

**The Guidelines for
the Protection of Personal Information
for Business Operations Handling
Personal Genetic Information**

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Introduction

As human genome and genetic analysis research progresses, personal genetic information is likely to play an important role in an expanding array of medical and health services that combine personal genetic information with advanced information technology. Such combination will give rise to new industries of innovative medical and health services that promote higher standards of health and quality of life of the Japanese public.

On the other hand, personal genetic information poses ethical, legal and social issues because of its sensitive nature; it identifies the donors and reveals the predispositions of not only the donors themselves but also their genetic family. Improper handling and unauthorized divulgence of such sensitive information can cause unrecoverable damage to them. Thus, the business operators who handle personal genetic information must respect human rights and do their business under the strict control of the confidentiality of personal genetic information. It is also important for them to advocate the usefulness of personal genetic information and seek public acceptance and cooperation.

To meet the needs, the Present Guidelines set out the necessary measures that business operators should take to securely protect personal genetic information.

I. Purpose and scope

The Present Guidelines entitled the *Guidelines for the Protection of Personal Information for Business Operations Handling Personal Genetic Information* have been developed by the Ministry of Economy, Trade and Industry (METI) as a derivative of the *Industrial Guidelines to Implement the Act on the Protection of Personal Information* (Joint Notification No. 4 of the Ministry of Health, Labor and Welfare (MHLW) and the METI of October 2004), hereinafter referred to as the “Industrial Guidelines.” The more general *Industrial Guidelines* have been developed in accordance with the *Basic Policy on the Protection of Personal Information* approved at the Cabinet meeting of April 2, 2004. The establishment of the *Basic Policy* had been called for in Article 7 (1)¹ of the *Act on the Protection of Personal Information* (Act No. 57 of May 30, 2003), hereinafter referred to as the “Act.”

In accordance with Article 6² of the Act, the Present Guidelines set out, for the business operators who use personal genetic information within the industry sectors over which the METI has jurisdiction, the necessary measures that they should take to ensure that special measures will be taken for the protection of the personal information. In accordance with Article 8³ of the Act, the

¹ Article 7(1) of the Act:

The Government shall establish a basic policy on the protection of personal information (hereinafter referred to as “Basic Policy”) in order to ensure the comprehensive and integrated promotion of measures for the protection of personal information.

² Article 6 (Legislative Measures, etc.) of the Act:

The Government shall take necessary legislative and other measures to ensure that special measures will be taken for the protection of the personal information which especially needs to be ensured the strict implementation of its proper handling for the further protection of the rights and interests of individuals in view of the nature and the method of utilization of the personal information.

³ Article 8 (Support to Local Governments and Others) of the Act:

In order to support the measures for the protection of personal information formulated or implemented by local governments and the activities performed by citizens, entities, and others to ensure the proper handling of personal information, the State shall provide information, formulate guidelines to ensure the appropriate and

Present Guidelines also provide specific guides in support of the activities by business operators to ensure the proper handling of personal information.

In view of the ethical, legal and social implications of personal genetic information, the Present Guidelines also take into account the *Ethics Guidelines for Human Genome/Gene Analysis Research* (Joint Notification No. 1 of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the MHLW and the METI of 2001).

The Present Guidelines specify the measures that “business operators handling personal genetic information” and “business operators handling genetic information” should take in handling “personal genetic information” and “genetic information,” respectively. Where there is no applicable provision in the Present Guidelines, the provisions of the Industrial Guidelines shall apply.

The Present Guidelines do not apply to the personal information of the employees of the business operators who are covered by the guidelines. For the purpose of the Present Guidelines, *shall* or *must* means that disregard of the provisions can be deemed by the METI Minister as the violation of the Act. Although *shall* does not constitute the violation of the Act when the provisions are disregarded, such provisions should be observed to the extent possible as a social responsibility of business operators as is stated in the basic principle (Article 3) of the Act. The Act says, “*Personal information should be handled cautiously under the philosophy of respecting the personalities of individuals, proper handling of personal information shall be promoted.*” Observation of such provisions is also recommended to ensure strict implementation of proper handling of personal genetic information. It should be noted, however, in view of the purpose (Article 1) of the Act which recognizes the usefulness of personal information, the Present Guidelines are not intended to limit lawful business activities or other activities that serve public interest.

Designated personal information protection organizations, and business operators handling genetic information may develop and implement their own voluntary regulations specifying additional measures to meet the specific needs of their business operations so that proper handling of personal information is ensured.

“Business operations that use personal genetic information” provide testing, analysis and result interpretation services concerning personal genetic information. Such services include, but not limited to, analysis of base sequences, single nucleotide polymorphisms and physical predispositions, parentage and other DNA testing, and contract genetic analysis. Such business operators may collect genetic information directly from individual persons or accept samples from medical institutions and other organizations for testing, analysis and/or result interpretation. If separate applicable guidelines are present, the Present Guidelines shall apply to the following operations that fall within the scope of the above services:

Predisposition, DNA and parentage tests are examples of services in which samples are often collected directly from individual persons. If such tests are performed by medical institutions and nursing care service providers, the *Guidelines on the Proper Handling of Personal Information for Medical Institutions and Nursing Care Service Providers* apply. If such analyses are conducted by research laboratories, the *Ethics Guidelines for Human Genome/Gene Analysis Research* apply. Clinical trials and post-market studies on pharmaceutical products performed in accordance with *Pharmaceutical Affairs Law* (Act No. 145 of 1960) are already regulated by the *Standards for the Implementation of Clinical Trials on Pharmaceutical Products* (Ordinance No. 28 of the former Ministry of Health and Welfare of 1997) and the *Standards for Post-Market Studies on Pharmaceutical Products* (Ordinance No. 10 of the former Ministry of Health and Welfare of 1997) that are issued based on the law. The same standards also apply to the clinical trials and post-market studies on medical devices for production or imports. The Present Guidelines apply to other business

effective implementation of measures to be taken by entities and others, and take any other necessary measures.

operations that collect samples directly from individual persons to provide testing, analysis and/or result interpretation services.

The Present Guidelines also apply to contract laboratories who accept samples from medical institutions and other organizations for testing, analysis and/or result interpretation. If such contract laboratories participate in joint research projects with research laboratories who collect samples directly from individual persons, the *Ethics Guidelines for Human Genome/Gene Analysis Research* also apply to participating contract laboratories.

The activities of hygienic laboratories are directly controlled by the Ministry of Health, Labor and Welfare and are excluded from the Present Guidelines.

Predisposition tests must meet the Present Guidelines and their validity must be shown as an objective data.

Although forensic DNA and parentage testing is covered by the Present Guidelines, business operators handling personal genetic information shall also follow the specific guidelines developed by related scientific societies in view of the unique nature of the business. While business operators who handle genetic information of only 5,000 identifiable individual persons or less in total sum in any one day during the latest six months are exempt from the Act by the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No. 507 of 2003), they shall also follow the Present Guidelines due to the sensitive nature of genetic information.

II. Law/regulation interpretation guide and case studies

1. Definitions (Related to Article 2 of the Act)

1-1 Terms concerning the characteristics of information

(1) *Personal information* (Related to Article 2(1)⁴ of the Act)

For the aspects of personal information not mentioned under this item, consult the Industrial Guidelines.

For the purpose of the Present Guidelines, “personal information” means personally identifiable information. As defined under Item (6) *Anonymization* of this section, this includes code- or number-attached anonymous information held by a business operator if the codes or numbers are linked to identifiers in a separate list held by the business operator. Outside the business operator, however, such code- or number-attached anonymous information will be treated as unlinked anonymous information and falls outside the scope of personal information if there is no access to the list linking the information to identifiers.

(2) *Genetic information*

“Genetic information” is generally defined as either any information obtained directly from bodily samples during the course of testing or analysis performed by a business operator, or one attached to bodily samples that describes genetic traits and predispositions estimated from them. For the purpose of the Present Guidelines, genetic information is divided into two types: personal and anonymous.

⁴ Article 2(1) of the Act:

The term “personal information” as used in this Act shall mean information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information (including such information as will allow easy reference to other information and will thereby enable the identification of the specific individual).

- a. “Personal genetic information” contains an individual’s genetic traits and/or predispositions and is “personal information” defined under Item (1) of this section.
- b. “Anonymous genetic information” also contains an individual’s genetic traits and/or predispositions but is not personally identifiable.

(3) *Human specimen*

For the purpose of the Present Guidelines, a “human specimen” is either (a) any blood, tissue, cell, body fluid or excrement; (b) any portion of a human body, such as DNA, extracted from those listed in (a); or (c) the medical information of the donor.

(4) *Medical information*

For the purpose of the Present Guidelines, “medical information” is the names of the disease and medications, the results of examinations, and other information obtained during the course of medical examinations and treatments.

(5) *Anonymization*

For the purpose of the Present Guidelines, “anonymization” means to replace, in part or in whole, the part of personal information by which the individual person can be identified with a code or number that has no relevance to the individual. This is to protect the privacy of an individual from unauthorized divulgence of his/her personal information against the confidentiality provisions of applicable national laws and regulations, the Present Guidelines and business operators’ in-house protocol. Even if the information attached to a human specimen alone cannot identify the donor, it may become identifiable when combined with other data in literature available from other sources. In such a case, the part of the information attached to a human specimen that is needed to link it to other data from other sources must be deleted to make it impossible to identify the individual.

There are two modes of anonymization. One is linked anonymization. When a business operator who holds code- or number-attached anonymous information also keeps a list that links the information to identifiers, the information is classified as personal information as long as it is held by the business operator because the information is personally identifiable. The other is unlinked anonymization. When the business operator who holds code- or number-attached anonymous information does not keep a list that links the information to identifiers, the information is classified as unlinked anonymous information.

a. *Linked anonymization*

In this mode of anonymization, a business operator keeps a list that links the codes or numbers attached to individuals’ information to their identifiers so that the information may be personally identifiable.

b. *Unlinked anonymization*

In this mode of anonymization, a business operator does not keep a list that links the codes or numbers attached to individuals’ information to their identifiers to make the information personally unidentifiable.

(6) **Personal information database, etc.** (Related to Article 2 (2)⁵ of the Act)

The Present Guidelines will not use the term “personal information database, etc.” because the Act defines the term as “an assembly of information systematically arranged in such a way that specific personal information can be retrieved by a computer,” but the Present Guidelines also applies to information that is *not* systematically arranged.

(7) **Personal data** (Related to Article 2 (4)⁶ of the Act)

For the purpose of the Present Guidelines, “personal data” means “personal genetic information” although the Act defines it as “personal information constituting a personal information database, etc.” This is because the Present Guidelines cover personal data whether or not it is systematically arranged.

(8) **Retained personal data** (Related to Article 2 (5)⁷ of the Act)

For the purpose of the Present Guidelines, “retained personal data” means “personal genetic information” although the Act classifies it as part of “personal information constituting a personal information database, etc.” This is because the Present Guidelines cover personal data whether or not it is systematically arranged.

1-2 Terms concerning persons and business operators

(9) **Person** (Related to Article 2 (6)⁸ of the Act)

⁵ Article 2(2) of the Act:

The term “a personal information database, etc.” as used in this Act shall mean an assembly of information including personal information as set forth below:

- (i) *an assembly of information systematically arranged in such a way that specific personal information can be retrieved by a computer; or*
- (ii) *in addition to what is listed in the preceding item, an assembly of information designated by a Cabinet Order as being systematically arranged in such a way that specific personal information can be easily retrieved.*

⁶ Article 2(4) of the Act:

The term “personal data” as used in this Act shall mean personal information constituting a personal information database, etc.

⁷ Article 2(5) of the Act:

The term “retained personal data” as used in this Act shall mean such personal data over which a business operator handling personal information has the authority to disclose, to correct, add or delete the content, to discontinue its utilization, to erase, and to discontinue its provision to a third party, excluding the data which is specified by a Cabinet Order as harming public or other interests if its presence or absence is known and the data which will be erased within a period of no longer than one year that is specified by a Cabinet Order.

⁸ Article 2(6) of the Act:

The term “person” as to personal information as used in this Act shall mean a specific individual identified by personal information.

(10) Business operators handling personal information (Related to Article 2(3)⁹ of the Act)

Consult the Industrial Guidelines for the definition¹⁰ of this term. Note that, for the purpose of the Present Guidelines, all the appearances of “personal information” in the definition of the Industrial Guidelines should be replaced with “personal genetic information.”

(11) Business operators handling personal genetic information

“Business operators handling personal genetic information” are, of the “business operators handling personal information” defined under Item (9) of this section, those who collect samples directly from persons and handle “personal genetic information” as either the main line or part of their business. They shall follow the Present Guidelines even if they handle genetic information of only 5,000 identifiable individual persons or less in total sum in any one day during the latest six months.

(12) Business operators handling anonymous genetic information

“Business operators handling anonymous genetic information” are those who handle personally unidentifiable genetic information only as either the main line or part of their business. They are contract testing and analysis laboratories who accept anonymous samples and information from other entities. Although they are exempt from the Act, they should follow the Present Guidelines even if they handle genetic information of only 5,000 identifiable individual persons or less in total sum in any one day during the latest six months.

⁹ Article 2(3) of the Act:

The term “a business operator handling personal information” as used in this Act shall mean a business operator using a personal information database, etc. for its business; however, the following entities shall be excluded;

- (i) *The State organs*
- (ii) *Local governments*
- (iii) *Incorporated administrative agencies, etc. (which means independent administrative agencies as provided in Paragraph 1 of Article 2 of the Act on the Protection of Personal Information Held by Incorporated Administrative Agencies, etc. (Act No. 59 of 2003; the same shall apply hereinafter))*
- (iv) *Local independent administrative institutions (which means local incorporated administrative agencies as provided in Paragraph 1 of Article 2 of the Local Incorporated Administrative Agencies Law. (Act No. 118 of 2003; the same shall apply hereinafter))*
- (v) *Entities specified by a Cabinet Order as having a little likelihood to harm the rights and interests of individuals considering the volume and the manner of utilization of personal information they handle.*

¹⁰ The Industrial Guidelines define the term as follows:

The term a “business operator handling personal information” means a business operator using a personal information database, etc. for its business excluding: (i) the state organs; (ii) local governments; (iii) incorporated administrative agencies, etc. (which means independent administrative agencies as provided in Paragraph 1 of Article 2 of the Act on the Protection of Personal Information Held by Incorporated Administrative Agencies, etc. (Act No. 59 of 2003)); (iv) local independent administrative institutions (which means local incorporated administrative agencies as provided in Paragraph 1 of Article 2 of the Local Incorporated Administrative Agencies Law. (Act No. 118 of 2003; the same shall apply hereinafter)); and (v) entities specified by a Cabinet Order as having a little likelihood to harm the rights and interests of individuals considering the volume and the manner of utilization of personal information they handle.

According to the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No. 507 of 2003), “entities having a little likelihood to harm the rights and interests of individuals considering the volume and the manner of utilization of personal information they handle” are those who handle genetic information of 5,000 identifiable individual persons or less in total sum in any one day during the latest six months. The total number is determined by counting the number of all identifiable individual persons consisting personal information databases, etc. they use. However, duplicated persons shall be excluded from the count.

1-3 Terms concerning the handling of personal genetic information

(13) *Informed consent*

“Informed consent” means the consent given in writing by a person of his/her own free will to a business operator handling personal genetic information after receiving adequate prior explanations from the business operator concerning the value, purpose, methodology, expected results, possible disadvantage to the person and his/her family, and reliability.

(14) *Anonymous information custodian*

An “anonymous information custodian” is appointed by each business operator handling personal genetic information and is responsible for keeping the personal information held by the business operator confidential. The custodian is also responsible for anonymizing personal genetic information.

(15) *Personal genetic information handling committee*

A “*personal genetic information handling committee*” is a council comprised of the representatives from business operators handling personal genetic information, and studies and discusses, from the ethical, legal and social point of view, the appropriateness of the services provided by business operators handling personal genetic information and other issues.

(16) *Genetic counseling*

“Genetic counseling” is the service provided by medical doctors or other professionals with sufficient knowledge, experience and counseling skills in the area of genetic medicine who can support mentally and socially the persons and their family members. Genetic counselors provide supports and information that they need in their making decisions and acting on their own will by answering questions concerning the genetic testing they are going to receive and relieving their anxieties and problems arising from inherited predispositions.

1-4 Terms concerning the responses to persons

(17) *Notification to the person*

The “notification” required by the Act shall generally be given to the person in the form of *informed consent* which includes written explanation and consent, except that, for the notification required under Article 24(2) and (3)¹¹ of the Act, the specifications¹² of the Industrial Guidelines

¹¹ Article 24(2) and (3) of the Act:

- (2) *When a business operator handling personal information is requested by a person to notify him/her of the Purpose of Utilization of such retained personal data as may lead to the identification of the person concerned, the business operator shall meet the request without delay. However, this provision shall not apply to cases falling under either of the following items:*
 - (i) *Cases in which the Purpose of Utilization of such retained personal data as may lead to the identification of the person concerned is clear pursuant to the provision of the preceding paragraph*
 - (ii) *Cases falling under any of items 1 to 3 of paragraph 4 of Article 18*
- (3) *When a business operator handling personal information has decided not to notify the Purpose of Utilization of such retained personal data as is requested under the preceding paragraph, the business operator shall notify the person of that effect without delay.*

¹² The Industrial Guidelines state in II.2.(5)1.2.:

“A business operator handling personal information shall, except for the cases described under Items i through iv below, notify without delay to the person the purpose of the utilization of the personally identifiable data retained by the business operator when requested by the person. If the business operator decides not to notify the purpose of the utilization of the data, the business operator shall also notify without delay to the effect to the person:

- i. *Cases in which the purpose of utilization of the personally identifiable data retained by the business*

should be followed.

(18) Public announcement

Regardless the specifications of the Industrial Guidelines, for the purpose of the Present Guidelines, the “public announcement” required by the Act shall in any case be given in the form of *informed consent* which includes written explanation and consent.

(19) Indication of the purpose of utilization

Regardless the specifications of the Industrial Guidelines, for the purpose of the Present Guidelines, the “indication of the purpose of utilization” shall be given to the person in the form of *informed consent* which includes written explanation and consent.

(20) Consent of the person

Regardless the specifications of the Industrial Guidelines, for the purpose of the Present Guidelines, the “consent of the person” required by the Act shall in any case be given in the form of *informed consent* which includes written explanation and consent.

(21) Readily accessible condition for the person

See the Industrial Guidelines¹³ for the definition of a “readily accessible condition for the person.”

(22) Accessible condition for the person (including cases in which a response is made without delay at the request of the person)

See the Industrial Guidelines¹⁴ for the definition of an “accessible condition for the person (including cases in which a response is made without delay at the request of the person).”

(23) Provision (of personal genetic information)

See the Industrial Guidelines¹⁵ for the definition of the term “provision (of personal genetic

operator is self-evident by the measures described under Item II.2.(5)1.1. above;

- ii. *Cases in which notifying the person of the purpose of utilization or publicly announcing it are likely to harm the life, body, property, or other rights or interests of the person or a third party*
- iii. *Cases in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to harm the rights or legitimate interests of the business operator handling personal information*
- iv. *Cases in which it is necessary to cooperate with a state organ or a local government in executing the affairs prescribed by laws and regulations and in which notifying the person of the purpose of utilization or publicly announcing it are likely to impede the execution of the affairs”*

¹³ The definition under II.1.(11) of the Industrial Guidelines:

A “readily accessible condition for the person” means a condition in which a person can easily, in terms of time and means, obtain the information he/she needs or desires. The means must be appropriate and reasonable for a person in his/her comprehending the contents while the means can vary depending on the nature of the business and how personal information is handled.

¹⁴ The definition under II.1.(12) of the Industrial Guidelines:

An “accessible condition for the person (including cases in which a response is made without delay at the request of the person)” means putting reasonably latest and then accurate information in a condition in which a person can access if he/she wants to, such as putting it in the business operator’s WEB pages, publishing brochures, or providing information without delay at the request of a person. While it does not necessarily mean that information be put on display continuously in WEB pages, on boards at the office or others, information must be provided using reasonable and appropriate means so that a person can comprehend the contents.

¹⁵ The definition under II.1.(13) of the Industrial Guidelines (Note that for the purpose of the Present Guidelines,

information).”

2. Duties of business operators handling personal genetic information

2.1 Purpose of utilization of personal genetic information (Related to Articles 15¹⁶ and 16¹⁷ of the Act)

(1) Specifying the purpose of utilization of personal genetic information (Related to Article 15(1) of the Act)

For the aspects of specifying the purpose of utilization of personal genetic information not mentioned under this item, consult the Industrial Guidelines.

Business operators handling personal genetic information must specify the purpose of utilization of personal genetic information as part of the informed consent procedure whenever they handle the information.

The purpose of utilization of personal genetic information must be specified more in detail than the examples¹⁸ given in the Industrial Guidelines. More specifically, the informed consent

replace all appearances of “personal data” to “personal genetic information”):

“Provision” means putting personal data in an accessible condition. Personal data is considered to be provided if the data is accessible from a person (or a person is entitled to use the data) through the internet for example even if the data is not provided using a tangible media to a person.

¹⁶ Article 15 (Specification of the Purpose of Utilization) of the Act:

- (1) *When handling personal information, a business operator handling personal information shall specify the purpose of utilization of personal information (hereinafter referred to as “Purpose of Utilization”) as much as possible.*
- (2) *A business operator handling personal information shall not change the Purpose of Utilization beyond the scope which is reasonably considered that the Purpose of Utilization after the change is duly related to that before the change.*

¹⁷ Article 16 (Restriction by the Purpose of Utilization) of the Act:

- (1) *A business operator handling personal information shall not handle personal information about a person, without obtaining the prior consent of the person, beyond the scope necessary for the achievement of the Purpose of Utilization specified pursuant to the provision of the preceding article.*
- (2) *When a business operator handling personal information has acquired personal information as a result of taking over the business of another business operator handling personal information in a merger or otherwise, the acquiring business operator shall not handle the personal information concerned, without obtaining the prior consent of the persons, beyond the scope necessary for the achievement of the Purpose of Utilization of the personal information concerned before the succession.*
- (3) *The provisions of the preceding two paragraphs shall not apply to the following cases:*
 - (i) *Cases in which the handling of personal information is based on laws and regulations*
 - (ii) *Cases in which the handling of personal information is necessary for the protection of the life, body, or property of an individual and in which it is difficult to obtain the consent of the person*
 - (iii) *Cases in which the handling of personal information is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the person*
 - (iv) *Cases in which the handling of personal information is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by either of the former two in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the person is likely to impede the execution of the affairs concerned.*

¹⁸ The Industrial Guidelines state:

“In indicating the purpose of utilization, business operators handling personal information must describe in the greatest detail possible, rather than in abstract and general wording, how the personal information is going to finally be used. This does not mean, however, that the business operator is required to indicate the type of personal information to be used or the business partner from which the personal information has been obtained.

document specifying the purpose of utilization of personal genetic information must indicate the target genes of the testing.

Business operators handling anonymous genetic information shall also specify, following the Industrial Guidelines, the purpose of utilization of anonymous genetic information.

(2) Changes in the purpose of utilization (Related to Articles 15(2)¹⁹ and 18(3)²⁰ of the Act)

For the aspects of changes in the purpose of utilization, consult the Industrial Guidelines²¹.

If a business operator handling personal genetic information intends to change the purpose of utilization of a sample originally collected from a person for DNA and parentage testing on the basis of so-specified informed consent from the person so that the business operator can store and use the sample for a study to improve result interpretation techniques, for example, the business operator must be provided with either a renewed or an additional written informed consent by the person specifying: an appropriate and clear purpose (*i.e.* a study to improve interpretation techniques) of utilization of the sample and/or personal genetic information; the identity of a third party to whom the sample and/or personal genetic information is provided, if any; the storing method; the security measures; the disposal of the sample and/or personal genetic information; and others.

(3) Restriction by the purpose of utilization (Related to Article 16(1)²² of the Act)

For the aspects of restriction by the purpose of utilization of personal genetic information not mentioned under this item, consult the Industrial Guidelines.

More specifically, a business operator handling personal information might specify the purpose of utilization of personal information by such an expression as 'product shipment, direct mailing on new product introduction, and after-sale servicing concerning XXX business'^(Note). Such an expression can be specific enough if a person can determine the nature of the business or the scope of utilization. In general, however, such ambiguous expressions as 'In our business activities' or 'To improve the quality of our customer service' are not considered 'specific to the extent possible.'

Note: 'XXX business' should be specific to such an extent that a person would find helpful considering a generally accepted idea of specificity. The Major Group- or the Group-level industry classification of the Japan Standard Industrial Classification might serve for this purpose."

¹⁹ Article 15(2) of the Act:

(2) A business operator handling personal information shall not change the Purpose of Utilization beyond the scope which is reasonably considered that the Purpose of Utilization after the change is duly related to that before the change.

²⁰ Article 18(3) of the Act:

(3) When a business operator handling personal information has changed the Purpose of Utilization, the business operator shall notify the person of the changed Purpose of Utilization or publicly announce it.

²¹ The Industrial Guidelines state:

"It is allowed to change the purpose of utilization of personal information which has been specified under (1) Specifying the purpose of utilization of personal genetic information above to the extent that a person would find it 'foreseeable' (note) (Original expression: 'to the extent that a person would not find it difficult to foresee). The business operator handling personal information must, however, inform the person of the allowable change either directly by mail or other appropriate method or indirectly by public announcement. Any change in the purpose of utilization of personal information that fall outside the scope of allowable change requires a written prior consent by the person.

Note: An example of such an allowable change: In a case in which a business operator handling personal information originally specified the purpose of utilization of personal information by such an expression as 'The personal information may be used to inform you by e-mail of a new product or service introduction in our XXX business,' the business operator may add 'postal mail' to 'e-mail.'"

²² Article 16(1) of the Act:

A business operator handling personal information shall not handle personal information about a person, without obtaining the prior consent of the person, beyond the scope necessary for the achievement of the Purpose of Utilization specified pursuant to the provision of the preceding article.

As provided for under Article 16(1) of the Act, business operators handling personal genetic information shall not handle personal genetic information about a person, without obtaining the prior informed consent of the person, beyond the scope necessary for the achievement of the purpose of utilization of personal genetic information. Such informed consent must clearly indicate appropriate purpose and handling of personal genetic information. Other exceptions are listed under Article 16(3)²³ of the Act.

(4) Succession of business (Related to Article 16(2)²⁴ of the Act)

For the aspects of succession of business, consult the Industrial Guidelines²⁵.

(5) Exemptions from use restriction (Related to Article 16(3) <Footnote 23> of the Act)

For the aspects of exemptions from use restriction, consult the Industrial Guidelines²⁶.

²³ Article 16(3) of the Act:

(3) *The provisions of the preceding two paragraphs shall not apply to the following cases:*

- (i) *Cases in which the handling of personal information is based on laws and regulations*
- (ii) *Cases in which the handling of personal information is necessary for the protection of the life, body, or property of an individual and in which it is difficult to obtain the consent of the person*
- (iii) *Cases in which the handling of personal information is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the person*
- (iv) *Cases in which the handling of personal information is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by either of the former two in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the person is likely to impede the execution of the affairs concerned*

²⁴ Article 16(2) of the Act:

(2) *When a business operator handling personal information has acquired personal information as a result of taking over the business of another business operator handling personal information in a merger or otherwise, the acquiring business operator shall not handle the personal information concerned, without obtaining the prior consent of the persons, beyond the scope necessary for the achievement of the Purpose of Utilization of the personal information concerned before the succession.*

²⁵ The Industrial Guidelines state:

“When a business operator handling personal information has acquired personal information as a result of taking over the business of another business operator handling personal information in a merger, spin-off, transfer or otherwise, the acquiring business operator need not obtain a renewed or additional written prior consent from the person if the personal information is used after the succession within the scope of its original purpose of utilization.”

²⁶ The Industrial Guidelines state,

“1. *Item (i) of Article 16(3) of the Act exempts the ‘cases in which the handling of personal information is based on laws and regulations’ from Paragraphs (1) and (2) of Article 16 of the Act. The provisions of laws justifying such exemptions would include, for example, Article 218 (Investigations Based on Warrants) of the Code of Criminal Procedure and Article 72(63) (Question and Inspection Jurisdiction Concerning Business Tax) of the Local Tax Law.” These provisions have compelling power and thus the cases that fall under these provisions are exempt from use restrictions of the Act.*

Such cases would include the submission of payment records to the superintendent of a taxation office in accordance with Article 225(1) of the Income Tax Law, etc. Meanwhile, the submission of personal information in response to the request for cooperation with investigation under Article 197(2) of the Code of Criminal Procedure can fall under the scope of exemption but would demand case-by-case consideration because the submission is optional rather than mandatory.

Other examples of such cases are a subsidiary cooperating with the auditor of the parent company under Article 274(3) of the Commercial Code, and a corporate disclosing its financial statements in audits under Article 2 of the Act on Special Provisions of the Commercial Code concerning Audits of business corporation and Article 193(2) of the Securities Exchange Law.

2. *Item (ii) of Article 16(3) of the Act also exempts the ‘cases in which the handling of personal information is necessary for the protection of the life, body, or property of an individual and in which it is difficult to obtain*

2.1-2 Sensitive information

Business operators handling personal genetic information shall restrict acquisition and use of information to only those needed for their business and shall not acquire or use information on the persons' political positions, religious beliefs/ideas/principles, labor union membership, race/ethnicity, lineage/family registration place, health and healthcare/sex life, or criminal record unless it is mandated by a law or regulation.

the consent of the person' from Paragraphs (1) and (2) of Article 16 of the Act. The paragraphs do not apply when the rights or benefits of a person (including a legal person) such as life and property are at risk and there is no other way than to use his/her personal information to protect him/her but it is difficult to obtain his/her consent.

One example is informing the blood type and contact of a person when he/she is in emergency such as sudden illness and injuries. Another example is exchanging personal information between business corporations when he/she willfully obstructs their business.

3. *Item (iii) of Article 16(3) of the Act exempts the 'cases in which the handling of personal information is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the person' from Paragraphs (1) and (2) of Article 16 of the Act.*

One example is providing the record of examinations of a person conducted in the cancer examinations and other health maintenance activities of a health insurance association to epidemiological and statistical studies for the formulation of better health promotion policies and the improvement of the association's health maintenance activities. Another example is sharing the personal information of a pupil with problem behaviors such as school absence and delinquencies among the school, child consultation office and medical institution

4. *Item (iv) of Article 16(3) of the Act exempts the 'cases in which the handling of personal information is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by either of the former two in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the person is likely to impede the execution of the affairs concerned' from Paragraphs (1) and (2) of Article 16 of the Act.*

One example is a business operator voluntarily providing personal information to tax officers in their non-compulsory investigation. Another example is a business operator voluntarily providing personal information to police officers in their non-compulsory investigation."

2.2 Acquisition of personal genetic information (Related to Articles 17²⁷ and 18²⁸ of the Act)

(1) Informed consent procedure

Business operators shall conduct their business of handling personal genetic information only after they are supplied with the written consent of each affected person for the use of his/her personal genetic information. Before writing the consent, each person shall be given an adequate explanation of each of the items listed below. In the case of DNA, parentage and other testing the results of which have legal effects, the person shall also be given, in advance, an appropriate and adequate explanation of such legal effects.

The revocation of informed consent for the use of personal genetic information shall be provided for in the contract signed by a business operator and a person. In view of the unique and sensitive nature of personal genetic information, however, it is advisable for a business operator to accept the request submitted by a person for the revocation of the consent. Apart from the case in which the person desires to handle the personal genetic information other than disposal, the business operator shall dispose the sample and the record of testing or analysis only after unlinkably anonymizing both the sample and record. The business operator may stipulate the cost to be billed to the person for the disposal of personal genetic information in the contract.

Items to be included in the informed consent document

- The values, objectives and methodology of the activity; possible addition and/or changes of the target genetic elements, analytic methods and/or reliability if any (In the case of predisposition tests, their values must also be shown as an objective data); duration of the activity; sample handling after the completion of the activity; and possible results and potential disadvantages (including possibilities for social discrimination and other disadvantages);

²⁷ Article 17 (Proper Acquisition):

A business operator handling personal information shall not acquire personal information by a deception or other wrongful means.

²⁸ Article 18 (Notice of the Purpose of Utilization at the Time of Acquisition, etc.):

- (1) *When having acquired personal information, a business operator handling personal information shall, except in cases in which the Purpose of Utilization has already been publicly announced, promptly notify the person of the Purpose of Utilization or publicly announce the Purpose of Utilization.*
- (2) *Notwithstanding the provision of the preceding paragraph, when a business operator handling personal information acquires such personal information on a person as is written in a contract or other document (including a record made by an electronic method, a magnetic method, or any other method not recognizable to human senses. hereinafter the same shall apply in this paragraph.) as a result of concluding a contract with the person or acquires such personal information on a person as is written in a document directly from the person, the business operator shall expressly show the Purpose of Utilization in advance. However, this provision shall not apply in cases in which the acquisition of personal information is urgently required for the protection of the life, body, or property of an individual.*
- (3) *When a business operator handling personal information has changed the Purpose of Utilization, the business operator shall notify the person of the changed Purpose of Utilization or publicly announce it.*
- (4) *The provisions of the preceding three paragraphs shall not apply to the following cases:*
 - (i) *Cases in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to harm the life, body, property, or other rights or interests of the person or a third party*
 - (ii) *Cases in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to harm the rights or legitimate interests of the business operator handling personal information*
 - (iii) *Cases in which it is necessary to cooperate with a state organ or a local government in executing the affairs prescribed by laws and regulations and in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to impede the execution of the affairs*
 - (iv) *Cases in which it is considered that the Purpose of Utilization is clear in consideration of the circumstances of the acquisition*

- Procedures to revoke an informed consent; requirements for revocation; responses to the request for revocation (including the methodology to dispose samples and records); and costs billed to the person;
- The name, address, telephone number and representative of the business operator;
- Specific description of anonymization and other security measures to be taken to protect the privacy of personal genetic information in each phase from sample collection to disposal.
- If business partners are used to outsource sample analysis and/or to share the samples/records, their names, and specific description of anonymization and other security measures to be taken to protect the privacy of personal genetic information;
- The statement that the activity is approved as appropriate by a personal genetic information handling committee.
- Information about the disclosure of personal genetic information, including the contact, procedure and any fee if required.
- Information about genetic counseling
- Information about the contact for inquiry (e.g., correction of personal information and revocation of consent) and complaints.

(2) **Proper acquisition** (Related to Article 17²⁹ of the Act)

For the aspects of proper acquisition, consult the Industrial Guidelines³⁰.

²⁹ Article 17 (Proper Acquisition)

A business operator handling personal information shall not acquire personal information by a deception or other wrongful means.

³⁰ The Industrial Guidelines state,

“A business operator handling personal information shall not acquire personal information by a deception or other wrongful means.

Acquiring by fraud or other unlawful means, using and/or disclosing commercially useful personal information which is kept confidential and is not publicly available may be criminally punished by imprisonment with work of up to 3 years or a fine of up to 3 million yen under Article 14 of the Unfair Competition Prevention Act (Act No.47 of 1993).

Cases of wrongful acquisition of personal information:

Case 1: Acquiring the household income and other personal information of a family that falls outside the scope of information acquisition approved by a prior consent from the minor member of the family without the consent of the parent;

Case 2: Acquiring personal information by forcing other business operators to violate Article 23 (Restriction of Provision to A Third Party) of the Act; and

Case 3: Acquiring personal information from other business operators by instructing them to acquire personal information through such means as those described under Case 1 and 2.”

(3) Notification and public announcement of the purpose of utilization (Related to Article 18(1)³¹ of the Act)

For the aspects of notification and public announcement of the purpose of utilization, disregard the Industrial Guidelines and observe the following instruction:

Personal genetic information shall be acquired only after a written informed consent is provided, rather than making notice or public announcement after acquiring personal genetic information as specified in the Industrial Guidelines.

(4) Direct acquisition from a person (Related to Article 18(2)³² of the Act)

For the aspects of direct acquisition of personal genetic information from a person, consult the Industrial Guidelines³³ except that the purpose of utilization shall be indicated in an informed consent document:

(5) Changes in the purpose of utilization (Related to Article 18(3) <Footnote 20> of the Act)

For the aspects of changes in the purpose of utilization, consult the Industrial Guidelines <Footnote 21>.

³¹ Article 18(1) of the Act:

- (1) *When having acquired personal information, a business operator handling personal information shall, except in cases in which the Purpose of Utilization has already been publicly announced, promptly notify the person of the Purpose of Utilization or publicly announce the Purpose of Utilization.*

³² Article 18(2) of the Act:

- (2) *Notwithstanding the provision of the preceding paragraph, when a business operator handling personal information acquires such personal information on a person as is written in a contract or other document (including a record made by an electronic method, a magnetic method, or any other method not recognizable to human senses. hereinafter the same shall apply in this paragraph.) as a result of concluding a contract with the person or acquires such personal information on a person as is written in a document directly from the person, the business operator shall expressly show the Purpose of Utilization in advance. However, this provision shall not apply in cases in which the acquisition of personal information is urgently required for the protection of the life, body, or property of an individual.*

³³ The Industrial Guidelines state:

“When a business operator handling personal information acquires personal information directly from a person through a document written by him/her, typing his/her oral statement into a computer in his/her presence or any other electronic or electro-magnetic means, the business operator must expressly show the purpose of utilization in advance. This requirement does not apply, however, to orally-presented personal information.

The purpose of utilization must be shown in advance when personal information is acquired directly from a person in, for example:

- *an application form or written contract;*
- *a questionnaire; and*
- *a postcard entry for a prize.”*

(6) Exemptions from notification requirement (Related to Article 18(4)³⁴ of the Act)

For the aspects of exemptions from notification requirement, consult the Industrial Guidelines³⁵.

2.3 Management of personal genetic information (Related to Articles 19 through 22 of the Act)

(1) Maintenance of the accuracy of data (Related to Article 19³⁶ of the Act)

Consult the Industrial Guidelines for other aspects of maintenance of the accuracy of data than that specified below:

Business operators handling anonymous genetic information shall endeavor to maintain

³⁴ Article 18(4) of the Act:

- (4) *The provisions of the preceding three paragraphs shall not apply to the following cases:*
- (i) *Cases in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to harm the life, body, property, or other rights or interests of the person or a third party*
 - (ii) *Cases in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to harm the rights or legitimate interests of the business operator handling personal information*
 - (iii) *Cases in which it is necessary to cooperate with a state organ or a local government in executing the affairs prescribed by laws and regulations and in which notifying the person of the Purpose of Utilization or publicly announcing it are likely to impede the execution of the affairs*
 - (iv) *Cases in which it is considered that the Purpose of Utilization is clear in consideration of the circumstances of the acquisition.*

³⁵ The Industrial Guidelines state,

- “(i) *The requirements for notification of the purpose of utilization at the time of acquisition does not apply when notifying the person of the purpose of utilization or publicly announcing it is likely to harm the life, body, property, or other rights or interests of the person or a third party.*

One example of such cases is when business operators share the personal information of so-called ‘fixers’ of shareholders’ meetings in an effort to prevent their unjustified demands and notifying them the purpose of utilization of their personal information or publicly announcing it could lead to damage to the information providers as a result of retaliation by the fixers.

- (ii) *The requirements for notification of the purpose of utilization at the time of acquisition does not apply when notifying the person of the purpose of utilization or publicly announcing it are likely to harm the rights or legitimate interests of the business operator handling personal information.*

One example of such cases is when the personal information reveals the business operator’s confidential information such as new product developments and trade secrets.

- (iii) *The requirements for notification of the purpose of utilization at the time of acquisition does not apply when it is necessary to cooperate with a state organ or a local government in executing the affairs prescribed by laws and regulations and in which notifying the person of the purpose of utilization or publicly announcing it are likely to impede the execution of the affairs.*

One example of such cases is when the personal information of a criminal suspect is provided by the police in its closed investigation. Notifying the person or the suspect the purpose of utilization or publicly announcing it would hinder the police’s investigation.

- (iv) *The requirements for notification of the purpose of utilization at the time of acquisition does not apply when it is considered that the purpose of utilization is clear in consideration of the circumstances of the acquisition.*

One example of such cases is when a business operator acquires the address and telephone number of a person for to deliver its products and services to the person.

Another example is the acquisition, through exchange of business cards, of the personal information of a person including the name, title, department and contact, and the information is used only for future contact. If the information is used to send a direct mail to the person, however, the purpose of utilization may not fall within the scope of ‘self-evident’ uses.”

³⁶ Article 19 (Maintenance of the Accuracy of Data) of the Act:

A business operator handling personal information shall endeavor to maintain personal data accurate and up to date within the scope necessary for the achievement of the Purpose of Utilization.

anonymous genetic information accurate and up to date within the scope necessary for the achievement of the purpose of utilization.

(2) Security control measures (Related to Article 20³⁷ of the Act)

Consult the Industrial Guidelines for other aspects of security control measures than those specified below:

In handling personal genetic information, business operators shall take systematic, human, physical and technical security control measures to prevent divulgence, loss or impairment of personal genetic information. In maintaining the security of personal genetic information, business operators shall anonymize it following the anonymizing procedures described below before taking any security measures that are the most appropriate for their business taking the “Recommended actions” specified in the Industrial Guidelines.

The same systematic, human, physical and technical security control measures shall also be taken in handling anonymous genetic information. Considering the size of the harm and disadvantage that a person must incur when his/her information is divulged, lost or impaired, business operators shall take any necessary and appropriate measures depending on the risk arising from the handling of the information including anonymizing procedures.

Anonymization

Each business operator handling personal genetic information shall appoint its anonymous information custodian and anonymize without delay personal genetic information whenever it acquires a sample and before it send the sample to outside contract laboratories or a third party.

An anonymous information custodian shall be responsible for the conduct of anonymization, the management and disposal of informed consent documents and the tables linking personal codes and identities, and the maintenance of the strict confidentiality of personal genetic information.

When a business operator handling personal genetic information receives, from an outside contract laboratory, samples and other materials that are not anonymized, it shall anonymize such materials and handle them as personal genetic information.

(3) Supervision of employees (Related to Article 21³⁸ of the Act)

For the aspects of supervision of employees, consult the Industrial Guidelines.

(4) Supervision of trustees (Related to Article 22³⁹ of the Act)

For the aspects of supervision of trustees, consult the Industrial Guidelines.

³⁷ Article 20 (Security Control Measures):

A business operator handling personal information shall take necessary and proper measures for the prevention of leakage, loss, or damage, and for other security control of the personal data.

³⁸ Article 21 (Supervision of Employees) of the Act:

When a business operator handling personal information has an employee handle personal data, it shall exercise necessary and appropriate supervision over the employee to ensure the security control of the personal data.

³⁹ Article 22 (Supervision of Trustees) of the Act:

When a business operator handling personal information entrusts an individual or a business operator with the handling of personal data in whole or in part, it shall exercise necessary and appropriate supervision over the trustee to ensure the security control of the entrusted personal data.

2.4 Provision to a third party (Related to Article 23 of the Act)

For the aspects of provision to a third party, consult the Industrial Guidelines.

(1) Basic principles (Related to Article 23(1)⁴⁰ of the Act)

Consult the Industrial Guidelines for other aspects of basic principles than those specified below:

In principle, personal genetic information shall not be provided to any third party. However, personal genetic information may be provided to a third party if an informed consent is given by the person specifying an appropriate and clear purpose and sample handling.

A sample originally collected for DNA or parentage testing may be stored for or used in a study intended to improve result interpretation techniques only after the person gives a renewed or an additional written informed consent specifying: an appropriate and clear purpose (*i.e.* a study to improve interpretation techniques) of utilization of the sample and/or personal genetic information; the identity of a third party to whom the sample and/or personal genetic information is provided, if any; the storing method; the security measures; the disposal of the sample and/or personal genetic information; and others.

(2) Opting-out (Related to Article 23(2)⁴¹ of the Act)

Business operators handling personal genetic information shall not use an “opting-out” process for the information they retain.

According to the Industrial Guidelines, “opting-out” is an exemption to the specification of (1) *Basic principles* of the preceding paragraph. In the opting-out process, the information listed below is either directly given to the person or put in a readily accessible condition for the person. A business operator may provide the personal data without prior consent of the person under the condition that the business operator discontinues, at the request of a person, the provision of such personal data. Article 23(2) of the Act provides that if this process is selected, the business operator can provide personal data to a third party without prior consent of the person.

⁴⁰ Article 23 (Restriction of Provision to A Third Party) of the Act:

- (1) *A business operator handling personal information shall not, except in the following cases, provide personal data to a third party without obtaining the prior consent of the person :*
- (i) *Cases in which the provision of personal data is based on laws and regulations*
 - (ii) *Cases in which the provision of personal data is necessary for the protection of the life, body, or property of an individual and in which it is difficult to obtain the consent of the person*
 - (iii) *Cases in which the provision of personal data is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the person*
 - (iv) *Cases in which the provision of personal data is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by one in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the person are likely to impede the execution of the affairs*

⁴¹ Article 23(2) of the Act:

- (2) *With respect to personal data intended to be provided to a third party, where a business operator handling personal information agrees to discontinue, at the request of a person, the provision of such personal data as will lead to the identification of the person, and where the business operator, in advance, notifies the person of the matters listed in the following items or put those matters in a readily accessible condition for the person, the business operator may, notwithstanding the provision of the preceding paragraph, provide such personal data to a third party:*
- (i) *The fact that the provision to a third party is the Purpose of Utilization*
 - (ii) *The items of the personal data to be provided to a third party*
 - (iii) *The means or method of provision to a third party*
 - (iv) *The fact that the provision of such personal data as will lead to the identification of the person to a third party will be discontinued at the request of the person*

- (i) The fact that the provision to a third party is the Purpose of Utilization
- (ii) The items of the personal data to be provided to a third party
- (iii) The means or method of provision to a third party
- (iv) The fact that the provision of such personal data as will lead to the identification of the person to a third party will be discontinued at the request of the person

(3) An individual or business operator not deemed as a third party (Related to Article 23(4)⁴² of the Act)

Consult the Industrial Guidelines for the aspects of an individual or business operator not deemed as a third party except that a medical doctor or other medical professional who is a third party may be entrusted with the handling of personal data.

(4) Handling of personal data in employee management

Consult the Industrial Guidelines for the aspects of handling of personal data in employee management.

2.5 Disclosure, correction, and use discontinuance of matters concerning retained personal genetic information, etc. (Related to Articles 24 through 30 of the Act)

(1) Public announcement of matters concerning retained personal genetic information, etc. (Related to Article 24 of the Act)

(a) Notification to a person of matters concerning his/her personal genetic information (Related to Article 24(1)⁴³ of the Act)

For the aspects of notification to a person of matters concerning his/her personal genetic information, consult the Industrial Guidelines.

(b) Notification of the purpose of personal genetic information (Related to Article 24(2) and (3) <Footnote 11> of the Act)

For the aspects of notification of the purpose of personal genetic information, consult the Industrial Guidelines.

⁴² Article 23(4) of the Act:

- (4) *In following the cases, the individual or business operator receiving such personal data shall not be deemed a third party for the purpose of application of the provisions of the preceding three paragraphs:*
- (i) *Cases in which a business operator handling personal information entrust the handling of personal data in whole or in part within the scope necessary for the achievement of the Purpose of Utilization*
 - (ii) *Cases in which personal data is provided as a result of the succession of business in a merger or otherwise*
 - (iii) *Cases in which personal data is used jointly between specific individuals or entities and in which this fact, the items of the personal data used jointly, the scope of the joint users, the purpose for which the personal data is used by them, and the name of the individual or business operator responsible for the management of the personal data is, in advance, notified to the person or put in a readily accessible condition for the person*

⁴³ Article 24(1) of the Act:

- (1) *With respect to the retained personal data, a business operator handling personal information shall put the matters listed in the following items in an accessible condition for the person (such condition includes cases in which a response is made without delay at the request of the person):*
- (i) *The name of the business operator handling personal information*
 - (ii) *The Purpose of Utilization of all retained personal data (except in cases falling under any of items 1 to 3 of paragraph 4 of Article 18)*
 - (iii) *Procedures to meet requests made pursuant to the provisions of the next paragraph, paragraph 1 of the next article, paragraph 1 of Article 26, or paragraph 1 or paragraph 2 of Article 27 (including the amount of charges if set pursuant to the provision of paragraph 2 of Article 30)*
 - (iv) *In addition to what is listed in the preceding three items, such matters, specified by a Cabinet Order, as being necessary for ensuring the proper handling of retained personal data*

(2) **Disclosure of personal genetic information** (Related to Article 25⁴⁴ of the Act)

Consult the Industrial Guidelines for the aspects of disclosure of personal genetic information other than those specified below:

When disclosing genetic information to the person, business operators handling personal genetic information shall follow the procedures for genetic counseling described under (a) of this item:

(a) Genetic counseling

Business operators handling personal genetic information, when they intend to disclose genetic information to the persons, shall offer the persons opportunities for genetic counseling at their offices or other appropriate institutions if necessary taking the medical and mental impacts and other factors into account.

Genetic counseling must be conducted by medical doctors or other professionals with sufficient knowledge, experience and counseling skills in the area of genetic medicine who can support mentally and socially the persons and their family members. Genetic counseling offered by personnel other than a medical doctor or other medical professional shall be attended by a medical doctor or other medical professional with sufficient skills in genetic counseling.

The objective of genetic counseling is to support and assist the persons in making decisions and acting on their own will by answering questions concerning the genetic testing and the business operation in general, and relieving their anxieties and problems arising from inherited predispositions.

The genetic counselor shall provide the most up-to-date information with easy language and continuously make sure that the person understands his/her words. Continued counseling sessions should be offered if the person wishes so.

(b) Considerations in DNA and parentage testing

In DNA and parentage testing, personnel with sufficient legal knowledge and experience shall cooperate in providing the persons necessary information and advice concerning the legal effects that the results of such testing have.

In parentage testing, it is important to respect the well-being of the person and his/her family and thus the following factors shall be considered:

- (i) The well-being of minors, especially infants who have virtually no voice; and
- (ii) Parents and the child who are directly affected by the testing or the donor of the

⁴⁴ Article 25 (Disclosure) of the Act:

- (1) *When a business operator handling personal information is requested by a person to disclose such retained personal data as may lead to the identification of the person (such disclosure includes notifying the person that the business operator has no such retained personal data as may lead to the identification of the person concerned. The same shall apply hereinafter.), the business operator shall disclose the retained personal data without delay by a method prescribed by a Cabinet Order. However, in falling under any of the following items, the business operator may keep all or part of the retained personal data undisclosed:*
- (i) *Cases in which disclosure is likely to harm the life, body, property, or other rights or interests of the person or a third party*
 - (ii) *Cases in which disclosure is likely to seriously impede the proper execution of the business of the business operator handling personal information*
 - (iii) *Cases in which disclosure violates other laws and regulations*

sample have agreed on the conduct of the testing.

(3) Correction of personal genetic information, etc.

Consult the Industrial Guidelines for the aspects of correction of personal genetic information.

(4) Utilization discontinuance of personal genetic information, etc.

Consult the Industrial Guidelines for the aspects of utilization discontinuance of personal genetic information.

(5) Explanation of reasons (Related to Article 28⁴⁵ of the Act)

Consult the Industrial Guidelines for the aspects of explanation of reasons.

(6) Procedures to meet requests for disclosure and others (Related to Article 29⁴⁶ of the Act)

Consult the Industrial Guidelines for the aspects of procedures to meet requests for disclosure and others.

Business operators handling personal information shall ensure that the procedures to confirm that the person who requests disclosure of personal genetic information is the person himself/herself or the authentic proxy of the person are adequate and appropriate.

Business operators handling personal information may refuse the request for disclosure by the proxy of the person under Article 8(2) of the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No. 507 of 2003), and limit the eligibility to make the request to the person only.

⁴⁵ Article 28 (Explanation of Reasons) of the Act:

When a business operator handling personal information notifies a person requesting the business operator to take certain measures pursuant to the provisions of paragraph 3 of Article 24, paragraph 2 of Article 25, paragraph 2 of Article 26, or paragraph 3 of the preceding article that the business operator will not take all or part of the measures or that the business operator will take different measures, the business operator shall endeavor to explain the reasons.

⁴⁶ Article 29 (Procedures to Meet Requests for Disclosure and Others) of the Act:

- (1) A business operator handling personal information may, as prescribed by a Cabinet Order, determine procedures for receiving requests that may be made pursuant to the provisions of paragraph 2 of Article 24, paragraph 1 of Article 25, paragraph 1 of Article 26 or paragraph 1 or paragraph 2 of Article 27 (hereinafter referred to as "a request for disclosure and others" in this article). In such a case, any person making a request for disclosure and others shall comply with the procedures.*
- (2) A business operator handling personal information may request a person making a request for disclosure and others to show sufficient items to identify the retained personal data in question. In this case, the business operator shall provide the information contributing to the identification of the retained personal data in question or take any other appropriate measures in consideration of the person's convenience so that the person can easily and accurately make a request for disclosure and others.*
- (3) A person may, as prescribed by a Cabinet Order, make a request for disclosure and others through a representative.*
- (4) When a business operator determine the procedures for meeting requests for disclosure and others under the provisions of the preceding three paragraphs, the business operator shall take into consideration that the procedures will not impose excessively heavy burden on the persons making requests for disclosure and others*

- (6) **Charges** (Related to Article 30⁴⁷ of the Act)
Consult the Industrial Guidelines for the aspects of charges.
- 2.6 **Processing of complaints** (Related to Article 31⁴⁸ of the Act)
Consult the Industrial Guidelines for the aspects of processing of complaints.
- 2.7 **Transitional measures** (Related to Articles 2 through 5⁴⁹ of the Supplementary Provisions of the Act)
Consult the Industrial Guidelines for the aspects of transitional measures.

2.8 Personal genetic information handling committee

Business operators handling personal genetic information shall set up a personal genetic information handling committee to examine the appropriateness of the business operations handling personal genetic information and other issues. If the trade could not agree on the establishment of the committee, a personal genetic information handling committee set up by a partnership, non-profit corporation, scientific society or the trade organization can replace the former. If a similar committee has already been established by business operators handling personal genetic information, the committee may be reorganized to meet the requirements of the Present Guidelines without changing its name.

The committee may send a letter of opinion to the business operator handling personal genetic information in question after examining, based on the Present Guidelines, the appropriateness of its business operation from the ethical, legal and social point of view.

In the letter of opinion, the committee may advise the business operator handling personal

⁴⁷ Article 30 (Charges) of the Act:

- (1) *When a business operator handling personal information is requested to notify the Purpose of Utilization under the provision of paragraph 2 of Article 24 or to make a disclosure under the provision of paragraph 1 of Article 25, the business operator may collect charges for taking the measure.*
- (2) *When a business operator handling personal information collects charges pursuant to the provision of the preceding paragraph, the business operator shall determine the amounts of charges within the scope considered reasonable in consideration of actual costs.*

⁴⁸ Article 31 (Processing of Complaints by Entities Handling Personal Information) of the Act:

- (1) *A business operator handling personal information shall endeavor to appropriately and promptly process complaints about the handling of personal information.*
- (2) *A business operator handling personal information shall endeavor to establish a system necessary for achieving the purpose set forth in the preceding paragraph.*

⁴⁹ Article 2 (Transitional Measures Concerning a Consent of a Person) of the Supplementary Provisions of the Act:

Where a person has given consent to the handling of his or her personal information prior to enforcement of this Act, and where the consent is equivalent to the consent that allows the personal information to be handled for a purpose other than the Purpose of Utilization specified under paragraph 1 of Article 15, then it shall be deemed that there is such consent as is prescribed in paragraph 1 or 2 of Article 16.

Article 3 of the Supplementary Provisions of the Act:

Where a person has given consent to the handling of his or her personal information prior to enforcement of this Act, and where the consent is equivalent to the consent that allows the personal data to be provided to a third party under paragraph 1 of Article 23, then it shall be deemed that there is such consent as is prescribed in the same paragraph.

Article 4 (Transitional Measures Concerning Notices) of the Supplementary Provisions of the Act:

If an individual has been notified, prior to enforcement of this Act, of the matters that shall be notified to the individual or be put in a readily accessible condition for the individual under paragraph 2 of Article 23, then it shall be deemed that the notice concerned has been given under the provision of the same paragraph.

Article 5 of the Supplementary Provisions of the Act:

If an individual has been notified, prior to enforcement of this Act, of the matters that shall be notified to the individual or be put in a readily accessible condition for the individual under item 3 of paragraph 4 of Article 23, then it shall be deemed that the notice concerned has been given under the provision of the same paragraph.

genetic information in question modifications in or discontinuance of its business operation and/or other actions necessary to make it appropriate.

The committee shall be organized and operated so that its examinations are conducted independently by members with different positions allowing pluralistic discussions.

The proceedings of examinations at the committee shall be made public. However, parts of the proceedings can be made confidential by the committee decision considering the privacy of the sample donor, confidentiality of original studies, protection of intellectual properties or competitive advantages, and other factors. In such a case, the committee shall make public the reasons for confidential handling of the parts of the proceedings.

Members of the committee shall not divulge or otherwise disclose during and after the term of membership, without due reason, the information with which they have become acquainted in the course of their duty.

2.9 Business plan of business operator handling personal genetic information

Business operators handling personal genetic information shall prepare a written business plan that fully takes into account such factors as:

- the sensitive nature of personal genetic information;
- any potential disadvantages that the business can bring to the person and/or his/her family members;
- the need for the business; and
- the business practices that can effectively prevent any potential disadvantages that the person and/or his/her family members.

Business operators handling personal genetic information shall dispose, in accordance with the terms of consent agreed to with the person or his/her proxy, all the samples and other records after the storage period expires.

Business operators handling personal genetic information shall decide the plans of the business operations that use personal genetic information and their modifications respecting the opinions of a personal genetic information handling committee.

Items to be included in the written business plan

- methods and procedures of informed consent;
- methods for protecting personal information;
- anticipated consequences of the business and the position toward disclosure of the consequences;
- methods of storing and using samples and records; and
- position toward genetic counseling, and that toward the counseling for DNA and parentage testing.

3. Handling of personal information at the laboratories operated by private organizations

For the aspects of the handling of personal information at the laboratories operated by private organizations, consult the Industrial Guidelines.

The Present Guidelines provides for the protection of personal information in the sector of business operations handling personal genetic information only. For that in the research sector, the Ethics Guidelines for Human Genome/Gene Analysis Research shall apply.

III. Ideas of Recommendations, Orders and Urgent Orders

The ideas of *recommendations*, *orders* and *urgent orders* are presented in the *Industrial Guidelines to Implement the Act on the Protection of Personal Information*.

IV. Review of the Present Guidelines

The Present Guidelines will be reviewed in the same manner⁵⁰ as the *Industrial Guidelines to Implement the Act on the Protection of Personal Information*.

V. References

The following are the published guidelines that business operators handling personal genetic information may find useful in their efforts to properly and effectively carry out their duties, etc.

Industrial Guidelines to Implement the Act on the Protection of Personal Information (Joint Notification No. 4 of the MHLW and the METI of October 2004) See *I. Purpose and Scope* of the Present Guidelines for details.

Depending on the nature and needs of their activities, business operators handling personal genetic information shall make their best in meeting the following guidelines:

Guidelines for Genetic Testing

Published in August 2003 as a joint effort by eleven genetics-related scientific groups including the Japanese Society for Genetic Counseling, the Japanese Society for Gene Diagnosis and Therapy, the Japan Society of Obstetrics and Gynecology, the Japanese Society of Pediatric Genetics, the Japan Society of Human Genetics, the Japanese Teratology Society, the Japanese Society for Inherited Metabolic Diseases, the Japanese Society for Mass-screening, and the Study Group for Familial Tumors (now the Japanese Society for Familial Tumors)

Guidelines for DNA Testing

Published in December 1997 by the Study Committee for DNA Testing of the Japanese Society for DNA Polymorphism Research

Guidelines for Parentage Testing

Published in June 1999 by the Working Group on Parentage Testing of the Japanese Society of Legal Medicine

Ethical Guidelines for Contract Human Genetic Testing

Published in April 2001 by the Ethics Study Committee on Genetic Testing of the Japan Registered Clinical Laboratories Association

⁵⁰ The Industrial Guidelines state,

“In view of the fact that the idea of personal information protection can change as social climate and public perception change and technology advances, the present guidelines should be reviewed basically every year taking into account the changes in the environment including the situation after the enforcement of the Act.”