

Regulations for Maintaining Ethics and Safety in the Life Sciences and Other Research Fields at Kyoto University

December 22, 2015

Established as Order No. 72

Revised Order No. 40 issued on March 31, 2016

Objectives

Article 1

These regulations aim to serve as provisions for the maintenance of ethics and safety in life sciences and other research fields at Kyoto University (hereinafter “the University”), and ensure appropriate practices in life sciences and other research fields.

Definitions

Article 2

1. The term “department” used in these regulations refers to a research department (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 Paragraph 1, Article 47) of the organizational regulations of National University Corporation Kyoto University (hereinafter “KU Regulations,” Order No. 1 issued in 2004), including the administrative office of each department defined in Paragraph 1 of Article 56 of the KU Regulations]), university headquarters, and joint administration offices.
2. The term “faculty and staff members” used in these regulations refers to directors, teachers, and other staff members of the University.
3. The term “life science researchers” used in these regulations refers to teachers, staff members, students, and all other members who are involved in the life sciences and other research fields at the University.
4. The term “the life sciences and other research fields” used in these regulations refers to academic investigation of organisms, life phenomena, human health, etc., or a study on the use of the results of such an investigation.
5. The term “research rules” used in these regulations refers to the laws and guidelines on the maintenance of ethics and safety in the life sciences and other research fields.

Responsibility of Life Science Researchers

Article 3

Life science researchers shall maintain strong ethics and self-discipline, and observe the research rules and regulations of the University in pursuing the life sciences and other research fields.

Responsibility of the President

Article 4

1. The President shall govern the University and appropriately perform the administrative duties defined in the research rules regarding the maintenance of ethics and safety in the life sciences and other research fields.
2. The president may entrust the administrative duties described in the preceding paragraph to the director of a department (or for the administrative headquarters, the executive vice-president for research, hereinafter “EVP”).

Article 5

EVP shall support the president in the maintenance of ethics and safety in the life sciences and other research fields.

Responsibility of the Director of a Department

Article 6

1. The director of a department shall oversee the maintenance of ethics and safety in the life sciences and other research fields in his/her department.
2. The director of a department shall promptly report to the President if a serious event, such as a violation of the research rules regarding the maintenance of ethics and safety in the life sciences and other research fields (hereinafter “serious event”), has occurred, or may occur in the department’s activities.

Research Ethics and Safety Promotion Committee

Article 7

The Research Ethics and Safety Promotion Committee is established to deliberate on following items regarding the maintenance of ethics and safety in the life sciences and other research fields at the University.

- (1) Matters concerning systems and organizations relating to maintenance of ethics and safety in the life sciences and other research fields.
- (2) Matters concerning countermeasures and improvement plans for serious events related to maintenance of ethics and safety in the life sciences and other research fields.
- (3) Matters concerning education and educational activities relating to the maintenance of ethics and safety in the life sciences and other research fields for life science researchers.

- (4) Other matters required for the maintenance of ethics and safety in the life sciences and other research fields.

Article 8

1. The Research Ethics and Safety Promotion Committee is composed of members in the following categories:
 - (1) EVP
 - (2) Director or vice-president appointed by the president (one or more)
 - (3) The head of the Environment, Safety, and Health Organization
 - (4) Chairperson of a university committee who was appointed by the president (one or more)
 - (5) Professor or associate professor at the University (one or more)
 - (6) Others members considered necessary by the president (one or more)
2. The members in Items 5 and 6 above are delegated by the president.
3. The term of office for the members in Items 5 and 6 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 9

1. EVP shall serve as Chairperson of the Research Ethics and Safety Promotion Committee.
2. The chairperson shall call meetings of the Research Ethics and Safety Promotion Committee and serve as the chair.
3. If the chairperson has an accident, a member who was appointed by the chairperson in advance shall perform the duties of the chairperson.

Article 10

Subcommittees may be established within the Research Ethics and Safety Promotion Committee as needed.

Article 11

Non-members may participate in the Research Ethics and Safety Promotion Committee and subcommittees to provide explanation or opinions as needed.

Article 12

The administrative tasks for the Research Ethics and Safety Promotion Committee shall be performed by the Research Promotion Department.

Article 13

Any matters relating to the Research Ethics and Safety Promotion Committee and subcommittees not covered by the provisions of Articles 7–12 shall be decided by the Research Ethics and Safety Promotion Committee.

Research Ethics and Safety Promotion Office

Article 14

1. The Research Ethics and Safety Promotion Office (hereinafter “Promotion Office”) shall be established under the leadership of EVP to perform planning, regulation, and other tasks relating to the maintenance of ethics and safety in the life sciences and other research fields.
2. A faculty member appointed by EVP shall serve as the manager of the Promotion Office.
3. The manager shall oversee the affairs of the Promotion Office.
4. Faculty and staff members of the University shall be appointed by EVP to serve as members of the Promotion Office.
5. Any matters relating to the organization and operation of the Promotion Office not covered by the provisions above shall be decided by EVP.

Reporting

Article 15

1. The president may request the director of a department to report on the situation in the department pertaining to its management and operations in relation to the maintenance of ethics and safety in the life sciences and other research fields.
2. When requested to make a report as described above, the director of the department shall promptly give a report on the situation in the department pertaining to its management and operations in relation to the maintenance of ethics and safety in the life sciences and other research fields

Corrective Measures

Article 16

1. If a deficiency is found in the University’s management and operation pertaining to the maintenance of ethics and safety in the life sciences and other research fields, the president shall, based on the research rules, take the necessary measures to rectify the deficiency and prevent their reoccurrence (hereinafter “corrective measures”), or order the director of the department to take corrective measures.
2. The director of the department shall take the corrective measures described above as instructed,

and report the details and results of the corrective measures to the president.

Exemptions

Article 17

In cases in which there are other regulations concerning the maintenance of ethics and safety in the life sciences and other research fields at the University, those regulations shall be followed.

Miscellaneous Regulations

Article 18

Matters concerning the maintenance of ethics and safety in the life sciences and other research fields at the University that are not provided for in these regulations shall be decided by EVP.

Supplementary Regulations

- These regulations shall come into effect as of January 1, 2016.
- The term of office for the members described in Article 8, Paragraph 1, Items (5) and (6), who are newly appointed after the enactment of these regulations shall end on March 31, 2017, notwithstanding the provisions of Article 8, Paragraph 3.
- The Kyoto University Human Genome/Gene Analysis Research Management Regulations (Order No. 20, issued in 2001) shall be abolished.

Supplementary Regulations (Order No. 40, issued in 2016)

- These regulations shall come into effect as of April 1, 2016.