Ethics Regulations on Clinical Research and Development and Human Genome and Genetic Analysis Research

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(Objective)

Article 1 The objective of these regulations is to ensure that Sysmex Corporation and Sysmex Corporation's subsidiaries in Japan (hereinafter, collectively referred to as "Group companies") comply with national Ethical Guidelines for Medical Research Involving Human Subjects and Ethical Guidelines for Human Genome and Genetic Analysis Research as well as the Clinical Trials Act and Clinical Trials Act Enforcement Regulations, obtain societal understanding and cooperation, respect human dignity and human rights, and conduct research smoothly.

(Scope of application)

Article 2

1. These regulations apply to Group companies conducting clinical research and development, or human genome and genetic analysis research.

2. Domestic group companies included in Article 1 shall include all companies owned by Sysmex Corporation and those in which Sysmex Corporation owns directly a majority of the voting rights.

(Classification of regulations)

Article 3

1. These regulations apply to Group companies as Group regulations comprising common standards for the execution and management of Group operations.

2. In principle, all people involved in research who are subject to these regulations must comply with the laws, ordinances and guidelines of the locations in which such research is conducted. These regulations serve as a standard; however, in the event that the laws, ordinances or guidelines of the locations in which such research is conducted are more stringent than these regulations, such laws, ordinances or guidelines must be followed in conducting clinical research and development and human genome and genetic analysis research.
(Definition of terminology)

Article 4  The definitions of the terminology used in these regulations are as follows. Terminology not defined in these regulations shall be the same as the “definitions of terminology” provided in the Ethical Guidelines for Medical Research Involving Human Subjects and Ethical Guidelines for Human Genome and Genetic Analysis Research, as well as the Clinical Trials Act and Clinical Trials Act Enforcement Regulations.

(1) Clinical Research and Development
Activities involving human subjects (including specimens and information) conducted with the aim of gaining knowledge aimed at understanding the genesis of injuries and diseases (including the frequency and distribution of various health-related events and the factors affecting them) and disease states, methods of preventing injuries and diseases, improving medical diagnostic approaches and treatment methods, maintaining and improving citizens’ health, and contributing to patient quality of life substantially through recovery from injuries and diseases through effective verification, including clinical research regulated under the Clinical Trials Act. These regulations include the performance evaluation of instruments and reagents, the calibration of instruments and product shipment inspections, but exclude medical acts for the purpose of diagnosis or treatment.

(2) Clinical Research
Research which applies pharmaceuticals to humans in order to clarify the efficacy or safety of the pharmaceuticals concerned (excluding research corresponding to clinical trials and others defined under the Ministry of Health, Labor and Welfare Ordinances) (details are given in Appendix 1).

(3) Specified Clinical Research
Clinical research that corresponds to either one of the following (details are given is Appendix 1).

a. Clinical research carried out by providing research funds

b. Clinical research using pharmaceutical products etc. (drugs, medical devices, regenerative medicine etc.) that are not approved or outside of their indicated use.
(4) Human Genome and Genetic Analysis Research
Research using specimens to clarify the structure and function of human genomes and genes, which are common to the cells that form the individual providers and their descendants. Also includes the provision only of specimens and information used in this research.

(5) Research
When these regulations refer simply to "research," this includes clinical research and development, human genome, and genetic analysis research.

(6) Research Ethics Guidelines
When these regulations refer simply to "Research Ethics Guidelines," this includes both Ethical Guidelines for Medical Research Involving Human Subjects and Ethical Guidelines for Human Genome and Genetic Analysis Research.

(7) Researchers, etc.
This refers to people responsible for research at Sysmex, as well as other people involved in conducting research, including people conducting operations involving the provision of specimens and information and activities related to personal information protection. Also included are people performing genetic counseling with regard to human genome and genetic analysis research.

(8) People Responsible for Research
People involved in conducting research and people managing activities related to the research concerned in Sysmex.

(9) Head of the Research Institution
Refers to the representative of the company conducting the research.

(10) Implementation Party of Specified Clinical Research
The party implementing the specified clinical research refers to the party which is responsible for submitting a plan on the implementation of the specified clinical research to the Ministry of Health, Labor and Welfare.

(11) Specimens and Information
Specimens obtained from the human body and information used in research. Definitions
pertaining to clinical research and development and human genome and genetic analysis research are described below.

a. In clinical research and development, specimens refer to blood, tissues, cells, bodily fluids and excreta, as well as DNA extracted from these substances, used in clinical research and development, and other items from parts of a human body (including items obtained from cadavers) used in research. Information refers to the names of injuries and diseases obtained through the diagnosis and treatment of research subjects, as well as the content of drug administration, testing and measurement results, information related to human health and other information used in research (including items related to cadavers).

b. In human genome and genetic analysis research, specimens refer to blood, tissues, cells, bodily fluids, excreta, as well as DNA extracted from these substances, used in human genome and genetic analysis research, and other items from a part of the human body. Information refers to the provider’s diagnostic information, genetic information and other information used in research (including items obtained from cadavers). However, these definitions exclude tissues, cells, bodily fluids and excreta, as well as DNA extracted from these substances, for which academic value is determined, research results are substantially understood, are widely and generally used in research, and are generally available.

(Basic policy)

Article 5 The basic policy for conducting clinical research and development, and human genome and genetic analysis research is as follows.

(1) Respect for the lives, health, human rights and human dignity of the research subjects
(2) Ample prior explanation and freely given informed consent
(3) Thorough protection by appropriate control of personal information etc.
(4) The conduct of research that has academic significance and benefits society by contributing to the intellectual foundation, health and welfare of humanity
(5) Prioritization of the protection of individual human rights over scientific and societal benefits
(6) Assurance of research appropriateness through research plans prepared on the basis of and in compliance with these regulations and prior examination and approval by the independently established Research Ethics Examination Committee
(7) Assurance of research transparency and quality through third-party site investigations of
research implementation status and the publication of research results

(8) Assurance of scientific rationality in accordance with the characteristics of research fields

(9) Comprehensive evaluation of the burden, as well as the anticipated risks, benefits and other disadvantages, to the research subjects

(10) Take necessary and suitable measures for those who require special considerations socially

(11) Awareness activities to enhance society’s understanding of human genome and genetic analysis research and public dialog concerning research content

(Responsibilities of the head of the research institution)

Article 6

1. The head of the research institution is responsible for overall supervision of research, the formulation of systems and regulations for conducting research, obtaining research permissions and, where necessary, reporting to the Minister of Health, Labour and Welfare.

2. When requested by people responsible for research for the conduct of research or a change in research planning documents, the head of the research institution must seek the opinion of the Research Ethics Examination Committee, respect that opinion, and determine permission or lack of permission and necessary measures for research.

3. In the case of specified clinical research, when requested by people responsible for research for the conduct of the specified clinical research or a change in the research planning documents, the head of the research institution must seek the opinion of the Research Ethics Examination Committee, respect that opinion, and determine other measures necessary for the research as examined by the certified clinical research examination committee stipulated under the Clinical Trials Act. The clinical research cannot be permitted if approval is not given by the Research Ethics Examination Committee.

4. In the event of research that is invasive (excluding minimally invasive) in which intervention was conducted but led to unforeseen severe damage that has an undeniable direct relationship to the research, the head of the research institution must, in accordance with the Ethical Guidelines for Medical Research Involving Human Subjects, report such information promptly to the Minister of Health, Labour and Welfare and publicize it. In the case of specified clinical research, the information must be reported promptly to the party implementing the specified
clinical research.

5. The head of the research institute shall implement the following:

a. When conducting clinical research and development for which research funds etc. are provided, an agreement that defines the amount and details of the research funds concerned, the details of the research concerned and other information as stipulated in the Ministry of Health, Labor and Welfare Ordinances must be concluded.

b. Information on research funds etc. for clinical research and development as stipulated in the Ministry of Health, Labor and Welfare Ordinances must be posted on the Internet and made public by other methods as stipulated in the Ministry of Health, Labor and Welfare Ordinances.

6. The head of the research institution may delegate the authority or practical tasks provided in these regulations to appropriate people within the Company.

(Responsibilities of people responsible for research)

Article 7

1. Prior to conducting research, people responsible for research must prepare research planning documents and obtain permission to conduct research from the head of the research institution or the party to whom the head of the research institution has delegated this authority.

2. As provided in the Research Ethics Guidelines, people responsible for research must take overall charge of activities related to that research.

(Responsibilities of researchers, etc.)

Article 8

1. Researchers, etc., involved in clinical research and development must abide by the provisions of the Ethical Guidelines for Medical Research Involving Human Subjects.

2. Researchers, etc., involved in clinical research must abide by the provisions of the Clinical Trials Act and Clinical Trials Act Enforcement Regulations. In addition, in the case of specified clinical research, the applicability must be clearly stated in the research planning documents.

3. Researchers, etc., involved in human genome and genetic analysis research must abide by the provisions of the Human Genome and Genetic Analysis Research
Guidelines. Concerning items not provided in these guidelines, researchers, etc., must abide by the provisions of the Ethical Guidelines for Medical Research Involving Human Subjects.

4. Prior to conducting research, researchers, etc., must undergo education and training in research-related ethics and to ensure they have the necessary knowledge and technical proficiency to conduct research. They must also continue undergoing such education and training as appropriate during the research period.

(Responsibilities of Researchers)

Article 9 In the event of intervention in research that is invasive (excluding minimally invasive), people responsible for research must conduct monitoring and undergo necessary audits provided in research planning documents that have been approved by the head of the research institution.

Bylaws

(Effective date)

Article 1 These regulations are effective as of April 1, 2019.