

“Guidelines on Conflict of Interest in Medical Research”

The Organization of JDDW aims to promote the advancement and dissemination of gastroenterology with the intention of contributing to the progress of the medical sciences, public welfare and medical care through the improvement of gastroenterological research, education, diagnosis, and treatment. The Organization of JDDW held the first DDW-Japan in 1993, following the recommendation made at a strategic meeting by representatives of various gastroenterological societies, and has held its annual meetings since then as a collaborative effort of member societies and participating societies. Though originally known as “Japanese Gastroenterological Societies Joint Conference”, the organization was renamed Japan Digestive Disease Week in 2001 and incorporated on April 1, 2010. The organization pursues its missions by hosting Japan Digestive Disease Week (JDDW) and joint conferences for post-graduate education and by disseminating to the general public up-to-date information on gastroenterological diagnosis and treatment. The member societies of the organization include The Japanese Society of Gastroenterology, Japan Gastroenterological Endoscopy Society, The Japan Society of Hepatology, and The Japanese Society of Gastroenterological Surgery and continue to play an integral role in jointly hosting the JDDW annual meetings.

Academia in our nation is no exception in facing spontaneous and inevitable conflicts between the responsibilities of academic organizations and personal benefits obtained via collaboration between industry and academia. Such a situation is commonly referred to as a “conflict of interest (COI)”, and the academic organizations must manage and resolve situations that pose COI in their promotion of cooperative activities between industry and academia. In recent years, there has been a global trend in all countries to pursue and advance efforts in translational research from basic efforts to search for research seeds through to clinical research. Research that is subject to COI management is not limited to clinical research and clinical tests (including trials) on humans, but has also expanded to cover basic life sciences-related research implemented in cooperation with industry, with a trend towards obliging basic researchers who are engaged in research collaborations with corporations and other for-profit corporations and organizations, to also voluntarily submit a personal statement on their economic COI status. Therefore, this Organization defines “medical research” as research that is conducted in collaboration with industry with the objective of improving methods for preventing, diagnosing or treating illnesses, improving understanding about the causes and conditions of illnesses, or improving patient quality of life, encompassing all research from life sciences-related research, basic medical research, clinical medical research for humans (including research on both subject-derived specimens and data that enable individuals to be identified), and clinical tests. All of these areas that are defined as “medical research” are subject to COI management.

The basic concept of the Organization of JDDW and the member societies to COI management is as follows: (1) When accepting provision of external funding (donations, research grants, agreement-based research funding, etc.),

drugs and medical devices, and services, etc. from companies, corporate organizations, and other organizations that have interest in the university-industry medical research, such research institutes and researchers should do so justly and appropriately on the basis of guaranteeing medical, ethical, and scientific integrity in carrying out such university-industry medical research; (2) In order to ensure the quality and reliability of the results of such research, the research institutes and researchers should take precautionary measures in managing the research results based on detailed information on the external funding, drugs and medical devices, and services, etc. provided, and appropriately record and make public such detailed information in a plan of clinical research implementation, COI declaration form, and published papers; and (3) The research institutes and researchers should be accountable to any questions raised by a third party.

Even JDDW, which is a collaborative program of multiple gastroenterological societies, is required to properly manage COI of participants by ensuring full disclosure of any COI to the general public. For this reason, the JDDW stipulates the following COI guidelines based on discussions by the member societies.

I. Purpose

Ethical principles for medical research involving humans mandate special considerations for protection of the rights and life of test subjects and assurance of their safety as already described in the Helsinki Accords and Ethical Guideline for Clinical Research (Ministry of Health, Welfare and Labor Bulletin No. 255, revised in 2008).

In view of social responsibilities and a high level of ethical integrity required for its organizational activities, JDDW has adopted the following Guidelines on Conflict of Interest in Medical Research (hereinafter “these Guidelines”). The purpose of these Guidelines is to properly promote neutral and impartial activities of reporting and disseminating research findings by managing potential COI of the JDDW members, and thereby fulfilling our social responsibilities of contributing to the advancement of prevention, diagnosis and treatment of gastroenterological diseases. Accordingly, the Organization requires all academic societies partaking in JDDW to adopt and properly implement COI guidelines and bylaws of their own. Moreover, the Organization requires that presentations for JDDW be made as per the guidelines of the associated academic society and that disclosure of any COI be appropriately made.

II. Applicable Persons

These Guidelines apply to any of the below persons with a potential COI.

- (1) Persons making presentations at JDDW (including non-members)
- (2) Officers (presidents, directors, auditors, staff and advisors) and chairpersons of standing committees (Administration & Planning Committee, Finance & Donation Committee, Academic Conference Committee, PR Committee, Conflict of Interest Committee and Integrated Program Committee) and special committees of this Organization,

and persons in charge of society meetings in JDDW (chairpersons of annual meetings of member societies and participating societies)

(3) Personnel of the secretariat of the Organization

(4) Spouses, first degree relatives of and persons sharing revenue or property with (1) ~ (3)

III. Applicable Activities

These Guidelines apply to all projects and activities of the Organization.

(1) JDDW

(2) Joint seminars for medical education

(3) Dissemination of information on gastroenterology to the general public or related public outreach activities

(4) Other projects and activities necessary for attaining the missions of the Organization

Compliance to the Policy is particularly required in carrying out the following activities:

1. Making presentations at academic lectures organized by the Organization (such lectures hereafter called the “lectures, etc.”)

2. Publishing articles in journals and other publicity papers

3. Work carried out by provisionally set up investigative committees and advisory committees

4. Making presentations at lectures, workshops, and sponsored events hosted or cohosted by companies, corporate organizations, or for-profit organizations

IV. Matters to Report

Applicable persons must report to the president of the Organization the exact circumstances pertaining to the following activities (1) ~ (8) when they exceed the standards stipulated in the bylaws. Specific methods of disclosing reported matters are separately stipulated in the bylaws.

(1) Appointment to the post of officer, advisor, employee or other position of a business, incorporated organization or commercial enterprise

(2) Possession of stock in a company

(3) Receiving royalties from a business, incorporated organization or commercial enterprise

(4) Receiving daily allowances (lecture fee, etc.) paid by a business, incorporated organization or commercial enterprise to a researcher to attend (speak at) a meeting as compensation for time and labor

(5) Receiving manuscript fees paid by a business, incorporated organization or commercial enterprise for contributed articles for pamphlets, etc.

(6) Acquiring medical research (clinical studies, consigned research, collaborative research, donations, etc.) funds

supported by a business, incorporated organization or commercial enterprise

(7) Participating in courses funded by a business, incorporated organization or commercial enterprise

(8) Receiving travel support or gifts unrelated to research, study or diagnosis/treatment provided by a business, incorporated organization or commercial enterprise

V. Situations to Avoid Because of Potential Conflicts of Interest

1. Situations All Applicable Persons Must Avoid

The dissemination of medical research results and the adoption of diagnosis and treatment guidelines should be based purely on scientific evidence and conclusions, and public benefit. In reporting medical research results and interpretations or preparing diagnostic or treatment guidelines, manuals or other material, applicable persons must not be influenced by the selfish intentions of individuals or businesses that provide funds for the said medical research and must not sign any contracts with said parties in which such influences cannot be avoided.

2. Situations Clinical Research Investigators Must Avoid Relating to Medical Research

Primary investigators who plan and manage medical research, particularly clinical testing and trials, must select researchers who are socially recognized to have no serious COI with a study solicitor on the following activities and to maintain such status after selection.

(1) Possession of stock of the business that requests and supports medical research

(2) Acquisition of patent royalties or rights for products or technologies obtained from results of the medical research

(3) Serving as an officer, director, advisor or other position of the business or commercial enterprise that requests and supports medical research (excluding uncompensated scientific advisors)

However, researchers that meet the criteria (1) ~ (3) above may serve as investigating physicians in medical research that has very important social significance provided that the said researchers are indispensable towards planning and managing the said medical research and the fairness, neutrality and transparency of their decisions and actions can be unquestionably ensured.

VI. Method of Implementation

1. Obligations of Presenters at JDDW

Presenters at JDDW must, upon presenting medical research results, etc., properly disclose in writing using the specified form as per the bylaws on COI of the associated academic society, any COI with regard to the said medical research. And, for educational lectures and other events planned by this Organization, presenters must properly disclose any COI with regard to the said medical research using the specified form as per the bylaws on COI of this

Organization. If a violation of the COI guidelines is indicated in the presentation of research, the Board of Directors of this Organization shall contact the respective society and demand appropriate action. If a violation of these Guidelines is indicated in the presentation at educational lectures and other events planned by this Organization, the Board of Directors of this Organization shall instruct the committee with jurisdiction over COI (hereinafter shortened as “COI Committee”) to weigh in on the matter and shall take appropriate action based on the Committee’s recommendation.

2. Obligations of Officers, Etc.

The officers (president, directors, auditors, staff and advisors) and chairpersons of standing committees and special committees of this Organization, the persons in charge of academic conferences of societies participating in JDDW (annual chairpersons of member societies and participating societies) and secretariats have important roles and responsibilities in all projects and activities related to JDDW. Upon assuming such positions, these persons must submit in writing using the specified form, personal disclosures of any COI with regards to the said related projects and activities. Moreover, if any new COI arises after assuming the said position, they must update their personal disclosures as per stipulations.

3. Roles of the COI Committee

In the event that a serious COI arises with an officer or presenter in projects or activities of this Organization, or an officer or presenter inappropriately reported COI in the personal disclosures, the COI Committee must notify the concerned person to that effect and instruct that person to follow the necessary procedures. Moreover, if suspicion is indicated over a personal disclosure on COI within an academic society, the COI Committee shall mandate the concerned society to appropriately manage the COI.

4. Roles of the Board of Directors

The Board of Directors may report to the COI Committee a serious COI or inappropriate personal COI disclosure made by an officer or presenter of JDDW, and based on the Committee’s recommendation, order the concerned person to improve the situation or take corrective actions.

5. Roles of Chairpersons of Member Societies and Participating Societies

Persons in charge of academic conferences of societies participating in JDDW (annual chairpersons of member societies and participating societies) must verify that reporting of medical research findings at the annual meetings are implemented in compliance with these Guidelines and may take action to ban or otherwise manage any reporting that violates these Guidelines. In such case, the chairpersons are required to promptly notify the candidate presenter thereof and explain the reason for said action.

6. Other

Committee chairpersons must verify that the projects and activities they are involved in, are implemented in compliance with these Guidelines and, in the event a violation of these Guidelines arises, must promptly examine ways to improve that situation. In dealing with these matters, committee chairpersons may seek the counsel of the COI Committee and, based on the Committee's recommendation, the Board of Directors may order concerned persons to improve the situation or take corrective actions.

VII. Action against Violators of These Guidelines and Accountability

1. Action against Violators of These Guidelines

The Board of Directors of this Organization has the authority to discuss violations of these Guidelines. In event of acts committed by officers or others of this Organization, the Board of Directors may seek the counsel of the COI Committee. If the Committee's recommendation and further discussions by the Board deem that the said act constitutes a serious failure to comply with these Guidelines, the Board may take necessary actions in accordance with the degree of the violation including but not limited to penalties. Moreover, in the event of acts by presenters at JDDW that violate these Guidelines, the Board of Directors may notify the associated academic societies and require them to take necessary actions with the violator as per their rules and regulations.

2. Petition for Appeal

Persons accused of violating these Guidelines may petition for an appeal with this Organization. Promptly upon accepting this petition, the president of this Organization shall form a board for reviewing the petition (Review Board), entrust that committee with reviewing the concerned matters, discuss the committee's report with the Board of Directors and notify the petitioner of a final decision.

3. Accountability

This Organization must, in the event it is deemed that a presentation of medical research results planned by the Organization (educational lectures and other events) is in a serious violation of these Guidelines, demonstrate its accountability to general public following discussions and decisions by the Board of Directors.

VIII. Coordination with Related Societies

This Organization shall coordinate closely with JDDW member societies and participating societies, and provide opportunities to share with them information on reviews of these Guidelines and bylaws.

IX. Establishment of Bylaws

This Organization may establish bylaws necessary towards managing these Guidelines.

X. Amendments to These Guidelines

This Organization may periodically review and amend these Guidelines in line with social factors, the establishment of or amendment to laws and regulations governing cooperation between industry and academia, and the various situations surrounding medical care and research.

XI. Date of Enforcement

These Guidelines shall come into force as of April 19, 2013.

These Guidelines shall be revised on July 28, 2015 to take effect as of January 1, 2016.