

Kyoto University Regulations for Conflict of Interest Management

Enacted by Order No. 79, January 21, 2014

Chapter 1: General Provisions

(Purpose)

Article 1

The purpose of these regulations is to set forth provisions to ensure appropriate conflict of interest management (hereinafter referred to as “Conflict of Interest Management”) for industry-government-academia collaboration activities, concurrent businesses, and other social engagement activities implemented by Kyoto University (hereinafter referred to as “the University”) and its faculty and staff members.

(Definitions)

Article 2

For the purpose of these regulations, the terms below shall have the meanings defined in the following items.

(1) “Conflict of Interest” to be managed under these regulations refers to the following situations:

- A. A situation in which commitment to collaborative projects with companies or external organizations (hereinafter referred to as “Industry-Government-Academia Collaboration Activities”) conflicts with the social responsibilities of the University due to prioritizing the acquisition of benefits from the companies or organizations, or in which external parties may express the same concern.
- B. A situation in which faculty and staff members’ engagement in Industry-Government-Academia Collaboration Activities conflicts with the fulfillment of their duties as the University’s faculty and staff members due to prioritizing their own benefits or the companies’ profits as they receive financial and other types of benefits from the companies or other organizations, including licensing fee revenue, concurrent business rewards, and unlisted stocks, or external parties may express the same concern.
- C. A situation in which faculty and staff members’ concurrent businesses conflict with the fulfillment of their duties as the University’s faculty and staff members due to prioritizing their responsibilities for the fulfillment of businesses of the companies and other organizations as they are responsible for the businesses, or external parties may express the same concern.

(2) “Faculty and Staff Members” refers to the following people:

- A. Executive directors
- B. Faculty and staff members employed under the University’s employment regulations.
- C. The persons appointed by the Conflict of Interest Management Committee specified in Article 6.

(3) “Companies and Other Organizations” refers to companies, national and local government agencies, and other organizations.

(4) “Conflict of Interest Counselors” refers to persons with specialized knowledge about conflict of interest who can provide consultation to faculty and staff members regarding conflict of interest management.

(5) “Departments” refers to research departments (individual research divisions, individual attached laboratories, university libraries, the university hospital, and individual centers, etc. [facilities defined in Sections 7–11 of Chapter 3 (excluding the Library Network defined in Article 47-1) of the Organizational Regulations of National University Corporation Kyoto University (hereinafter referred to as the “Organizational Regulations,” Order No. 1 of 2004), including the administrative office of each department defined in Article 56-1 of the Organizational Regulations]), university headquarters, and joint administration offices.

(6) “Corrective Measures” refers to necessary measures to be taken to avoid or correct a situation of conflict of interest, including non-permission and conditional permission to implement activities.

Chapter 2: Structure of Conflict of Interest Management

(General Management)

Article 3

The President shall govern conflict of interest management at the University.

(Responsibilities of the Director of a Department)

Article 4

The director of a department (or the executive vice-president for general affairs in the case of the university headquarters) shall oversee conflict of interest management for the faculty and staff members in their department.

(Responsibilities of Faculty and Staff Members)

Article 5

1. Faculty and staff members shall maintain a high sense of ethics and comply with the rules concerning the conflict of interest management.

2. Faculty and staff members shall endeavor to avoid any conflict of interest by taking appropriate actions, such as consulting with the Conflict of Interest Counselors specified in Article 13-2, if a potential conflict of interest is identified.

(The Conflict of Interest Committee)

Article 6

1. The Conflict of Interest Management Committee (hereinafter referred to as “the Committee”) is established at the University.

2. The Committee shall conduct the operations specified in the following items regarding conflict of interest management.

(1) Matters concerning planning and implementation of measures for conflict of interest management.

(2) Matters necessary for other conflict of interest management.

Article 7

1. The Committee is composed of members specified in the following items.

(1) The executive vice-president for personnel and the executive vice-president for industry-government-academia collaboration.

(2) The vice-president for legal affairs and compliance and the vice-president for university reform.

(3) Several directors of departments.

(4) The deputy-director of Kyoto University Hospital appointed by the director of the hospital.

(5) Several other members appointed by the President.

2. The members in Items (3) and (5) above are delegated by the President.

3. The term of office for the members in Items (3) and (5) above shall be two years, and reappointment is possible. The term of office for a substitute member shall be the remaining period of the predecessor.

Article 8

1. A chairperson and a vice-chairperson shall be appointed for the Committee.

2. The vice-president for legal affairs and compliance shall serve as the chairperson, and the deputy-director of Kyoto University Hospital in Item (4) of Article 1-1 shall serve as the vice-chairperson.

3. The chairperson shall call meetings of the Committee and serve as the chair.

4. The vice-chairperson shall assist the chairperson. If the chairperson has an accident, the vice-chairperson shall perform the duties of the chairperson.

Article 9

The Committee shall manage the committee meetings and determine other necessary matters in addition to the matters specified in Articles 7, 8, and 9.

(The Conflict of Interest Review Board)

Article 10

1. The Conflict of Interest Review Committee (hereinafter referred to as “the Review Committee”) is established under the Committee to conduct the operations specified in the following items (excluding the operations specified in Article 11).

(1) Matters concerning reviews of self-report forms and other documents specified in Article 14.

(2) Matters concerning advice for corrective measures based on review results in Item (1) above.

(3) Matters concerning confirmation of the facts that would constitute a conflict of interest for the University

defined in Article 19.

2. The Review Committee is composed of members specified in the following items.

- (1) The chairperson of the Committee
- (2) Several professors of the University
- (3) Several external experts
- (4) Several other members appointed by the President

3. The members in Items (2) to (4) above are delegated by the President.

4. The term of office for the members in Items (2) to (4) above shall be two years, and reappointment is possible. The term of office for a substitute member shall be the remaining period of the predecessor.

5. The person specified in Item (1) of Article 10-2 shall serve as the chairperson of the Review Committee.

6. The Review Committee shall determine necessary matters for its organization and operations in addition to the matters specified in the preceding items.

(The Conflict of Interest Review Board for Clinical Research)

Article 11

1. The Conflict of Interest Review Committee for Clinical Research (hereinafter referred to as “the Review Committee for Clinical Research”) is established under the Committee to conduct the operations related to clinical research specified in the following items (including clinical trials conducted in compliance with the Act on Ensuring the Quality, Effectiveness, and Safety of Drugs and Medical Devices, etc. [Act No. 145 of 1960] and clinical research involving invasion and intervention and other clinical research conducted in compliance with 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, Labor and Welfare, No. 3 of 2014]).

- (1) Matters concerning reviews of self-report forms and other documents specified in Article 14.
- (2) Matters concerning advice for corrective measures based on review results in Item (1) above.
- (3) Matters concerning confirmation of the facts that would constitute a conflict of interest for the University defined in Article 19.

2. The Review Committee for Clinical Research is composed of members specified in the following items.

- (1) The chairperson of the Committee
- (2) The person specified in Item (4) of Article 7-1
- (3) Several professors of the departments engaged in clinical research
- (4) Several external experts
- (5) Several other members appointed by the President

3. The members in Items (3) to (5) above are delegated by the President.

4. The term of office for the members in Items (3) to (5) above shall be two years, and reappointment is possible. The term of office for a substitute member shall be the remaining period of the predecessor.

5. The person specified in Item (2) of Article 11-2 shall serve as the chairperson of the Review Committee for Clinical Research.

6. The Review Committee for Clinical Research shall determine necessary matters for its organization and operations in addition to the matters specified in the preceding paragraphs.

(The Conflict of Interest Advisory Board)

Article 12

1. The Conflict of Interest Advisory Board (hereinafter referred to as “the Advisory Board”) is established at the University to conduct the operations in the following items.

- (1) Matters concerning reviews of objections made in accordance with Article 18-1.
- (2) Matters concerning regular examinations and evaluations for conflict of interest management.
- (3) Matters necessary for advice regarding other conflict of interest management.

2. The Advisory Board is composed of members specified in the following items.

- (1) Several external experts
- (2) Several other members appointed by the President

3. The members in the items above are delegated by the President.

4. The term of office for the members in the items of Article 12-2 above shall be two years, and reappointment is possible. The term of office for a substitute member shall be the remaining period of the predecessor.

(The Conflict of Interest Management Office)

Article 13

1. The Conflict of Interest Management Office (hereinafter referred to as “the Management Office”) is established at the University to conduct operations related to conflict of interest management, including response to consultations from faculty and staff members, administrative work, and other support.
2. A director and conflict of interest counselors (hereinafter referred to as “the Counselors”) shall be appointed for the Management Office.
3. A faculty or staff member of the University appointed by the President shall serve as the director.
4. The director manages the operations of the Management Office.
5. The Counselors, who are selected from among the University’s faculty and staff members or external experts, are delegated by the director.
6. If necessary, other staff members can be assigned to the Management Office.
7. The director shall determine necessary matters for the Management Office in addition to the matters in the preceding paragraphs.

Chapter 3: Conflict of Interest Management Measures

(Submission of Self-Report Forms and Other Documents)

Article 14

1. Faculty and staff members must submit self-report forms and other documents to their departmental directors (or the President in the case of executive directors and directors of departments, the same shall apply hereinafter).
2. If a potential conflict of interest is identified, faculty and staff members can consult with the Counselors, or request an examination as specified in Article 15-1 or a review as specified in Article 16-1 by submitting their self-report forms and other documents to their departmental directors as needed.
3. The Committee shall decide the time of submission, format, and other details of self-report forms and other documents specified in the preceding paragraphs.

(Examination by a Department)

Article 15

1. When directors of departments receive self-report forms and other documents provided in Article 14-1 and 14-2, they shall assess the existence and extent of a potential conflict of interest in accordance with their departmental policies. During the examination, directors of departments or others involved in the examination can consult with the Counselors.
2. In addition to the examination specified in the preceding paragraph, directors of departments shall provide guidance or advice to faculty and staff members engaged in industry-government-academia collaboration activities or concurrent businesses regarding conflict of interest management of the activity in question, or shall ask the faculty and staff members for further explanations as needed.
3. Directors of departments shall submit self-report forms and other documents specified in Article 14-1 and 14-2 to the Review Committee or the Review Committee for Clinical Research (hereinafter referred to as “the Review Committees”).

(Reviews by the Review Committees)

Article 16

1. The Review Committees shall review the self-report forms and other documents specified in Article 15-3.
2. The Review Committees shall report review results to the director of department after conducting the review in the preceding paragraph. As a result of the review, if the Review Committees determines that it is necessary to take corrective measures for the situation in question which may cause a conflict of interest, they will report the corrective measures to be taken and other necessary information to the departmental director, and have advance consultations on the matter with the departmental director as needed.

Article 17

1. After directors of departments receive such notification specified in Article 16-2, they shall notify the relevant faculty and staff members of the review results and the corrective measures to be taken if it is determined necessary to take corrective measures for the situation in question which may cause a conflict of interest.
2. If faculty and staff members receive such notification, including details of corrective measures, as described in the preceding paragraph, they must take the corrective measures to avoid or correct the situation of conflict

of interest.

3. Faculty and staff members must report the implementation status of the corrective measures described in the preceding paragraph to their directors of departments as appropriate.

(Objection against the Review Results)

Article 18

1. Notwithstanding Article 17-2, if faculty and staff members are dissatisfied with the review result described in Article 17-1, they are allowed to make an objection in writing against the Advisory Board within thirty (30) days from the day following receipt of the notification. However, it should be noted that they are allowed to make only one objection per case.

2. If the Advisory Board receives an objection as described in the preceding paragraph, they shall decide whether or not it is necessary to conduct an additional review of the matter considering the effect, reasons and other aspects of the objection, and notify the faculty or staff member, their director of department, and the Review Committees of their decision and its reasons.

3. If the Review Committees receive a request for an additional review as described in the preceding paragraph, they shall conduct an additional review on the matter, and notify the results to the director of department and the Advisory Board.

4. The provisions in Article 17 shall apply mutatis mutandis to cases where an objection is made.

(The University's Response to a Conflict of Interest)

Article 19

1. If the Review Committees determines that the situation in question may cause a conflict of interest, they shall confirm the facts of the matters that may constitute a conflict of interest.

2. If the Review Committees determines that it is necessary to correct the situation after confirming the facts as described in the preceding paragraph, they shall report the corrective measures to be taken to the Committee.

3. If the Committee receives a report as described in the preceding paragraph, they shall examine the details of the corrective measures and the necessity of their implementation, and report their conclusions and the corrective measures to be taken to the President or the relevant director of department.

4. If the President or the relevant director of department determines that it is necessary to take the corrective measures after receiving the report, the corrective measures shall be taken to avoid or correct the situation of conflict of interest.

Chapter 4: Miscellaneous Provisions

(Raising Awareness among Faculty and Staff Members)

Article 20

The Committee shall conduct educational activities and other awareness-raising activities to deepen understanding about conflict of interest, and raise consciousness about conflict of interest management.

(Confidentiality)

Article 21

1. Faculty and staff members involved in conflict of interest management shall not disclose secrets obtained in the course of duties. The same shall apply after they retire from the duties.

2. Directors of departments and the Review Committees shall appropriately manage and store self-report forms and other documents submitted.

(Administrative work related to the Committee)

Article 22

The Management Office shall be responsible for the administrative work of the Committee and the Review Committee, and the General Affairs Division of the Administration Office of Kyoto University Hospital shall be responsible for administrative work of the Review Committee for Clinical Research.

(Miscellaneous Provisions)

Article 23

In addition to the provisions of these regulations, other necessary rules relating to conflict of interest

management shall be determined by the Committee.

Supplementary Provisions

These regulations shall be effective from January 21, 2014.

[Other supplementary provisions in-between are omitted]

Supplementary Provisions (Order 73 of 2016)

These regulations shall be effective from October 1, 2016. However, the term of office for members who are delegated to their respective duties for the first time after these regulations are effective as provided in Items (3) and (5) of Article 7-1, Items (2) to (4) of Article 10-2, and Items of (3) to (5) of Article 11-2 shall be until March 31, 2018, notwithstanding the provisions of Article 7-3, Article 10-4, and Article 11-4.

Supplementary Provisions (Order 24 of 2017)

These regulations shall be effective from April 1, 2017.