

Policy regarding Management of Conflict of Interest (COI) in Health and Labour Science Research

(*Kahatsu* No. 0331001 dated March 31, 2008 decided by Chief of Health Science
Division)

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I Purposes

It is necessary to appropriately handle a relationship with a company, etc. with which an interest is assumed (conflict of interest) in order to ensure fairness and reliability of a health and labour science research, which is a public research. This policy aims at ensuring transparency and appropriately managing regarding the conflict of interest.

II Definitions

1 “Conflict of Interest: COI” subject to this policy

The conflict of interest in a broad sense includes both of a “conflict interest in a narrow sense” and a “conflict of duty” (Note 1), and the “conflict in a narrow sense” includes both of a “conflict of interest as an individual” and a “conflict of interest as an organization”. This policy basically focuses on the “conflict of interest as an individual” (hereinafter, referred to as the “COI”) among the “conflict of interest in a narrow sense”.

The COI specifically refers to a situation where a fair and appropriate judgement required in a public research is impaired by an economical interest, etc. with an outsider or where a third party may express a concern that the fair and appropriate judgement required in the public research is impaired by the economical interest, etc. with the outsider.

A situation where the fair and appropriate judgement has been interrupted is considered to include a situation where data is falsified or where a preferential research of a certain company is to be stopped but is continued, etc..

(Note 1) The conflict of duty refers to a situation where a judgement in a bounden duty is impaired or the bounded duty is neglected or where a third party may express a concern that such a situation exists, due to existence of a plurality of performance responsibilities caused by concurrent activities.

2 “Economical Interest”

The “economical interest” refers to a situation where a researcher has a relationship with an organization other than an organization to which the researcher belongs and in which the researcher implements a research (for example, receiving salaries, etc.). The ”salaries, etc.” include, but are not limited to, a compensation for services (a consulting fee and a reward, etc.), acceptance regarding academic-industrial activities (a consignment research technical training, acceptance of a guest researcher and a post-doctoral fellow, receipt of a research grant, a requested test and analysis, and provision of an apparatus, etc.), a stock, etc. (a stock and a stock option, etc.) and an intellectual property (a patent right and a copyright and a loyalty, etc. from such a right), other than salaries, and those having some monetary value. In the meantime, a reward, etc. supplied from a public organization are not included in the “economical interest”.

3 “Organization” and “Researcher” subject to this policy

This policy basically targets a researcher who is going to implement a health and labour science research (hereinafter, referred to as the “researcher”) and an organization to which the researcher belongs (hereinafter, referred to as the “researcher’s organization”). In the meantime, when a spouse making a living with the researcher and those in the first degree of kinship (parents and a child) have the economical interest for which the COI in the health and labour science research is assumed, such economical interest is to be subject to a review of a COI committee, etc. (COI committee, etc. provided in IV3).

III Basic Stance

In this country, academic-industrial collaboration activities are promoted as part of efforts to aim at a building nation that is creative in science and technology. Also in the health and labour science research, the academic-industrial collaboration activities such as a collaborative research with a company and a technology transfer are

to be appropriately promoted in order to contribute a research result in a university and a public research organization, etc. back to society.

On the other hand, when implementing a plurality of businesses, an interest of each relevant individual and organization may crash and conflict with each other. This occurs necessarily and inevitably if research activities are actively carried out and the academic-industrial activities become popular.

The health and labour science research is a target-oriented research for solving problems of medical treatment for health, welfare, environmental sanitation and occupational safety and health, etc. of citizens, and is also implemented in the university and the public research organization, etc. where there is a possibility that the academic-industrial activities are carried out. If all researchers who are considered to be somehow in a situation of the COI are excluded, there is no problem in the COI about the health and labour science research. On the other hand, that excludes researchers who are actively implementing researches and inhibits movement to coordinate respective research businesses organically and contribute the research result back to society as early as possible, and a decrease in the number of researchers who apply for the health and labour science research and a diminished quality of researches, etc. are concerned, and therefore such exclusion is considered to be inappropriate. (Note 2)

(Note 2)

Also in a review in the U.S.A., it is revealed that it is rare that a certain COI per se is a problem, and a problem is rather a measure in response to the COI, and a problem occurs in most cases when the COI is not expressed or is not assessed or managed. Also in influential universities in the U.S.A., measures in response to the COI vary, and also in universities that take relatively strict measures, a participation in a relevant clinical research is basically prohibited when there are incomes, etc. more than 10,000 dollars per year from a relevant company, etc.. However, an implementation is allowed after judging individually and taking measures (for example, not allowing the researcher to involve in setting of implementation plan of clinical research, relying on others who do not have an interest regarding data analysis, audit of third party for clinical research, etc.), when there is a situation where those other than the researcher cannot implement the research, etc..

However, a strict management such as a replacement of a chief researcher, etc. is necessary in some cases, when it is necessary to appropriately manage the COI in order to ensure the reliability of the health and labour science research, which is a public research and the strict management is judged to be necessary for ensuring public interest and the reliability of the health and labour science research.

Also, in view of the fact that efforts to manage crash and conflict between a duty as an academic organization such as education and research and an interest arising from the academic-industrial collaboration activities that an individual obtains in universities, the COI in the health and labour science research is to be managed in a manner that is consistent with the existing efforts as much as possible in order to avoid confusion and wasteful overlapping.

In the COI management, the COI between the health and labour science research and the researcher and the company (for example, a concern that the researcher or a company which is a sponsor may get a result favorable to himself, herself or itself) is to be managed to ensure scientific objectivity based on ensuring of transparency (for example, to disclose the COI at the time of paper presentation and conference presentation of the research result, etc.) after primary consideration is given to avoid a situation where a subject suffers an unfair unreasonable loss, and sufficient attention is given to an informed consent, etc.. (Note 3)

This policy is set to improve an environment where a motivated researcher undertakes a research at ease and has the following general rules.

- To protect research from bias;
- To avoid situation where subject suffers from unfair unreasonable loss in research involving human;
- To incorporate system for getting opinion from outside (for example, to allow outside member to participate in COI committee, etc.) ;
- To pay attention that this is not legal problem but problem presentation arising from social standards and to consider ensuring of transparency as basic criteria of management while protecting private information;
- To recognize that researcher is responsible for co-operating with COI management and researcher's organization has management responsibility and accountability and to exercise management; and

- To exercise management not to give society impression that objectivity and fairness are impaired.

It is to be also fully noted that the COI is necessary to be appropriately managed by persons concerned when participating in a research from an organization different from that of the researcher or when a learned conference, etc. implement the research in support of the researcher.

(Note 3) The conflict of interest includes a situation where a harmful influence does not actually occur but it seems to occur. It is necessary for the researcher and the researcher's organization to take appropriate measures in order to explain appropriately when such a situation is pointed out to occur (it is necessary to appropriate manage a potential possibility and fulfill accountability).

In the meantime, it is natural that a dishonest act such as fake and falsification of data, etc. is handled by the "Guidelines for Handling, etc. of Dishonest Act in Research Activity in Area of Health and Labour" (decided by section chief, Health Science Division, Minister's Secretariat, the Ministry of Health, Labour and Welfare on January 16, 2015), and guidelines, etc. such as the "Helsinki Declaration" and the "Ethical Guidelines for Medical and Health Research Involving Human Subjects" (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare No. 3 of December 2014), etc. are to be observed regarding protection of a subject, etc..

IV Duty of Chief of Researcher's Organization and Duty of Researcher

1 The director of the researcher's organization and the researcher are to observe provisions such as this policy and the "Clinical Research Act" (Act No. 16 of 2017), etc..

2 Setting of Provision regarding COI Management in Researcher's Organization

The director of the researcher's organization (hereinafter referred to as the "director of the organization") shall endeavor to set provisions regarding the COI management beforehand and ensure that the researcher who belongs to the organization is informed of such provisions with relevant rules.

The researcher shall faithfully co-operate with the COI management of the researcher's organization. Also, the chief researcher shall require a research member of the research to observe this policy.

3 COI Committee

The director of the organization shall establish a committee for examining the COI of the researcher in the organization and reviewing appropriate management measures (hereinafter referred to as the "COI committee"). Also, the director of the organization may entrust examination and review of the COI to an outside organization when it is difficult to establish the COI committee.

An outsider of the organization (Note 4) shall participate in a committee which accepts a commission from the COI committee or the director of the organization to examine and review the COI (referred to as the "COI committee, etc.") as a member. Also, it is possible to present information to the outside member after anonymization of private information of the researcher in order to handle private information in the COI committee, etc..

(Note 4) For example, a person who is familiar with management of the conflict of interest, a person who is familiar with relevant laws, etc. and a person who is familiar with academic-industrial activities, etc. are considered.

4 Report, etc. to COI Committee, etc.

Each researcher shall apply for examination of the COI regarding the research by the time of submitting a request for health and labour science grant and health and labour administrative promotion business project cost grant (hereinafter referred to as the "health and labour science grant, etc." after reporting the "economical interest" to the COI committee, etc..

In the meantime, each researcher shall report contents of the "economical interest" to the COI committee, etc. of the researcher's organization every fiscal year or every time the "economical interest" to be newly reported occurs during the research.

Also, it is possible to manage the COI by setting a certain standard in each researcher's organization and requiring a report of the "economical interest" which

exceeds such a standard. Although a criterion is considered to include [1] a case where annual total amounts from a same organization exceed 1,000,000 yen regarding income from company and party (excluding remuneration) and [2] a case where annual total amounts received from a same organization exceed 2,000,000 yen regarding amounts received regarding academic-industrial activities (relating to an applied research and including collaborative research, consignment research, consortium, license and assignment of rights, technical training, commission of member, etc., acceptance of visiting researcher and post-doctoral fellow, receipt of research grant and scholarship donation, requested test and analysis, supply of apparatus, etc.), etc. other than requiring a report about relationship with a partner of academic-industrial activities (stock (publicly offered stock and letter stock), fund, stock option and beneficial interest, etc.) for example, it is possible to set a certain standard in view of situations of each researcher's organization.

In the meantime, even in cases where an action does not conflict with the standard set by each researcher's organization, it is necessary to be fully careful (for example, to actively consult with the COI committee) in order not to give an impression that objectivity and fairness of the health and labour science research are undermined to society, when it is concerned from the outside that a harmful influence seems to occur.

5 Opinions, etc. of COI committee, etc.

The COI committee provides consultation and, when necessary, gives guidance for the economical interest of the researcher, the research that the researcher is going to implement and measures that are to be taken regarding the COI management. Also, the COI committee conducts hearing, examination and review, and states opinion regarding the measures for the COI management to the director of the organization in writing. Also, the COI committee shall periodically report their activity conditions to the director of the organization.

6 COI Management

The director of the organization presents opinion of the organization regarding the COI based on the opinion, etc. of the COI committee, etc. and gives guidance and exercises management for improvement. Contents of the guidance and management are considered to be a method in accordance with a standard recommended in the "Management of Conflict of Interest of Clinical Research in Clinical Research Act"

(*Iseikenhatsu* 0302 No. 1 Notification of Chief of Research and Development Promotion Division of Health Policy Bureau dated March 2, 2018) or a method in accordance with the following items (1) – (5). A review of cancellation of participation in the research and abandonment of the economical interest is considered when an extremely crucial COI exists and it is difficult to solve the COI by these methods.

In the meantime, since the contents of guidance and management are not limited to these, and they are appropriate in some cases and are inappropriate in other cases, it is necessary to review an appropriate method of management in view of individual research subject and COI condition, etc. in each COI committee, etc. and the director of the organization appropriately gives guidance and appropriately exercises management based on that. In the meantime, it is necessary to fully pay attention to ensuring transparency such as appropriate information disclosure, etc..

- (1) Disclosure of Economical Interest to General Public
- (2) Monitoring of Research by Independent Evaluator
- (3) Modification of Research Protocol
- (4) Change of Form of Participation in Research of Researcher in Situation of COI
- (5) Separation of Relationship that generates COI

7 Report to the Ministry of Health, Labour and Welfare, etc. .

(1) The director of the organization shall promptly report to the Ministry of Health, Labour and Welfare or an organization that receives delegation from the Ministry of Health, Labour and Welfare to make a decision, etc. regarding health and labour science grant, etc. (hereinafter referred to as the “allocation organization”) when the director of the organization judges that some harmful influence occurs or there is a possibility that some harmful influence is considered to occur in the health and labour science research, and appropriately exercise the COI management after that.

The same applies to a case where the director of the organization gets to know that the research has been implemented without exercising the COI management based on this policy.

(2) The chief researcher submits a “Report regarding Situation of Ethical Review and Management of Conflict of Interest in Health and Labour Science Research

Expense”, including that of research member, in a result report of each fiscal year of health and labour science research based on provisions of the detailed rules for handling health and labour science grant, etc. (*Koka* No. 256 dated April 9, 1998 decided by chief of Health Science Division).

8 Guidance from the Ministry of Health, Labour and Welfare

In response to receiving the report of 7, the Ministry of Health, Labour and Welfare or the allocation organization may give guidance regarding the COI management to the researcher’s organization in order to maintain fairness and objectivity of health and labour science research, when necessary.

9 Preservation of Relevant Documents

The researcher and the researcher’s organization shall preserve documents relating to the COI for 5 years.

10 Protection of Private Information and Research or Technical Information

A person concerned such as a member, etc. of the COI committee, etc. shall not leak information that could be known through activities, etc. in the COI committee without justifiable reasons in order to appropriately protect private information and research or technical information.

11 Accountability regarding COI.

Each researcher’s organization is accountable when a problem related to the COI is pointed out, etc., and the director of the organization shall fully review and take necessary measures beforehand in order to appropriately fulfill accountability.

V Search, etc. of the Ministry of Health, Labour and Welfare

1 Search and Cooperation for Search

The Ministry of Health, Labour and Welfare or the allocation organization may conduct a search on the researcher’s organization regarding the COI regarding health and labour science grant, etc. that decided by itself, when necessary, and the researcher’s organization offers information necessary for the search (status of review

regarding the COI and method for management of the COI, etc.), submits a record and co-operates with a field search, etc..

The search is implemented while attention is fully paid to private information of the person concerned.

2 Notification of Search Result and Guidance for Improvement

The Ministry of Health, Labour and Welfare or the allocation organization promptly informs the researcher's organization for which the search is conducted of a search result, when the search is conducted. The allocation organization promptly reports the search result to the main office of the Ministry of Health, Labour and Welfare, when the search is conducted.

The Ministry of Health, Labour and Welfare or the allocation organization gives guidance for improvement to the researcher's organization when it is recognized that the COI in research activities regarding health and labour science research grant, etc. is not appropriately managed and improvement is required as a result of the search.

3 Measures when Appropriate Action is not taken in response to Guidance for Improvement.

The Ministry of Health, Labour and Welfare or the allocation organization may take measures such as closure of funding, refund of unused research expense, etc., refund of whole research expense and limitation of grant of competitive fund, etc. when the COI management is not appropriately exercised, and improvement is not recognized without justifiable reasons regardless of the fact that guidance for improvement is given.

VI Others

1 Transitional Measures

The director of the organization shall endeavor to establish the COI committee as early as possible. Generally, it is not possible to receive health and labour science research grant, etc., when the COI committee has not been established before submitting a request for health and labour science research grant, etc. or entrustment of the outside COI committee is not made. For details, please refer to a public offer guide of each fiscal year, etc..

2 Review of Policy.

This policy stipulates that it is necessary to review provisions of this policy at a suitable time and, when necessary, take necessary measures based on a review result in view of activity conditions of the COI committee, etc. and conditions of conflict of interest, etc. in each researcher's organization.

3 Others

Although no clear provision regarding the conflict of interest as organization is provided in this policy, it is necessary for the researcher and each researcher's organization to pay sufficient attention to the conflict of interest as organization and take appropriate management measures in order to review management of conflict of interest in individual research, ensure transparency and fulfill accountability regarding objectivity and fairness of the research.