

Regulation on Group Research Ethics Examination Committee

[Created: 2004/06/18]

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(Purpose)

Article 1

This regulation is enacted based on the following purpose. Research can be kept transparent and appropriate by following Governmental Guideline and be implemented by understanding and evaluation from society. Sysmex Corporation and Domestic Affiliates (they are named as “Group companies”) sets up Research Ethics Examination Committee (they are named as “the Committee”) which examine research implementation by following “Group Ethical Guidelines for Clinical Research Development” while respecting dignity and human rights of human research subject.

(Classification of Regulation)

Article 2

This regulation applied to Group companies, it is group regulation which is common standard for implementing and managing group business activity.

2. Group companies are defined as corporation which is managed by Sysmex Corporation which holds more than half of voting rights.

(Scope of Application)

Article 3

This regulation applies to examinations of research implementation related to Research Ethics Regulation and related to commercial activity and operation related to public disclosure in committee. But the research implemented based on Pharmaceutical and Medical Device Act, Medical Device GCP, Pharmaceuticals GCP and ICH-GCP is not included.

(Rule and Responsibility of Committee)

Article 4

In case that the committee receives request from principal investigator should examine propriety of research implementation based on research ethics regulation by taking into consideration human research subject’s individual dignity and human rights from the ethical and scientific point of view. The committee should submit opinion to person responsible for research by document or electromagnetic methods. And, the committee can convey opinion regarding revision of research planning document, halt of research implementation and other matters to person responsible for research.

2. Committee members and staff of committee should not leak information received through

daily operation to others without any appropriate reasons. The same thing can be said to retired members.

3. Committee members and staff in Research Ethics Examination Committee should report to chairman immediately in case of finding serious concern.
4. Committee members and staff should take education, lecture or seminar to acquire knowledge required for examine from the ethical and scientific point of view. And it should be conducted continuously.

(Composition of Committee members and Meeting requirements)

Article 5

Committee should consist of more than 6 members including in-house or outside members. In addition, committee should be required to set the below-described condition.

- (1) Members should consist of 3 types and should not be mixed.
 - ① Expert in the Natural Science
 - ② Expert in the Humanities and Social Sciences, such as a professional in Ethics and Law
 - ③ Person who can provide opinions of the general public, including viewpoints of research subjects
 - (2) Outside members should consist of more than 3 members.
 - (3) Male and Female members should be 2 members each or more than that.
 - (4) Term of duty should be 2 years and reappointment are allowed.
2. The chief or person responsible for research which is the target of review should not be allowed to participate in this examination. But they can participate in it and explain based on the request of committee.
 3. Committee can request opinion from experts in the case of review of research planning document which includes human research subject needed special consideration or other matters.
 4. Committee consists of members who hold various standpoints of views and as a result, fair and neutral review can be made. Committee meeting can be established under the below-described condition.
 - (1) In case of deliberation or decision, more than 2 outside members should attend the meeting.
 - (2) Chief of the committee calls for the members to attend the meeting and conduct a duty as a chairman.
 - (3) In case that chief is absent, sub-chief should conduct a duty as a chairman.
 - (4) Committee cannot be held without clearing the below described all requirements.
 - ① Attendance of members for Article 5-1(1)①-③
 - ② Attendance of multiple numbers of outside members

- ③ Attendance of both male and female members
 - ④ Attendance of more than 5 members
5. Voting of committee is basically attendance committee unanimous. But the chief of committee decides to hold committee meeting by TV meeting methods which make the smooth two-way communication possible. In this case the chief of committee should establish the environment which is suitable to smooth meeting as is the same as ordinary meeting. And, the chief of committee should pay attention to establish the environment which is suitable to smooth communication and exchange opinions with committee members.
 6. Voting of committee is basically attendance committee unanimous. But in case that opinions are divided, the decision of the committee shall be by a majority of not less than two thirds of the attending members. In this case, committee should report the disapproval opinion to the principal investigator.
 7. Result of voting should be 5 ways as described below.
 - (1) Not applicable: not subject to examination
 - (2) Approval: approve as applied for
 - (3) Approval with condition: approve with condition
 - (4) Not approved: not approve
 - (5) Re-examination: examination after revision of planning

(Appointment and Dismissal of members)

Article 6

In-house members in committee should be appointed by President and CEO of Sysmex Corporation.

2. Outside members in committee should be appointed by President and CEO of Sysmex Corporation and commissioned by Executive Vice President in Technical Strategy.
3. The chief or sub chief of committee should be appointed by President and CEO of Sysmex Corporation.

(Research)

Article 7

Committee can inspect the research which has been already completed or still is implemented once a year to secure the adequacy and reliability of the research.

(Report of examination results)

Article 8

The chief of committee should report result of review to the principal investigator promptly.

2. The principal investigator should respect opinion of committee and decide matters related to research implementation. The principal investigator should refrain from implementing

research in case of receiving negative opinion regarding implementing research.

(Storage of Examination Data and Record)

Article 9

The data of review and records should be compiled by secretariat and approved by chief of committee. They should be storage for 5 years after approval of chief. But in case of invasion (excluding slight one), it should be storage for 5 years after report of research completion.

(Matters for disclosure)

Article 10

The content of meeting in committee should be disclosed together with matters of committee's organization and its operation.

2. The matters regarding organization to be disclosed is as follows.
 - (1) Structure of committee (Including lower organization)
 - (2) Name of committee members belongs and its status.
3. The content of meeting in the committee should be disclosed concretely.
4. Committee can decide not to disclose the review result in case of finding the fact that it damages human rights of person who offered sample or research originality or intellectual property right or protection of business confidentiality in group company. In this case, committee should disclose the reason.
5. The way of disclosure is basically home page of Sysmex Corporation or Ethics Examination Committee Reporting System established by Ministry of Health, Labor and Welfare. In case of disclosure by other way, the committee should decide the other way.

(Expedited review)

Article 11

The chief of committee can establish procedure for expedited review based on the acceptance of committee. The result of expedited review should be reported to all members in committee by document.

2. In case of receiving application, the chief of committee decides to conduct expedited review or not. If deciding expedited review, the chief should hold committee by gathering 2 members or more than that including one outside or in-house member. This result of review is regarded as committee's result of review.
3. The chief of committee can review the planning in case of slight revision which committee has already decided to handle in a simple way without holding committee. This result is regarded as approval or expedited review by committee.
4. Committee members who received result of expedited review can request to hold committee to the chief of committee within 14 days after receiving result with the reason to review again.

The chief of committee holds the committee and review this planning promptly again.

5. In case of result of expedited review and that committee does not hold meeting, committee should disclose the fact and reason based on Article 10.
6. Expedited review also applied to Article 8-9.

(Handling matters for modification without expedited review)

Article 12

The chief of committee should handle the planning by only reporting to committee members in case of slight revision which committee has already decided to handle in a simple way without expedited review. But committee members can request to review the planning in the committee within 14 days after receiving report together with the reason to review. In this case, the chief of committee holds the committee and review this planning promptly.

(Review for research implemented by other research institution)

Article 13

In case that the principal investigator requests review to Research Ethics Examination Committee established outside of its own research institution, this Research Ethics Examination Committee should review and submit opinion to this responsible researcher by checking and understanding research implementation system to full extent. And, committee should review and submit opinion continuously in case of being requested.

(Primary Review)

Article 14

Chief of committee can request opinion from in-house experts about scientific and ethical adequacy of research planning before reviewing research planning at the committee meeting.

(Collective Review)

Article 15

The principal investigator can request collective review regarding joint research planning document with another research institution by other Research Ethics Examination Committee approved in advance. In this case the principal investigator should report review result to committee. In case of special clinical research, collective review by Authorized Clinical Research Ethics Examination Committee is required.

(Secretariat)

Article 16

Committee should set up Secretariat for committee's operation.

2. Secretariat is set up in Technology Strategy.

3. To send or receive document in the committee is made through Secretariat except for documents designated by this regulation.
4. Documents regarding committee can be handled by digital media and be allowed to use E-mail.

(Others)

Article 17

The committee should define matters which are not included in this regulation regarding committee's operation

(Disclosure of Regulation)

Article 18

This regulation should be disclosed to public based on the Government Guideline.

Additional Clause

(Enforcement Deadline)

Article 1

This regulation is enforced from June 30, 2021 .

Article 2

Detailed procedure and document format are defined separately.