Ethical Guidelines for Human Genome/Gene Analysis Research

Table of Contents

Preamble

PART I: BASIC IDEAS

1. Basic Principles

2. Scope of Application

PART II: OBLIGATIONS, ETC. OF INVESTIGATORS, ETC.

3. Basic Obligations of All Investigators, etc.

4. Obligations of Chief Executives of Research Implementing Entities

5. Obligations of Principal Investigators

6. Collaborative Research with Overseas Institutions

PART III: BASIC STANCE TOWARD DONORS

7. Informed Consent, etc.

8. Disclosure of Genetic Information

9. Genetic Counseling

PART IV: ETHICAL REVIEW COMMITTEES

10. Responsibilities and Composition of Ethical Review Committees

PART V: HANDLING, ETC. OF SPECIMENS AND/OR INFORMATION

11. Provision, etc. of Specimens and/or Information to Other Research Implementing Entities

12. Handling of Anonymized Information

13. Preservation and Disposal of Specimens and/or Information

14. Use of Existing Specimens and/or Information at Research Implementing Entities

15. Use of Existing Specimens and/or Information from External Institutions

PART VI: PROTECTION OF PERSONAL INFORMATION

16. Personal Information to be Protected

17. Security Control Measures

18. Handling of Personal Information

19. Disclosure, etc. of Personal Information

20. Handling of Anonymously Processed Information

21. Responsibilities of Privacy Officers

PART VII: GLOSSARY

22. Glossary

(1) Specimen and/or information

(2) Medical information

(3) Human genome/gene analysis research

(4) Genetic information

(5) Anonymization
Preamble

The promotion of scientific research is an important issue for achieving a society in which people can lead healthy and fulfilling lives. In this context, human genome/gene analysis research begun in the latter half of the twentieth century has made significant contributions to the progress of both life science and health care science, and is playing an important role in the development of the health and welfare of humanity and in the growth of new industries.

On the other hand, human genome/gene analysis research depends largely on research activities targeted at individuals, and genetic information obtained in the course of research reveals genetic predispositions of both donors (those persons who provide a specimen or information for human genome/gene analysis research) and their blood relatives, which might cause various ethical, legal or social problems. Therefore, research must be conducted properly on the basis of respect for human dignity and human rights as well as understanding and cooperation from society. Furthermore, guaranteeing the rights of individual donors should be given priority over scientific or societal benefits in accordance with ethical standards stipulated in such documents as the World Medical Association’s Declaration of Helsinki. It is also essential that society be given adequate explanation on this aspect of research, and that research be conducted on the basis of this understanding.
In view of these circumstances, these Guidelines were jointly prepared by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry, and are presented to society at large as ethical guidelines to be universally applied to human genome/gene analysis research. The Guidelines set basic rules, taking into consideration that human genome/gene analysis research can take a variety of forms. These rules are to be taken into account when investigators, etc. formulate research protocols and when ethical review committees make decisions on the appropriateness of those protocols, so that appropriate decisions can be made according to the content and so forth of individual research protocols.

In handling information used in research, entities conducting human genome/gene analysis research shall give heed to the requirement for them to observe the Act on the Protection of Personal Information (Act No. 57 of 2003; hereinafter referred to as the “Personal Information Protection Act”), the Act on the Protection of Personal Information retained by Administrative Organs (Act No. 58 of 2003; hereinafter referred to as “Administrative Organs Personal Information Protection Act”), the Act on the Protection of Personal Information retained by Independent Administrative Agencies, etc. (Act No. 59 of 2003; hereinafter referred to as “Independent Administrative Agencies, etc. Personal Information Protection Act”) and prefectural and municipal ordinances established by local government in accordance with the aim of Article 11(1) of the Personal Information Protection Act, applied according to such categories as private-sector enterprises, administrative organs and incorporated administrative agencies, etc.

PART I: BASIC IDEAS

1. Basic Principles

Given the special characteristics of human genome/gene analysis, such as that genetic information can be obtained in the course of such analysis, these Guidelines were established as ethical guidelines to be applied to all human genome/gene analysis research and to be observed in every research locale. The purpose of these Guidelines is for human dignity and human rights to be respected and for research to be promoted properly based on an understanding and cooperation of society. Thus, the following matters have been set as the basic principles of these Guidelines:

(1) Respect for human dignity
(2) Adequate prior explanation and consent on the basis of free will (informed consent)
(3) Thorough protection of personal information
(4) Conduct of socially beneficial research that contributes to the intellectual foundation, health and welfare of humanity
(5) Priority of guaranteeing individual human rights over scientific or societal benefits
(6) Guarantee of the propriety of research through preparation of and compliance with research protocols pursuant to these Guidelines as well as prior review and authorization by the ethical review committee established as an independent body
(7) Guarantee of the transparency of research, through on-site investigation of research progress by third parties as well as through the disclosure of research results
(8) Advancement of the understanding of the public and society such as through campaigns to promote public awareness about human genome/gene analysis research, and dialogue with the public conducted based on the content of the research

>Note>
Recognizing the distinctive characteristic of human genome/gene analysis research—that is, that various problems might be raised as a result of the risk of genetic information obtained in the course of research possibly revealing genetic predispositions of both donors and their blood relatives, or of the potential for the research to possibly go beyond just issues for an individual donor and characterize the properties of the group to which that donor belongs—the definition and scope of research to which these Guidelines should apply are stipulated in paragraph 22(3) of Part VII.

2. Scope of Application

These Guidelines shall apply to human genome/gene analysis research and require investigators, etc. involved in that research to comply with them. In order for research to be conducted properly, in addition to each and every investigator, etc. making efforts to this end, it is also important that an organizational structure and environment, needed for the appropriate protection of personal information and appropriate ethical conduct, be put in place at the research implementing entity.

The issue of clinical examinations or equivalent human genome/gene analyses which are conducted in the course of a medical treatment and whose analytical results are medically established as instruments to be utilized directly for the medical treatment of donors and their blood relatives will have to be carefully discussed in the future as a matter regarding medical treatment, and these Guidelines therefore do not apply. However, with regard to these human genome/gene analyses, along with observing guidelines for the appropriate handling of personal information at medical care and nursing care providers pursuant to the Personal Information Protection Act, medical doctors giving treatment should be responsible for taking appropriate measures based on the purposes of these Guidelines, referring to guidelines etc. prepared by pertinent academic societies or other authorized organizations.

<Note>
The definition and scope of human genome/gene analysis research are stipulated in paragraph 22(3) of Part VII in these Guidelines.

PART II: OBLIGATIONS, ETC. OF INVESTIGATORS, ETC.

3. Basic Obligations of All Investigators, etc.

(1) All investigators, etc. shall conduct human genome/gene analysis research for such purposes as elucidating life phenomena, preventing diseases, improving diagnosis and treatment protocols, and promoting health.

(2) All investigators, etc. shall ensure the societal usefulness of their human genome/gene analysis research and shall pay attention to guaranteeing the human rights of individuals by prioritizing them over scientific or societal benefits.

(3) All investigators, etc. shall make it a basic practice to conduct human genome/gene analysis research only after obtaining the informed consent of donors or legally acceptable representatives, etc.

(4) All investigators, etc. shall not, in the absence of any justifiable reason, divulge personal information obtained in the course of their duties. This shall continue to apply after they resign their position.

(5) All investigators, etc. shall endeavor to protect personal information and shall also respond in good faith to inquiries, complaints, etc. concerning the handling of personal information.

(6) All investigators, etc. shall, when any serious concerns arise in terms of guaranteeing the human rights of
donors, etc., such as an unexpected divulgence of personal information, immediately report this to both the chief executive of their research implementing entity and to a principal investigator.

(7) All investigators, etc. shall conduct human genome/gene analysis research properly in compliance with these Guidelines and with respect for human dignity and human rights by, for instance, conducting research in accordance with a research protocol as authorized by the ethical review committee and approved by the chief executive of their research implementing entity.

(8) All investigators, etc. shall endeavor to guarantee the transparency of their research through, for instance, ensuring due process when conducting research, on-site investigations by outside experts, appropriate responses to inquiries from donors, etc. regarding the progress of research, and the release of research results into the public domain.

(9) All investigators, etc. shall, in consideration of the fact that the donation of specimens and/or information is based on goodwill, make efforts to minimize the amount of specimens and/or information donated by people by, for instance, properly preserving and utilizing the specimens and/or information already provided.

(10) No investigators, etc. shall, when conducting human genome/gene analysis research, acquire personal information or specimens and/or information by deception or other wrongful means.

(11) All investigators, etc. shall, prior to the conduct of any human genome/gene analysis research, undertake education and training about the ethics of human genome/gene analysis research and about other knowledge necessary for conducting human genome/gene analysis research.

4. Obligations of Chief Executives of Research Implementing Entities

(1) The chief executive of a research implementing entity shall assume ultimate responsibility for the conduct of human genome/gene analysis research at their entity, and shall supervise principal investigators and researchers in charge so that they conduct research properly in accordance with a research protocol. In doing so, the chief executive of the research implementing entity shall endeavor to have all investigators, etc. at their entity understand thoroughly that they should guarantee the human rights of donors, etc. as much as possible and that they may be subject to adverse disposition, such as disciplinary action, if they violate these Guidelines, a research protocol or the like.

(2) The chief executive of a research implementing entity may, pursuant to rules stipulated by the entity, delegate the authority or affairs prescribed in these Guidelines to an appropriate person within the entity.

<Detailed regulations concerning delegation of the authority or affairs prescribed in these Guidelines>

1. The chief executive of a research implementing entity may, in an effort for the smooth and flexible conduct of human genome/gene analysis research, delegate all or part of the authority or affairs prescribed in these Guidelines by designating a person with overarching responsibility.

2. The term “a person with overarching responsibility” is someone who gives orders necessary for supervision to principal investigators, etc. and supervises the whole research, and includes, for instance:

   - In the case of a university hospital, the hospital director
   - In the case of a health center, the health center director
   - In the case of a faculty of medicine at a university, the faculty dean
   - In the case of a corporate research laboratory, the laboratory director

3. In cases where research and the receipt of specimens and/or information are conducted within the same
corporation or administrative organ, the authority or affairs may be delegated by designating a person with overarching responsibility for each operation.

(3) In determining whether or not to approve a research protocol or alteration thereof, the chief executive of the research implementing entity shall always seek the opinions of the ethical review committee and respect those opinions. In this case, the chief executive shall not approve the conduct of any research for which the ethical review committee has submitted an opinion expressing disagreement.

(4) When conducting collaborative research within Japan, the chief executive of the research implementing entity shall obtain authorization for the research protocol from the ethical review committee, after first presenting such information as the status of authorization for the research protocol at the other collaborative research implementing entity, the status of informed consent and the status of anonymization.

(5) The chief executive of a research implementing entity may submit a matter to a single ethical review committee for deliberation to make a comprehensive review on research protocol for research to be conducted collaboratively with other research implementing entities.

(6) The chief executive of a research implementing entity shall keep track of the progress of human genome/gene analysis research by, for instance, receiving research progress reports from principal investigators on a regular basis, at least annually, and having on-site investigations conducted by outside experts on a regular basis, at least annually, and shall order the research be altered or discontinued based on the ethical review committee expressing an opinion of alteration or discontinuation, or if necessary for any reason.

5. Obligations of Principal Investigators

(1) A principal investigator shall, prior to conducting human genome/gene analysis research, prepare a research protocol, and seek approval from the chief executive of the research implementing entity. The same shall apply when the principal investigator intends to change the research protocol.

<Detailed regulations concerning cases when changing a research protocol>
Where a research protocol, including research objectives, has been changed after obtaining the informed
consent, section 14 of Part V shall apply to any specimens and/or information received before the change for the purpose of using in the said research.

(2) In preparing a research protocol, the principal investigator shall give careful consideration to such factors as the necessity of the research and a research method to prevent disadvantage to donors, etc., in view of the various impacts that donors, etc. could be expected to experience as a result of the proposed human genome/gene analysis research.

<Detailed regulations concerning cases when donors have an illness involving a mental disorder, intellectual disability or severe physical disability>

When a donor has a single-gene disorder or the like, for which a treatment or prevention method has not been established and which involves a mental disorder, intellectual disability or severe physical disability, the principal investigator shall take particular caution in examining such factors as the necessity of the research, medical/psychological impacts on the donor, and the propriety of the research method proposed, and the ethical review committee shall take particular caution in reviewing such factors.

(3) A principal investigator (excluding principal investigators of organizations collecting and providing specimens and/or information) shall prepare a research protocol in full consideration of the characteristics of human genome/gene analysis research. In particular, the principal investigator shall clearly describe such matters as the process and method of obtaining informed consent, the method of personal information protection, the principles concerning disclosure of genetic information, the method of preservation and use of specimens and/or information, the possibility of their use in other human genome/gene analysis research in the future, the provision of specimens and/or information to other research implementing entities, and the principles of genetic counseling.

<Detailed regulations concerning matters to be stated in research protocols>

The following items shall, in general, be stated in a research protocol, but adjustments may be made according to the details of the research:

- Donor selection policy (specific selection method which shows that selections are made in a reasonable manner; when a donor has a disease, a drug response abnormality or the like, the means to inform the donor of the disease name or an equivalent description of the condition)

- The significance, objectives, method and period of research, the expected results and risks, and the methods for protecting personal information and the like (including the method of anonymization, a statement to the effect that anonymously processed information or unidentifiably-processed personal information is to be created, if such is the case, and the handling of any unanonymized information)

- The types and quantities of specimens and/or information

- Site-specific information for the research (including the name of the research implementing entity and the names of the investigators, etc.; if collaborative research is to be conducted, also include a statement to this effect, as well as the names of all collaborative research implementing entities and the names of investigators, etc. at the collaborative research implementing entities; in addition, if donations of specimens and/or information are to be received from an organization collecting and providing specimens and/or information, also include the name of that organization and the person responsible)

- The procedures and method for obtaining informed consent

- The explanatory document and letters of agreement for obtaining informed consent
• Where obtaining the informed consent of donors is difficult, the importance of the research, the reasons why the research cannot be realized without the donation of specimens and/or information from donors, and the approach to selecting legally acceptable representatives, etc.
• The approach regarding the disclosure of genetic information (including, where necessary, the methods for receiving requests for disclosure)
• Where using existing specimens and/or information, whether or not consent has been obtained, the details thereof, the timing of provision, and the conformity with these Guidelines
• Where receiving donation of a specimen and/or information from an external institution, the details of the informed consent pertaining to that specimen and/or information
• Where providing specimens and/or information or entrusting part of the research to an external institution, such matters as the method of anonymization (including details of the contracts concerned)
• The method of preserving specimens and/or information and the necessity for this (a statement to the effect that the specimens and/or information will be used in other research, if such is the case)
• The method for controlling the security of genetic information
• A statement to the effect that specimens and/or information will be provided to other research implementing entities and used in other research, if such is the case
• The method for disposing of specimens and/or information
• The necessity of genetic counseling and the related system
• The method of raising research funds, potential conflicts of interest, and any relationships between investigators, etc. and relevant organizations

(4) The principal investigator of an organization collecting and providing specimens and/or information shall prepare a research protocol for the collection and provision of specimens and/or information in full consideration of the characteristics of human genome/gene analysis research. In particular, the principal investigator of the organization collecting and providing specimens and/or information shall clearly describe the method for confirming the details of informed consent, the details of personal information protection, and the method for preserving and controlling the quality of specimens and/or information.

<Detailed regulations concerning matters to be stated in research protocols for the collection and provision of specimens and/or information>
The following items shall, in general, be stated in a research protocol for the collection and provision of specimens and/or information, but adjustments may be made according to the details of the collection and provision of specimens and/or information:
• The significance, objectives, method and period of collecting and providing specimens and/or information, the methods for protecting personal information and the like (including the method of anonymization, a statement to the effect that anonymously processed information or unidentifiably-processed personal information is to be created, if such is the case, and the handling of any unanonymized information)
• The types of specimens and/or information being collected and provided
• Site-specific information for the research (including the name of the organization collecting and providing specimens and/or information, the person responsible for the collection and provision of specimens and/or information, and the name of the institution receiving donations of specimens and/or information; if
research is to be conducted collaboratively, also include a statement to this effect, as well as the names of all collaborative research implementing entities and the names of investigators, etc. at the collaborative research implementing entities)

- The method for confirming the details of the informed consent pertaining to specimens and/or information
- The method for confirming conformity with these Guidelines by the institution receiving donations of specimens and/or information and by the institutions to which specimens and/or information are provided
- Where specimens and/or information are provided to other research implementing entities, the method of anonymization
- The method for preserving and controlling the quality of specimens and/or information
- The method for controlling the security of genetic information
- The handling of specimens and/or information after completion of the program
- The method of raising research funds, potential conflicts of interest, and any relationships between investigators, etc. and relevant organizations

(5) A principal investigator shall supervise researchers in charge to ensure that they conduct human genome/gene analysis research properly, such as by having all researchers in charge observe matters included in an approved research protocol.

(6) A principal investigator shall, with regard to the progress of human genome/gene analysis research, report in writing to the chief executive of the research implementing entity on a regular basis, at least annually.

<Detailed regulations concerning the reported items>

A principal investigator shall, in general, include the following items in their regular reports on research progress submitted to the chief executive of the research implementing entity, but may make adjustments according to the details of the research:

- The method of retaining specimens and/or information
- The provision of specimens and/or information to external institutions
- The quantity of specimens and/or information on which human genome/gene analysis research was conducted
- The research results and the progress of research
- Whether or not any problems arose

(7) When conducting research on a group of people who have certain characteristics, such as a group of local residents (hereinafter referred to as “local residents, etc.”), where that research may reveal the genetic characteristics of the local residents, etc., the principal investigator shall explain the details and significance of the research, such as by holding a briefing for the local residents, etc. prior to the research, and shall endeavor to gain the understanding of the local residents, etc. for the research. In addition, during the research, the principal investigator shall endeavor to maintain dialogue with the local residents, etc., such as by providing information on the research.

(8) A principal investigator shall, in principle, conduct human genome/gene analysis research using anonymized specimens and/or information.

However, in cases where the donor or legally acceptable representative, etc. agrees, and where it is permitted in a research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity, the principal investigator may elect to not anonymize specimens and/or
information.

(9) A principal investigator shall not, in principle, provide unanonymized specimens and/or information to external institutions.

However, in cases where the donor or legally acceptable representative, etc. agrees to providing unanonymized specimens and/or information to an external institution, and where it is permitted in a research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity, the principal investigator may provide unanonymized specimens and/or information to the external institution.

(10) When entrusting part of the business of human genome/gene analysis research, the principal investigator shall first obtain the authorization of the ethical review committee and the approval of the chief executive of the research implementing entity, and shall indicate this to the entrustee in writing.

(11) In cases where part of the business of human genome/gene analysis research has been entrusted, when providing specimens and/or information to the entrustee, the principal investigator shall, in principle, anonymize the specimens and/or information.

However, in cases where the donor or legally acceptable representative, etc. agrees, and where it is permitted in a research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity, the principal investigator may provide unanonymized specimens and/or information.

(12) A principal investigator shall, both on a regular basis and in response to any requests from donors, etc., explain or publicly announce the progress and results of the human genome/gene analysis research.

However, this shall not apply to any parts necessary for guaranteeing the human rights of donors, etc. or protecting intellectual property rights.

6. Collaborative Research with Overseas Institutions

(1) In cases where a Japanese research implementing entity conducts collaborative research with an overseas research implementing entity, it shall conduct the research paying careful attention that human dignity and human rights are also respected when specimens and/or information are donated and during human genome/gene analysis research in the country where the collaborative research is conducted.

(2) In cases where a research implementing entity in Japan conducts collaborative research with an overseas research implementing entity, it shall, in principle, conduct the research in accordance with these Guidelines while also observing the laws, regulations, guidelines and so forth stipulated in the country where the collaborative research is conducted.

However, in the following cases, the research implementing entity may accept donations of specimens and/or information and handle specimens and/or information in the other country by observing the standards set forth in the laws, regulations, guidelines and so forth stipulated in the other country:

(a) When these Guidelines are more rigorous than the standards in the other country, and when both of the following conditions are met:

(i) Application of these Guidelines is difficult in the other country

(ii) With the authorization of the ethical review committee of the Japanese research implementing entity, the chief executive of the said entity has determined it appropriate to properly action the matters
specified in the detailed regulations

(b) When the standards in the other country are more rigorous than these Guidelines

<Detailed regulations when conducting collaborative research with overseas research implementing entities>

1. The matters prescribed in paragraph 6(2)(a)(ii) of Part II shall be as follows:
   (1) That informed consent is obtained
   (2) That appropriate measures are taken for the protection of personal information of donors
   (3) Regarding the scientific and ethical propriety of research protocols, that authorization is given by the other country, or authorization is given by an ethical review committee or equivalent organization within the entity in the other country based on the laws, regulations, guidelines and so forth, and approval is given by the chief executive of the research implementing entity in the other country

2. In the case set forth in paragraph 6(2)(b) of Part II, research shall be conducted in line with the standards in the other country.

PART III: BASIC STANCE TOWARD DONORS

7. Informed Consent, etc.

   (1) A principal investigator (excluding those who conduct research by receiving specimens and/or information from an external institution or from other divisions within the research implementing entity, and those who carry out the collection and provision of specimens and/or information; the same shall apply hereinafter in section 7 of Part III) shall not select persons to receive requests for the donation of specimens and/or information in an unreasonable, improper or unfair manner.

   (2) Where a person receiving a request for the donation of a specimen and/or information has or may have a disease or drug response abnormality, that person shall have been informed of the disease name or an equivalent description of the condition.

   (3) A principal investigator shall receive the donation of a specimen and/or information after first giving to the donor adequate explanation of such matters as the significance, objectives and method of the research, the expected results, any disadvantage that the donor might incur, the policy regarding disclosure of genetic information, the methods of preserving and using the specimen and/or information, and the possibility of using the specimen and/or information in other human genome/gene analysis research in the future and the procedures in such cases, and upon obtaining written consent made on the basis of free will (informed consent).

   There shall, however, be no requirement to obtain informed consent in cases where personal information or specimens and/or information need to be received urgently for the protection of the life or body of an individual.

   (4) A principal investigator shall not use deception or other wrongful means when obtaining informed consent. The principal investigator shall also give consideration when receiving the donation of specimens and/or information so as not to make the donor feel anxious.

   <Detailed regulations concerning matters to be considered when obtaining informed consent>

   The matters to be considered when obtaining informed consent include preventing unnecessary contact with donor information.

   (5) In obtaining informed consent, the principal investigator shall not harm the life, body, property or other rights
or interests of the donor or a third party by notifying the donor or legally acceptable representative, etc. of the purpose of using the specimens and/or information or by publicly announcing it.

(6) Where a principal investigator is unable to conduct the work necessary for obtaining informed consent, he/she may have all or part of that work performed, under his/her guidance and supervision, by an investigator, etc. at the institution receiving specimens and/or information who fully understands such factors as the details and significance of the research.

(7) By entering into a contract with a person other than an investigator, etc. affiliated with the entity (hereinafter referred to as an “aide”), which clarifies the scope and responsibilities of work, a principal investigator may have the aide conduct explanations necessary for obtaining informed consent, and may have the aide conduct part of the work necessary for obtaining informed consent.

   In such cases, the principal investigator shall include a description to this effect in the research protocol, and, where necessary, shall secure training opportunities for the aide.

<Detailed regulations concerning aides for informed consent>
1. When having informed consent obtained by someone other than persons affiliated with the institution receiving specimens and/or information, the principal investigator of the institution receiving specimens and/or information shall include in the research protocol that aides are designated and, where necessary, statements about research methods and so forth, and the said research protocol shall be authorized by the ethical review committee and approved by the chief executive of the entity receiving specimens and/or information.

2. Where an aide is made to conduct certain work that includes obtaining consent from the donor of a specimen and/or information or his/her legally acceptable representative, etc., the aide shall be a person who is prohibited by law or contract from divulging any confidential information obtained in the course of his/her duties.

(8) Where obtaining the informed consent of a donor is difficult, the principal investigator may obtain informed consent from a legally acceptable representative, etc. of the donor, but only when the importance of the proposed research is high, and when the ethical review committee has acknowledged and the chief executive of the research implementing entity has approved that the research cannot be realized without the donation of a specimen and/or information from that donor.

<Detailed regulations 1: Detailed regulations concerning the handling of cases when informed consent is obtained from a legally acceptable representative, etc.>
Cases where obtaining the informed consent of a donor is difficult but can be achieved by means of the informed consent of a legally acceptable representative, etc., and the handling of such cases shall be as follows. In any case, the principal investigator shall include in the research protocol: the importance of the research, the reasons why the research cannot be realized without the donation of specimens and/or information from donors and the approach to selecting legally acceptable representatives, etc., and the said research protocol shall be authorized by the ethical review committee and approved by the chief executive of the research implementing entity:

• When it is judged objectively that the donor is not capable of giving effective informed consent for a reason such as dementia

• When the donor is a minor. In this case, however, a principal investigator shall still give adequate
explanation to the donor in plain language and shall endeavor to gain their understanding (informed assent).

When the donor is a minor aged 16 year or older, the principal investigator shall obtain informed consent from both the donor and the legally acceptable representative

• When the donor is a deceased person, and there is no contradiction to their explicit wishes made before their death

<Detailed regulations 2: Detailed regulations concerning the basic principles of selecting legally acceptable representatives>

A principal investigator must state their approach to selecting legally acceptable representatives in research protocols. This shall be on the basis that, in general, people are selected as legally acceptable representatives from among those listed below, who are regarded as being able to represent the presumed intentions and interests of the donor, taking into account such factors as the donor’s family composition and the situation in which they are placed:

1. Voluntary guardians, persons who have parental authority, or any guardians or curators if appointed
2. The spouse, adult children, parents, adult siblings or grandchildren, or grandparents of the donor, relatives living with the donor, or other persons considered to be equivalent to these close relatives

<Detailed regulations 3: Detailed regulations concerning the basic principles of selecting surviving family members>

A principal investigator must state their approach to selecting surviving family members in research protocols. This shall be on the basis that, in general, people are selected as surviving family members from among those listed below, who are regarded as being able to represent the presumed intentions of the donor before their death, taking into account such factors as the deceased donor’s family composition, the situation in which they were placed and the deceased donor’s customs:

• The spouse, adult children, parents, adult siblings or grandchildren, or grandparents of the deceased donor, relatives who were living with the deceased donor, or other persons considered to be equivalent to these close relatives

(9) A donor or legally acceptable representative, etc. may revoke, in writing, their informed consent at any time without suffering any disadvantage.

(10) Where a donor or legally acceptable representative, etc. has revoked their informed consent, the principal investigator shall, in principle, take appropriate measures with respect to the specimens and/or information relating to the said donor to prevent specific individuals from being identified and dispose of these specimens and/or information, and shall provide notification of this, in writing, to the donor or legally acceptable representative, etc. The principal investigator shall also comply accordingly if the donor or legally acceptable representative, etc. requests some kind of measure other than disposal, unless there are exceptional grounds.

However, when any of the following conditions are met, the principal investigator may elect not to dispose of the specimens and/or information:

(a) When the specimens and/or information concerned have been anonymized (limited to specimens and/or information that cannot identify specific individuals, and for which a decoding index has not been created)

(b) When not disposing of the specimens and/or information has been authorized by the ethical review committee and approved by the chief executive of the research implementing entity, due to such
circumstances that the risk of personal information being revealed from not disposing of the specimens and/or information is very low and that the work involved in disposing of them is very excessive

<Detailed regulations concerning the handling of specimens and/or information relating to donors who have revoked their informed consent>

Where it is difficult to determine the scope, etc. of specimens and/or information to be disposed of, the principal investigator shall report to the chief executive of the research implementing entity.

In such cases, the chief executive of the research implementing entity shall seek the opinions of the ethical review committee with regard to the scope, etc. of specimens and/or information to be disposed of, including consideration of the following matters in particular, and based on those opinions, shall make a decision on the scope of specimens and/or information to be disposed of:
- The impact on the donor and the legally acceptable representative, etc.
- Details of the explanation on the revocation of informed consent, given at the time of the informed consent
- The impact on the proper execution of research work

(11) The principal investigator of an institution receiving specimens and/or information shall, when obtaining informed consent from a donor or legally acceptable representative, etc., give explanations to the donor or legally acceptable representative, etc. by issuing a written document describing the necessary matters in order to gain his/her full understanding.

<Detailed regulations concerning the content of explanatory documents>

The matters to be included in explanatory documents for donors and legally acceptable representatives, etc. shall, in general, be as follows, but adjustments may be made according to the details of the research:
- That the donation of specimens and/or information is voluntary, and that any person who has received a request for donation will not be treated in a disadvantageous manner as a result of not agreeing to donate
- That a donor or legally acceptable representative, etc. may revoke, in writing, the informed consent they gave, at any time without suffering any disadvantage (including, where necessary, the methods for receiving requests for revocation)
- The reasons for selection as a donor
- The name and position of the principal investigator
- The significance, objectives and method, and period of research
- A statement to the effect that specimens and/or information may be used in future human genome/gene analysis research not specified at the time of receiving the donation of specimens and/or information, if such is the case (that the procedures prescribed in section 14 of Part V on the use of existing specimens and/or information at research implementing entities will be followed when using the specimens and/or information for other human genome/gene analysis research within the said entity)
- A statement to the effect that specimens and/or information may be provided to other research implementing entities and used in future human genome/gene analysis research not specified at the time of receiving the specimens and/or information from the donor, if such is the case (that the procedures prescribed in section 15 of Part V on the use of existing specimens and/or information from external institutions will be followed when receiving the donation of the specimens and/or information and using them for other human genome/gene analysis research)
- Where personal information is used jointly with other institutions in collaborative research, the matters
listed in paragraphs 7(14) (a) through (d) of Part III

- The predicted research results and any predicted risks and/or disadvantages to a donor, etc. (including any disadvantages in social life, such as social discrimination)
- That a donor or legally acceptable representative, etc. may, upon request, obtain or inspect documents on the research protocol and research method to the extent that doing so does not impede the protection of personal information of other donors, etc. or the securing of research originality
- The specific method of anonymization for specimens and/or information; a statement to the effect that anonymously processed information or unidentifiably-processed personal information is to be created, if such is the case; where anonymization is not possible, a statement to this effect and the reasons for this
- A statement to the effect that specimens and/or information may be provided to external institutions or that part of the research may be entrusted, if such is the case, and the handling, etc. of those specimens and/or information
- Matters regarding the disclosure of genetic information (including the reasons for non-disclosure, if such is the case, and that genetic information may not be disclosed if the donor or legally acceptable representative, etc. has agreed that all or part of the genetic information not be disclosed)
- Matters regarding the disclosure of personal information (including where and how requests for disclosure are received, the method for confirming that a person is a donor or legally acceptable representative, etc., and if charges are incurred for disclosure, a description to this effect)
- A statement to the effect that research outcomes might generate patent rights or other intellectual property rights in the future, if such is the case, and the names of the organizations where it is expected such rights would belong
- The methods of preserving and using specimens and/or information
- The method of disposing specimens and/or information
- Information related to the use of genetic counseling (for instance, the necessity of the research and that genetic counseling is available in the case of single-gene disorders or the like)
- The method of raising research funds, potential conflicts of interest, and any relationships between investigators, etc. and relevant organizations
- That the donation of specimens and/or information is without compensation
- Information regarding the address and other details of contact points for inquiries (for instance, the correction of personal information and the revocation of consent) and complaints, etc.
- Other necessary matters

(12) Prior to conducting human genome/gene analysis research, when a principal investigator obtains informed consent from a donor or legally acceptable representative, etc. with the expectation that specimens and/or information will be used in human genome/gene analysis research or related medical research, the principal investigator shall clearly state the specific research objectives expected at that point in time, and shall explain to and gain the understanding of the donor or legally acceptable representative, etc. regarding how personal information will be controlled and protected, including the possibility of anonymization.

(13) With regard to the informed consent forms obtained from donors or legally acceptable representatives, etc., the chief executive of the entity receiving specimens and/or information shall have them administered by the principal investigator, privacy officer or other such person at the institution receiving specimens and/or
information who is capable of strict management.

(14) In the provisions set forth in sections 11, 14 or 15 of Part V, the matters to be notified to donors, etc. or to be made public shall include the items below:

(a) The purpose and method of the utilization of specimens and/or information (including the method in cases where the specimens and/or information are provided to other entities)
(b) The categories of specimens and/or information utilized or provided
(c) The scope of utilizing persons
(d) The name of the person responsible for managing specimens and/or information
(e) The fact that, at the request of a donor or his/her legally acceptable representative, etc., the utilization of specimens and/or information identifying the donor or the provision of such specimens and/or information to other research implementing entities will be discontinued
(f) The method for receiving requests made by donors or legally acceptable representatives, etc. as set forth in (e)

8. Disclosure of Genetic Information

(1) With regard to human genome/gene analysis research through which the genetic information of individual donors is revealed, when a donor has requested disclosure of his/her own genetic information, the principal investigator shall, in principle, disclose the requested information.

However, when providing genetic information is likely to either harm the life, body, property or other rights or interests of the donor or a third party, or seriously impede the research implementing entity in properly executing its research work, and when the informed consent of the donor regarding nondisclosure has been received, the principal investigator may withhold all or part of the genetic information from disclosure.

When the genetic information is not disclosed, the principal investigator shall explain the reasons for nondisclosure to the donor.

<Detailed regulations concerning the disclosure of genetic information>

1. In cases where a donor has requested disclosure of his/her own genetic information, the principal investigator shall report to the chief executive of the research implementing entity that all or part of the genetic information has been disclosed, or that genetic information will not be disclosed and the reason for this, depending on the case.

2. Specific cases where all or part of the genetic information may be withheld from disclosure because of the likelihood that the life, body, property or other rights or interests of the donor or a third party could be harmed, or that the research implementing entity could be seriously impeded in properly executing its research work, shall be as follows, but the applicability in each case requires objective and careful judgment on a specific case-by-case basis:

- Cases where the genetic information is not accurate or certain enough to evaluate the state of the person’s health, and where disclosing that genetic information is likely to place a psychological burden or lead to misunderstanding for the donor and/or blood relatives
- Cases where some of the genetic information is not accurate or certain enough, and disclosing all of the genetic information is likely to seriously impede the research implementing entity in executing its research
3. Given the possibility that it may not necessarily be appropriate to provide donors with an explanation, such as possible instances of psychological burden on a donor resulting from notification of the reason for nondisclosure, the principal investigator shall respond after careful consideration according to circumstances.

4. When a donor, who is a minor, has requested disclosure of his/her own genetic information, the principal investigator may disclose the information to the minor upon adequate consideration of potential psychological impacts etc. of disclosure. Where, however, the minor is under the age of 16 years, the principal investigator shall check the intention of the donor’s legally acceptable representative and respect that intention.

The principal investigator shall also report to the chief executive of the research implementing entity when, as a result of disclosing the minor’s genetic information, the donor might injure himself/herself or there is concern about discrimination against the donor, denial of fostering or negative impacts on treatments. The chief executive of the research implementing entity shall, prior to disclosure, seek the opinions of the ethical review committee where necessary and also seek dialogue with the minor and his/her legally acceptable representative, before making a decision regarding the propriety of disclosure and the details and method thereof.

5. Where the principal investigator has decided not to disclose the genetic information, the principal investigator shall notify the donor who requested the disclosure of that effect in writing.

6. Genetic information shall be disclosed by the delivery of written documents or by the method agreed to by the person requesting disclosure.

(2) A principal investigator shall establish a policy for disclosing to donors any genetic information obtained from proposed human genome/gene analysis research, based on the characteristics of the research and on the genetic information obtained therefrom, and when obtaining informed consent from a donor or legally acceptable representative, etc., the principal investigator shall explain the policy and gain his/her understanding. When determining that policy, the principal investigator shall give consideration to the following matters:

(a) Whether the genetic information is accurate and certain enough to evaluate the state of the donor’s health
(b) Whether the genetic information will indicate material facts for the health of the donor
(c) Whether disclosure of that genetic information is likely to seriously impede the proper execution of research work

<Detailed regulations concerning the policy on disclosing incidental findings>
A principal investigator shall also give consideration to the policy on disclosing genetic information in cases where incidental findings are discovered during the course of human genome/gene analysis research, which were not initially anticipated and which have a serious impact on the life of the donor and his/her blood relatives, and when obtaining informed consent from a donor or legally acceptable representative, etc., shall explain that policy and endeavor to gain his/her understanding.

(3) When disclosing genetic information, the principal investigator shall also endeavor to explain in so far as it is possible whether the genetic information is accurate and certain enough to evaluate the state of the donor’s health, and shall endeavor to avoid any misunderstanding for the donor and/or blood relatives.

(4) With regard to human genome/gene analysis research through which the genetic information of individual
donors is revealed, when a donor has not requested disclosure of his/her own genetic information, the principal investigator shall not disclose the information.

**<Detailed regulations concerning the nondisclosure of genetic information>**

A principal investigator shall, even if a donor has not requested disclosure of his/her own genetic information, report to the chief executive of the research implementing entity when it is discovered that the genetic information has a serious impact on the life of the donor and his/her blood relatives and, at the same time, there is an effective treatment protocol.

The chief executive of the research implementing entity shall seek the opinions of the ethical review committee regarding the propriety of disclosure and the details and method thereof, including consideration of, in particular, the following matters, and shall, based on those opinions, consult with the principal investigator, the medical doctor in charge of the donor’s medical care and the director of the medical institution to which the doctor belongs. The principal investigator shall, based on the results of the consultation, check the intention of the donor after giving him/her adequate explanations and, if the donor still does not want the genetic information to be disclosed, shall not disclose it:

- The impact on the life of the donor and his/her blood relatives
- Whether or not there is an effective treatment protocol, and the donor’s state of health
- The possibility that blood relatives are afflicted with the same disorder etc.
- Details of the explanation on the disclosure of research results, given at the time of the informed consent

**(5)** A principal investigator shall not, in the absence of consent from the donor, in principle, disclose the donor’s genetic information to any person other than the donor.

**<Detailed regulations concerning disclosure to persons other than the donor>**

1. Where a legally acceptable representative (excluding persons in 2. and 3.) requests disclosure of the donor’s genetic information, the chief executive of the research implementing entity shall, after presenting to the ethical review committee the reasons for or the necessity of the disclosure request by the legally acceptable representative, determine a response based on the opinions of the ethical review committee. In making this determination, the chief executive of the research implementing entity shall confirm that either of the following conditions has been met:

   1) That obtaining the consent of the donor is difficult, but is necessary for the protection of the life, body or property of an individual
   2) That obtaining the consent of the donor is difficult, but is particularly necessary for the improvement of public health

2. Where a surviving family member (blood relative) requests disclosure of the donor’s genetic information, the chief executive of the research implementing entity shall, after presenting to the ethical review committee the reasons for or the necessity of the disclosure request by the surviving family member (blood relative), determine a response based on the opinions of the ethical review committee.

3. In cases where a donor is a minor and his/her legally acceptable representative has requested disclosure of the minor’s genetic information, the principal investigator may disclose the information to the legally acceptable representative. Where, however, the minor is aged 16 years or older, the principal investigator shall check the intention of the minor and respect that intention. The principal investigator shall also report to the chief executive of the research implementing entity when, as a result of disclosing the minor’s genetic
information, there is concern about discrimination against the donor, denial of fostering or negative impacts on treatments. The chief executive of the research implementing entity shall, prior to disclosure, seek the opinions of the ethical review committee where necessary regarding the propriety of disclosure and the details and method thereof, and shall seek dialogue with the minor and his/her legally acceptable representative.

4. Even if a donor has not requested disclosure of his/her own genetic information to blood relatives, when all of the following conditions are met, a principal investigator may convey to the donor’s blood relatives information derived from the donor’s genetic information regarding any drug responses or disorders having a genetic predisposition:

1) That it is discovered that the donor’s genetic information is highly likely to have a serious impact on the life of the donor’s blood relatives and, at the same time, there is an effective treatment protocol

2) That the chief executive of the research implementing entity, who has received a report set forth in 1) from a principal investigator, seeks the opinions of the ethical review committee regarding the propriety of disclosure and the details and method thereof, including consideration of, in particular, the following matters, and, based on those opinions, reaches a conclusion, upon consultation with the principal investigator, that necessary information should be provided to blood relatives:

   a) The possibility that blood relatives are afflicted with the same disorder etc.
   b) The impact on the life of the blood relatives
   c) Whether or not there is an effective treatment protocol, and the blood relatives’ state of health
   d) Details of the explanation on the disclosure of research results, given at the time of the informed consent

3) In view of the conclusion reached in 2), that the principal investigator seeks the understanding of the donor again, and endeavors to obtain consent regarding the provision of necessary information to the blood relatives

4) That the intention of the donor’s blood relatives to request that information be provided is checked after giving an adequate explanation

(6) A principal investigator shall, when planning to disclose genetic information regarding a single-gene disorder or the like (including multifactorial disorders in which the associated gene is definite), disclose the information in adequate consideration of the medical or psychological impacts while keeping in close contact with the medical doctor in charge of medical care, and shall also, if necessary, offer opportunities for genetic counseling.

<Note>
The significance of the genetic information being disclosed depends largely on the medical care, and it is necessary to have close contact with the medical doctor in charge of medical care, especially a doctor specializing in medical genetics. Therefore, the person who should disclose the information might be either the medical doctor in charge of medical care who would disclose it as a part of their medical care at the request of the principal investigator, or the principal investigator who would do so under the direction of the medical doctor.

9. Genetic Counseling
(1) The objective of genetic counseling in human genome/gene analysis research is to support or assist a donor and his/her family or blood relatives through dialogue so that they can make choices and take action for their future of their own free will, by providing them with accurate information, answering their questions appropriately, deepening their understanding of their hereditary disorder, etc., and responding to their anxieties or worries concerning human genome/gene analysis research, hereditary disorders and so forth.

(2) Genetic counseling shall be provided by and in cooperation with medical doctors, health care professionals and others who have an adequate knowledge of medical genetics and who are proficient in genetic counseling.

<Note>
Matters regarding the establishment of a genetic counseling system for reference to chief executives of entities receiving specimens and/or information and matters regarding the provision of opportunities for genetic counseling are prescribed in paragraph 9(3) of Part III, matters regarding the description of principles of genetic counseling in research protocols are prescribed in paragraph 5(3) of Part II, matters to be explained at the time of obtaining informed consent are prescribed in paragraph 7(11) of Part III, and matters regarding the provision of opportunities for genetic counseling at the time of disclosing genetic information are prescribed in paragraph 8(6) of Part III.

(3) When receiving donations of specimens and/or information from a donor, the chief executive of the entity receiving specimens and/or information shall, as required, give consideration so that the donors and his/her family or blood relatives will be able to receive genetic counseling, such as by establishing an appropriate genetic counseling system or explaining about genetic counseling and referring them to appropriate facilities. Particularly when a donor has a single-gene disorder or the like (including multifactorial disorders in which the associated gene is definite), the principal investigator of the institution receiving specimens and/or information shall, when obtaining informed consent, give explanations, including information related to the use of genetic counseling and, as required, offer opportunities for genetic counseling.

<Detailed regulations concerning referrals to genetic counseling facilities>
Where an institution receiving specimens and/or information does not have an internal genetic counseling system, the institution shall, if requested for such counseling, refer donors and their families or blood relatives to appropriate facilities for genetic counseling.

PART IV: ETHICAL REVIEW COMMITTEES

10. Responsibilities and Composition of Ethical Review Committees

(1) An ethical review committee shall, in accordance with these Guidelines, review the appropriateness of conducting a research protocol and other relevant matters, including both ethical and scientific viewpoints, and shall state its opinion in writing to the chief executive of the research implementing entity.

(2) With regard to research in progress, an ethical review committee may state to the chief executive of the research implementing entity its opinion on the alteration or discontinuation of the research protocol or on any other matters it deems necessary.

(3) Members of an ethical review committee shall not, in the absence of any justifiable reason, divulge information obtained in the course of their duties. This shall continue to apply after they resign their position.

(4) An ethical review committee shall be properly composed of and operated by members from various backgrounds so that it can perform reviews in a fair and impartial manner from an independent standpoint,
based on an interdisciplinary and pluralistic approach.

<Detailed regulations concerning the composition and quorum, etc. of ethical review committees>

1. The composition of an ethical review committee shall meet each of the following requirements in order that the duties of the committee, such as the review of research protocols, can be executed appropriately. Those members as defined in each of the groups of (i) to (iii) below cannot concurrently hold status for other groups. The same requirements shall apply to the quorum of the committee’s meetings.

   (i) The committee shall have a member who is expert in natural science, such as a medicine and medical care professional, etc.

   (ii) The committee shall have a member who is expert in humanities and social sciences, such as a professional in ethics and law, etc.

   (iii) The committee shall have a member who can provide opinions of the general public, including viewpoints of donors.

   (iv) The committee shall have at least two members who do not belong to the organization to which the organizer of the committee belongs.

   (v) The committee shall have both male and female members.

   (vi) The committee shall have five or more members.

2. Investigators, etc. engaged in the research which is subject to deliberation shall not be present when the deliberation and adoption of opinions are made at the committee’s meeting. When so requested by the ethical review committee, however, such investigators, etc. may attend the meeting to provide information on the said research.

3. The chief executive of the research implementing entity who submitted the matter for which the ethical review committee makes deliberation shall not be present when deliberation and adoption of opinions are made at the committee’s meeting. When it is necessary to do so in order to understand the details of deliberation made by the ethical review committee, however, the said chief executive may attend the meeting by obtaining the committee’s consent.

4. The ethical review committee may invite nonmembers with expertise in special areas for assistance depending on matters subject to review and content of such.

5. When reviewing the research protocol of which donors are those who need special considerations and presenting its opinions on such research, the ethical review committee shall, as necessary, seek opinions of experts who have discernment on such donors.

6. The ethical review committee shall endeavor to make adoption of its opinions unanimously.

<Detailed regulations concerning the operating regulations of ethical review committees>

Operating regulations shall be established with regard to the following matters:

- The method for selecting the chairperson
- The retention period for review records
- Matters related to public announcements
- The method for making resolutions when unanimity is difficult

(5) An ethical review committee may, according to its decision, establish a fast-track review process to be conducted either by members nominated in advance by the chairperson or by a subcommittee. The results of a fast-track review shall be reported to all members other than those who performed the review or, in case of
a subcommittee, to its umbrella organization, the ethical review committee.

<Detailed regulations concerning the fast-track review process>

1. Matters that may be committed to a review through the fast-track review process shall, in general, be as follows:
   - The review of minor alterations to a research protocol
   - In the case of collaborative research, the review of a research protocol in cases where another collaborative research implementing entity intends to conduct a research protocol that has already been authorized by the ethical review committee of the principal research implementing entity
   - The review of a research protocol that does not involve any risk to donors and legally acceptable representatives, etc. in excess of the minimum risk (meaning types of risk which are socially acceptable, and which do not exceed the limits of potential physical, psychological and social harm sustained in everyday life and in routine medical tests)

2. An ethical review committee member who has received a report on the results of a fast-track review may, upon giving reasons, ask the chairperson for a separate review by the ethical review committee with regard to the said matter. In this case, the chairperson shall, provided that he/she acknowledges that there are reasonable grounds to do so, immediately hold an ethical review committee meeting and review the matter.

(6) When the chief executive of a research implementing entity submits a request for deliberation to an ethical review committee belonging to a separate entity, the said ethical review committee shall have a full understanding of the site-specific information for the research, in order to make reviews and present its opinions.

(7) With respect to research carried out by another entity, when an ethical review committee is requested by the chief executive of the said entity to continue to make reviews after the committee has made reviews on the same research, the said ethical review committee shall make reviews and present its opinions.

(8) An ethical review committee shall publicly announce the matters concerning its organization and the rules concerning its operation, and shall, in principle, also publicly announce the details of its proceedings.

<Detailed regulations 1: Detailed regulations concerning the public announcement of matters concerning organization>

The matters to be publicly announced concerning the organization of an ethical review committee shall be as follows:
   - The composition of the ethical review committee (including any subcommittees)
   - The names of the members, the organizations to which they are affiliated and their positions

<Detailed regulations 2: Detailed regulations concerning the public announcement of proceedings>

1. Proceedings of the ethical review committee must be publicly announced in a specific and clear manner.

2. Any parts of the proceedings which are likely to impede the protection of the human rights of donors, etc., the originality of research or intellectual property rights, or which are likely to impede the preservation of competitive position, may be kept undisclosed on the basis of a decision by the ethical review committee. In such cases, the ethical review committee must publicly announce the reasons for nondisclosure.

(9) The organizer of an ethical review committee shall endeavor to provide education and training to the committee members.
PART V: HANDLING, ETC. OF SPECIMENS AND/OR INFORMATION

11. Provision, etc. of Specimens and/or Information to Other Research Implementing Entities

(1) The chief executive of a research implementing entity shall, when providing specimens and/or information to another research implementing entity, notify in writing or by other means the details of the informed consent or the details of measures taken when providing the specimens and/or information pursuant to the provisions of paragraph 15(2). In addition, the chief executive of the research implementing entity shall prepare records about the provision of the specimens and/or information, and shall keep those records for a period until the day on which three years have elapsed from the date on which the specimens and/or information were provided.

(2) The chief executive of an entity receiving specimens and/or information shall, in principle, anonymize specimens and/or information (excluding existing specimens and/or information) when providing them to an external institution.

The chief executive of an entity receiving specimens and/or information shall also, in principle, anonymize specimens and/or information when providing them to a research division conducting human genome/gene analysis research within the entity (hereinafter referred to as a “research division within an entity receiving specimens and/or information”).

However, when both of the following conditions are met, the chief executive of the entity receiving specimens and/or information may provide a specimen and/or information without anonymizing them:

(a) The donor or legally acceptable representatives, etc. agrees to the specimen and/or information being provided to an external institution or to a research division within the entity receiving specimens and/or information without being anonymized.

(b) A research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity allows for the provision of unanonymized specimens and/or information to external institutions or to a research division within the entity receiving specimens and/or information.

<Note>

The provisions of paragraph 11(2) of Part V establish standards for anonymization when the chief executive of an entity receiving specimens and/or information provides specimens and/or information to an external institution or to a research division within the entity receiving specimens and/or information within the scope of a research protocol. Specimens and/or information shall not be provided beyond the scope of consent.

(3) A principal investigator receiving a donation of specimens and/or information from an external institution shall confirm the following matters in writing or by other means with that external institution. In addition, the principal investigator shall prepare records about the provision of the specimens and/or information, and shall keep those records for a period until the day on which five years have elapsed from the date on which the said research concludes:

(a) Details of the informed consent concerning the specimens and/or information, or details of the measures implemented when providing the specimens and/or information pursuant to the provisions of paragraph 15(2)

(b) Name and address of the external institution, and the name of its chief executive

(c) Details of the acquisition of the specimens and/or information by the external institution

(4) In cases where a specimen and/or information utilized in research are provided to a person located overseas
(including cases where all or part of the handling of the said specimen and/or information are entrusted to a person located overseas), the proper consent of the donor or legally acceptable representative, etc. shall be obtained for providing the specimen and/or information utilized in research to such a person, except where such a person is located in a country provided for in the Enforcement Rules for the Act on the Protection of Personal Information (Rule No. 3 of the Personal Information Protection Commission, Japan, 2016; hereinafter referred to as the “Personal Information Protection Act Enforcement Rules”), or where such a person has in place a system that conforms to the standards stipulated in the Personal Information Protection Act Enforcement Rules, or where the specimen and/or information are provided pursuant to the provisions of laws and regulations.

In addition, except in cases where a specimen and/or information are provided pursuant to the provisions of laws and regulations, records about the provision of the said specimen and/or information shall be kept, and shall be kept for a period until the day on which three years have elapsed from the date on which the specimen and/or information were provided.

However, in cases where obtaining proper consent is difficult and where either of the following (a) or (b) apply, the said specimen and/or information utilized in research may be provided to a person located overseas:

(a) Cases where the specimen and/or information fall under any of the following:

(i) That the specimen and/or information have been anonymized (limited to specimens and/or information that cannot identify specific individuals, and for which a decoding index has not been created)

(ii) That the information is anonymously processed information or unidentifiably-processed personal information

(iii) In cases where the specimen and/or information are used for academic research purposes or there are other exceptional grounds for providing the said specimen and/or information, and where the matters listed in paragraph 7(14) (a) through (d) of Part III have been notified to the donor, etc. or made public, that the specimen and/or information have been anonymized (limited to specimens and/or information which have been processed or managed so that it cannot be immediately distinguished whose it is)

(b) Cases that do not fall under (a), but where the specimen and/or information are used for academic research purposes or there are other exceptional grounds for providing them, and the ethical review committee has given authorization and the chief executive of the research implementing entity has given approval with respect to each of the following requirements being met:

(i) That the matters listed in paragraph 7(14) (a) through (f) of Part III regarding implementation of the relevant human genome/gene analysis research and provision of specimens and/or information have been notified to the donor, etc. or made public

(ii) That the donor or legally acceptable representative, etc. is, in principle, guaranteed the opportunity to reject the relevant human genome/gene analysis research being implemented and the specimen and/or information being provided

12. Handling of Anonymized Information

(1) The chief executive of a research implementing entity shall implement appropriate measures when handling anonymized information (limited to information that cannot identify specific individuals), such as thoroughly
familiarizing investigators, etc. with the importance of managing such information appropriately, managing
the information (including responses to accidents, etc.), clarifying responsibilities, and preventing the
handling of such information by persons other than investigators, etc.

<Detailed regulations concerning the handling of anonymized genetic information (limited to information
that cannot identify specific individuals)>

When handling anonymized genetic information (limited to information that cannot identify specific
individuals), the chief executive of a research implementing entity shall implement appropriate security
control measures to prevent any divulgence, loss or damage to the information handled and to otherwise
control the security of information. The security control measures to be implemented for the handling of
anonymized genetic information (limited to information that cannot identify specific individuals) shall, in
general, be as follows, but may be changed depending on such factors as the volume and quality of genetic
information handled. Also, the chief executive of a research implementing entity shall, when having
investigators, etc. handle anonymized genetic information (limited to information that cannot identify specific
individuals), implement appropriate measures in advance, such as presenting policies on the disclosure or
sharing of such information, depending on such factors as the volume and quality of anonymized genetic
information:

• Clarification of the responsibilities and authority with respect to the security control of genetic information
• Provision of procedures manuals, etc. stipulating security control measures for genetic information, and
  operation in accordance with those procedures manuals, etc.
• Courses of action for dealing with accidents, etc.
• Provision of education for investigators, etc. on the handling of genetic information
• Physical access control for buildings (rooms), prevention of theft, etc.
• Access controls to genetic information and to information systems that deal with such information,
  measures against unauthorized software, monitoring, etc.

(2) When entrusting all or part of the handling of anonymized information relating to the business of human
genome/gene analysis research (limited to information that cannot identify specific individuals), so that any
entrusted anonymized information (limited to information that cannot identify specific individuals) is handled
appropriately, the chief executive of the research implementing entity shall secure by means of contract any
matters to be observed by the entrusted person, and shall exercise necessary and appropriate supervision over
the entrusted person.

<Detailed regulations concerning the matters to be secured by means of contract when entrusting the handling of
anonymized information>

In terms of matters to be observed by an entrusted person, the matters to be secured by way of contract shall,
in general, be as follows, but other matters may be added according to the content of the entrusted work:

• Matters concerning the handling of anonymized information by the entrusted person
• Prohibition against using the information beyond the scope entrusted
• Prohibition against the provision of specimens and/or information to persons other than the entrusted
  person
• Duty of confidentiality for information obtained in the course of business
• Matters concerning the disposal of specimens and/or information, or their return, etc., following
termination of the contract

<Detailed regulations concerning the supervision of entrusted persons>

The term “necessary and appropriate supervision over the entrusted person” shall mean, for instance, explicitly prescribing the content of the security control measures stipulated by the entrustor in the entrustment contract and confirming whether such content is being observed.

13. Preservation and Disposal of Specimens and/or Information

(1) When preserving a specimen and/or information in a research implementing entity, the principal investigator shall observe matters agreed to by the donor or legally acceptable representative, etc. and shall comply with the method prescribed in the research protocol.

(2) When the retention period for a specimen and/or information prescribed in a research protocol expires, the principal investigator shall observe matters agreed to by the donor or legally acceptable representative, etc., and shall dispose of the specimen and/or information after taking appropriate measures to prevent specific individuals from being identified, except in cases where the principal investigator is preserving the specimen and/or information in accordance with a research protocol or the specimen is provided to another research implementing entity.

14. Use of Existing Specimens and/or Information at Research Implementing Entities

In cases where an existing specimen and/or information preserved within a research implementing entity is used for human genome/gene analysis research (excluding where the specimen and/or information are collected and provided), as a general rule, the principal investigator shall obtain consent from the donor or legally acceptable representative, etc. regarding use of the existing specimen and/or information, and shall keep a record on that consent. However, in cases where obtaining that consent is not possible, the principal investigator may use the existing specimen and/or information, but only if authorization of the ethical review committee and approval of the chief executive of the research implementing entity have been obtained for any of the cases corresponding to (a) through (d) below.

(a) Cases where the existing specimen and/or information fall under either of the following:
   (i) That the existing specimen and/or information have been anonymized (limited to specimens and/or information that cannot identify specific individuals, and for which a decoding index has not been created)
   (ii) That the information is anonymously processed information or unidentifiably-processed personal information

(b) Cases that do not fall under (a), but where the existing specimen and/or information have been anonymized (limited to that which cannot identify specific individuals), and matters listed in paragraph 7(14) (a) through (d) of Part III regarding implementation of the relevant human genome/gene analysis research have been notified to the donor, etc. or made public

(c) Cases that do not fall under (a) or (b), but where the consent of the donor or legally acceptable representative, etc. has only been given for research for which use of the existing specimen and/or information in the relevant human genome/gene analysis research was not made clear at the time of donation, and where the following requirements have been met:
(i) That the matters listed in paragraph 7(14) (a) through (d) of Part III regarding implementation of the relevant human genome/gene analysis research have been notified to the donor, etc. or made public

(ii) That the consent can be reasonably considered as having relevance corresponding to the objectives of the relevant human genome/gene analysis research in question

(d) Cases that do not fall under (a) through (c), but where the existing specimen and/or information satisfy all of the following requirements or is based on laws and regulations:

(i) That there is very little chance of the relevant human genome/gene analysis research causing risk or disadvantage to the donor, etc.

(ii) That the human genome/gene analysis research using the existing specimen and/or information is recognized as having high social importance

(iii) That implementing the relevant human genome/gene analysis research in another way is virtually impossible

(iv) That measures have been implemented to publicly announce the matters listed in paragraph 7(14) (a) through (f) of Part III regarding implementation of the relevant human genome/gene analysis research, and also to guarantee, in principle, the opportunity for the donor or legally acceptable representative, etc. to make inquiries and to reject use of the specimen and/or information in research

(v) That obtaining the consent of the donor or legally acceptable representative, etc. is difficult

15. Use of Existing Specimens and/or Information from External Institutions

(1) In cases where research is to be conducted using an existing specimen and/or information received from an external institution (excluding where the specimen and/or information are collected and provided), the principal investigator shall include in the research protocol details of the existing specimen and/or information being donated and the need for receiving the donation, and shall obtain authorization of the ethical review committee and approval of the chief executive of the research implementing entity.

In addition, where an existing specimen and/or information that can identify a specific individual is utilized (excluding cases where the principal investigator obtains informed consent), the principal investigator shall disclose to the public, the matters listed in paragraph 7(14) (a) through (f) of Part III, and shall, in principle, guarantee opportunities for the donor or legally acceptable representative, etc. to revoke his/her consent for the research to be conducted.

In cases where a donation has been received pursuant to the provisions of paragraph (2) as a consequence of falling under paragraph (2) (b), the principal investigator shall disclose to the public, the matters listed in paragraph 7(14) (a) through (d) of Part III regarding implementation of the relevant human genome/gene analysis research.

(2) In cases where an existing specimen and/or information are provided to another research implementing entity for use in human genome/gene analysis research, as a general rule, the individual providing the existing specimen and/or information shall, before providing the existing specimen and/or information, obtain consent from the donor or legally acceptable representative, etc. regarding provision of the specimen and/or information and its use in the said research, and shall keep a record on that consent. However, in cases where obtaining that consent is not possible, the existing specimen and/or information may be provided to the other research implementing entity, but only if any of the following cases apply:
(a) Cases where the existing specimen and/or information fall under either of the following:
   (i) That the existing specimen and/or information have been anonymized (limited to specimens and/or information that cannot identify specific individuals, and for which a decoding index has not been created)
   (ii) That the information is anonymously processed information or unidentifiably-processed personal information
(b) Cases that do not fall under (a), but where the existing specimen and/or information are used for academic research purposes or there are other exceptional grounds for providing them, where the existing specimen and/or information have been anonymized (limited to specimens and/or information which have been processed or managed so that it cannot be immediately distinguished whose it is), and where authorization of the ethical review committee and approval of the chief executive of the entity to which the committee belongs have been obtained for notifying to the donor, etc. or making public the matters listed in paragraph 7(14) (a) through (d) of Part III regarding implementation of the relevant human genome/gene analysis research and provision of existing specimens and/or information.
(c) Cases that do not fall under (a) or (b), but where the existing specimen and/or information are used for academic research purposes or there are other exceptional grounds for providing them, and the ethical review committee has given authorization and the chief executive of the research implementing entity has given approval with respect to each of the following requirements being met:
   (i) That the matters listed in paragraph 7(14) (a) through (f) of Part III regarding implementation of the relevant human genome/gene analysis research and provision specimens and/or information have been notified to the donor, etc. or made public
   (ii) That the donor or legally acceptable representative, etc. is, in principle, guaranteed the opportunity to reject the relevant human genome/gene analysis research being implemented and the specimen and/or information being provided

PART VI: PROTECTION OF PERSONAL INFORMATION

16. Personal Information to be Protected

(1) The term “personal information” shall mean information relating to a living individual which corresponds to any of the following:
   (a) those containing a name, date of birth, or other descriptions etc. (meaning any and all matters (excluding an individual identification code) stated, recorded or otherwise expressed using voice, movement or other methods in a document, drawing or electromagnetic record (meaning a record kept in an electromagnetic form (meaning an electronic, magnetic or other forms that cannot be recognized through the human senses; the same shall apply in paragraph (2) (b); hereinafter the same) whereby a specific individual can be identified (including those which can be readily collated with other information and thereby identify a specific individual)
   (b) those containing an individual identification code

(2) An “individual identification code” means those prescribed by the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No.507 of 2003) or by other Laws and ordinances which are any character, letter, number, symbol or other codes falling under any of each following item.
(a) those able to identify a specific individual that are a character, letter, number, symbol or other codes into which a bodily partial feature of the specific individual has been converted in order to be provided for use by computers

(b) those character, letter, number, symbol or other codes which are assigned in regard to the use of services provided to an individual or to the purchase of goods sold to an individual, or which are stated or electromagnetically recorded in a card or other document issued to an individual so as to be able to identify a specific user or purchaser, or recipient of issuance by having made the said codes differently assigned or, stated or recoded for the said user or purchaser, or recipient of issuance.

(3) “Special care-required personal information” means personal information comprising the person’s race, creed, social status, medical history, criminal record, fact of having suffered damage by a crime, or other descriptions etc. which need special considerations so as not to cause unfair discrimination, prejudice or other disadvantages to the person.

(4) Even if information handled in human genome/gene analysis research does not fall under personal information, any genetic information, medical information or other information that reflects the characteristics or constitution of an individual shall be handled appropriately in accordance with paragraph 12(1) and (2) of Part V in these Guidelines.

17. Security Control Measures

(1) The chief executive of a research implementing entity shall take systematic, human, physical and technological security control measures to prevent any divulgence, loss or damage of the personal information it handles and to otherwise control the security of personal information. Also, the chief executive of a research implementing entity shall, when having investigators, etc. handle personal information, exercise necessary and appropriate supervision over the investigators, etc. to ensure the security control of the personal information.

<Detailed regulations concerning security control measures>

The term “systematic, human, physical and technological security control measures” is a requirement for measures that are necessary and appropriate according to the nature of the information handled. In this regard, the chief executive of a research implementing entity shall take necessary and appropriate measures, taking into consideration the magnitude of the infringement of an individual’s rights and interests sustained in the event of any divulgence, loss or damage to personal information, and proportionate to risks such as those attributable to the nature of research, the handling of personal information and the nature of the medium on which personal information is recorded.

1. Systematic security control measures

Systematic security control measures include the following matters:

(i) Establishment of an organizational structure

(ii) Provision of rules concerning the handling of personal information, and operation in accordance with those rules

(iii) Establishment of means for confirming how personal information is being handled
(iv) Establishment of systems for responding to information leaks and other incidents
(v) Understanding how information is being handled, and revision of security control measures

2. Human security control measures

Human security control measures include the following matters:
(i) Education for investigators, etc.

3. Physical security control measures

Physical security control measures include the following matters:
(i) Control of areas handling personal information
(ii) Prevention of the theft of equipment and electronic media, etc.
(iii) Prevention of theft when electronic media, etc. are carried about
(iv) Deletion of personal information, and disposal of equipment and electronic media, etc.

4. Technological security control measures

Technological security control measures include the following matters:
(i) Access controls
(ii) Identification and authentication of persons accessing information
(iii) Prevention of unauthorized access, etc. from outside the entity
(iv) Prevention of leaks, etc. associated with the use of information systems

(2) In consideration of the human dignity of a deceased person, the feelings of their bereaved family members, and the fact that genetic information is common to their blood relatives, the chief executive of a research implementing entity shall also implement systematic, human, physical and technological security control measures for the security control of the personal information of deceased persons in the same way as information about living individual.

18. Handling of Personal Information

(1) When entrusting all or part of the handling of personal information relating to the business of human genome/gene analysis research, so that any entrusted personal information is controlled securely, the chief executive of the research implementing entity shall secure by means of contract any matters to be observed by the entrusted person, and shall exercise necessary and appropriate supervision over the entrusted person.

<Detailed regulations concerning the matters to be secured by means of contract when entrusting the handling of personal information>

In terms of matters to be observed by an entrusted person, the matters to be secured by way of contract shall, in general, be as follows, but may be added to according to the content of the entrusted work:
• Matters concerning the handling of personal information by the entrusted person
• Prohibition against using the information beyond the scope entrusted
• Prohibition against the provision of specimens and/or information to persons other than the entrusted person
• Duty of confidentiality for information obtained in the course of business
• Matters concerning the disposal of specimens and/or information, or their return, etc., following termination of the contract

<Detailed regulations concerning the supervision of entrusted persons>
The term “necessary and appropriate supervision over the entrusted person” shall mean the exercising of supervision so that measures equivalent to the security control measures to be taken by a research implementing entity pursuant to section 17 of Part VI are implemented, for instance, explicitly prescribing the content of the security control measures stipulated by the entrustor in the entrustment contract and confirming whether such content is being observed.

(2) When handling personal information in human genome/gene analysis research, the chief executive of the research implementing entity shall assign a privacy officer for the purpose of protecting the personal information.

Upon clearly defining the responsibilities, authority and chain of command, the chief executive of the research implementing entity may, as required, also designate a person who performs a portion of the work of the privacy officer (hereinafter referred to as a “privacy sub officer”), or assistants who conduct actual operations under the supervision of a privacy officer or privacy sub officer.

<Detailed regulations concerning the requirements for privacy officers>

Privacy officers and privacy sub officers shall, in principle, be persons (medical doctors, pharmacists, etc.) who are prohibited from divulging any confidential information obtained in the course of their duties under Article 134 of the Penal Code (Act No. 45 of 1907), Article 100 of the National Public Service Act (Act No. 120 of 1947) or any other law.

A privacy officer or privacy sub officer may not simultaneously hold the position of a principal investigator or researcher in charge who conducts human genome/gene analysis research (excluding the provision, or collection and provision, of specimens and/or information) using specimens and/or information provided by that privacy officer or privacy sub officer.

(3) The chief executive of a research implementing entity shall deliver to its privacy officers a copy of approved research protocols, a copy of regular reports regarding research progress and a copy of the results of on-site investigations conducted by outside experts.

(4) When handling personal information, the chief executive of a research implementing entity shall specify the purpose of using it (hereinafter referred to as the “purpose of use”) as much as possible. In addition, when changing the purpose of use, the chief executive of the research implementing entity shall not change it beyond the scope reasonably considered as having relevance corresponding to the purpose of use before the change.

(5) The chief executive of a research implementing entity shall not handle personal information beyond the scope necessary for achieving the purpose of use specified pursuant to paragraph 18(4) of Part VI, without first obtaining the consent of the donors.

(6) When personal information has been acquired as a consequence of taking over research from another research implementing entity on account of a merger or for any other reason, the chief executive of the research implementing entity shall not handle the said personal information beyond the scope necessary for achieving the purpose of use of personal information that was relevant prior to taking over the research, without first obtaining the consent of the donors.

(7) The chief executive of a research implementing entity shall, with respect to any personal information retained, make the following matters available to donors (including cases when responding immediately at the request of a donor):

(a) The name of the relevant research implementing entity
(b) The purpose of use of all retained personal information (excluding cases falling under paragraph 18(8) (a) through (c) of Part VI)

(c) Procedures responding to any requests made under paragraph 18(8) or paragraph 19(1), (2), (3) or (4) of Part VI (including the amount of any charges if set)

(d) Where complaints can be made concerning the handling of retained personal information

(8) When a request is received from a donor or legally acceptable representative, etc. for notification of the purpose of use of retained personal information by which the relevant donor can be identified, the chief executive of the research implementing entity shall provide notification of this, without delay, to the donor or legally acceptable representative, etc.

However, this shall not apply to any of the following cases:

(a) When notifying the donor or legally acceptable representative, etc. of the purpose of use or publicly announcing it is likely to harm the life, body, property or other rights or interests of the donor or a third party

(b) When notifying the donor or legally acceptable representative, etc. of the purpose of use or publicly announcing it is likely to harm the rights or legitimate interests of the research implementing entity

(c) When it is necessary to cooperate with a state organ or local government in their execution of affairs prescribed by laws and regulations, and when notifying the donor or legally acceptable representative, etc. of the purpose of use or publicly announcing it is likely to impede the execution of those affairs

When it has been decided to not notify the purpose of use, the chief executive of the research implementing entity shall notify the donor or legally acceptable representative, etc. of that effect without delay.

19. Disclosure, etc. of Personal Information

(1) When the chief executive of a research implementing entity is requested by a donor or legally acceptable representative, etc. to disclose retained personal information by which the relevant donor can be identified (including notifying if there is no such retained personal information by which the relevant donor can be identified), the chief executive of the research implementing entity shall disclose the retained personal information to the donor or legally acceptable representative, etc., without delay, by the delivery of written documents or by the method agreed to by the person requesting disclosure.

However, if disclosure would result in any of the following, the chief executive of the research implementing entity may withhold all or part of the personal information from disclosure:

(a) When disclosure is likely to harm the life, body, property or other rights or interests of the donor or a third party

(b) When disclosure is likely to seriously impede the research implementing entity in properly executing its research work

(c) When disclosure would violate laws or regulations

Where the chief executive of a research implementing entity has decided not to disclose all or part of its retained personal information, the chief executive of the research implementing entity shall notify the donors or legally acceptable representatives, etc. of that effect without delay.

<Note>

With regard to the disclosure of genetic information, the principal investigator shall be made responsible for
this under section 8 of Part III.

(2) When the chief executive of a research implementing entity is requested by a donor or legally acceptable representative, etc. to correct, add, or delete retained personal information by which the donor can be identified on the grounds that such retained personal information is contrary to fact, the chief executive of the research implementing entity shall, except in cases in which special procedures are prescribed by any other laws and regulations for such correction, addition, or deletion, make a necessary investigation without delay within the scope necessary for achieving the purpose of use and, on the basis of those results, correct, add, or delete the retained personal information.

In addition, when the chief executive of a research implementing entity has corrected, added or deleted all or part of the retained personal information, or has decided not to make such a correction, addition or deletion, the chief executive of the research implementing entity shall notify the donor or legally acceptable representative, etc. of that effect (including the details of any correction, addition or deletion) without delay.

(3) Where the chief executive of a research implementing entity is requested by a donor or legally acceptable representative, etc. to suspend using or to erase retained personal information by which the relevant donor can be identified on the grounds that the retained personal information concerned is being handled in violation of paragraph 18(5) or (6) of Part VI or that it has been acquired in violation of paragraph 3(10) of Part II, and where it is found that the request has reason, the chief executive of the research implementing entity shall suspend using or erase the retained personal information concerned without delay to the extent necessary for rectifying the violation.

However, this provision shall not apply to cases in which considerable expenses would be incurred or in which it would otherwise be difficult to suspend using or erase the retained personal information concerned, and in which necessary alternative measures are taken to protect the rights and interests of donors.

(4) Where the chief executive of a research implementing entity is requested by a donor or legally acceptable representative, etc. to suspend providing to a third party retained personal information by which the relevant donor can be identified on the grounds that the retained personal information concerned is being provided to the third party in violation of paragraph 15(2) of Part V, and where it is found that the request has reason, the chief executive of the research implementing entity shall suspend providing the retained personal information concerned to the third party without delay.

However, this provision shall not apply to cases in which considerable expenses would be incurred or in which it would otherwise be difficult to suspend providing the retained personal information concerned to the third party, and in which necessary alternative measures are taken to protect the rights and interests of donors.

(5) When the chief executive of a research implementing entity has suspended using or erased all or part of the retained personal information as requested under paragraph 19(3) of Part VI, or has decided not to suspend using or erase the retained personal information concerned, or when the chief executive of a research implementing entity has suspended providing to a third party all or part of the retained personal information as requested under paragraph 19(4) of Part VI, or has decided not to suspend providing the retained personal information concerned to the third party, the chief executive of the research implementing entity shall notify the donor or legally acceptable representative, etc. of that effect without delay.

(6) When the chief executive of a research implementing entity notifies a donor or legally acceptable representative, etc. that it will not be taking all or part of the measures as requested by the donor or legally
acceptable representative, etc. pursuant to paragraph 18(8) or paragraph 19(1), (2) or (5) of Part VI, or that it will take different measures, the chief executive of the research implementing entity shall endeavor to explain those reasons.

(7) The chief executive of a research implementing entity may provide the following matters as the method for receiving requests made pursuant to paragraph 18(8) or paragraph 19(1), (2), (3) or (4) of Part VI (hereinafter referred to as “request for disclosure, etc.”). In such a case, donors or legally acceptable representatives, etc. shall make any requests for disclosure, etc. in accordance with the said method:

(a) Where requests for disclosure, etc. can be made
(b) The form of any documents to be submitted when making a request for disclosure, etc. (including any records made by electronic, magnetic or any other means not perceptible to human senses) and other formalities for making requests for disclosure, etc.
(c) The method for confirming that the person making a request for disclosure, etc. is a donor or legally acceptable representative, etc.
(d) The method for collecting charges

(8) The chief executive of a research implementing entity may ask a donor or legally acceptable representative, etc. making a request for disclosure, etc. to present sufficient items to identify the retained personal data in question. In this case, the chief executive of the research implementing entity shall take appropriate measures that take into account the convenience of the donor or legally acceptable representative, etc. and the provision of information that is helpful in identifying the retained personal information in question, so that the donor or legally acceptable representative, etc. can make a request for disclosure, etc. easily and accurately.

(9) In determining the procedures for responding to requests for disclosure, etc. made pursuant to paragraphs 19(7) and (8) of Part VI, the chief executive of the research implementing entity shall give consideration to the procedures so that they do not impose an excessive burden on the donor or legally acceptable representative, etc.

(10) When the chief executive of a research implementing entity is requested to notify the purpose of use under paragraph 18(8) of Part VI or to make a disclosure under paragraph 19(1) of Part VI, the chief executive of the research implementing entity may collect charges for implementing the measure.

In such a case, the chief executive of the research implementing entity shall determine the amount of the charge within the scope considered reasonable in consideration of actual costs.

(11) The chief executive of a research implementing entity shall respond appropriately and promptly to any complaints, inquiries or the like from donors, etc., such as by setting up a contact point for complaints, etc.

The chief executive of the research implementing entity shall give consideration to the placement of contact persons, procedures for using the service and so on so that the contact point for complaints, etc. is easy for donors, etc. to use.

20. Handling of Anonymously Processed Information

(1) An investigator etc. (limited to a university or other academic or research-oriented institution or organization subject to the Personal Information Protection Act, or a person belonging thereto, for whom the purpose of handling personal information or anonymously processed information is entirely or partly for providing for use in academic research; hereinafter the same shall apply in this section 20) shall, when producing
anonymously processed information (limited to those constituting anonymously processed information database etc. (meaning a collective body of information comprising anonymously processed information, which is systematically organized so as to be able to search for specific anonymously processed information using a computer or otherwise systematically organized so as to be able to easily search for particular anonymously processed information); hereinafter the same), process personal information in accordance with standards prescribed as those necessary to make it impossible to identify a specific individual from being identified and restore the personal information used for the production.

(2) An investigator etc., when having produced anonymously processed information, shall take measures for the security control of such information, in accordance with standards prescribed as those necessary to prevent the leakage of information related to those descriptions etc. and individual identification codes deleted from the personal information used to produce the anonymously processed information and information relating to a processing method carried out pursuant to the provisions of (1) above.

(3) An investigator etc., when having produced anonymously processed information, shall disclose to the public the categories of information relating to an individual contained in the anonymously processed information.

(4) An investigator etc., when producing anonymously processed information and providing the anonymously processed information to another research implementing entity, shall, in advance disclose to the public the categories of information concerning an individual contained in the anonymously processed information to be provided to the other research implementing entity(s) and its providing method, and state to the other research implementing entity(s) explicitly to the effect that the information being provided is anonymously processed information.

(5) An investigator etc. shall, when producing anonymously processed information and making itself handle the anonymously processed information, not collate the said anonymously processed information with other information in order to identify the person concerned with the personal information used to produce the said anonymously processed information.

(6) An investigator etc. shall, when having produced anonymously processed information, strive to take itself necessary and appropriate action for the security control of the anonymously processed information and necessary action for ensuring the proper handling of the anonymously processed information such as dealing with a complaint about the handling, including producing, of the said anonymously processed information, and strive to disclose to the public the contents of such action taken.

(7) An investigator etc., when providing anonymously processed information (excluding those which produced itself by processing personal information; hereinafter the same shall apply in this section 20) to other research implementing entity(s), shall in advance disclose to the public the categories of personal information contained in the anonymously processed information to be provided to the other research implementing entity(s), and state to the other research implementing entity(s) explicitly to the effect that the provided information is anonymously processed information.

(8) An investigator etc. who has received anonymously processed information shall, in handling the said anonymously processed information, neither acquire information relating to descriptions etc. or individual identification codes deleted from the personal information and information relating to a processing method carried out pursuant to the provisions of (1) above, nor collate the said anonymously processed information with other information in order to identify the person concerned with personal information used to produce
the said anonymously processed information.

(9) An investigator etc. who has received anonymously processed information shall strive to take itself necessary and appropriate action for the security control of anonymously processed information and necessary action to ensure the proper handling of anonymously processed information such as dealing with complaints about the handling of anonymously processed information, and shall strive to disclose to the public the contents of such action taken.

21. Responsibilities of Privacy Officers

(1) Upon the request of the principal investigator based on a research protocol, a privacy officer (including privacy sub officers; the same shall apply in this section 21 of Part VI) shall, in principle, anonymize specimens and/or information prior to conducting the human genome/gene analysis research.

However, in cases where the donor or legally acceptable representative, etc. agrees, and where it is permitted in a research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity, the principal investigator may elect to not anonymize the specimens and/or information.

(2) A privacy officer shall not, in principle, provide any personal information that was removed at the time of anonymization to an external institution or a research division within an entity receiving specimens and/or information.

However, in cases where the donor or legally acceptable representative, etc. agrees, and where it is permitted in a research protocol authorized by the ethical review committee and approved by the chief executive of the research implementing entity, the privacy officer may provide personal information to external institutions and research divisions within entities receiving specimens and/or information.

(3) In addition to conducting anonymization work, a privacy officer shall also appropriately manage and dispose of any decoding indexes and so forth prepared during the anonymization work, and shall rigorously control any data containing personal information to prevent it from being divulged.

PART VII: GLOSSARY

22. Glossary

(1) Specimen and/or information

The term “specimen and/or information” shall mean any blood, tissue, cell, body fluid or excrement to be used in human genome/gene analysis research, and any portion of a human body such as DNA extracted therefrom, as well as medical information or genetic information of a donor or other information used in research (including specimens related to deceased persons).

Any tissue, cell, body fluid and excrement as well as DNA and so forth extracted therefrom, whose scientific value is fixed and, at the same time, whose research achievements are fully recognized, and which is used commonly and broadly in research and is commonly available shall, however, be excluded.

<Note 1>

With regard to the donation of specimens and/or information from persons determined to be brain-dead under the Act on Organ Transplantation (Act No. 104 of 1997), it is assumed that it would be sufficient to receive the donation of specimens and/or information through the removal of organs once the so-called “three
indications of death” have been reached, namely, absence of heartbeat, absence of breathing and dilation of pupils.

<Note 2>
With regard to conducting research by receiving the donation of fertilized eggs, embryos, fetuses, ES cells and the like, although taking the purport of these Guidelines into account is necessary, separate careful examination such as from an ethical point of view is also required. It is not the purport of these Guidelines that it would be appropriate to conduct such research solely on the basis of fulfilling these Guidelines.

(2) Medical information
The term “medical information” shall mean information including disease names, drug names, examination results, etc. which are obtained in the course of diagnosis and treatment.

(3) Human genome/gene analysis research
The term “human genome/gene analysis research” shall mean research conducted using specimens and/or information in an attempt to elucidate the structures or functions of the human genome and genes that commonly exist in the cells making up individual donors and which are possibly inheritable. This also includes instances where specimens and/or information are provided, or collected and provided, for use in such research.

With regard to clinical trials and post-marketing investigation and testing (limited to that pertaining to reexamination, reevaluation and usage-results surveys) of pharmaceutical products, medical devices or regenerative medicine products, conducted in accordance with the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), since, pursuant to this Act, these are already regulated by the Ministerial Order on Standards for Clinical Studies of Pharmaceuticals (Order of the Ministry of Health, Labour and Welfare, No. 28 of 1997), the Ministerial Order Concerning Implementation Standard of Investigation and Test Post Marketing Pharmaceuticals (Order of the Ministry of Health, Labour and Welfare, No. 171 of 2004), the Ministerial Order on Standards for Clinical Studies of Medical Devices (Order of the Ministry of Health, Labour and Welfare, No. 36 of 2005), the Ministerial Order Concerning Implementation Standard of Investigation and Test Post Marketing Medical Devices (Order of the Ministry of Health, Labour and Welfare, No. 38 of 2005), the Ministerial Order on Standards for Clinical Studies of Regenerative Medicine Products, etc. (Order of the Ministry of Health, Labour and Welfare, No. 89 of 2014) and the Ministerial Order Concerning Implementation Standard of Investigation and Test Post Marketing Regenerative Medicine Products, etc. (Order of the Ministry of Health, Labour and Welfare, No. 90 of 2014), these Guidelines shall not apply.

<Detailed regulations concerning the scope of human genome/gene analysis research subject to these Guidelines>

1. These Guidelines shall apply to human genome/gene analysis research intending to analyze the structures or functions of base sequences of DNA or complementary DNA derived from mRNA or the like by using leukocytes and other such tissue of a donor, a main example of which is research that analyzes what is called germline mutation or polymorphism. On the other hand, these Guidelines shall not, in principle, apply to research that targets mutation of a genome or a gene that appears a posteriori only on an affected region of a disease, such as cancer, and is not inherited by the next generation (this refers to research that analyzes what is called somatic mutation, which includes research that analyzes normal tissues to
corroborate the existence of a mutation), research regarding gene expression, or research regarding the structures or functions of proteins. When, however, the aforementioned research is conducted for the purpose of elucidating information regarding a genome or a gene to be possibly inherited by descendants, these Guidelines shall apply. Appropriate measures should still be taken, based on the purport of these Guidelines, in conducting research regarding somatic mutation, gene expression or the structures or functions of proteins to which these Guidelines do not apply.

2. In cases where, during the course of conducting any research indicated in paragraph 1. to which these Guidelines do not apply, genetic information (including any specimens and/or information used in obtaining the genetic information) is obtained by reason of chance, the treatment of such specimens and/or information, such as their use for human genome/gene analysis research objectives, their appropriate management (security control measures in cases where they fall under personal information, and appropriate handling in cases of anonymized information (limited to information that cannot identify specific individuals)), their preservation, and their method of disposal, shall be determined by the chief executive of the research implementing entity in consultation with the ethical review committee.

3. Research, whose main objective is not to conduct human genome/gene analysis research but which partially involves human genome/gene analysis research, and research, which secondarily uses specimens and/or information obtained in the course of medical care, shall also be included in the definition.

4. These Guidelines shall not apply to genetic structure analysis training, such as biology training for educational purposes, which is conducted in the study of a gene region whose structure and function is already known and, at the same time, does not involve the use of specimens and/or information or analysis results beyond training purposes. However, even in cases where gene analysis is conducted for these purposes, appropriate measures should still be taken based on the purport of these Guidelines.

(4) Genetic information

The term “genetic information” shall mean information possibly inherited by descendants which reflects the genetic characteristics or constitution of an individual person, which is obtained in the course of human genome/gene analysis research conducted using specimens and/or information or which is already contained in specimens and/or information.

(5) Anonymization

The term “anonymization” shall mean the deletion of all or part of descriptions, etc. (including individual identification codes) which enable identification of a specific individual (including a specific deceased individual) (including replacement of all or part of the descriptions, etc. with descriptions, etc. that are unrelated to the said specific individual).

(6) Decoding index

The term “decoding index” shall mean a table or other similar format which enables a donor to be identified where necessary from anonymized information, by allowing that donor to be matched against the descriptions, etc. that were replaced during the anonymization process.

(7) Anonymously processed information

The term “anonymously processed information” shall mean information relating to an individual that can be produced from processing personal information so as neither to be able to identify a specific individual by taking action prescribed in each following item in accordance with the divisions of personal information listed
in each item (limited to personal information prescribed in the Personal Information Protection Act; hereinafter the same in this paragraph (7)), nor to be able to restore the personal information (limited to information subject to the provisions of the Act):

(a) Personal information falling under paragraph 16(1)(a) of Part VI: Deleting part of the descriptions etc. contained in the said personal information (including replacing the said part of descriptions etc. with other descriptions etc. using a method with no regularity that can restore the said part of descriptions etc.)

(b) Personal information falling under paragraph 16(1)(b) of Part VI: Deleting all individual identification codes contained in the said personal information (including replacing the said individual identification code with other descriptions etc. using a method with no regularity that can restore the said personal identification codes).

(8) Unidentifiably-processed personal information

The term “unidentifiable processed information” shall mean information relating to an individual that can be produced from processing personal information so as neither to be able to identify a specific individual by taking action prescribed in each following item in accordance with the divisions of personal information listed in each item (limited to personal information subject to processing for unidentifiably-processed personal information pursuant to the provisions of the Administrative Organs Personal Information Protection Act or the Independent Administrative Agencies, etc. Personal Information Protection Act; hereinafter the same in this paragraph (8)), nor to be able to restore the personal information (limited to information subject to the provisions of the Act on the Protection of Personal Information Held by Administrative Organs or the Act on the Protection of Personal Information Held by Independent Administrative Agencies, etc.):

(a) Personal information falling under paragraph 16(1)(a) of Part VI: Deleting part of descriptions etc. contained in the said personal information (including replacing the said part of descriptions etc. with other descriptions etc. using a method with no regularity that can restore the said personal identification codes)

(b) Personal information falling under paragraph 16(1)(b) of Part VI: Deleting all individual identification codes contained in the said personal information (including replacing the said individual identification code with other descriptions etc. using a method with no regularity that can restore the said personal identification codes).

(9) Privacy officer

The term “privacy officer” shall mean a person in charge of controlling and anonymizing personal information at a research implementing entity in which personal information is handled, including institutions receiving specimens and/or information, under the direction of the chief executive of the entity so that the personal information of donors, etc. is not divulged outside the institution.

(10) Informed consent

The term “informed consent” shall mean consent regarding the provision and handling of a specimen and/or information which a person, who has been requested to provide a specimen and/or information, gives on the basis of his/her free will after receiving adequate prior explanations from a principal investigator with regard to human genome/gene analysis research and understanding the significance, objectives and method of the research, the expected results and the disadvantages. Under these Guidelines, informed consent is required to be given in writing.
(11) Legally acceptable representative, etc.

The term “legally acceptable representative, etc.” shall mean a person who gives informed consent in place of a donor when the said donor is incapable of giving informed consent. When a donor is a deceased person, this term shall mean a surviving family member.

When surviving family members are to be excluded from the definition, the expression “legally acceptable representative” shall be used.

>Note>

As a legally acceptable representative, etc. is, first and foremost, a person who decides whether or not to agree to the donation of a specimen and/or information in place of the donor from a viewpoint of protecting the human rights of the donor, separate measures need to be examined with regard to the genetic issues of the legally acceptable representatives, etc. themselves.

(12) Research implementing entity

The term “research implementing entity” shall mean an institution or individual business operator that conducts human genome/gene analysis research (including institutions receiving specimens and/or information and organizations collecting and providing specimens and/or information).

<Detailed regulations concerning research implementing entities>

Entities that conduct human genome/gene analysis research shall be juridical persons and administrative organs (as prescribed in Article 2 of the Act on the Protection of Personal Information Held by Administrative Organs).

(13) Institution receiving specimens and/or information

The term “institution receiving specimens and/or information” shall mean an institution, such as a medical institution or health center, which receives specimens and/or information from people.

<Detailed regulations concerning institutions receiving specimens and/or information>

In cases where a single university or similar type of corporation has both divisions that conduct research and divisions that receive specimens and/or information, the said corporation shall be an institution receiving specimens and/or information.

(14) Organization collecting and providing specimens and/or information

The term “organization collecting and providing specimens and/or information” shall mean a research implementing entity which receives donations of specimens and/or information from another institution, and which carries out quality control on these received specimens and/or information as resources to be used in human genome/gene analysis research, and provides them to other research implementing entities (these actions are collectively referred to as “collection and provision” in these Guidelines).

(15) Collaborative research implementing entity

The term “collaborative research implementing entity” shall mean a research implementing entity that collaboratively conducts human genome/gene analysis research described in a research protocol. When a research implementing entity receives donations of specimens and/or information from a separate institution receiving specimens and/or information, the institution receiving specimens and/or information shall also be included in the definition.

(16) External institution

The term “external institution” shall mean a research implementing entity or the like other than the research
implementing entity to which the investigator, etc. conducting the human genome/gene analysis research belongs.

(17) Ethical review committee

The term “ethical review committee” shall mean a council-type body established as an advisory board to the chief executive of a research implementing entity for the purposes of investigation and discussion of the propriety of conducting human genome/gene analysis research and other related matters, involving both ethical viewpoints, such as guaranteeing the human rights of donors, etc., and scientific viewpoints.

(18) Investigator, etc.

The term “investigator, etc.” shall mean a person in a research implementing entity who is involved in human genome/gene analysis research, such as principal investigators, researchers in charge (including those who conduct work receiving the donation of specimens and/or information, as well as those who conduct work collecting and providing specimens and/or information), persons who conduct genetic counseling, persons who conduct work protecting personal information, and chief executives of research implementing entities.

(19) Principal investigator

The term “principal investigator” shall mean an investigator in a research implementing entity who has sufficient knowledge of the usefulness and limited nature of human genome/gene analysis research and of bioethics, and, at the same time, carries out human genome/gene analysis research as well as supervises the operations related to the research protocols.

(20) Researcher in charge

The term “researcher in charge” shall mean a person who conducts human genome/gene analysis research in accordance with the direction or entrustment of a principal investigator and, at the same time, has the necessary knowledge and skills according to the details of the operation concerned, such as investigators, medical doctors, pharmacists, nurses and clinical laboratory technologists.

(21) Donor

The term “donor” shall mean a person who provides a specimen and/or information for human genome/gene analysis research. When a person who could possibly have relevance to the genetic information of a donor, including his/her family, blood relatives or legally acceptable representative, etc., is to be included in the definition, the expression “donor, etc.” shall be used.

(22) Genetic counseling

The term “genetic counseling” shall mean targeting, supporting or assisting in the solution or relief of various medical or psychological problems that could arise with regard to a hereditary disorder, through repeated dialogue and provision of information, by making use of knowledge of medical genetics and counseling techniques.

(23) Existing specimen and/or information

The term “existing specimen and/or information” shall mean a specimen and/or information corresponding to either of the following:

(a) A specimen and/or information which already existed at the time the research protocol for human genome/gene analysis research was prepared; or

(b) A specimen and/or information which were collected after the research protocol for human genome/gene analysis research was prepared, and which, at the time of collection, were not intended for use in the
relevant human genome/gene analysis research.
PART VIII: AMENDMENT

23. Amendment

These Guidelines shall be examined and reviewed in their entirety, as necessary or approximately five years after they come into force, taking into account changes in social conditions and changes in other various circumstances such as the progress of human genome/gene analysis research.

PART IX: DETAILED REGULATIONS

24. Detailed Regulations

In addition to the detailed regulations provided for in these Guidelines, necessary matters concerning enforcement of these Guidelines shall be separately prescribed.

PART X: EFFECTIVE DATE

25. Effective Date

These Guidelines shall come into effect as of April 1, 2013.

SUPPLEMENTARY PROVISIONS


1. This Public Notice comes into effect as from the date of enforcement of the Act for Partial Amendment of the Act on the Protection of Personal Information and the Act on the Use of Numbers to Identify a Specific Individual in Administrative Procedures (May 30, 2017); provided, however, that the provisions of paragraphs 4 and 5 of these Supplementary Provisions come into effect from the date of promulgation.

2. Notwithstanding the provisions of the Ethical Guidelines for Human Genome/Gene Analysis Research amended by this Public Notice (hereinafter referred to as the “New Genome Guidelines”; the same shall apply hereinafter), prior laws may continue to govern human genome/gene analysis research (meaning human genome/gene analysis research prescribed in paragraph 22(3) of Part VII of the New Genome Guidelines), for which prior laws were to continue to govern pursuant to the provisions of section 25 of Part XI of the Ethical Guidelines for Human Genome/Gene Analysis Research prior to the revision by this Public Notice (hereinafter referred to as the “2013 Genome Guidelines”), but to which provisions of the Ethical Guidelines for Human Genome/Gene Analysis Research prior to enforcement of the 2013 Genome Guidelines (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry No. 1 of 2004; hereinafter referred to as the “2004 Genome Guidelines”) were not to apply pursuant to the provisions of paragraph 2(2) of Part I of the 2004 Genome Guidelines, for a period until the day on which six months have elapsed from the date on which this Public Notice comes into effect (hereinafter referred to as the “enforcement date”).

3. Prior laws may continue to govern applicability of the provisions of the New Genome Guidelines for human genome/gene analysis research for which prior laws were to continue to govern pursuant to the provisions of section 25 of Part XI of the 2013 Genome Guidelines (excluding human genome/gene analysis research to which the provisions of the preceding paragraph are applicable) (limited to the provisions set forth in paragraphs 3(11) and 4(8) of Part II, paragraphs 8(2) and (3) of Part III, paragraph 10(9) of Part IV, paragraphs 12(1) and (2) of Part V and paragraph 18(1) of Part VI) for a period until the day on which six months have elapsed from the enforcement date.

4. Even prior to the enforcement date, a principal investigator or other relevant person prescribed in paragraph 22(19)
of Part VII of the New Genome Guidelines may prepare or revise a research protocol or take other necessary preparatory actions pursuant to the provisions of the New Genome Guidelines.

5. Even prior to the enforcement date, the chief executive of a research implementing entity prescribed in paragraph 22(12) of Part VII of the New Genome Guidelines or an ethical review committee prescribed in paragraph 22(17) of Part VII of the New Genome Guidelines may request or conduct a review of a research protocol or present opinions, pursuant to the provisions of section 4 of Part II and section 10 of Part IV of the New Genome Guidelines.

6. Where a person has given consent to the handling of his/her personal information (meaning personal information prescribed in paragraph 16(1) of Part V of the New Genome Guidelines) prior to the enforcement date, and where that consent is equivalent to consent that allows provision of personal information to persons overseas pursuant to the provisions of paragraph 11(4) of Part V of the New Genome Guidelines, then it shall be deemed that such consent was given.