

Implementation Standards for Management and Audit of Public Research Funds

8th Edition

1. Objective

Kissei Pharmaceutical Co., Ltd. (“we,” “our,” “the Company”) establishes these standards for the purpose of properly managing competitive research funds (“competitive funds, etc.”), which includes open-call research funds distributed by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) or independent administrative corporations under MEXT’s jurisdiction (“funding agencies”), pursuant to the Guidelines for Management and Audit of Public Research Funds at Research Institutions (Implementation Standards) established by MEXT (the “MEXT Guidelines”).

2. Organization and Roles

2.1. Responsibility hierarchy

We establish the following hierarchy for the operation and management of competitive funds, etc. as set forth in the MEXT Guidelines.

Chief administrative officer	President
General manager	Division director of Clinical Development Division
Public funds compliance promotion officers	Senior Director of Research Strategy and Planning Department, Research Division Senior Director of Clinical Research Department, Clinical Development Division Senior Director of Corporate Finance and Management Department

2.2. Authorities and responsibilities

The specific authorities and responsibilities of each of the above officers are governed by the Company’s rules and regulations, in addition to the provisions set forth in the following items.

- 1) The chief administrative officer oversees the entire company and bears final responsibility for the operation and management of competitive funds, etc. The general manager also demonstrates appropriate leadership to ensure that the general manager and public funds compliance promotion officers are able to operate and manage competitive funds, etc. responsibly.
- 2) The general manager assists the chief administrative officer and has the practical responsibility and authority for the oversight of all relevant divisions concerning the operation and management of competitive funds, etc. The general manager is also responsible for overseeing cross-organizational frameworks for the prevention of misconduct related to the operation and management of competitive funds, etc., and verifying information pertaining to misconduct across all relevant divisions. In the event that misconduct occurs, the general manager reports the status of such misconduct to the chief administrative officer.
- 3) The public funds compliance promotion officers have the practical responsibility and authority for the operation and management of competitive funds, etc. in the individual divisions. In addition, under the direction of the general manager, they implement measures for the prevention of misconduct in the individual divisions and report on the status of their implementation to the general manager. To prevent misconduct, they provide compliance training to all researchers and

administrative personnel involved in the operation and management of competitive funds, etc. (“members”) in the individual divisions and manage and supervise members’ attendance of such training. In the relevant divisions, they monitor whether members are managing and executing competitive funds, etc. appropriately and provide corrective guidance if that management and execution is inadequate.

3. Establishment of environment

We establish an appropriate environment for the operation and management of competitive funds, etc. under our internal control framework pursuant to the Companies Act and our financial reporting reliability framework pursuant to the Financial Instruments and Exchange Act. This environment includes the following conditions.

3.1. Administrative authority

The authorities and responsibilities of members concerning the administrative processing of competitive funds, etc. will be governed by Organization Regulations, Duty Segregation Regulations, and Job Authority Regulations separately established.

3.2. Members’ code of conduct

In the operation and management of competitive funds, etc., members must understand both the letter and the spirit of the principle that research funds are public funds requiring proper management by the Company. Using their professional skills, they must carry out administrative procedures to ensure that public funds are used appropriately while aiming for efficient execution of research.

3.3. Compliance training

Under the direction of the public funds compliance promotion officers of each division, the Clinical Management Group of the Clinical Management Office in the Clinical Development Division’s Clinical Research Department provides members with compliance training (including on company rules regarding competitive funds, etc.) and confirms the attendance status and degree of attendees’ understanding of such training. It will also obtain written pledges from members at various opportunities such as training sessions upon the appointment and replacement of members.

4. Appropriate operation and Management of Research Funds

- 1) The management of competitive funds, etc. is governed by internal regulations, including these standards, in addition to the following regulations. Members are expected to adhere to the principle of conducting fair and equitable transactions and procurement with business partners.
 - Basic Policy on the Establishment and Assessment of Internal Controls over Financial Reporting
 - Organization Regulations
 - Job Authority Regulations
 - Duty Segregation Regulations
 - Budget Management Regulations
 - Regulations on the Management of Operations Related to Contracts, etc.
 - Internal Audit Regulations
 - Purchasing Regulations
 - Kissei Pharmaceutical Purchasing Policy
 - Conduct Guidelines for Purchasing Officers

- 2) Orders for goods and services are to be placed by the ordering department in accordance with the contract with the relevant supplier. When concluding a contract with a supplier, approval is to be obtained from the person with appropriate authority after first having the contract examined by the Legal Department.
- 3) The acceptance inspection of goods and services is to be conducted by the designated inspection department in accordance with the product specifications, delivery specifications, and related documents that have been established in advance.
- 4) If a supplier has been involved in an improper transaction, we will exercise our right to terminate the contract and cease transactions with that supplier. We will also exercise our right to claim compensatory damages.
- 5) Members are to manage expenses in accordance with the separately established important notes on reimbursement of expenses.
- 6) The Clinical Management Group of the Clinical Management Office in the Clinical Development Division's Clinical Research Department verifies the status of budget execution to ensure that it aligns with the actual situation. If budget execution varies significantly from initial plans, we will check for any problems with the execution of the research plans and undertake corrective measures as necessary.

5. Misconduct Prevention Measures

5.1. Identification of factors leading to misconduct and formulation of misconduct prevention plans

Under the Corporate Finance and Management Department, which has oversight over the systems for financial reporting reliability pursuant to the Financial Instruments and Exchange Act, we identify the factors that lead to misconduct in the use of competitive funds, etc. and formulate plans for the prevention of such misconduct.

5.2. Implementation of misconduct prevention plans

- 1) The Finance and Accounting Section in the Corporate Finance and Management Department, the Research Planning Group in the Research Division's Research Strategy and Planning Department, and Clinical Management Group of the Clinical Management Office in the Clinical Development Division's Clinical Research Department ("prevention planning departments") work together to advance plans for the prevention of misconduct regarding competitive funds, etc., and confirm the status of implementation of such plans.
- 2) The chief administrative officer takes the lead in the prevention of misconduct and personally strives to manage progress of the misconduct prevention plans. The fact that the chief administrative officer leads the prevention of misconduct is announced both within and outside the company.

5.3. Investigation of misconduct and disciplinary measures

If a member or other party is found to have engaged in misconduct in the use of competitive funds, etc., we will investigate the facts through the disciplinary committee, and disciplinary measures will be taken at the decision of the president. Where necessary, a special project team may be set up in place of the disciplinary committee.

5.4. Handling of complaints

If we receive a whistleblowing report (complaint), we will conduct an investigation in accordance with the Compliance Program Regulations and report to the funding agency in accordance with the MEXT Guidelines.

6. Communication of Information

- 1) The following contact points are established to receive both internal and external inquiries regarding the rules concerning the use of competitive funds, etc., related administrative procedures, and other matters.

Research Planning Group, Research Strategy and Planning Department, Research Division	Phone: +81-(0)263-82-8820
Clinical Management Group, Clinical Management Office, Clinical Research Department, Clinical Development Division	Phone: +81-(0)3-5684-3596
Finance and Accounting Section, Corporate Finance and Management Department	Phone: +81-(0)263-25-9651

- 2) The following contact points are established to receive both internal and external whistleblowing reports (complaints) regarding the rules and other matters concerning the use of competitive funds, etc.

Compliance Promotion Office, Legal Department	Phone: +81-(0)263-25-9081
Tanaka Yoshikubo Law Office	Phone: +81-(0)3-3230-0137
Kubota Law Office	Phone: +81-(0)263-32-0610

- 3) Any person receiving inquiries or whistleblowing reports who obtains information regarding misconduct is to report it to the chief administrative officer immediately.
- 4) We report our policies and decision-making processes regarding our approach to misconduct related to competitive funds, etc. to the funding agency, in lieu of public disclosure.

7. Monitoring

We monitor whether activities for the use of competitive funds, etc. are conducted appropriately in accordance with relevant regulations and whether those activities are being operated reasonably for the achievement of management objectives through our organization, job architecture, internal procedures, and internal audits.

8. Internal Audits

We conduct annual audits in accordance with the Internal Audit Regulations to determine whether the accounting procedures concerning activities that use competitive funds, etc. are being conducted properly and the relevant accounting documents are being prepared and retained appropriately. The internal audit department engages in this work in coordination with the prevention planning departments and the accounting auditor.

9. Monitoring by MEXT, etc.

The Clinical Management Group of the Clinical Management Office in the Clinical Development Division's Clinical Research Department provides written reports to MEXT and other concerned parties on the status of establishment of systems and other matters based on the MEXT Guidelines. We cooperate with investigations (through documents, interviews, and on-site inspections) conducted by MEXT under the MEXT Guidelines. If any issues are identified as a result of such investigations, we will immediately prepare and implement a corrective action plan.

10. Supplementary Provisions

Established March 26, 2009 (1st Edition)

However, these standards apply retrospectively from December 24, 2008.

Revised April 1, 2010 (2nd Edition)

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