

Detailed Rules Concerning the Guidelines on Conflict of Interest in Medical Research The Japanese Society for Helicobacter Research

The Japanese Society for Helicobacter Research (JSHR) has drawn up the Guidelines on Conflict of Interest in Medical Research in order to justly manage all cases of conflict of interest (COI) in which JSHR members and presenters of research findings may be involved. The purposes of the Guidelines are to ensure the appropriateness and fairness of all medical research activities that take place at the JSHR and to maintain the transparency of all presentations at academic conferences and social trust, while properly facilitating medical research activities in industry-academia collaboration projects. The JSHR hereby stipulates these Detailed Rules Concerning the Guidelines on Conflict of Interest in Medical Research in order to ensure that the Guidelines are properly and efficiently implemented.

Article 1 Report on COI information concerning presentation of research findings, etc. at the JSHR Section 1

If any medical research findings are to be presented in a special lecture, educational lecture, or luncheon seminar at a JSHR-hosted academic lecture event, etc. or at an extension course, etc. that is open to the public, the presenter must comply with the reporting criteria as specified by the JSHR and report its COI status pertaining to any economic ties that exist with the private enterprise and other for-profit organizations that are involved in the medical research project, including spouse, relatives within the first degree of kinship, and those living in the same household, that existed within the last 3 years (January to December), by submitting Form 1 to the academic conference secretariat before the day of the academic conference.

Each presenter or lecturer having such COI status must clearly state on the first slide shown in the presentation or lecture (or on the next slide following the one that introduces the presentation topic, presenter or lecturer, etc.) about the COI using Form 1-A. Even if there is no COI, each presenter and lecturer must provide COI information using Form 1-B. In regard to each poster presentation topic, the COI information pertaining to the presentation must be stated at the end by following Form 1-A or 1-B, as the case may be.

Section 2

“Private enterprises, corporations, or other for-profit organizations involved in medical research” means private enterprises, organizations, or groups that have the following types of relationships in regard to the medical research:

- 1) relationships in which they requested to conduct the medical research or jointly conducted the medical research (regardless of whether or not any remuneration was provided for the research);
- 2) relationships in which they jointly own patent rights, etc. pertaining to any treatment method, medication, equipment, etc. being evaluated in the medical research;

- 3) relationships in which any medication, machinery, material, etc. being used in the medical research are provided by them free of charge or at a particularly steep discount;
 - 4) relationships in which they provide a research grant, donation, etc. for the medical research;
 - 5) relationships in which they provide any unapproved medical drug, equipment, etc. in the medical research;
- or
- 6) relationships in which they are sponsoring grant-funded courses, etc.

Section 3

“Medical research” in regard to presentation of research findings means any type of medical research activities in order to improve disease prevention methods, diagnosis methods, and treatment methods; better understand the causes of various diseases and their pathological conditions; and enhance the quality of life of patients in the field of medicine, which involve humans subjects. Medical research projects that involve humans as the subjects include those that study human-derived samples and data that can be used to identify the individuals to which they pertain. Any decision as to whether any sample or data is of the type that can be used to identify the individuals shall be made pursuant to the Ethical Guidelines on Medical Research on Humans stipulated by the Ministry of Health, Labour and Welfare.

Article 2 Self-reporting criteria on COI cases

The monetary amount based on which a COI must be self-reported as well as the type of information to be disclosed in each type of circumstance are as specified below.

- 1) Assumption of a post as officer or advisor at any private enterprise, corporation, or other for-profit organization that is involved in the medical research (hereinafter referred to as “Private Enterprise, Organization, or Group”): It must be self-reported if the amount of the remuneration provided by any single Private Enterprise, Organization, or Group is ¥1 million or more.
- 2) Possession of shares: It must be self-reported if the amount of profit (i.e., the sum of all dividends and capital gain) achieved by possessing shares of any single Private Enterprise per year is ¥1 million or more, or if 5% or a larger percentage of all outstanding shares of the Private Enterprise are owned.
- 3) Payment of patent royalties by the Private Enterprise, Organization, or Group: It must be self-reported if the amount of royalties paid for the right to use any single patent per year is ¥1 million or more.
- 4) Payment of allowances (i.e., lecture fee, etc.) made by the Private Enterprise, Organization, or Group to a researcher to attend or make a presentation at a conference for the time spent or labor expended by the researcher: It must be self-reported if the amount of the lecture fees paid by any single Private Enterprise or Group per year is ¥500,000 or more.
- 5) Payment of manuscript fees by the Private Enterprise, Organization, or Group for authoring text to be included in a pamphlet, etc.: It must be self-reported if the amount of the manuscript fees paid by any single Private Enterprise, Organization, or Group per year is ¥500,000 or more.

- 6) Payment of research fees by the Private Enterprise, Organization, or Group: It must be self-reported if the total amount of the fees paid by any single Private Enterprise or Group for the medical research (i.e., in the form of contracted research fee, joint research fee, entrusted government fund that must be accounted for, etc.) per year is ¥5 million or more.
- 7) Payment of clinical trial fees and scholarship (incentive) donations by the Private Enterprise, Organization, or Group: It must be self-reported if the total amount of the fees paid by any single Private Enterprise, Organization, or Group to the reporting individual, the department (course or field) where the reporting individual is a member, or the individual representing the laboratory is ¥1 million or more per year.
- 8) If a person is a member of a grant-funded course program provided by the Private Enterprise, Organization, or Group: Each such instance must be self-reported.
- 9) Other benefits such as funding of travel expenses, provision of gifts, etc. that are unrelated to the research, educational endeavor, or medical practice: It must be self-reported if the total amount of all monies paid by any single Private Enterprise, Organization, or Group per year is ¥50,000 or more.

In regard to the types of circumstances that must be reported as set forth above, there may be cases where the recipient of a scholarship donation provided by the Private Enterprise, Organization, or Group is the head of an organization (head of an academic institution or hospital), head of a course or field, or the self-reporting individual itself. In any case where such recipient is not the self-reporting individual, no researcher tie at an individual level is usually assumed. However, if the scholarship donation is distributed to any person presenting research findings, the department (course or field) where the presenter is a member, or the laboratory through the head of the organization from the Private Enterprise, Organization, or Group, the amount of money involved must be investigated and confirmed to the extent possible and reported.

As for items to be reported concerning which issues often arise, they involve cases where donations, etc. from Private Enterprises are provided through not-for-profit entities (e.g., NPOs) and public-interest corporations (e.g., incorporated foundations) in the form of monetary support (i.e., contracted research fee, research grant), all of which must be self-reported in the same manner as the aforementioned cases. As the amount of financial assistance becomes higher, outside parties will receive a worse impression as to the objectivity and fairness of the research findings. Therefore, each person involved in any research activity where assistance is deemed to be indirectly provided by a concerned Private Enterprise should self-report the COI, in order to avoid any doubt or social issue that may arise.

Article 3 Publishing of reported information in JSHR journals, etc.

Section 1

If an author that is publishing any research findings (in the form of a review, original paper, etc.) in any JSHR journal has any economic tie to a Private Enterprise, Organization, or Group as set forth in Article 1, Section 2 hereof regarding publication of those findings, the author must disclose its COI status for the year (January to

December) preceding the contribution of the text by submitting a report to the editorial committee in advance pursuant to the contribution rules of JSHR journals. Such COI status shall be stated at the end of each such paper. In cases where there is no COI as defined, an appropriate statement such as “There are no potential conflicts of interest to disclose.” shall be indicated in the same place instead. In regard to each COI case that must be disclosed at the time of publication, the names of the Private Enterprise, Organization, or Group involved must be reported with reference to IV. “Matters that require reporting” of the Guidelines on Conflict of Interest in Medical Research, or Article 2 hereof regarding what sorts of information must be disclosed, etc.

Section 2

In regard to each case of publication of a set of medical practice guidelines, etc. for which the JSHR was involved in the editorial process, the COI status of respective members of the document preparation committee, review committee, and supervising committee that were involved in the process must be investigated, summarized, and disclosed in the published document. The scope of such information disclosure shall be limited to the private enterprises, corporations, and for-profit organizations that concern the content of such publications.

Article 4 Submission of COI reports by JSHR officers, committee chairs, and chairs of academic conferences, etc.

Section 1

Each JSHR officer (president, vice president, trustee, supervisor), secretary, representative, various committee member, and organizer of academic lectures must report its COI status concerning the circumstances as set forth in IV. “Matters that require reporting” of the Guidelines on Conflict of Interest in Medical Research by creating a self-report using Form 2 and submitting it to the secretariat on whether any COI existed over the previous year (from January to December) at the time of assuming the post and also by the general JSHR employee assembly each year. As for each chair of an academic conference, it must report its COI status by creating a self-report using Form 2 and submitting it to the secretariat on whether any COI existed over the previous year when the decision is made for the person to become the chair. If a self-report on COI has already been submitted, there is no need to resubmit another self-report. In this connection, the scope of such self-report on COI shall be limited to the private enterprises, corporations, and for-profit organizations that concern any of the JSHR activities or projects.

Section 2

In regard to the COI status to be reported using Form 2, all applicable circumstances as set forth in IV. “Matters that require reporting” of the Guidelines on Conflict of Interest in Medical Research must be self-reported. Regarding each circumstance to be disclosed or otherwise made public, the amount of money at or above which a self-report must be submitted as specified in Article 2 hereof in each type of circumstance must be referred to, based on which an itemized statement must be provided including all monetary amounts

involved, using Form 2. When filling out Form 2, the information for the previous fiscal year must be provided, while clearly specifying the time period for which the amounts have been calculated.

Article 5 Procedure for handling self-reports on COI

Section 1

Each self-report on COI that is submitted at the time of academic presentation at any JSHR event must be stored and strictly managed by the secretariat for a period of two years. Likewise, each document, etc. that contains COI information on a person who has served as an officer or committee chair at the JSHR, or a person whose nomination as officer or committee chair has been definitively revoked, must be stored and strictly managed by the corporation office for a period of two years following the expiry of the final term of assumption or the revocation of the committee member nomination. In regard to each self-report submitted by a member of the JSHR secretariat, it must be stored and strictly managed by the corporation office for the duration of employment of the secretariat member at the JSHR and also for a period of two years following the date on which the secretariat member leaves employment with the JSHR. All documents that have been duly stored for their respectively designated two-year periods must be promptly deleted or disposed of under the supervision of the president. Notwithstanding the foregoing, if the board of trustees should decide that deletion or disposal of any particular documents would be inappropriate, the deletion or disposal of such documents containing COI information on the pertinent individuals may be postponed for an extended period of time to be specified as needed. The COI information on each chair of academic lectures (including the one for the following fiscal year) shall be treated in the same manner as the COI information on any JSHR officer should be treated.

Section 2

COI information may be used by any JSHR trustee or concerned individual in a managerial position, etc. from time to time as needed pursuant to these Detailed Rules, in order to decide whether any COI exists between the person to whom the COI information pertains and the JSHR activity or project involved as well as the level of COI if it exists, so that the JSHR can properly conduct its activities or project management and implement any measures based on the decision.

Use of any COI information shall be kept within the necessary scope of use, depending on the purpose of use of the information. In addition, no COI information shall be disclosed to a party to which disclosure of the information is not required for the purpose of use of the information (i.e., non-disclosure obligation applies).

Section 3

Excluding the cases as set forth in Article 5, Section 2 hereof, COI information shall be kept confidential and shall not be disclosed to the public, in principle. If it is necessary to disclose or publish any COI information concerning any activity of the JSHR or any of its various committees, etc. in order for the JSHR to fulfill its accountability obligation for social or ethical purposes, such disclosure or publication of the COI information

may be allowed, either internally at the JSHR or externally, only to the extent necessary, after a discussion is held and consent is reached by the board of trustees. Notwithstanding the foregoing, such restrictive procedure shall not prevent the JSHR from entrusting a particular trustee to handle such issue and asking it to make a decision on the issue for the JSHR, based on the advice of the COI Committee. In such a case, the person to whom the COI information being disclosed or published pertains shall be entitled to express its opinion to the board of trustees or the trustee that has been entrusted to make the decision. The foregoing procedure, however, may not be followed if the COI information at issue must be disclosed or published in an urgent manner and there is not time to hear the opinion of the person to whom the COI information pertains.

Section 4

If a request has been filed to disclose information on any particular member of the JSHR (including statutory request), and if there is a reasonable ground to consider that such request is valid, the COI Committee shall properly handle such request while protecting the personal information involved, at the suggestion of the president. Notwithstanding the foregoing, if it is deemed impossible for the COI Committee to properly handle such request, the president shall set up a COI investigation committee consisting of a particular trustee to be specified, a small number of JSHR members, and at least one outside member, to handle the issue instead. The COI investigation committee must hold a committee meeting within 30 days of receiving the disclosure request and make a decision on it as soon as possible.

Article 6 COI Committee

The president must form the COI Committee, which shall consist of a small number of JSHR members, and also appoint a committee chair. Each member of the COI Committee shall be bound by non-disclosure obligations as to all COI information that becomes known to it pertaining to the JSHR members. The COI Committee must work with the board of trustees to conduct proper activities and project management to prevent deterioration of the COI status of any members and also to respond to any non-conformance that has been identified, pursuant to the COI Guidelines and these Detailed Rules. If a significant COI case should arise with any JSHR member in regard to any activity or project being led by the JSHR, or if any self-report on COI is found to be inappropriate, the COI Committee must notify the person involved in the case and provide proper instructions by advising correction of the COI report that was previously filed, etc. In regard to the procedure for reporting COI cases and handling COI information, the provisions of Article 5 hereof shall be applied, *mutatis mutandis*.

Article 7 Measures against breaching individuals

Section 1

If any doubt or issue of a social or ethical nature should arise pertaining to the content of any COI self-report that has been submitted by an author publishing research findings in a JSHR journal, etc. or by a presenter at a

JSHR-hosted academic conference, etc., the COI Committee shall conduct an investigation, interviews, etc. on the matter in a thorough manner and implement proper measures accordingly, in order to allow the JSHR to fulfill its obligation of accountability to society. If the JSHR is unable to fulfill its accountability obligation on a critical COI case, the president may consult the COI Committee, discuss the case at the board of trustees based on the advice of the COI Committee, and implement appropriate measures that may include preventing the author or presenter from making its presentation at the academic conference or publishing its paper, etc. If any doubt or issue is raised with a presentation or paper after it has already been delivered or published, relevant facts must be investigated and proper measures must be reviewed for implementation if the investigation indeed detects an infraction, which may include retraction of the published paper. In addition, if an act of any concerned party is deemed to cause significant damage to the reputation of the JSHR in society, the information must be submitted to the ethics committee for review so that appropriate measures may be implemented.

Section 2

If any COI information that has been reported by a JSHR officer, the chair of any of various committees, committee member that is required to submit a self-report on COI, or candidate for any of the aforementioned posts is found to have an issue, before or after such person assumed its post, the chair of the COI Committee must provide a written report on the case to the president, based on which the president must promptly hold a board of trustees meeting, and pass a resolution to either approve or deny such claim that there is an issue with the COI information. If the board of trustees passes a resolution approving the validity of such claim, the JSHR officer or committee member in question must resign from its post, in which case, the president may also revoke the nomination of the candidate for the post as officer or committee member, as the case may be. If any doubt or issue of a social or ethical nature should arise pertaining to the content of any COI self-report that has been submitted by a presenter at a JSHR-hosted academic conference, etc., or if an act of any concerned party could cause significant damage to the reputation of the JSHR in society, the board of trustees may implement appropriate measures to address the situation.

Article 8 Objecting motions

Section 1 Filing of objecting motions

If a person receives a notification indicating that the person committed an infraction concerning its presentation or publication with the JSHR pursuant to Article 7, Section 1 hereof, or if a person has been notified of a decision requiring resignation from its post as officer or committee member, or revoking its nomination for such post pursuant to Article 7, Section 2 hereof, and if the person does not agree with the decision, the person shall be entitled to request a review of the case by filling out and submitting to the JSHR secretariat a review request form addressed to the president, within 14 days of receiving the notification from the board of trustees. The person must concisely state in the review request form its specific grounds for

rebuttal of and objection to the reasons for the decision as described in the document by the president. In such a case, the person filing the form may also present additional pieces of information to support its objection grounds in addition to the information that has been disclosed to the president.

Section 2 Procedure for reviewing objecting motions

1. If a review request has been filed by a person who does not agree with the decision it has been notified of, the president must promptly set up an objecting motion review committee (hereinafter referred to as "Review Committee"). The Review Committee must consist of a small number of JSHR members to be appointed by the president and at least one outside committee member. The committee chair shall be chosen by the members. None of the members of the COI Committee may be appointed to serve on the Review Committee simultaneously. The Review Committee must hold a committee meeting and conduct an actual review of the case within 30 days of receiving the review request form.
2. The Review Committee shall be allowed to conduct interviews with the chair of the COI Committee that concern the case and also with the person who filed the objecting motion to hear their opinions, unless such person fails to show up on the specified interview date.
3. Unless there is a special circumstance, the Review Committee must draft a decision on the case and submit it to the board of trustees within one month of the date on which the first committee meeting was held to review the case.
4. The board of trustees shall make its final decision on how to treat the case based on the judgment made by the Review Committee based on the objecting motion.

Article 9 Measures against persons who have breached their non-disclosure obligations

To ensure proper management of COI information, each employee working at the JSHR secretariat who comes to know COI information that is personal in nature shall be bound by the non-disclosure obligations as set forth in Article 5, Section 2 hereof, in the same manner as each JSHR trustee and concerned person in a managerial position. If any concerned person or secretariat member is found to have intentionally divulged any COI information to outside parties without following the specified appropriate procedure, the board of trustees may enforce a penalty on such person or member by expelling them from the JSHR or terminating their employment, etc.

Article 10 Modification of the Detailed Rules

Any part of these Detailed Rules may need to be modified on a case-by-case basis to adapt to various social conditions and statutory changes concerning industry-academia collaboration, etc. Therefore, the board of trustees may consult the COI Committee to properly review these Detailed Rules and pass resolutions to modify these Detailed Rules based on the advice of the COI Committee.

Supplementary Provisions

Article 1 Enforcement date

These Detailed Rules shall be enforced from March 16, 2017.

Article 2 Revision of these Detailed Rules

In principle, these Detailed Rules must be reviewed and revised once every few years in order to adapt to various social factors, statutory amendments and enactments concerning industry-academia collaboration, and changes in circumstances surrounding the field of medicine and medical research.

Article 3 Special provision on the application of these Detailed Rules to JSHR officers, etc.

In regard to those persons who had already assumed their posts as JSHR officers, etc. at the time when these Detailed Rules came into force, these Detailed Rules shall be applied to them, *mutatis mutandis*, to ensure that they promptly submit required reports, etc. accordingly.