

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

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## **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, Executive Vice-President for Research Ethics, 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) Executive Vice-President 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 charge 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 Office of Research Acceleration.

## **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.

## **Reporting**

### **Article 14**

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 15**

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 16**

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 Provisions**

### **Article 17**

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 Provisions**

(1) These regulations shall come into effect as of January 1, 2016.

(2) 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.

(3) The Kyoto University Human Genome/Gene Analysis Research Management Regulations (Order No. 20, issued in 2001) shall be abolished.

(Interim supplementary provisions are omitted.)

**Supplementary Provisions (Order No. 83, 2024)**

These regulations shall come into force on January 1, 2025.