

Policy on Conflict of Interest in Medical Research

Japanese Society of Nuclear Medicine

Foreword

Japanese Society of Nuclear Medicine (hereinafter called JSNM) is dedicated to public well-being through promotion of innovative Nuclear Medicine research and cooperation with other medical societies involved both in Japan and abroad, and to academic advancement through improvement of the quality of Nuclear Medicine research, educational activities and medical practice by members of JSNM.

Research findings presented at JSNM academic conferences or in JSNM publications encompass basic and clinical research related to Nuclear Medicine diagnosis and therapy, and development of radiopharmaceuticals, medical devices, and technology. There are high expectations that such research including industry-academia collaboration would provide benefits to the front lines of clinical medicine and contribute to public well-being.

In some cases, industry-academia collaborative medical research entails benefits to the society (public interests), as well as other benefits (private interests) including finance, status, and equity (such as share held) that are acquired by members and board members (hereinafter called the members) of JSNM. When these two types of benefits are in conflict within an individual member of JSNM, it is called a conflict of interest (COI). The potential occurrence of COI is unavoidable for any of the members in modern complex society and diversified organization. Legal restrictions apply to certain activities; however, COI may occur in activities outside the framework of legal regulation. JSNM defines the policy to control COI to ensure fairness and impartiality in research, safety of human subjects, openness and fairness in academic presentations, as well as social trust of the members, thereby requiring the scientifically and ethically appropriate conduct in Nuclear Medicine research.

1. Purpose

As stated in the Helsinki Declaration and the Ethical Guidelines for Clinical Studies (2003 The MHLW Ministerial Notification No. 255), special consideration is required to protect the rights and lives of subjects and safely conduct research.

JSNM, in view of the fact that social responsibility and high ethics are required in their activities, hereby establishes the Policy on Conflict of Interest in Medical Research (hereinafter called the Policy). The purpose of the Policy is to ensure that the presentation and dissemination of research findings, and public awareness activities are appropriately conducted in circumstances where neutrality and impartiality are maintained by means of appropriate management of the member COI, as well as to discharge social responsibility by contributing to the advancement of diagnosis and treatment in Nuclear Medicine. For the purpose of controlling COI, JSNM organizes its structure under which sound promotion of industry-academia collaboration and well-organized medical research environment for the members are ensured.

The crux of the Policy is to enhance transparency of research by means of disclosing the circumstances of the COI. In cases where fairness and impartiality of research are ensured, JSNM should not reject research presentations via academic conferences and publications even under such circumstances that interests of the members and that of companies involved are conflicted.

2. Subject Individuals

The Policy applies to all of the following individuals for whom a COI may arise.

- 2.1 JSNM members including honorary members, members of merit, and students
- 2.2 JSNM employees
- 2.3 Presenters at JSNM academic meetings and conferences (first authors and principal investigators)
- 2.4 Members of JSNM Board of Directors, committees, and working groups

3. Subject Activities

The Policy applies to all activities associated with JSNM. In particular, observance of the Policy is required for presentations at any JSNM academic conferences, symposiums, and lecture meetings (hereinafter collectively called the conferences), publications in JSNM journals, establishment of guidelines related to Nuclear Medicine, and research conducted with the financial support from JSNM, etc.

4. Matters Requiring Disclosure

If any of the items 4.1 to 4.8 below exceeds separately stipulated criteria with respect to a covered individual, the individual shall have the obligation to accurately disclose by self-declaration of the

circumstances of the COI in accordance with the prescribed form.

In addition, if any of the items 4.1 to 4.3 below exceeds separately stipulated criteria with respect to a covered individual's spouse, first-degree relatives, or any other persons who share income or asset with the individual, the individual shall have the obligation to report the exact circumstances to JSNM.

The declarer shall bear responsibility for the self-declaration and the declared content. Specific methods of disclosure and publication are separately stipulated in the bylaws according to the covered activities.

- 4.1 Position as an officer, an advisor or an employee of a company or for-profit organization
- 4.2 Ownership of stock or equity including new share subscription rights
- 4.3 Patent royalties or licensing fees from a company or organization
- 4.4 Honoraria (such as lecture fees) from a company or organization paid as compensation for the time and/or labor of a researcher engaged in conference attendance (presentation)
- 4.5 Manuscript fees paid by a company or organization as compensation for writing a pamphlet or other publication
- 4.6 Clinical trial research funding provided by a company or organization
- 4.7 Research funding provided by a company or organization (entrusted research funding, collaborative research funding, and donation)
- 4.8 Others (Other remunerations excluding those listed above, invitation of guest researcher)

5. Methods of Enforcement

5.1 Establishment of the COI Review Committee

The COI Review Committee consists of directors named by the chairperson of the board, councilors, and at least one external member. The COI Review Committee investigates the circumstances of COI related to every undertaking by JSNM. When a violation of the Policy is found, the committee submits a report to the board. The committee is required to keep given information on the members confidential and protect it from leakage.

5.2 Obligation of the Members

The members shall have the obligation to appropriately disclose any COI in connection with the conduct of the research when presenting research findings at academic conferences or other venues. The members shall disclose COI by using the form prescribed in the bylaws.

5.3 Obligation of the Officers

Chairperson of board of directors, board of directors, auditors, managers, presidents of congress, chairperson of the Congress Program Committee, chairperson of the Editing Committee, chairpersons of other committees (hereinafter collectively called the officers) have important roles and responsibilities for all undertakings and activities related to JSNM and have obligations to self-declare COI in connection with the above-mentioned undertakings by means of the prescribed form at the time they assume their posts.

5.4 Roles of the Board of Directors

If a serious COI has occurred during the execution of any JSNM activities or an officer's COI self-declaration has been determined inappropriate, the Board of Directors of JSNM may refer the matter to the COI Review Committee and prescribe remedial measures based on the findings.

5.5 Roles of the President of Congress and others

When medical research findings are presented at JSNM venues, the president of congress, the chairperson and members of Program Committee, as well as program referees examine whether or not the conduct of the presentation is in accordance with the Policy, and may prohibit presentations on subjects that are determined violated. In such cases, the program committee chairman, committee members, and program referees of the society promptly notify the presenters with reasons the suspension of presentations. These measures are discussed by the COI Review Committee and implemented following the approval of the Board of Directors on the basis of the findings.

5.6 Roles of the Editing Committee

When medical research findings are presented in JSNM publications, the COI Review Committee of JSNM examines whether or not the conduct of the presentation is in accordance with the Policy, and the Editing Committee may prohibit presentations on subjects that are determined violated. In such cases, the Editing Committee promptly notifies the authors with reasons the suspension of posting presentations. In case that a presentation has been found nonconformity with the Policy after JSNM publication is issued, such fact may be informed in another issue of JSNM publication under the name of the chairperson of the Editing Committee. These measures are discussed by the COI Review Committee and implemented following the approval of the Board of Directors on the basis of the findings.

5.7 Roles of Chairpersons and Members of Other committees

Chairpersons and members of other committees examine whether or not the conduct of academic undertakings in which they are involved is in accordance with the Policy and promptly consider remedial measures in cases of violations. These measures are discussed by the COI Review Committee and implemented following the approval of the Board of Directors on the basis of the findings.

5.8 Filing of Objections

A person who has been subjected to remediation instructions or prohibition in accordance with 5.4 to 5.7 above may file an objection. When JSNM has received an objection, the COI Review Committee promptly reviews the matter and notifies the objecting individual of the result following the consultation with the Board of Directors

5.9 Lawsuits

The Policy is interpreted under Japanese laws. In case of a legal action, judicial proceedings shall be taken, and the Tokyo District Court shall have exclusive jurisdiction for the first hearing.

6. Matters to be avoided to restrict COI

6.1 Matters to be avoided by all individuals concerned

Publication of medical research findings should be on the basis of purely scientific judgment or the public interest. In terms of the medical research findings and their interpretation, a JSNM member must not be influenced by the arbitrary intentions of a company or entity providing funding for medical research.

6.2 Matters to be avoided by principal investigators

Persons with decision-making rights regarding planning and conduct of clinical research (including clinical studies and clinical trials) and under any of the following COI should not be selected as principal investigators of medical research. In case where collaborative clinical research is conducted at multiple institutions, each representative researcher in charge at these institutions is not applied. Principal investigators should avoid the following COI while they are in their position.

6.2.1 Ownership of equity of a company sponsoring the clinical research

6.2.2 Acquisition of royalties or patent rights for products or technologies obtained from the clinical research findings

6.2.3 Position as an officer, a board member, or an advisor of a company or organization sponsoring the clinical research (except as an unremunerated scientific advisor)

6.2.4 Reception of substantial amount of research funding from companies for entrusted clinical research

In case where an individual is essential to the planning and implementation of the clinical research, and this research is exceptionally significant from a global perspective, it is possible for a person with COI as described in 6.2.1 to 6.2.3 to apply and serve as a principal investigator for the clinical research.

7. Measures Against Policy Violators and Accountability

7.1 Measures Against Policy Violators

The Board of Directors of JSNM has the authority to deliberate actions that violate the Policy according to the regulations that are separately set, and when as the result of deliberation the Board of Directors of JSNM has determined that an action falls under the category of a serious breach of the Policy, the Board may take one or more of the following measures for a fixed period of time in accordance with the seriousness of the breach.

7.1.1 Prohibition of presentation at all conferences held by JSNM

7.1.2 Prohibition of publication in JSNM journals

7.1.3 Prohibition from serving as president of JSNM Congress

7.1.4 Prohibition from participating in JSNM board of directors, committees, and working groups

7.1.5 Expulsion from the JSNM Council or prohibition from becoming a councilor

7.1.6 Expulsion from JSNM or prohibition from becoming a member

7.2 Filing of Objections

When JSNM has received an objection, the COI Review Committee conscientiously reexamines the matter and notifies the individual subject to measures of its findings following the consultation with the Board of Directors.

7.3 Accountability

When JSNM has determined that there has been a serious violation of compliance with the Policy in medical research presented at a venue in which JSNM is involved, JSNM shall discharge its accountability to the society following the discussion by the Board of Directors.

8. Establishment of Bylaws

JSNM can establish necessary bylaws for the actual implementation of the Policy.

9. Date of Enforcement and Method of Amendment

The Policy came into effect on October 4th, 2009. The need to amend the Policy due to individual cases arising from social influences or laws concerning industry-academia collaboration is anticipated. The JSNM may jointly discuss and amend the Policy by means of resolutions from the Board of Directors of JSNM.

Revised on November 7th, 2014