Conflict of Interest Policy on Clinical Research
Japanese Society of Nuclear Medicine

Foreword

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

Much of the research presented via Japanese Society of Nuclear Medicine academic conferences and publications is basic and clinical research relating to Nuclear Medicine diagnosis and therapy, and development of radioactive medicines, medical devices, or technology. There are high expectations that such research including industry-academic collaborative research would provide benefits to the front lines of clinical medicine to contribute to public well-being.

In some cases, industry-academic collaborative clinical research entails benefits to society (public interest) from the fruits of discharging academic responsibility, as well as money, status, equity (such as share held), and other benefits (private interest) acquired by Japanese Society of Nuclear Medicine members including board members (herein after called members) who get involved in industry-academic collaboration. When these two types of benefit are in conflict within an individual member of Japanese Society of Nuclear Medicine, it is called a “conflict of interest.”

The potential occurrence of conflict of interest is unavoidable for any members in today’s complex society and diversified organization. Legal restrictions apply to certain activities. Nevertheless, conflicts of interest may occur in activities outside the framework of legal regulation. Japanese Society of Nuclear Medicine defines the policy to control conflicts of interest to ensure fairness and impartiality in research, safety of human subjects, openness and fairness in academic presentations as well as social trust of members, thereby requiring the scientifically and ethically appropriate conduct in Nuclear Medicine clinical research.

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

JSNM, in view of the fact that social responsibility and high ethics are required in their activities, hereby establishes this Conflict of Interest Policy on Clinical Research (hereinafter abbreviated as the “Policy”). The purpose for establishment of the Policy is for JSNM 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 member conflicts of interest, as well as to discharge social responsibility by contributing to the advancement of diagnosis and treatment in Nuclear Medicine. For the purpose of controlling conflicts of interest, JSNM organizes its structure under which sound promotion of industry-academic collaboration and well-organized clinical research environment for members are ensured.

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

2. Subject Individuals
The Policy applies to all of the following individuals for whom a conflict of interest may arise.

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

3. Subject Activities
The Policy applies to activities in all undertakings concerned with JSNM. In particular, observance of this policy is required for presentations at any JSNM academic conferences, symposiums, or lecture meetings (hereinafter collectively called conferences), publications of papers in JSNM journals, creation of guidelines related to Nuclear Medicine, researches conducted with the
financial support of JSNM and so on.

4. Matters Requiring Disclosure
If any of 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 the circumstances of the conflict of interest in accordance with the prescribed form.

In addition, if any of items 4.1 to 4.3 below exceeds separately stipulated criteria with respect to a covered individual’s spouse, relatives in the first degree, 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 himself or herself 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 or labor of a researcher engaged for conference attendance (presentation)
4.5 Manuscript fees paid by a company or organization as compensation for writing for 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 (Others remuneration than those listed above, invitation of guests researcher)

5. Method of Enforcement
5.1 Establishment of the Conflict of Interest Committee
The Conflict of Interest Committee consists of some directors named by the chairperson of the board and some councilors and at least one external member. The Conflict of Interest Committee investigates the circumstances of conflicts of interest 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 about members confidential and protect it from leakage.

5.2 The Obligation of Members

Members shall have the obligation to appropriately disclose any conflict of interest in connection with the conduct of the research in the cases where presenting clinical research findings at academic conferences or other venues. Members shall disclose conflicts of interest using the form prescribed in the bylaws.

5.3 The Obligation of 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 officers) have important roles and responsibilities for all undertakings and activities related to JSNM and have obligations to make self-declarations concerning conflicts of interest in connection with said 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 conflict of interest has occurred in the execution of any JSNM business or an officer’s conflict of interest self-declaration has been judged inappropriate, the Board of Directors of JSNM may refer the matter to the Conflict of Interest Committee and prescribe remedial measures on the basis of the findings.

5.5 Roles of the President of Congress and others

When clinical research findings are presented at JSNM venues, the president of congress, the chairperson and members of Program Committee and program referees verify that the conduct of the presentation is in accordance with the Policy, and may prohibit presentations about subjects that violate the Policy. In such cases, the program committee chairman, committee members, and program referees of the society promptly notify the presenters the suspension of presentations, providing reasons. These measures are discussed by the Conflict of Interest Committee and implemented following approval of the Board of Directors on the basis of the findings.

5.6 Roles of the Editing Committee

When clinical research findings are presented in JSNM publications, the Conflict of Interest Committee of JSNM verifies that the conduct of the presentation is in accordance with the Policy, and the Editing Committee may prohibit presentations about subjects that violate the Policy. In such cases, the Editing Committee promptly notifies the individuals the
suspension of posting presentations, providing reasons. In case that a presentation has been found nonconformity with this 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 Conflict of Interest Committee and implemented following 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 verify that the conduct of academic undertakings with which they are involved is in accordance with the Policy and promptly consider remedial measures in cases of activities that violate the Policy. These measures are discussed by the Conflict of Interest Committee and implemented following approval of the Board of Directors on the basis of the findings.

5.8 Filing of Objections

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

5.9 Lawsuits

This policy is interpreted under Japanese laws. In case that any troubles occur related to the Policy, lawsuit proceedings shall be taken and The Tokyo District Court shall have exclusive jurisdiction for the first instance over it.

6. Matters to be avoided to restrict Conflict of Interest

6.1 Matters to be avoided by all individuals concerned

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

6.2 Matters to be avoided by principal investigators

Persons under any of the following conflicts of interest should not be selected as principal investigators of clinical researches who have decision making right regarding planning and conduct of clinical researches (including clinical studies and clinical trials). (In the case where a clinical research is conducted in collaboration with multiple institutions, each representative researcher in charge at these institutions is not applied.) Principal
investigators should avoid the following conflicts of interest 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

It is provided, however, that in the case where an individual is essential to the planning and implementation of the clinical research concerned and the clinical research is extremely significant even from a global perspective, it is possible for even a person under any of conditions of conflict of interest from 6.2.1 to 6.2.3 above apply to serve as a principal investigator for the clinical research concerned.

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 this policy according to the regulations that separately set and, when as the result of deliberation the Board of Directors of JSNM has judged 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 from presenting at all conferences held by JSNM
7.1.2 Prohibition from publication of papers in JSNM publications
7.1.3 Prohibition from serving as president of JSNM Congress
7.1.4 Prohibition from participation in JSNM board of directors, committees, or 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 Conflict of Interest Committee conscientiously reexamines the matter and notifies the individual subject to measures of its findings following consultation with the Board of Directors.

7.3 Accountability
When JSNM has judged there has been a serious violation of compliance with this policy in clinical research presented at a venue in which JSNM is involved, JSNM shall discharge its accountability to the society following 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 comes into effect on October 4th 2009. The need to amend the Policy due to individual cases arising from social influences or laws concerning industry-academic collaboration is anticipated. The JSNM Ethics Committee may jointly discuss and amend the Policy by means of resolutions of the Board of Directors, Councils, and General Committees of JSNM.