

ENGLISH SUMMARY

Breast Cancer Clinical Research Conflict of Interest Disclosure Policy Japanese Breast Cancer Society

Foreword

The purpose of the Japanese Breast Cancer Society ("JBCS") is to promote basic and clinical research regarding breast cancer, and to contribute to public well-being through member education activities, the provision of venues for the presentation of clinical research findings, and public awareness activities.

Most of the research presented through JBCS academic conferences and publications is clinical research on breast cancer patients aimed at the standardization of treatment methods or clinical research conducted using new pharmaceuticals, medical devices, or techniques, and in not a few cases industry-academic collaborative research and development is conducted. As the results of such researches providing benefits on the front lines of clinical medicine, the importance of breast cancer research involving industry-academic collaboration is increasing every day.

In some cases, industry-academic collaborative research entails benefits to society (public interest) from the fruits of discharging academic and ethical responsibility, as well as money, status, rights, and other benefits (private interest) acquired attendant on industry-academic collaboration. When these two types of benefit are in conflict within an individual researcher, it is called a "conflict of interest."

In cases of serious conflicts of interest, the risk of distortion of research methods, data analysis or results interpretation arises. A situation may also occur whereby fair assessment is not made, even though research findings are appropriate. This time, JBCS has decided to clearly indicate conflict of interest disclosure policy to members, in order to actively conduct clinical research, to develop activities concerning the prevention, diagnosis, and treatment of breast cancer and to contribute to the public welfare.

I. Purpose of Policy Establishment

As has been mentioned in the Helsinki Declaration, the Ethical Guidelines for Clinical Studies, and the Ethical Guidelines for Epidemiological Research, clinical research differs greatly from research in other academic fields in that, as the research subjects are human beings, special consideration to protect the rights and lives of subjects and safely conduct research is required. Clinical research shall be carried out only for the public interest.

To secure the achievement of this purpose, the proper disclosure of the state of conflict of interest by individuals who carry out research is absolutely essential. JBCS, in view of the fact that social responsibility and high ethics are required in its activities, does hereby establish this Breast Cancer Clinical Research Conflict of Interest Policy ("Policy").

The crux of this Policy is to indicate the basic concepts of conflict of interest to JBCS members and to ensure that conflicts of interest are appropriately disclosed by self-declaration in cases where

members participate and make presentations at JBCS undertakings. JBCS will require its members to observe this Policy as follows.

II. Basic Concept

Publication of clinical research findings should be made on the basis of purely scientific judgments or the public interest. A JBCS member must not be influenced by the arbitrary intentions of a company or entity providing funding for clinical research when deciding whether to present clinical research findings at conferences or in research papers, nor when deciding the essential presentation content, namely the clinical research findings or their interpretation, and must not enter into any contracts under which such influence cannot be avoided.

Principal investigators who have decision making rights regarding planning and conduct of clinical research (including clinical trials and treatment) shall avoid conflicts of interest that may arise from (1) a position as an officer, board member, or advisor of a company or for-profit organization sponsoring the clinical research (except as an unremunerated scientific advisor), (2) owning stock in a company sponsoring the clinical research, or (3) acquiring royalties or patent rights for products or technologies obtained from the clinical research findings.

It is provided, however, that in the case where an individual is essential to the planning and conduct of the clinical research concerned and that clinical research is extremely significant on global level, the foregoing may be unavoidable even for a person who has conflict described above.

III. Subject Individuals

This Policy applies to all of the following subject individuals for whom a conflict of interest may arise.

- (1) JBCS members and honorary members
- (2) Persons who make presentations at JBCS meetings, and authors who make presentations in the Society's bulletin.
- (3) Officers, the President, the President-elect, and the Members of the designated Committees.

IV. Subject Activities

This Policy applies to all the activities in the undertakings pursued by JBCS. In particular, observance of the Policy is required of researchers who present at any JBCS academic conference, symposium, or lecture meeting or who publish presentations in any JBCS bulletin, article, or book must observe this Policy. Rigorous observance of this Policy is required of lecturers who conduct educational lectures for JBCS members or who conduct open lectures for the general public.

V. Matters Requiring Disclosure

In accordance with separately-prescribed regulations, subject individuals shall be obligated to accurately disclose by self-declaration Items (1) through (7) below with respect to a subject individual and Items (1) through (3) below with respect to a subject individual's spouse or relative in

the first degree with whom the individual lives, or any other person who shares his or her income or assets.

- (1) Position as an officer or advisor of a company or for-profit organization;
- (2) Ownership of stock;
- (3) Patent royalties or licensing fees from a company or for-profit organization;
- (4) Honoraria (such as lecture fees) from a company or for-profit organization paid as compensation for the time or labor of a researcher engaged for attending a conference (presentations)
- (5) Manuscript fees paid by a company or for-profit organization as compensation for writing for a pamphlet or other publication
- (6) Research funding provided by a company or for-profit organization
- (7) Other remuneration (travel, gifts, or other in-kind payments not directly related to research)

VI. Punishment of Violators and Accountability

1) When it is discovered that a conflict of interest is not disclosed or that the disclosed conflict of interest is false in violation of this Policy, the Conflict of Interest Committee shall deliberate the actions in violation of this Policy and shall report its findings to the Board of Directors. The Board shall then recommend improvement measures to the violator in question, and if said violator does not comply, then a motion shall be made based on the Article of Incorporation to discipline or dismiss the violator. Otherwise, the Board may take one or more of the following measures regarding said violator for a fixed period of time in accordance with the seriousness of the breach.

- (1) Prohibit presenting at all conferences held by JBCS
- (2) Prohibit the publication of papers in JBCS publications
- (3) Prohibit serving as chairman of JBCS academic conferences
- (4) Prohibit participation in JBCS boards of directors, committees, or working groups

2) When JBCS has received an objection, the Conflict of Interest Committee shall conscientiously reexamine the matter and notify the individual subject to disciplinary measures of its findings upon holding consultation with the Board of Directors.

3) When JBCS finds that there has been a serious violation of this Policy in clinical research presented at a venue in which it is involved, JBCS shall publish the fact of the violation upon holding consultations with the Conflict of Interest Committee and Board of Directors.

VII. Establishment of Regulation

JBCS shall establish the necessary regulations for the actual implementation of the Policy taking into consideration their independence and special characteristics.

VIII. Appendices

- 1) This Policy becomes effective on August 1, 2009.
- 2) The Chairman of the Board of Directors can revise this Policy through decisions by the Board of Directors and the General Committees of JBCS.
- 3) The measures described in VI shall not be implemented until August 2011.

Members of the JBCS Ethical Committee

Name	Profession	Institution
Sadako Akashi-Tanaka	Surgeon	National Cancer Center Hospital
Mayumi Honda	Writer	The Yomiuri Shimbun
Kouki Inai	Pathologist	Hiroshima University Graduate School of Biomedical Sciences
Hiroataka Iwase	Surgeon	Kumamoto University Faculty of Medical and Pharmaceutical Sciences
Norihiro Nomura	Lawyer	The Dai-ichi Tokyo Bar Association
Noriaki Ohuchi*	Surgeon	Tohoku University Graduate School of Medicine
Toshiaki Saeki	Surgeon	Saitama Medical University

*Committee_Chairman