately facilitate the industry-academia collaborations it is engaged in. It must also be noted that healthy individuals, patients, etc. could be participating in such collaborative endeavors as the subjects of medical studies. The possibility of jeopardizing the human rights and safety of such research subjects increases as the level of conflicts of interest rises with business operators, organizations, etc. that provide funding and other benefits. In addition, there is a risk that research procedures, data analyses, and interpretation of findings might be compromised or skewed due to a conflict of interest.

A number of medical research institutes and academic societies have drawn up policies on conflict of interest in medical research in order to ensure the appropriateness and fairness of their research activities, the transparency of their presentations of research findings at academic conferences, and to properly promote medical research in industry-academia collaborations. This is all part of their continuous efforts to give back to society through proper research results. In line with such principle, the JSHR hereby stipulates its own guidelines on conflict of interest, under which its members, etc. will disclose information on any economic relations that they may have with sponsors that have conflicts of interest with the JSHR's activities based on certain requirements, and will be held accountable to society.

I. Purpose

According to the Declaration of Helsinki that sets forth ethical principles concerning medical research on humans as well as the Ethical Guidelines on Medical Research on Humans (Public notice No. 3 issued by the Ministry of Health, Labour and Welfare in fiscal 2014), particular attention must be paid to protecting the human rights and lives of all research subjects and ensuring safety in general during research projects. In light of the fact that all its activities involve social responsibility and must meet strict ethical requirements, the JSHR stipulates these Guidelines on Conflict of Interest (COI) in Medical Research (hereinafter referred to as the “Guidelines”).

The purpose of these Guidelines is to maintain neutrality, fairness, and transparency concerning publication of research findings, relevant education activities, etc. and to contribute to the advancement of disease prevention, diagnoses, treatment, etc., through proper management of all COI cases that the JSHR members, etc. may be involved in. Consequently, all JSHR members, etc. that participate in various projects and activities where they publish research findings, etc. must properly disclose their COI status and comply with these Guidelines.

II. Types of persons to whom these Guidelines apply

These Guidelines shall apply to the following types of persons who may be involved in COI cases:

- (1) members of the JSHR;
- (2) persons making presentations at JSHR-hosted academic conferences and other events; persons submitting their papers for publication with the JSHR; persons preparing guidelines, etc.;
- (3) officers (president, vice president, trustees, supervisors), secretaries, representatives, organizers of academic conferences (conference chairs, etc.), organizers of extension courses open to the public, etc., members of various committees at the JSHR;
- (4) administrative staff members at the JSHR; and
- (5) the spouses of persons as described in (1) to (4) above, their relatives that are within the first degree of kinship, and other persons who share or co-own income or property with them.

III. Types of activities to which these Guidelines apply

These Guidelines shall apply to all operational activities that are conducted by the JSHR:

- (1) holding of academic lectures, etc.;
- (2) publication of the JSHR’s journals and other academic literature;
- (3) performance of research and investigative activities;
- (4) encouragement to conduct research, and commendation of good research performance;
- (5) implementation of a doctor certification system (to produce JSHR-certified physicians, etc.);

- (6) promotion of lifelong learning activities (provision of educational lectures, etc.);
- (7) coordination and cooperation with other relevant academic societies;
- (8) promotion of international cooperation in research; and
- (9) other operational activities that are necessary for the JSHR to achieve its goal.

In particular, these Guidelines must be strictly followed when conducting the following types of activities:

- 1) presentations at JSHR-hosted academic conferences and other events;
- 2) announcement of research findings in the JSHR's journals and other publications;
- 3) formulation of medical practice guidelines, manuals, etc.; and
- 4) operational tasks to be performed by any investigative and advisory committees, etc. that are set up from time to time as needed.

IV. Matters that require reporting

In regard to each person to whom these Guidelines apply and that falls into any of the following circumstances as specified in (1) to (9) below to an extent that exceeds any of the thresholds as set forth in the Detailed Rules, the person must accurately report the information to the president of the JSHR. In this connection, the specific procedure and method of disclosing and publishing the content of such reports are separately set forth in the Detailed Rules:

- (1) acceptance of appointment as officer, adviser, employee, etc. at a private enterprise, corporation, or other for-profit organization;
- (2) possession of shares of a private enterprise;
- (3) payment of any royalty for the right to use a patent by a private enterprise, corporation, or other for-profit organization;
- (4) payment of any allowance by a private enterprise, corporation, or other for-profit organization to a researcher attending a conference (or making a presentation) for the time spent or labor expended by the researcher (i.e., lecture fee, etc.);
- (5) payment of any manuscript fee by a private enterprise, corporation, or other for-profit organization for authoring text to be included in a pamphlet, etc.;
- (6) payment of any medical research fee by a private enterprise, corporation, or other for-profit organization (i.e., clinical trial fee, clinical testing fee, etc.);
- (7) payment of any research fee by a private enterprise, corporation, or other for-profit organization (i.e., contracted research or joint research fee, donation, etc.);
- (8) provision of a grant-funded course by a private enterprise, corporation, or other for-profit organization; and

- (9) payment of a travel expense or provision of a gift by a private enterprise, corporation, or other for-profit organization that is not related to any research, educational endeavor, or medical practice.

V. Circumstances to be avoided in COI cases

1. Circumstances to be avoided by all persons to whom these Guidelines apply

Publication of medical research findings, formulation of medical practice guidelines, etc. must be conducted based on purely scientific grounds or for the public good. Therefore, each member of the JSHR, etc. involved in the interpretation or publication of research findings, preparation of medical practice (diagnosis and treatment) guidelines and manuals, etc. should not be affected by the biased intention of the party or private enterprise that is funding the medical research, nor should it execute a contract with the party providing the funds, etc. if such influence is unavoidable.

2. Circumstances to be avoided by persons who are responsible for managing clinical research projects and formulating medical practice guidelines and manuals

When appointing a person who will ultimately be responsible for making decisions concerning the planning and execution of a clinical test, clinical trial, etc. or for formulating medical practice guidelines or manual, the person should be a researcher who is socially acceptable as having no significant COI in the following respects (i.e., having little tie to the party requesting the research), and the person should remain that way after being appointed to the aforementioned post:

- (1) possession of any share of the private enterprise that is requesting the medical research project;
- (2) receipt of any patent royalty payment or patent right pertaining to a product or technology, or technique that is achieved as a result of the medical research project; or
- (3) acceptance of appointment as officer, trustee, advisor, etc. (excluding any scientific advisory post for which no remuneration is provided) at a private enterprise or for-profit organization that is requesting the medical research project.

Notwithstanding the foregoing, even in a case where a researcher meets any of the descriptions as specified in (1) to (3) above, the researcher may still serve as a doctor responsible for managing the tests in the medical research project, if that person is needed for planning and executing the medical research project, and the medical research project has highly significant implications for society, provided that the appropriateness, fairness, and transparency of the person's decisions to be made and measures to be taken during the project can be clearly assured.

VI. Implementation procedure

1. Members' responsibility

Each JSHR member that will be presenting research findings at a JSHR's academic conference, etc. must properly disclose the status of any COI concerning the research project at the time of the presentation, pursuant to the Detailed Rules of the JSHR. If any infraction of these Guidelines is suspected, the board of trustees must request the committee that oversees COI cases (hereinafter referred to as the "COI Committee") to review the case and take appropriate measures based on the advice of the COI Committee.

2. Officers' responsibility

Each JSHR officer (president, vice president, trustee, supervisor), secretary, representative, organizer of academic lectures (lecture chairs, etc.), and member of a various committee has an important role as well as responsibility that concern all operational activities pertaining to the JSHR. Hence, each such person must report any COI that may exist concerning the operation or project that the person is or will be involved in at the time of assuming the post and also by the time of the general JSHR employee assembly each year, by submitting the information to the secretariat using the prescribed form.

3. Roles of the COI Committee

The roles of the COI Committee are to identify each instance where a significant COI has arisen with any member involved in a JSHR-related project or where any inappropriate self-reporting on COI exists, notify such member of the infraction, and provide proper instructions. In addition, if an issue is raised with any self-reported COI case, the COI Committee must conduct an interview, etc. with the member involved to investigate the COI status of the member, and report the result to the JSHR president.

4. Roles of the board of trustees

The roles of the board of trustees are to identify each instance where a significant COI has arisen with any officer, etc. during the course of a JSHR project or where any inappropriate self-reporting on COI exists, report the information to the COI Committee for review, and provide instructions and suggest other remedial measures based on the advice of the COI Committee.

5. Roles of the organizers of academic conferences

The roles of the organizers of academic conferences (conference chairs, etc.) are to make sure that all research findings are presented at the academic conferences pursuant to these Guidelines, and to exercise their right to stop any presentation from being delivered, etc. if it is in breach of these Guidelines. In such event, they must promptly notify those presenters that they are prohibited from delivering their presentations, while clearly stating the grounds based on which such decision has been reached. In this connection, the board of trustees may report such cases to the COI Committees and provide instructions and suggest other remedial measures based on the advice of the COI Committee.

6. Roles of the JSJR publication editorial committee

The roles of the JSJR publication editorial committee are to verify each original paper, review, medical practice guidelines, editorial article, opinion, etc. that will be included in the JSJR journal or other publication before it is published to make sure that it conforms to these Guidelines, and to stop it from being published if it does not conform to these Guidelines, or to implement other appropriate measures. In such event, the committee must promptly notify the contributing author of such decision along with an explanation of the grounds based on which the decision has been reached. If any non-conformance to these Guidelines is identified after the paper, etc. have already been published, such non-conformance may be publicly announced by the editor-in-chief in the publication, etc. In such case, the editor-in-chief may report the information to the COI Committee, and provide instructions and suggest other remedial measures based on the advice of the COI Committee.

7. Other committees

The chairs and members of all other committees must verify the JSJR activities and projects that they are respectively involved in to ensure that they conform to these Guidelines, and examine what sorts of remedial measures should be implemented if any non-conformance is identified. In this connection, the board of trustees may report any such non-conformance to the COI Committee, and provide instructions and suggest other remedial measures based on the advice of the COI Committee.

VII. Measures against and accountability of persons who do not conform to these Guidelines

1. Measures against persons who do not conform to these Guidelines

Pursuant to the relevant rules that are separately set, the board of trustees is authorized to review any act that does not conform to these Guidelines, and may report any non-conformance to the COI Committee for review. If any such case is deemed to be a significant non-conformance by the board of trustees based on the advice of the COI Committee, the board of trustees may enforce a penalty or take other appropriate measures, depending on the severity of the non-conformance.

2. Filing of objecting motions

Each person who has become the subject of such measure against non-conformance is entitled to file a motion with the JSJR to object to the decision to enforce the measure. If the president of the JSJR should receive such a motion, the president should set up a committee for reviewing the objecting motion (i.e., tentative advisory committee), have the committee review the case, discuss the result of the review at a board of trustees meeting, and notify the decision to the person who filed the objecting motion.

3. Accountability

If any significant non-conformance with these Guidelines is deemed to exist in regard to the publication of any JSJR-related research findings, the board of trustees must review and discuss the case, and fulfill its duty to explain the non-conformance to society.

VIII. Cooperation with other relevant academic societies

The JSJR shall exchange relevant information and engage in other cooperative activities with other relevant academic societies when reviewing and revising these Guidelines and the Detailed Rules from time to time as needed.

IX. Enactment of detailed rules

The JSJR may enact any detailed rules for efficient implementation of these Guidelines.

X. Revision of the Guidelines

These Guidelines may be reviewed and revised periodically in line with various social factors, statutory changes and developments concerning industry-academia collaborations, and circumstances related to the field of medicine and research in general.

XI. Enforcement date

These Guidelines shall be fully enforced from March 16, 2017.

XII. Management

The JSJR secretariat shall be administratively responsible for properly managing and handling COI case submissions pursuant to these Guidelines and the Detailed Rules. Notwithstanding the foregoing, the president of the JSJR shall be responsible for handing and reviewing all COI case submissions that concern presentations and poster presentations to be made at academic conferences.