Group Ethics Regulation on Clinical Research and Development

[Created: 2004/06/18]
[Revised: 2023/07/01]

(Purpose)
Article 1

This regulation is enacted based on the following purpose. Research can be implemented by getting cooperation and understanding from society. So Sysmex and Domestic Affiliates (they are named as “Group companies”) should implement research activity by following “Ethical Guidelines for Life science / medical and health research Involving Human Subjects”, “Clinical Research Law”, “Clinical Research Law Enforcement Regulations” and by respecting dignity of human being and human rights.

(Scope of Application)
Article 2

This regulation applies to Clinical Research and Development implemented within Group companies. In addition, when only existing specimens and information are provided from Japan to researchers outside Japan, these regulations apply, and the relevant regulations in Article 9 must be complied with.

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

(Classification of Regulation)
Article 3

This regulation is regarded as common standard on implementing and managing group business activity and applied to Group companies.

2. All members involved in research targeted in this regulation should follow this regulation basically while following local regulation, guidelines in the district where the research is implemented. In case that local regulation is much stricter than Sysmex regulation, Clinical Research and Development should be implemented based on this local regulation.
   The items which is not regulated by local one should be followed by “Ethical Guidelines for Life science/medical and health research Involving Human Subjects”, “Clinical Research Law”, “Clinical Research Law Enforcement

Regulations”.

(Basic Principle)
Article 4

In case of implementing Clinical Research and Development, the research should be implemented by respecting human dignity and right, life and health of researcher and below-mentioned basic principle.

(1) Socially and academically significant research should be implemented.
(2) Scientific rationality should be kept according to the characteristics of research field.
(3) Comparison of profit received through research and loss and burden to researcher should be considered.
(4) Screening by Research Ethics Review Committee or Authorized Clinical Research Review Committee which are regarded as independently fair organization should be passed.
(5) Explanation in advance to researcher should be made sufficiently and consent based on free opinion should be received.
(6) Special consideration to person in socially weak position should be taken into.
(7) Personal information and so on which are used in research implementation should be managed properly.
(8) Quality and transparency in research should be kept properly.

(Definition of Terminology)
Article 5

The definition of term which is used in this regulation is as follows. The definition of term which is not used in this regulation should be the same as the definition of term which is used in “Ethical Guidelines for Life science/medical and health research Involving Human Subjects”, “Clinical Research Law”, “Clinical Research Law Enforcement Regulations”.

(1) Life Science and Medical Research Involving Human Subjects
An Activity which is implemented by getting knowledge of keeping nationals in good health, recovering from diseases, improvement of life quality, structure/function of genome and genetically modified organism through below-described ①-④.
① Understanding on cause of diseases (including frequency of

health-related various　factor)

② Understanding on diseases

③ Verification of improvement of preventive measure for diseases or effectiveness

④ Improvement of diagnostics methods and treatment method and verification of effectiveness

(2) Clinical Research and Development

Life Science and Medical Research Involving Human Subjects. This regulation includes performance evaluation of instrument and reagent/proofreading of instrument and inspection of product before delivery. Also, medical practice targeting on diagnostics and treatment is not included in this regulation.

(3) Clinical Research

A Research through which effectiveness and safety of the medicine can be clarified by using them in human being (excluding clinical research and research specified by an Ordinance of the Ministry of Health, Labor and Welfare). (Detail is defined in attached sheet 1)

(4) Specified Clinical Research

Specified Clinical Research is either of below-described ①or②
(Detail is defined in attached sheet 1)

① A research described below. Clinical Research by sponsoring research funding.

② Clinical Research by using unapproved or not applicable medicine and so on. （Medicine, Medical Instrument, Regenerative Medicine and so on）

(5) Research

In this Regulation, the term "Research" refers to Clinical Research and Development.

(6) Research Ethical Guideline

Ethical Guideline regarding Life Science and Medical Research involving Human Subjects.

(7) Invasiveness

To cause injuries or distress to research subjects' body and/or mind by conducting a procedure for investigational purpose, such as puncture, incision, administration of drugs, irradiation and questions related to the subject's mental trauma, etc. Of various types of invasiveness, one

causing minor injury and/or distress on the research subjects' body and/or mind is called "minor invasiveness."

(8) Intervention

A practice for investigational purpose to control the presence or absence of factors, which can affect a variety of events occurring in relation with human health (including activities to maintain and promote good health and medical practices such as medication and examinations for prevention, diagnosis and treatment of the patients), or the degree of such factors. The above-defined intervention also includes medical technique beyond usual medical practice that is conducted for investigational purpose.

(9) Human Biological Specimen

Items obtained from the human body (including that of deceased individuals) to be utilized (or which has been utilized) in research, such as blood, body fluids, tissues, cells, excrement and DNA extracted from these, etc.

(10) Information Utilized in Research

Information on human health, such as the name of disease, details of medication and results of examination and measurement obtained through diagnosis and treatment of research subjects, and other information (including that concerning deceased individuals) to be utilized (or which have been utilized) in research.

(11) Specimen and/or Information

The above-defined human biological specimen and/or the above-defined information utilized in research.

(12) Existing Specimen and/or Information

Of the above-defined specimen and/or information, specimen and/or information which corresponds to any of the following below-mentioned :

① Specimen and/or information already existing prior to the preparation of the research protocol; or

② Specimen and/or information acquired after the preparation of the research protocol however not intended to be utilized in the research defined in the research protocol at the time the said specimen and/or information were acquired.

(13) Genetic information

An information which is received through the process of research using specimen, information or is passed on to progeny and showing personal genetic characteristics and constitution.

(14) Research Subject

A person (including deceased individual) who corresponds any of the following descriptions:

① An individual on whom research is implemented (including an individual asked to be enrolled in the research); or

② An individual from whom existing specimen or information had arisen.

(15) Targeted Researcher, etc.

In addition to targeted researcher, Legally Acceptable Representative is included.

(16) Research Implementing Entity

A legal entity, administrative organ or individual business owner who carries out research, not including contractors for a part of research work such as storage of specimens and/or information and statistical processing.

(17) Collaborative Research Implementing Entity

A research implementing entity collaboratively conducting research in accordance with the research protocol, including any entities which newly acquire specimens or information from research subjects for the said research and provide the above to other research implementing entity(s).

(18) Research Cooperation Institution

Institution which implements research not based on research planning document and receives specimen and information (excluding invasiveness, not minor invasiveness) newly from researcher and gives them to other research implementing entity.

(19) Institution which collects specimen and information

Institution which receives specimen and information from research subject or receives from other institutions and gives them to other research implementing entity continuously.

(20) Multi Implementing Entities Joint Research

A Research implemented by Multi-Research Implementing Entities based on one research planning document.

(21) Researcher and so on

Person who are responsible for research or implements research (including implementation of collecting specimen and information and protecting personal information and counseling regarding genetically modified organism). But it excludes the below – mentioned person.

① Person who receives specimen and information newly and gives them to research implementing entity only.

① Person who gives only existing specimen and information to research implementing entity.

② Person who engage in only part of research work by being consigned.

(22) Person who is responsible for research

Person who engages in research implementation and manages research. In addition, person who engages in multi-implementing entities joint research is called research representative if necessary.

(23) Research representative

A researcher who is responsible research in case of multi implementing entities research implementation.

(24) Chief Executive of Research Implementing Entity

The representative of a legal entity, the head of an administrative organ or an individual business owner who carries out research.

(25) Specified Clinical Research implementer

Person who implements specific clinical research and submits specific research implementation planning document to Minister of Health, Labor and Welfare.

(26) Research Ethics Review Committee

An organization utilizing a consensual decision-making system, which is organized to make examination and reviews concerning the ethical justification and scientific validity to commence or continue research and other relevant matters.

(27) Informed Consent

Consent to implement research continuously including handling of specimen and information by checking purpose and significance of research, anticipated burden on researcher and result including risk and benefit.

(28) Appropriate consent

Acquisition and use of samples and information (including provision)
The consent of the Research Subjects, etc. with respect to the provisions of the Personal Information Protection Act with respect to the consent of the Research Subjects, etc., which is made after the matters necessary for the Research Subjects, etc. to judge the consent of the Research Subjects, etc. have been clearly stated in a reasonable and appropriate manner, and the consent of the Principal under the Act on the Protection of Personal Information with respect to Personal Information, etc. among the samples and information. With respect to the research that the Research Subject intends to conduct or continue, the purpose, significance and method of the Research, the burden on the Research Subject, and the expected results (including risks and benefits) Receiving sufficient explanations from researchers, etc. or persons who only provide existing samples and information, and after understanding them, give to researchers, etc. or persons who only provide existing samples and information based on their free will. Consent to be implemented or continued. (Among these, for personal information, etc., the consent of the person under the Personal Information Protection Law will be satisfied addition)

(29) Legally Acceptable Representative
Person who can express opinion and benefit on behalf of human research subject and give informed consent to person who offers existing specimen and information only to researcher. Legally Authorized representative who can gives informed consent in case that human research subject is dead is called as Legally Authorized Representative and so on.

(30) Legally Acceptable Representative and so on
Legally Authorized representative who can gives informed consent in case that human research subject is dead is called as Legally Authorized Representative and so on.

(31) Informed Ascent
Those who are objectively judged to lack the ability to give informed consent among the research subjects should be explained in plain language in order to understand and agree on the research to be conducted or continued.

(32) Personal Information

An information regarding living person and below mentioned.

① Name, birth date and other information which can enable other person to specify targeted person individually (including items which can be compatible with others and specified).

② Items in which personal identification code is included.

(33) Personal Information and so on

Personal information, Non-identification processing information, or Anonymization processed information and Personal data

(34) Personal Identification Code

The below-mentioned character, number, mark and other code which is specified in Cabinet Order regarding protection of personal information (2003 Cabinet Order No.507) and other laws.

① The character, number, mark and other code which is switched from person's specific aspect of body in order to fit for electric computer and can be identified as specific person.
Example) Sequences of the bases constituting DNA (genomic data (sequences of bases constituting deoxyribonucleic acid (also known as DNA) collected from cells expressed as strings), whole nuclear genome sequence data, whole exome sequence data, whole nucleotide polymorphism (SNP) data, and more than 40 locations independent of each other Sequencing data composed of SNPs, those that enable a person to be authenticated by genotype information such as repeating sequences (short tandem repeat: STR) of 4 bases of 9 loci or more), etc

② Card and other documents issued to specific person which enables other person to identify specific person by character, number, mark and other code which is recorded electrically in the data base.
Example) Number of passports, number of driver's license, my number card and so on

(35) Personal information required for special consideration when handling

Personal information such as race, brief, social status, medical history, crime history, fact of getting involved in crime and unlawful discrimination which should be handled with special consideration.
Example) medical history, physical disability, intellectual disability,

mental disorder (including developmental disorders) The applicant has a mental or physical impairment prescribed by other rules of the Personal Information Protection Commission, or has been instructed or given medical treatment or dispensing for the improvement of the mental and physical condition by a physician or the like based on or due to illness, injury, or other mental or physical changes, etc.

(36) Non-identification processing information

The processed Information about individuals which we cannot pick up the specific personal information. It must execute based on below - mentioned. (But it is limited one which is regulated by Personal Information Protection Law.)

① Personal information applied to this article (32)①Deleting the part of the descriptions or replacing with other descriptions which cannot be restore original information.

② Personal information applied to this article (32)②Deleting all Personal Identification Code or replacing with other descriptions which cannot be restore original information.

(37) Anonymization processed information

The processed Information about individuals which we cannot pick up the specific personal information. It must execute based on below - mentioned. (But it is limited one which is regulated by Act on the Protection of Personal Information Held by Administrative Organs or Law for the Protection of Personal Information Retained by Independent Administrative Institutions.)

① Personal information applied to this article (32)① Deleting the part of the descriptions or replacing with other descriptions which cannot be restore original information.

② Personal information applied to this article (32)② Deleting all Personal Identification Code or replacing with other descriptions which cannot be restore original information.

(38) Personal data

Information on living individuals that does not fall under any of the categories of personal information, , Non-identification processing information or Anonymization processed information.

(39) Deleted Information, etc.

Refers to descriptions deleted from personal information used for the

creation of Non-identification processing information, individual identification codes, and information on the processing method performed in accordance with the provisions of the preceding paragraph.

(40) Information such as processing method

Descriptions, etc. deleted from personal information used for the creation of Anonymization processed information, individual identification codes, and information on the method of processing based on the provisions of the Act on the Protection of Personal Information (limited to those that can restore the personal information)

(41) Adverse Event

Any unfavorable and unintended injury and illness or any sign of such (including an abnormal laboratory finding) caused to research subjects, regardless of whether there is or is not any causal relation with the research implemented.

(42) Serious Adverse Event

Of the above-defined adverse events, an event that:

① Results in death;

② Is life-threatening;

③ Requires inpatient hospitalization or prolongation of existing hospitalization;

④ Results in persistent or significant disability or incapacity; or

⑤ Is a congenital anomaly or birth defect to offspring.

(43) Unexpected Serious Adverse Event

An event which is not described in research planning document or informed consent or contents of documents which do not match the serious adverse event.

(44) Monitoring

An act of overseeing the progress of research, and of determining whether the research is being conducted in compliance with these Guidelines and the research protocol, in order to ensure that the research is properly conducted. Such act is performed by an individual appointed by the principal investigator.

(45) Audit

An examination of research-related activities to determine whether the research has been conducted in compliance with these Guidelines and

the research protocol, in order to assure the reliability of results of the research. Such examination is performed by an individual appointed by the principal investigator.

(46) Genetic counseling

Counseling is conducted for the purpose of supporting future life of research subject or relatives by giving information regarding medical or psychological problem through the measure of genetic medical knowledge.

(Responsibility of researcher and so on)

Article 6

Researcher who engages in Clinical Research and Development should implement research properly based on “Ethical Guidelines for Life Science Medical Research Involving Human Subjects”, “Clinical Research Law”, “Clinical Research Law Enforcement Regulations” and respecting dignity of research subject and its Human rights according to research planning document approved by chief of Research Ethics Review Committee and research implementing entity.

2. Researcher who engages in clinical research development should follow Clinical Research Law and Clinical Research Law Enforcement Regulation. And adequacy of research should be described in the research planning document in case of Specific Clinical Research.
3. Researcher and so on should take education, lecture regarding research ethics, knowledge and technic before implementing research. And researcher should continue to take education, lecture even during research period.

(Responsibility of chief executive of research implementing entity)

Article 7

Chief executive of research implementing entity should establish structure of the research teams and related regulation for managing and implementing research.

2. In case of specified clinical research, chief executive of research implementing entity should request opinion to Research Ethics Review Committee when person responsible for research requests permission regarding implementation of the specific clinical research or revision of its

research planning document to the chief. The chief should respect the opinion received from committee and decide the measure required from Authorized Clinical Research Review Committee regulated by Clinical Research Law. In case that the research goes against the Committee's opinion, the chief should refrain from permitting the research.

3. The chief executive of research implementing entity should implement below-described matters.
   (1) In case of implementing Clinical Research and Development by receiving research fund, contract should be concluded by describing amount of research fund, content of research and issues designated by Ordinance of the Ministry of Health, Labor and Welfare.
   (2) Information of Clinical Research and Development fund or others designated by Ordinance of the Ministry of Health, Labor and Welfare should be disclosed through such measures as internet or other ways designated by Ordinance of the Ministry of Health, Labor and Welfare.
4. The chief executive of research implementing entity should arrange for education or lecture for the purpose that researcher can acquire the knowledge regarding ethics and other research related matters. Also, the chief should also take the education or lecture.
5. The chief executive of research implementing entity can entrust authority and its related business procedure designated by this regulation to appropriate employees in the company.

(Procedure regarding research planning document)

Article 8

Person responsible for research should compile research planning document before implementing research. In case of implementing research, which is different from original planning, person responsible for research should revise research planning document and request the opinion from Research Ethics Review Committee.

2. The person responsible for research should submit documents to the chief executive of research implementing entity and receive permission after hearing opinion from Research Ethics Review Committee. But in case that public health hazards are expanding and required to prevent them from expanding further through urgent research implementation, this research can be implemented after receiving permission from the chief without

hearing opinion from Research Ethics Review Committee. In this case, person responsible for research should hear the opinion from Research Ethics Review Committee immediately and respect the opinion & take appropriate measure if Committee express the opinion to halt or revise the content of research planning.

3. The persons responsible for multi implementing entities joint research should select representative from the persons responsible for this joint research.
4. In case of implementing multi implementing entities joint research, the representative should clarify the responsibility of each person responsible for this research in each multi implementing entities. And representative should request committee to review research planning document in principle after compiling or revising the document.
5. The person responsible for research should submit to committee such information as result of review and progress of research reviewed by other committee in case of hearing opinion about multi implementing entities joint research from individual Research Ethics Review Committee.
6. The person responsible for research should compile or revise research planning document and manage it properly in case of entrusting some parts of research works to other entity. In addition, the person responsible for research should take appropriate measures to compensation for research subject who suffers from invasiveness (excluding minor invasiveness) and requires medical treatment which is more serious than usual.
7. The person responsible for research should report the outline of Result to Research Ethics Review Committee and chief of research implementing entity by document or electromagnetic method without fail immediately after ending research (including halt case of research). In addition, the person responsible for research should take care of research subject who suffered from invasion as a result of the research and take the best preventive measure as a result of research in case of implementing research by which research subject needed more serious medical practice than usual.
8. The person responsible for research should educate and manage persons who get involved in this research for the purpose that this research can be implemented properly according to the research planning document and reliability assurance should be secured.
9. The chief executive of research implementing entity should take appropriate

measure to decide the permission while respecting opinion from Research Ethics Review Committee when requested implementation of research or revision of research planning document from person responsible for research. The chief should not permit research implementation if committee does not permit it. In addition, the chief should take appropriate measure promptly upon receiving information or fact which affects continuation of research.

(Procedure for Informed Consent)

Article 9

When a Researcher, etc. intends to conduct research, in principle, the Researcher, etc. must obtain informed consent in advance based on the procedures of the Research Ethics Guidelines in accordance with the research plan approved by the head of the research institution. However, this shall not apply to the case where existing samples and information are provided in accordance with the provisions of laws and regulations, or when existing samples and information are provided.

2. In the event that a Researcher, etc. withdraws or refuses consent from a Research Subject, etc., the Researcher, etc. shall, without delay, take measures in accordance with the content of the withdrawal or refusal and explain to the Research Subjects, etc. to that effect. provided, however, that this shall not apply in cases where it is difficult to take such measures and the head of the research institution has approved the non-implementation of such measures after hearing the opinions of the Ethical Review Committee. In this case, the Researcher, etc. shall endeavor to explain to the Research Subjects, etc. the fact that measures will not be taken in accordance with the contents of the withdrawal or refusal and the reasons for the refusal.
3. Based on the Research Ethics Guidelines, Researchers, etc. are allowed to receive informed consent by electromagnetic method instead of written informed consent.
4. When providing samples and information, the Principal Investigator or the person who only provides the samples and information must prepare a record of the provision of the samples and information. In addition, when receiving samples or information used for research from other research institutions, the Researchers, etc. must confirm that appropriate procedures have been followed by the person providing the samples and information

and must prepare a record of the provision of the samples and information. The Principal Investigator shall retain such records for a period of time from the date on which the completion of the research is reported until the expiration of five years. The head of the research institution shall also exercise the necessary supervision to ensure that the records are properly kept.

5. When a researcher, etc. or a person who only provides existing samples and information receives informed consent from a Legally Acceptable Representative, etc., he or she must satisfy all the requirements listed in the Research Ethics Guidelines.
6. When a Researcher, etc. or a person who only provides existing samples and information receives informed consent from the Legally Acceptable Representative and it is judged that the Research Subject can express his or her intention to conduct the research, the Researcher shall endeavor to obtain an informed Ascent.

(Explanation about the result from research implementation)

Article 10

The person responsible for research should set the result disclosure policy to research subject and describe it in the research planning document.

2. When receiving informed consent from the Research Subjects, etc., the Researchers, etc. must explain the policy on the explanation of the results, etc. obtained through the research and obtain their understanding. In addition, if the Research Subjects, etc. do not wish to explain the results obtained from the research, their will must be respected. However, even if the Researcher, etc. does not wish to explain the results obtained through the research, the Researcher, etc. shall report to the Principal Investigator if it is found that the results, etc. will have a significant impact on the lives of the Research Subjects or the Researcher's blood relatives, etc., and there is an effective countermeasure. When the Principal Investigator receives a report, the Principal Investigator shall request the opinion of the Ethical Review Committee regarding the availability, method, and content of the explanation to the Research Subjects, etc.
3. In principle, Researchers, etc. shall not explain the results obtained through the research of the Research Subjects, etc. to persons other than the Research Subjects, etc. without the consent of the Research Subjects, etc.

However, if a blood relative, etc. of a research subject wishes to explain the results obtained through the research, and the Principal Investigator may explain whether or not to explain the results obtained through the research, etc., after hearing the opinions of the Ethical Review Committee on whether or not to explain based on the reason and necessity of requesting the explanation, the Principal Investigator may give an explanation if he deems it necessary. Based on the opinions of the Ethical Review Committee, the Researcher, etc. shall not give an explanation to the Research Subjects, etc., after sufficient explanation, confirm the intentions of the Research Subjects, etc., and if they do not wish to explain, they shall not explain.

4. When handling the results, etc. obtained through research, the Principal Investigator shall take into full account the medical or psychological effects, etc., based on the characteristics of the results, etc., and establish a system that allows the Research Subjects, etc. to conduct consultations related to the research as appropriate. In addition, it is important for the Research Supervisor to work closely with the physician in charge of medical care in the course of establishing a system, and when handling genetic information, efforts must be made to ensure cooperation with those who provide genetic counseling and specialists in genetic medicine.

(Appropriate response and report regarding research)

Article 11

The researcher and so on should secure ethical adequacy and scientific rationalism. In case of being not secured, researcher should report it to the chief of institution and person responsible for research.

2. The person responsible for research should check progress management, supervision and grasp adverse event. The person responsible for research should report it to chief if necessary. And the person responsible for research should stop, halt or revise the research planning document.
3. The person responsible for research should share necessary information regarding multi implementing entities joint research with the person responsible for multi joint research in case of implementing multi implementing entities joint research.
4. The chief executive of research implementing entity should hear opinion from Research Ethics Review Committee in case that the chief gets fact that implemented research in the past is not fit for Research Ethics Guideline. In

case of very serious incompatibility, the chief should report this fact to Minister of Health, Labor and Welfare and disclose it to the public.

(Conflict of interest management)
Article 12

The researcher and so on should report conflict of interest management regarding research such as personal revenue to the person responsible for research and ensure transparency.

2. The person responsible for research should check conflict of interest management situation and describe it in the research planning document in case of implementing research related to commercial activity.

(Storage of specimen and information regarding research)
Article 13

The researcher and so on should keep research related information and data accurate.

2. The person responsible for research should storage sample extracted from human body or information based on Item 3 of Procedure Manual in order to avoid leakage, mixed, stolen, loss of specimen and information. It should be described in the research planning document. And the person responsible for research should report management situation and condition to the chief of research implementing entity.
3. The chief executive of research implementing entity should compile procedure manual for storing specimen extracted from human body and information and manage it.

(Monitoring & Review)
Article 14

The person responsible for research should conduct monitoring, review Instruct and manage it based on the research planning document permitted by the chief in case of implementing research requiring invasiveness (except for minor invasiveness).

(Response to serious adverse events)
Article 15

The researcher and so on should report to the person responsible for

Research in case of finding the fact of serious adverse events as a result of implementing research requiring invasiveness. And the researcher should take appropriate measure such as explanation to research subject according to Item 4 of Procedure manual.

2. The person responsible for research should describe measure in case of serious adverse events such as invasiveness in the research planning document. In case of finding serious adverse events, the person responsible for research should request opinion from Research Ethics Review Committee. In addition, the person responsible for research should report this fact to the chief and take appropriate measure based on Item 4 of Procedure Manual.
3. The research representative should share information with the person responsible for joint research in case of finding serious adverse events including invasiveness.
4. The chief executive of research implementing entity should compile procedure manual describing necessary measure to be taken in case of serious adverse events such as invasiveness.
5. The person responsible for research should report this situation to the chief in case of unexpected serious adverse events such as invasiveness (excluding minor invasiveness). In addition, the person responsible for research should report this situation to Minister of Health, Labor and Welfare including result after taking measure and disclose to the public. In case of specific clinical research, it should be reported to specific clinical research implementer promptly.

(Basic responsibility for personal information handling and so on)

Article 16

The researcher and the chief executive of research implementing entity should follow Law and Ordinance [Personal Information Protection Law, Government Agency Personal Information Protection Law, Incorporated Administrative Agency, etc.] in case of handling anonymization processed information and unidentified processed information.

2. The researcher and so on should handle personal information properly in case of implementing research.
3. In light of the dignity of the deceased and the feelings of the bereaved families, etc., the Researchers, etc. and the heads of research institutes

shall, in the same way as information on living individuals, appropriately handle samples and information that can be identified as an specific individual regarding the deceased in accordance with the provisions of the Personal Information Protection Act, ordinances, etc., and endeavor to take necessary and appropriate measures.

(Transitional Measures)

Article 17

At the time of enforcement of these Regulations, research currently being conducted under these Regulations prior to revision may still be based on the previous examples only if the provisions of laws and regulations and guidelines related to the protection of personal information are complied with.