

## **Regulation on Group Research Ethics Examination Committee**

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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 The 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 The 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 The 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

The composition of the ethics review committee should be required to set the below-described condition in order to properly perform duties such as the review of research protocols. Persons listed in (1) to (3) cannot concurrently hold each other. The same requirements apply to the establishment of meetings.

- ① Including Natural Science Experts, such as medical and medical experts
- ② Including experts in the Humanities and Social Sciences, such as a professional in Ethics and Law
- ③ Including person who can provide opinions of the general public, including viewpoints of research subjects
- ④ It includes multiple persons who do not belong to the organization to which the person who established the Ethical Review Committee belongs
- ⑤ Attendance of both male and female members
- ⑥ Attendance of more than 5 members

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. Person responsible for research who requested Ethics examination is not allowed to participate in it. But he or her can be allowed to attend it by receiving consent from Ethics Examination Committee in case checking examination content is absolutely necessary.

3. The 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. 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.
5. 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.

(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 Director of R&D Support Center
3. The chief or sub chief of committee should be appointed by President and CEO of Sysmex Corporation.

(Storage of Examination Data and Record)

Article 7

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.

The founder of the committee must properly store review materials concerning research reviewed by the committee until the date on which the completion of the research is reported. In case of invasion (excluding slight one), it should be storage for 5 years after report of research completion.

(Matters for disclosure)

#### Article 8

The founder of the committee shall, prior to commencing the operation of the committee, publish the regulations concerning the organization and operation of the committee and the list of members in the committee reporting system. In addition, the founder of the committee must publish the status of the committee meeting and an overview of the examination at least once a year in the system.

2. 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.
3. 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 9

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. Expedited review also applied to Article 7-8.

(Handling matters for modification without expedited review)

#### Article 10

The 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.

(Review for research implemented by other research institution)

#### Article 11

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

(Primary Review)

#### Article 12

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 13

The principal investigator can request collective review regarding joint research planning document with another research institution by other The 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 The Committee is required.

(Secretariat)

Article 14

Committee should set up Secretariat for committee's operation.

2. Secretariat is set up in R&D Support Center.
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 15

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