Ethical Guidelines for Epidemiological Research

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Ministry of Education, Culture, Sports, Science and Technology
Ministry of Health, Labour and Welfare

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Preamble

Epidemiological research is the scientific study of investigating the incidence and distribution of health-related events, such as the contraction of a disease, and clarifying the main factors for such events. It is essential for identifying the causes of a disease, for examining the efficacy of the methods used for preventing and treating diseases, and for elucidating the relationship between health and the environment and lifestyles, and it plays a considerable role in advancing medicine and in maintaining and promoting public health.

Epidemiological research involves the handling of specific information on the physical and mental conditions of a large number of research subjects as well as on other factors such as their surroundings and lifestyles. Another characteristic of epidemiological research is that many people besides medical doctors are involved in the research.

The following ethical guidelines are thus established both to protect the personal dignity and human rights of research subjects and to enable researchers, etc. to conduct research smoothly.

In view of the World Medical Association's Declaration of Helsinki and Japan's Act on the Protection of Personal Information and other related acts, the general principle of these Guidelines is the protection of personal information during the conduct of epidemiological research, such as obtaining the informed consent of research subjects. In consideration of the exceedingly diverse approaches to epidemiological research, these Guidelines profile only the basic principles. When researchers, etc. formulate research protocols and when ethics review committees determine the propriety of such protocols, they should make appropriate judgments according to the content of each research protocol, taking these principles into account.

Also, with respect to the protection of personal information, organizations conducting research should give heed to the requirement for them to observe the Act on the Protection of Personal Information (Act No. 57 of 2003), the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58 of 2003), the Act on the Protection of Personal Information Held by Independent Administrative Agencies, etc. (Act No. 59 of 2003), and prefectural and municipal ordinances established by local government in accordance with the aim of Article 11(1) of the Act on the Protection of Personal Information, applied according to such categories as private-sector enterprises, administrative organs and incorporated administrative agencies, etc.

All people involved in epidemiological research should engage in research in accordance with these Guidelines, in order to gain the understanding and confidence of society and to make further contributions to society. At the same time, it is expected that the broad understanding of the general public will be obtained for the conduct of epidemiological research needed to maintain and promote public health.

PART I: BASIC IDEAS

1. Purpose

The purpose of these Guidelines is for epidemiological research to be promoted appropriately based on an understanding and cooperation of society, by stipulating the matters to be observed by all persons engaged in epidemiological research from ethical viewpoints, such as respect for personal dignity and human rights and the protection of personal information, as well as from scientific viewpoints, in view of academic freedom and the importance of epidemiological research in maintaining and promoting public health.

2. Scope of Application

These Guidelines shall apply to epidemiological research aimed at clarifying the causes and pathological conditions of human diseases and establishing methods for their prevention and treatment, and shall require that all persons involved in such research comply with them; provided however that these Guidelines shall not apply to any epidemiological research that falls under any of the following:
(i) Surveys conducted pursuant to the provisions of law
(ii) Research conducted based on the Ethical Guidelines for Human Genome/Gene Analysis Research (Public Notice No. 1 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, 2004)
(iii) Research which only uses information that has already been anonymized in an unlinkable fashion as materials or information
(iv) An intervention study involving medical practices such as surgery and medication

<Detailed regulations concerning the scope of application>
1. Proviso (i) to this rule corresponds to surveys specifically authorized by law, such as the infectious diseases reports based on the provisions of the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases.
2. The following table shows examples of cases where research falls within/beyond the scope of application of these Guidelines.

Examples of research	
Within scope of Guidelines	Beyond scope of Guidelines
(Medical care and research) • For the purpose of examining patient numbers and other data concerning a particular disease, making requests to multiple medical institutions to collect, tabulate and analyze the medical information of patients afflicted with the	(Medical care and research) • For the purpose of examining methods for treating a disease affecting specified patients, investigating the medical records and other medical information of those patients afflicted with the disease. Treatment of those patients is carried out

particular disease, thereby obtaining new knowledge, investigating different methods of treatment and so forth. Note: The mere supply of existing materials and information or materials and information extracted from existing materials and information is subject to the provisions of section 3 of Part IV.	based on this.
(Medicines and foods) • Dividing subjects (patients or ordinary persons) into two groups, and giving one group a specific food (including health foods, designated health foods and the like) and the other group ordinary food, thereby examining the health-related effects of the food.	(Medicines and foods) • Dividing subjects (patients or ordinary persons) into two groups, and giving one group a specific medicine and the other group a placebo, thereby examining the health-related effects of the medicine.
	(Unlinkable, anonymized information) • Combining patient surveys and national nutrition surveys to investigate their relationship based on the medical treatment rate for lifestyle-related diseases and energy intake on a regional basis.
(Relationship with public health services) • Examining methods for the prevention of a specific disease or investigating the regional characteristics of diseases using medical examination data or biological specimens obtained through public health services (including the cerebral apoplexy information system and the cancer registry programs; the same shall apply hereinafter in this table) (excluding research conducted as a public health program).	(Relationship with public health services) • Public health programs (including quality control) conducted regionally by a municipality, prefecture, health center or the like, as well as surveys conducted by an occupational health physician or school physician within the scope of their business based on laws and regulations in the areas of industrial health or school health, the cerebral apoplexy information system program, or the cancer registry program.
(Epidemiological research in the clinical setting) • An observational study in which medical records and other medical information is collected and tabulated for the purpose of evaluating the efficacy and safety of diagnosis, treatment and other medical	(Epidemiological research in the clinical setting) • An intervention study conducted on subjects for the purpose of investigating the efficacy and safety of new methods of treatment.

practices.	
	(Practical training) • Practical training, conducted under a certain curriculum, designed for participants to learn processes up to achieving outcomes.

3. With regard to collaborative research undertaken with an overseas research institution, researchers shall, in principle, abide by these Guidelines. However, in cases where application of these Guidelines is difficult in view of the social circumstances and other factors in the country where the said overseas research institution is located, if authorized by the ethics review committee of the Japanese research institution and approved by the director of the research institution, researchers may conduct their research in accordance with the standards set forth in the laws, regulations, guidelines and so forth stipulated in the other country. In cases where the standards in the country where the relevant overseas research institution is located are more rigorous than these Guidelines, researchers shall abide by those rigorous standards.

3. Basic Rules for Researchers, etc.

(1) Ensuring the scientific rationale and ethical propriety of epidemiological research

(i) A researcher, etc. shall conduct epidemiological research with respect for the personal dignity and human rights of research subjects.

(ii) A researcher, etc. shall not conduct epidemiological research that is not recognized as having scientific rationale and ethical propriety, and when conducting epidemiological research, shall prepare a clear and detailed research protocol based on these points.

(iii) A researcher, etc. shall, when intending to conduct epidemiological research, obtain approval for the research protocol from the director of the research institution. The same shall apply when the researcher, etc. intends to change the research protocol.

<Detailed regulations concerning the directors of research institutions>
The term “director of a research institution” includes, for instance:

- In the case of a 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

<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. All matters required by these

Guidelines to be included and all matters subject to review by the ethics review committee, however, must be stated.

- Policy for selecting research subjects
- The significance, objectives and method of research, the period of research, and the method for protecting personal information
- The names of the research institutions (including any collaborative research institutions)
- The names of the researchers, etc.
- The procedures for obtaining informed consent (in cases where informed consent is not obtained, the reason for this, and the method used for notifying or publicly announcing matters to be disclosed regarding conduct of the said research)
- The explanatory matters and letters of agreement for obtaining informed consent
- The expected benefits, any potential risks and any inevitable discomfort resulting from participating in the research
- Compensation and other forms of support befitting the research in cases where there are potential risks or inevitable discomfort
- The sources of funding for the research, potential conflicts of interest, and any relationships between researchers, etc. and associated organizations
- In cases where a human specimen is to be used without obtaining the informed consent of the research subject, and where the research is particularly necessary for improving public health, the reason that it is difficult to obtain the consent of the person. In cases where proxy consenters are selected, the thinking behind that
- The methods of preserving and using the materials and information, and the retention period
- The method of preservation, use or disposal of materials and information after completion of the research (including the possibility of using them in other research and the predicted details of the research)

(iv) A researcher, etc. shall conduct epidemiological research appropriately in accordance with laws and regulations, these Guidelines and research protocols.

(v) A researcher, etc. shall not select research subjects in an unreasonable or improper manner.

(2) Protection of personal information

(i) A researcher, etc. shall properly handle information pertaining to research subjects, and shall protect their personal information.

(ii) A researcher, 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.

(3) Obtaining informed consent

(i) Before conducting any epidemiological research, the researcher, etc. shall, in principle, obtain the informed consent of the research subjects in advance.

(ii) A researcher, etc. shall include in a research protocol, the details of the explanation given to research subjects, how their consent is confirmed and any other matters pertaining to the process of obtaining informed consent.

<Detailed regulations concerning obtaining informed consent>
In general, the following matters shall be included in the explanation given to research subjects:

- The names of the research institutions and the names of the researchers, etc.
- Reasons why the research subjects were selected
- The objectives, significance and method of research, the period of research
- That participation in the research is voluntary
- That a research subject should not suffer any disadvantage, even in cases where he/she will not give consent to the research being conducted
- Even in cases where a research subject will consent to the research being conducted, that he/she may revoke that consent at any time
- The expected benefits, any potential risks and any inevitable discomfort resulting from participating in the research
- Compensation and other forms of support befitting the research in cases where there are potential risks or inevitable discomfort
- The sources of funding for the research, potential conflicts of interest, and any relationships between researchers, etc. and associated organizations
- The handling of personal information
- In cases where it is envisaged that there will be matters which may not be disclosed even in response to a request for disclosure from a research subject, etc., those matters and the reasons for nondisclosure
- The possibility that research outcomes will be publicly announced in a way that research subjects cannot be identified
- In cases where consent is obtained from proxy consenters, the importance and essentialness of the research
- The possibility that personal information may be provided to a third party (excluding proxy consenters), and details of any matters other than those listed in paragraph 1(9)(i)(a) through (d) of Part IV (such as items of personal information which will be provided to a third party)
- When collaborative research is conducted: (i) the fact that it is collaborative research, (ii) the items of the personal information used jointly, (iii) the scope of the joint users, (iv) the purpose for which the personal information is used by them, and (v) the names of the persons responsible for the management of the personal information
- Procedures responding to any requests made pursuant to the provisions of paragraph 1(10)(ii), (11)(i), (12)(i) or (13)(i) or (ii) of Part IV (including the amount of any charges if set pursuant to the provisions of paragraph (16))
- Where complaints can be made concerning the handling of personal information
- The methods of preserving and using the materials and information, and the retention period

- The method of preservation, use or disposal of materials and information after completion of the research (including the possibility of using them in other research and the details of the predicted research)

(4) Public announcement of research results
A research director shall publicly announce the findings of epidemiological research after taking measures necessary for protecting the personal information of research subjects.

(5) Responsibility of instructors
A person at a university or other educational institution who provides guidance to students and others on epidemiological research shall provide such guidance and supervision so that the epidemiological research is conducted in compliance with the matters listed in paragraphs (1) to (4) and other necessary matters.

4. Responsibilities of Research Institution Directors

(1) Emphasis of ethical considerations
The director of a research institution shall communicate widely and thoroughly to its researchers, etc. that, in conducting epidemiological research, they must respect the personal dignity and human rights of research subjects and must take measures necessary for protecting personal information, so as to prevent the epidemiological research at the research institution in question from giving rise to any ethical, legal or social issues.

(2) Establishment of ethics review committees
The director of a research institution shall establish an ethics review committee to conduct reviews on necessary matters concerning epidemiological research, such as whether a research protocol conforms to these Guidelines. When, however, it is difficult to set up an ethics review committee within the research institution for reasons such as the small size of the said research institution, or when otherwise necessary, this committee may be substituted by making a request for a review to an ethics review committee established by a collaborative research institution, a general incorporated association, a general incorporated foundation or an academic society.

<Detailed regulations concerning the establishment of ethics review committees>
1. The ethics review committee referred to in the proviso to this rule includes an ethics review committee established jointly by the directors of multiple collaborative research institutions.

2. Cases where a request for a review may be made to an ethics review committee established by a collaborative research institution, etc. shall be as follows:
(i) When an ethics review committee cannot be established within a research institution for reasons such as the small size of the said research institution

(ii) In the case of collaborative research, when a research institution is a secondary research institution, such as one solely engaged in the accumulation of data
(iii) In the case of collaborative research, when making a request for a review to an ethics review committee established by a collaborative research institution, etc. is recognized as particularly necessary for the smooth promotion of epidemiological research given the responsibilities and composition of the ethics review committee listed in paragraph 1(1) of Part II.

(3) Referring to an ethics review committee
When asked by a researcher, etc. for approval set forth in paragraph 3(1)(iii), the director of a research institution shall hear the opinion of the ethics review committee; provided however, that this shall not apply to any research protocol that falls under any of the following:
(i) Cases where a person belonging to the ethics review committee or another person nominated in advance by the ethics review committee (referred to as the “person nominated in advance” in (ii)) has determined that the research protocol in question satisfies all of the following requirements, and that it does not need to be brought before the ethics review committee
(a) Information that has been already anonymized in a linkable fashion will be collected at another institution, the survey will be conducted on an anonymous basis and other personal information will not be handled
(b) The research does not use human biological specimens
(c) The research is an observational study and does not involve any intervention or burden upon a human body
(d) In the survey, responses are left to the wishes of the research subject, and the content of the questions is not expected to cause the research subject any psychological distress

(ii) Cases where the person nominated in advance has judged that the research protocol does not need to be brought before the ethics review committee because the research is concerned exclusively with carrying out aggregation and simple statistical processing or the like using the medical records and other medical information of patients at the medical institution to which the researcher, etc. belongs

(iii) Cases where only the aggregation of data or statistical processing is entrusted, based on a contract which includes provisions concerning the following matters:
(a) Security control measures for data
(b) A duty of confidentiality

<Detailed regulations concerning researchers who do not belong to a research institution>
1. A researcher not belonging to a research institution is not required to obtain approval from the director of a research institution as prescribed in paragraph 3(1)(iii) of Part I, sections 1 and 2 of Part III, paragraph 2(2) of Part IV and paragraphs (2)(ii) and (iii) and 3(1) of Part IV.

2. A researcher not belonging to a research institution should, according to the field of study, voluntarily hear the opinion of the ethics review committee established at the organization to which the collaborating researchers of the epidemiological research belong (for instance: university, general incorporated association, general incorporated foundation or academic society).

(4) Approval given by the directors of research institutions
In determining the approval or disapproval for a research protocol or other necessary matters concerning epidemiological research, the director of the research institution shall respect the opinions of the ethics review committee. In this case, the director of the research institution shall not approve the conduct of any epidemiological research for which the ethics review committee has expressed an opinion of disapproval.

<Detailed regulations concerning the approval given by directors of research institutions>
The director of a research institution may decide to give approval before hearing the opinion of the ethics review committee if he/she determines that the research needs to be conducted urgently to prevent a serious public health threat from occurring or spreading. In this case, the director of the research institution shall hear the opinion of the ethics review committee as soon as possible after giving approval, and shall issue instructions to the research director for the alteration or discontinuation of the research should the ethics review committee express an opinion of alteration or discontinuation.

(5) Preparation of response procedures for adverse events
In view of the epidemiological research conducted at a research institution, the director of the research institution shall, where necessary, establish rules in advance concerning response procedures should an adverse event occur.

PART II: ETHICS REVIEW COMMITTEES

1. Ethics Review Committees

(1) Responsibilities and composition of ethics review committees
(i) When requested by the director of a research institution to provide opinions on necessary matters concerning epidemiological research, such as whether a research protocol conforms to these Guidelines, the ethics review committee shall review such matters from ethical and scientific viewpoints, and shall state their opinion in writing.

(ii) An ethics review committee shall be appropriately composed of members from various backgrounds so that it can perform reviews in a fair and impartial manner, based on an interdisciplinary and pluralistic approach.

<Detailed regulations concerning the composition of ethics review committees>

An ethics review committee shall be composed of experts in the fields of human/social sciences, such as medical science, medical care and law, as well as persons with a general background, and shall include external members. The ethics review committee shall also be composed of both male and female members.

(iii) Members of an ethics 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.

(2) Operation of ethics review committees
(i) A committee member connected with a research protocol that is subject to review shall not be involved in reviewing the said research protocol; provided, however, that this shall not preclude the member from attending meetings and providing explanations at the request of the ethics review committee.

(ii) An ethics review committee shall publicly announce the rules concerning its operation, the names of its members, the composition of its members and summaries of its proceedings. This shall, however, not apply to any parts of a summary of proceedings that need to be kept undisclosed for the purpose of protecting the human rights of research subjects, the originality of research or intellectual property rights, or for the purpose of preserving competitive position.

(iii) An ethics review committee may stipulate that a director of the research institution is able to bring necessary matters concerning epidemiological research, such as whether a research protocol conforms to these Guidelines, before another ethics review committee established by an academic society or the like.

<Detailed regulations concerning other ethics review committees established at academic societies, etc.>
“Another ethics review committee established by an academic society or the like” shall include an ethics review committee jointly established by the directors of multiple collaborative research institutions.

(iv) An ethics review committee may stipulate necessary matters, such as that reviews of insignificant matters may be referred to a fast-track review conducted by a single committee member nominated by the committee chairperson. The results of a fast-track review shall be reported to all members other than those who performed the review.

<Detailed regulations concerning the fast-track review process>
Matters that may be committed to a review through the fast-track review process shall, in general, be as follows:
(i) The review of a minor alteration to a research protocol
(ii) In the case of collaborative research, the review of a research protocol in cases where a research institution intends to conduct a research protocol that has already been authorized by the ethics review committee of the principal research institution.

(iii) The review of a research protocol that does not include any risks exceeding the minimum risks for research subjects. (The term “minimum risks” shall mean risks not exceeding the limit of potential physical, psychological and social harm suffered in everyday life or in an ordinary medical examination, and which is socially acceptable; the same shall apply hereinafter.)

2. Reporting on Epidemiological Research

(i) In the case of research that extends over several years, the research director shall submit research progress reports to the ethics review committee via the director of the research institution pursuant to the provisions of the research protocol.

<Detailed regulations concerning the period for submission of research progress reports>

The period for submission of research progress reports shall be stated in the research protocol and approved by the ethics review committee. The benchmark period shall be, for instance, once every three years.

(ii) When a risk or disadvantage is incurred by a research subject, the research director shall immediately report it to the ethics review committee via the director of the research institution.

(iii) Upon receiving the submission of a research progress report or receiving a report of research progress from the research director pursuant to the provisions of items (i) or (ii), the ethics review committee may provide a statement to the director of the research institution on necessary opinions concerning the alteration or discontinuation of the research protocol in question and on other issues concerning epidemiological research.

(iv) The director of a research institution shall, where necessary, conduct his/her own checks and assessments concerning the conformity of research at the research institution with these Guidelines.

<Detailed regulations concerning the methods and timing of the checks and assessments conducted directly by directors of research institutions>

The methods and timing of the checks and assessments conducted directly by the director of a research institution shall be established by the director of the research institution in accordance with such factors as the content of the research.

(v) The director of a research institution shall respect the opinions provided by the ethics review committee set forth in item (iii), and, based on the results of the checks and assessments set forth in item (iv), shall, where necessary, make decisions on altering or discontinuing the research protocol and on other necessary matters concerning epidemiological research.

(vi) When the director of the research institution has made a decision on altering or discontinuing the research protocol or on other necessary matters concerning

epidemiological research pursuant to item (v), the research director shall comply with this decision.

(vii) At completion of the epidemiological research, the research director shall report a summary of the research results without delay to the ethics review committee via the director of the research institution.

<Detailed regulations concerning the reports of researchers not belonging to a research institution>
A researcher not belonging to a research institution is required to make his/her own report under paragraphs 2(i), (ii) and (vii) of Part II to the ethics review committee from which the researcher has sought opinions on a research protocol.

PART III: INFORMED CONSENT

1. Procedures for Obtaining Informed Consent from Research Subjects, etc.

The procedures for obtaining informed consent from research subjects shall, in principle, be provided as follows. However, in cases where this is not possible due to such reasons as the method or content of the epidemiological research or the circumstances of the research subjects, the procedures for obtaining informed consent from research subjects may be simplified or waived, or another appropriate method for obtaining informed consent may be selected, to the extent necessary, but only when so authorized by the ethics review committee and approved by the director of the research institution.

<Detailed regulations concerning the simplification, etc. of informed consent>
When an ethics review committee acknowledges that the method for obtaining informed consent is to be simplified or waived or conducted using a different method to the general rules, the committee should make certain that the epidemiological research in question satisfies all of the following requirements:
(i) The epidemiological research in question should not include any risks exceeding the minimum risks for research subjects.

(ii) Using the method in question should not disadvantage the research subjects.

(iii) If the method in question was not used, in effect, the epidemiological research would not be able to be conducted or the value of the epidemiological research would be significantly impaired.

(iv) Whenever appropriate, any of the following measures should always be taken:
(a) The population that includes the research subjects should be publicly informed about the details and purpose of collecting and using the materials and information, including the methods thereof.

(b) Research subjects should be provided with ex-post briefings as soon as practically possible (group briefings are also acceptable).
(c) In cases where materials and information are to be collected or used continuously for a long period of time, efforts should be taken to keep the public fully informed of the situation by publicizing pertinent information including the objectives and method of collecting and using the materials and information.

(v) The epidemiological research in question should be recognized as having great social importance.

(1) Intervention studies
(i) Studies using human biological specimens
(a) In the event specimens are collected by invasive methods (such as the drawing of blood; the same shall apply hereinafter)
Informed consent shall, in principle, be obtained from research subjects by providing an explanation in writing and by obtaining consent in writing.

(b) In the event specimens are collected by non-invasive methods
Informed consent shall, in principle, be obtained from research subjects. In this case, although providing an explanation in writing and obtaining consent in writing is not necessary, the researcher, etc. shall prepare records on the explanations provided and consent obtained.

(ii) Studies not using human biological specimens
(a) In the event the intervention study is conducted on an individual basis
Informed consent shall, in principle, be obtained from research subjects. In this case, although providing an explanation in writing and obtaining consent in writing is not necessary, the researcher, etc. shall prepare records on the explanations provided and consent obtained.

(b) In the event the intervention study is conducted on an population basis
Informed consent does not necessarily need to be obtained from research subjects. In this case, the researcher, etc. shall disclose information regarding the conduct of the study, including the objectives of the said research, and shall provide each prospective research subject an opportunity to refuse inclusion in the research.

<Detailed regulations concerning persons who have refused to act as research subjects>
1. Personal information of someone who has refused to act as a research subject shall not be collected, but it may be included when counting the population.

2. In this case, information needs to be disclosed in a way that is particularly easy for research subjects to obtain.

(2) Observational studies
(i) Studies using human biological specimens

(a) In the event specimens are collected by invasive methods
Informed consent shall, in principle, be obtained from research subjects by providing an explanation in writing and by obtaining consent in writing.

(b) In the event specimens are collected by non-invasive methods
Informed consent shall, in principle, be obtained from research subjects. In this case, although providing an explanation in writing and obtaining consent in writing is not necessary, the researcher, etc. shall prepare records on the explanations provided and consent obtained.

(ii) Studies not using human biological specimens
(a) Observational research using materials and information pertaining to data other than existing materials and information
Informed consent does not necessarily need to be obtained from research subjects. In this case, the researcher, etc. shall disclose information regarding the conduct of the study, including the objectives of the said research, and shall provide each prospective research subject an opportunity to refuse inclusion in the research.

(b) Observational research using only existing materials and information
Informed consent does not necessarily need to be obtained from research subjects. In this case, the researcher, etc. shall disclose information regarding the conduct of the study, including the objectives of the said research.

<Detailed regulations concerning matters to be disclosed regarding research being conducted in cases where informed consent is not obtained>
In cases where informed consent is not obtained, the following matters should be included when disclosing information on the research being conducted. These matters should also be stated in the research protocol:

- The significance, objectives and method of the research
- The name of the research institution
- With respect to any retained personal information, procedures for responding to any requests made pursuant to the provisions of paragraph 1(10)(ii), (11)(i), (12)(i) or (13)(i) or (ii) of Part IV (including the amount of any charges if set pursuant to the provisions of paragraph (16))
- With respect to any retained personal information, information regarding the address and other details of contact points for inquiries and complaints, etc. made pursuant to paragraph 1(17) of Part IV
- In cases where notification of the purpose of use pursuant to paragraph 1(10)(ii) of Part IV, disclosure pursuant to paragraph 1(11) or explanation of reasons pursuant to paragraph 1(14) cannot be performed, the said matter and the reasons therefor

2. Procedures for Obtaining Informed Consent from Proxy Consenters, etc.

Where obtaining the informed consent of a research subject is difficult, informed consent may be obtained from a proxy consenter, etc. (meaning a person, such as the statutory agent of the research subject in question, who is regarded as being able to represent the intentions and interests of the research subject), but only when the ethics review committee authorizes and the director of the research institution approves that it is particularly necessary for the improvement of public health and conducting the epidemiological research on the relevant research subject is absolutely essential.

<Detailed regulations concerning informed consent obtained from proxy consenters, etc.>
Cases where obtaining informed consent from a research subject is difficult and obtaining informed consent from a proxy consenter, etc. is permissible, and the handling of such cases are as follows:

(i) When it can be objectively determined that a research subject is not capable of giving effective informed consent for a reason such as dementia

(ii) When the research subject is a minor (excluding cases where the research subject is aged 16 years or older, and where the ethics review committee has authorized and the director of the organization conducting research has approved that the research subject is able to provide effective informed consent); provided, however, that, even in this case, the research director shall provide an adequate explanation to the research subject in simple and plain language, and shall endeavor to gain their understanding. Furthermore, in cases where the research subject is under the age of 16 years and research has commenced with informed consent provided by a proxy consenter, if the research will be continued after the research subject reaches 16 years of age, in principle, informed consent shall again be obtained from the research subject in question at the time he/she turns 16 years of age and it can be objectively determined that he/she is capable of giving effective informed consent.

(iii) When the research subject is a deceased person, and there is no contradiction to their explicit wishes made before their death

PART IV: PROTECTION OF PERSONAL INFORMATION

1. Measures Concerning the Protection of Personal Information

(1) Responsibilities of the directors of organizations conducting research
(i) The director of an organization conducting research shall, when conducting epidemiological research, provide a necessary system for the protection of personal information. Also, the director of an organization conducting research shall, when having a person engaged in research handle personal information, exercise necessary and appropriate supervision over that person to ensure the security control of the personal information.

(ii) The director of an organization conducting research may, pursuant to the rules stipulated by the organization, delegate the authority or affairs prescribed in this Chapter to an appropriate person within the organization.

(2) Specification of the purpose of use

(i) When handling personal information, the director of an organization conducting research shall specify the purpose of using it (hereinafter referred to as the “purpose of use”) as much as possible.

(ii) When changing the purpose of use of personal information, the director of the organization conducting research shall not change it beyond the scope reasonably considered as having relevance corresponding to the purpose of use before the change.

(3) Restriction by the purpose of use

(i) Without obtaining the prior consent of the research subject or proxy consenter, etc. (hereinafter referred to as the “research subject, etc.”), the director of an organization conducting research shall not handle personal information beyond the scope necessary for achieving the purpose of use specified pursuant to paragraph (2).

(ii) When personal information has been acquired as a consequence of taking over research from another organization conducting research on account of a merger or for any other reason, the director of the organization conducting research 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 research subject, etc.

(iii) The provisions prescribed in items (i) and (ii) shall not apply to the following cases:
(a) When provided by laws and regulations

(b) When there is a requirement for the protection of the life, body or property of an individual, and it is difficult to obtain the consent of the research subject, etc.

(c) When it is particularly necessary for the improvement of public health, and it is difficult to obtain the consent of the research subject, etc.

(d) When it is necessary to cooperate with a state organ or local government, or with a person so entrusted, in their execution of affairs prescribed by laws and regulations, and when obtaining the consent of the research subject, etc. is likely to impede the execution of those affairs

(4) Proper acquisition
The director of an organization conducting research shall not acquire personal information by deception or other wrongful means.

(5) Notice of purpose of use at the time of acquisitions, etc.

(i) When having acquired personal information, the director of an organization conducting research shall observe the matters listed in items (ii) to (iv); provided however, that this shall not apply in the following cases when authorized by the ethics review committee:
(a) When notifying the research subject, 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 research subject or a third party

(b) When notifying the research subject, etc. of the purpose of use or publicly announcing it is likely to harm the rights or legitimate interests of the organization conducting research

(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 research subject, etc. of the purpose of use or publicly announcing it is likely to impede the execution of those affairs

(d) When it is considered that the purpose of use is clear given the circumstances of the acquisition

(ii) Except in cases where the purpose of use has already been publicly announced, the director of the organization conducting research should promptly notify the research subject, etc. of the purpose of use or publicly announce it.

(iii) Notwithstanding the provisions of item (ii), when the director of an organization conducting research acquires such personal information on a research subject as is written in a contract or other document (including any records made by electronic, magnetic or any other means not perceptible to human senses; hereinafter the same shall apply in this paragraph) as a result of concluding a contract with the research subject, etc. or acquires such personal information on a research subject as is written in a document directly from the research subject, etc., the director of the organization conducting research should clearly indicate the purpose of use in advance to the research subject, etc. This shall, however, not apply to cases where there is an urgent requirement for the protection of the life, body or property of an individual.

(iv) When the purpose of use has been changed within the scope reasonably considered as having relevance corresponding to the purpose of use set forth in item (ii), the director of the organization conducting research should notify the research subject, etc. of the changed purpose of use, or publicly announce it.

(6) Maintenance of accuracy
The director of an organization conducting research shall endeavor to keep personal information accurate and up to date within the scope necessary for achieving the purpose of use.

(7) Security control measures

(i) The director of an organization conducting research 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.

(ii) 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 director of an organization conducting research shall also implement systematic, human, physical and technological security control measures for the security control of information about deceased persons (meaning information of similar content to the personal information defined in paragraph (5) of Part V; the same shall apply hereinafter) in the same way as information about a living individual.

<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.

1. Systematic security control measures
The term “systematic security control measures” shall mean clearly stipulating the responsibilities and authority of researchers, etc. for security control, providing and implementing rules and procedures manuals for security control (hereinafter referred to as “rules, etc.”), and keeping track of the implementation thereof. Systematic security control measures include the following matters:

(i) Establishment of an organizational structure for implementing security control measures for personal information
(ii) Provision of rules, etc. stipulating the security control measures for personal information, and operation in accordance with those rules, etc.
(iii) Establishment of means for summarizing how personal information is being handled
(iv) Assessment, revision and improvement of security control measures for personal information
(v) Courses of action for dealing with accidents or violations

2. Human security control measures
The term “human security control measures” shall mean concluding nondisclosure agreements with researchers, etc. for personal information designated as business in confidence, and conducting education and training for them. Human security control measures include the following matters:

(i) Conclusion of nondisclosure agreements at the time of entering an employment contract or entrustment contract
(ii) Provision of education and training for researchers, etc.

3. Physical security control measures
The term “physical security control measures” shall mean such measures as controlling the entering and leaving to buildings or rooms, and preventing the theft of personal information. Physical security control measures include the following matters:

(i) Controlling the entering and leaving to buildings or rooms
(ii) Prevention of theft, etc.
(iii) Physical safeguarding of equipment, apparatus, etc.

4. Technological security control measures
The term “technological security control measures” shall mean technology-based measures for controlling the security of personal information, such as access controls to personal information and to information systems that deal with such information, measures against unauthorized software, and the monitoring of information systems. Technological security control measures include the following matters:

(i) Identification and authentication for accessing personal information
(ii) Access controls to personal information
(iii) Management of access rights to personal information
(iv) Records of access to personal information
(v) Measures against unauthorized software for information systems that deal with personal information
(vi) Measures when transferring or otherwise communicating personal information
(vii) Measures when checking the operation of information systems that deal with personal information
(viii) Monitoring of information systems that deal with personal information

(8) Supervision of entrusters
When entrusting the conduct of epidemiological research, the director of the organization conducting research shall exercise necessary and appropriate supervision over the entrusted person to ensure the security control of any personal information handled with respect to the entrusted business, and to ensure the appropriate handling of any personal information.

<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 entruster in the entrustment contract and confirming whether such content is being observed.

(9) Restrictions on provision of information to third parties
(i) Except in the following cases, the director of an organization conducting research shall not provide personal information to a third party without obtaining the prior consent of the research subject, etc.:
(a) When provided by laws and regulations

(b) When there is a requirement for the protection of the life, body or property of an individual, and it is difficult to obtain the consent of the research subject, etc.
(c) When provision of personal information is particularly necessary for improving public health or promoting the sound growth of children, and it is difficult to obtain the consent of the research subject, etc.
(d) When it is necessary to cooperate with a state organ or local government, or with a person so entrusted, in their execution of affairs prescribed by laws and regulations, and when obtaining the consent of the research subject, etc. is likely to impede the execution of those affairs

(ii) With respect to personal information to be provided to a third party, where the director of an organization conducting research agrees to discontinue, at the request of a research subject, etc., the provision to a third party of personal information by which the relevant research subject can be identified, and where the director of an organization conducting research has given advance notice of the following matters to the research subject, etc. or has made them readily available, the director of an organization conducting research may, notwithstanding the provisions of item (i), provide such personal information to a third party:
(a) The fact that the provision to a third party is the purpose of use
(b) The items of personal information to be provided to a third party
(c) The means or method of provision to a third party
(d) The fact that the provision to a third party of personal information by which the relevant research subject can be identified will be discontinued at the request of the research subject, etc.

(iii) When the director of an organization conducting research changes the matters listed in items (ii)(b) or (c), the director shall, in advance, either notify the research subjects, etc. about the details of the change or shall make them readily available.

(iv) In the following cases, the person receiving such personal information shall not be deemed to be a third party for the purpose of application of the provisions of items (i) to (iii), and thus, may be provided the personal information without first obtaining the consent of the research subject, etc.:
(a) When the research institution entrusts all or part of the handling of personal information within the scope necessary for achieving the purpose of use
(b) When personal information is provided as a consequence of taking over research on account of a merger or for any other reason
(c) When personal information is used jointly between specific persons, and when this fact, the items of the personal information used jointly, the scope of the joint users, the purpose for which the personal information is used by them, and the names of the persons responsible for the management of the personal information are, in advance, notified to the research subject, etc. or made readily available to them

(v) When the director of an organization conducting research changes the purpose for which the personal information is used or the names of the persons responsible for the management of the personal information, as provided in (iv) above, the director of the

organization conducting research shall, in advance, either notify the research subjects, etc. about the details of the change or shall make them readily available to the research subjects, etc.

(10) Public announcement of matters concerning retained personal information, etc.
(i) The director of an organization conducting research shall, with respect to any retained personal information, make the following matters available to research subject, etc. (including cases when responding promptly at the request of a research subject, etc.):
(a) The name of the relevant organization conducting research
(b) The purpose of use of all retained personal information (excluding cases falling under (5)(i) (a) through (d))
(c) Procedures responding to any requests made pursuant to the provisions of paragraph (10)(ii), (11)(i), (12)(i) or (13)(i) or (ii) (including the amount of any charges if set pursuant to the provisions of paragraph (16))
(d) Where complaints can be made concerning the handling of retained personal information

(ii) When a request is received from a research subject, etc. for notification of the purpose of use of retained personal information by which the relevant the relevant research subject can be identified, the director of the organization conducting research shall provide notification of this, without delay, to the research subject, etc. However, this provision shall not apply to cases falling under either of the following items:
(a) Cases in which the purpose of use of retained personal information by which the relevant research subject can be identified is clear pursuant to the provisions of item (i)

(b) Cases falling under any of items (5)(i)(a) to (d)

(iii) Where the director of an organization conducting research has decided not to notify the purpose of use of retained personal information as requested pursuant to the provisions of item (ii), the director of the organization conducting research shall notify the research subject, etc. of that effect without delay.

(11) Disclosure of personal information
(i) When the director of an organization conducting research is requested by a research subject, etc. to disclose retained personal information by which the relevant research subject can be identified (including notifying if there is no such retained personal information by which the relevant research subject can be identified; the same shall apply hereinafter), the director of the organization conducting research shall disclose the retained personal information to the research subject, etc. by means of documents (or by another method if the research subject, etc. has consented to such method). However, if disclosure would result in any of the following, the director of the organization conducting research 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 research subject or a third party

(b) When disclosure is likely to seriously impede the proper execution of the business of the organization conducting research

(c) When disclosure would violate other laws or regulations

(ii) Where the director of an organization conducting research has decided not to disclose all or part of the information as requested pursuant to the provisions of item (i), the director of the organization conducting research shall notify the research subject, etc. of that effect without delay.

(iii) If the provisions of any other laws or regulations require that all or part of such retained personal information, by which the relevant research subject can be identified, be disclosed to the research subject, etc. by a method equivalent to the method prescribed in the main clause of item (i), the provisions of item (i) shall not apply to such all or part of the retained personal information.

(12) Correction, etc.
(i) When the director of an organization conducting research is requested by a research subject, etc. to correct, add, or delete such retained personal information by which the relevant research subject, etc. can be identified on the grounds that the retained personal information is contrary to fact, the director of the organization conducting research 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.

(ii) When the director of an organization conducting research has corrected, added or deleted all or part of the retained personal information as requested pursuant to the provisions of item (i), or has decided not to make such a correction, addition or deletion, the director of the organization conducting research shall notify the research subject, etc. of that effect (including the details of any correction, addition or deletion) without delay.

(13) Suspension of use, etc.
(i) Where the director of an organization conducting research is requested by a research subject, etc. to suspend using or to erase retained personal information by which the relevant research subject can be identified on the grounds that the retained personal information concerned is being handled in violation of paragraph (3) or that it has been acquired in violation of paragraph (4), and where it is found that the request has reason, the director of the organization conducting research 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 research subjects.

(ii) Where the director of an organization conducting research is requested by a research subject, etc. to suspend providing to a third party retained personal information by which the relevant research subject can be identified on the grounds that the retained personal information concerned is being provided to the third party in violation of paragraph (9), and where it is found that the request has reason, the director of the organization conducting research 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 research subjects.

(iii) When the director of an organization conducting research has suspended using or erased all or part of the retained personal information as requested pursuant to the provisions of item (i), or has decided not to suspend using or erase the retained personal information concerned, or when the director of an organization conducting research has suspended providing to a third party all or part of the retained personal information as requested pursuant to the provisions of item (ii), or has decided not to suspend providing the retained personal information concerned to the third party, the director of the organization conducting research shall notify the research subject, etc. of that effect without delay.

<Detailed regulations concerning suspension of use or erasure>
Measures to suspend use or erase do not need to be taken in the following cases:

- Even in cases where there has been a request for correction, addition, or deletion: (i) cases where the correction, addition, or deletion is not necessary given the purpose of use; (ii) cases where the indication of error is incorrect; or (iii) the information to be corrected, added or deleted is not fact, but is information pertaining to an evaluation
- Even in cases where there has been a request for suspension of use or erasure or discontinuation of provision to a third party, the indication, such as for deviation from procedure, is incorrect

(14) Explanation of reasons
When the director of an organization conducting research notifies a research subject, etc. that it will not be taking all or part of the measures as requested by the research subject, etc. in the cases set forth in paragraph (10)(iii), (11)(ii), (12)(ii) or (13)(iii), or that it will take different measures, the director of the organization conducting research shall endeavor to explain those reasons to the research subject, etc. In such cases, given the possibility that it may not necessarily be appropriate to provide research subjects, etc. with an explanation, such as possible instances of psychological burden on a research subject, etc. resulting from notification of the fact that the content of the request by the

research subject, etc. is contrary to fact, for instance, the research director shall respond after careful consideration according to circumstances.

(15) Procedures responding to requests for disclosure, etc.
(i) Regarding the following matters, the director of an organization conducting research may stipulate the method for receiving requests made pursuant to the provisions of paragraph (10)(ii), (11)(i), (12)(i) or (13)(i) or (ii) (hereinafter referred to as “request for disclosure, etc.”). In such a case, research subjects, 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 research subject, etc.
(d) The method for collecting charges

(ii) The director of an organization conducting research may ask a research subject, etc. making a request for disclosure, etc. to present sufficient items to identify the retained personal information in question. In this case, the director of the organization conducting research shall take appropriate measures that take into account the convenience of the research subject, etc. and the provision of information that is helpful in identifying the retained personal information in question, so that the research subject, etc. can make a request for disclosure, etc. easily and accurately.

(iii) In determining the procedures for responding to requests for disclosure, etc. made pursuant to the provisions of items (i) and (ii), the director of the organization conducting research shall give consideration to the procedures so that they do not impose an excessive burden on the research subject, etc.

(16) Charges
When the director of an organization conducting research is requested to notify the purpose of use pursuant to the provisions of paragraph (10)(ii) or to make a disclosure pursuant to the provisions of paragraph (11)(i), the director of the organization conducting research may collect charges for implementing the measure. In such a case, the director of the organization conducting research shall determine the amount of the charge within the scope considered reasonable in consideration of actual costs.

(17) Responding to complaints
The director of an organization conducting research shall respond appropriately and promptly to any complaints, inquiries or the like from research subjects, etc., such as by setting up a contact point for complaints, etc. made by research subjects, etc. The director of the organization conducting research 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 research subjects, etc. to use.

2. Preservation, etc. of Materials and Information

(1) Preservation, etc. of materials and information
(i) When preserving materials and information pertaining to epidemiological research, the research director shall state the relevant methods and so forth in the research protocol, and shall manage them appropriately to protect the personal information from divulgence, mixing, theft and loss, and systematically to facilitate verification of research results.

(ii) In cases where the retention period for materials and information prescribed in a research protocol has expired, the research director shall observe matters agreed to by the research subject, etc., and shall anonymize and dispose of the materials and information.

(iii) In cases where materials and information for which no retention period has been set are preserved, the research director, at completion of the epidemiological research, shall report the following matters, without delay, to the director of the research institution. The same shall apply when changes to these materials and information arise.
(a) The name of the materials and information
(b) Where the materials and information are preserved
(c) The custodian of the materials and information
(d) The details of the consent obtained from the research subject, etc.

(2) Use of human biological specimens
In cases where a researcher, etc. intends to use human biological specimens taken prior to the commencement of research, he/she shall, in principle, obtain consent from the research subjects, etc. on the use of the specimens before starting the research, and he/she shall prepare records on the said consent. In cases where the said consent cannot be obtained, however, the relevant specimens may be used, but only when the ethics review committee authorizes and the director of the research institution approves that they fall under any of the following:

(i) The specimens concerned have been anonymized (meaning cases of unlinkable anonymization or linkable anonymization where there is no index table).

(ii) In cases where the specimens concerned do not fall under item (i), if consent had only been given for research for which the use of specimens in the said epidemiological research was not clearly indicated at the time specimens were provided, those cases that satisfy the following requirements:
(a) Information has been disclosed, including the purpose for using the specimens in conducting the said epidemiological research.
(b) The consent can be reasonably considered as having relevance corresponding to the purpose of the said epidemiological research.

(iii) In cases where the specimens concerned do not fall under items (i) and (ii), those cases that satisfy the following requirements:
(a) Information has been disclosed, including the purpose for using the materials and information in conducting the said epidemiological research.
(b) Prospective research subjects are provided an opportunity to refuse inclusion in the research.
(c) Cases where it is particularly necessary for the improvement of public health, and where it is difficult to obtain the consent of the research subject, etc.

3. Using Materials and Information from Other Institutions, etc.

(1) Measures when conducting research
When intending to conduct research with existing materials and information provided from a person outside the organization, the research director shall describe the content of the materials and information to be provided and the need for such provision in the research protocol, and shall obtain the authorization of the ethics review committee and the approval of the director of the organization conducting research.

(2) Measures when providing existing materials and information
When a person who provides existing materials and information intends to provide materials and information for use in research to a person outside the organization, he/she shall, in principle, obtain consent pertaining to the provision of the materials and information and their use in the said research from the research subjects, etc. by the time the materials and information are provided, and shall prepare records on the said consent. However, in cases where the said consent cannot be obtained, the person providing existing materials and information may provide the materials and information to a person outside the organization but only in any of the following cases:

(i) The materials and information concerned have been anonymized (meaning cases of unlinkable anonymization or linkable anonymization where no index table is provided). However, in cases where all or part of the materials and information concerned are human biological specimens, this fact shall be reported to the director of the organization.

(ii) In cases where the materials and information concerned do not fall under item (i), the ethics review committee has authorized and the director of the organization has approved that the following requirements have been satisfied:

(a) With respect to conducting the research and providing materials and information, advance notice of the following information has been given to the research subjects, etc. or has been publicly disclosed:
- The fact that the provision to a person outside the organization is the purpose of use
- The items of personal information to be provided to a person outside the organization
- The means or method of provision to a person outside the organization

- The fact that the provision of personal information by which the relevant research subject can be identified to a person outside the research institution will be discontinued at the request of the research subject, etc.

(b) Prospective research subjects should be provided an opportunity to refuse inclusion in the research.

(iii) In cases where information related to human health is to be provided for use in epidemiological research of great social importance, if the conditions set forth in items (i) and (ii) cannot be met due to such reasons as the method or content of the epidemiological research or the content of the information in question, the ethics review committee has authorized and the director of the organization has approved that other appropriate measures will be implemented to the extent necessary.

<Detailed regulations concerning measures implemented when providing existing materials and information>
1. In cases where an ethics review committee has not been established in the organization to which the person providing existing materials and information belongs, when attempting to obtain the authorization of the ethics review committee set forth in items (ii) or (iii), a request for review may be made to an ethics review committee established by another institution, a general incorporated association, a general incorporated foundation or an academic society, etc.

2. When approving the provision of materials and information by other appropriate measures under item (iii), the ethics review committee should ensure that the said epidemiological research and provision of materials and information satisfies all of the requirements in (i) to (v) of the Detailed Regulations Concerning the Simplification, etc. of Informed Consent.

4. Measures When Disclosing Research Results

When publicly disclosing research results, the researcher, etc. shall ensure that individual research subjects cannot be identified.

PART V: DEFINITIONS OF TERMS

The terms used in these Guidelines shall be defined as follows.

(1) Epidemiological Research
The term “epidemiological research” shall mean scientific research that elucidates the incidence and distribution of various health-related events that appear within a well-defined human population, as well as the factors influencing them.

<Detailed regulations concerning the definition of epidemiological research>

The minimum requirements for research subject to the epidemiological research guidelines shall be as follows:

- Either knowledge pertaining to efficacy, prognoses or the like is unknown, or a verification of already-established knowledge
- Greater importance is placed on broad contributions to society rather than the benefit of only the actual research subjects

(2) Intervention Study

The term “intervention study” shall mean epidemiological research whereby a researcher, etc. divides a population of research subjects, in principle, into two or more groups, deliberately or randomly allocates each group a different method of treatment, method of prevention or other factor believed to affect health, and compares the results.

(3) Observational Study

The term “observational study” shall mean epidemiological research other than intervention studies.

(4) Materials and Information

The term “materials and information” shall mean any blood, tissue, cell, body fluid or excrement to be used in epidemiological research, any human biological specimens extracted from these, such as DNA, any information related to human health, including disease names, drug names, examination results, etc. which are obtained in the course of diagnosis and treatment, and other information used in research (including that related to deceased persons).

(5) Personal Information

The term “personal information” 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).

(6) Retained Personal Information

The term “retained personal information” shall mean personal information for which the director of the organization conducting research has the authority to disclose, correct, add or delete, suspend its use, erase, or suspend its provision to a third party, and which excludes that information which will be erased within six months and that information listed in the following items as information for which elucidation of its existence would be detrimental to public interest or other interests:

(i) Retained personal information for which elucidation of its existence could cause harm to the life, body or property of the research subject or a third party

(ii) Retained personal information for which elucidation of its existence could encourage or induce illegal or unjust acts

(iii) Retained personal information for which elucidation of its existence could cause harm to national security, could cause damage to relationships of mutual trust with another countries or international organization, or could cause a disadvantage in negotiations with another country or international organization

(iv) Retained personal information, the elucidation of which could cause impediments to the prevention, suppression or investigation of crimes, or otherwise to the maintenance of public safety and public order

(7) Anonymization
The term “anonymization” shall mean to remove from personal information, in part or in whole, information through which the individual could be identified and to give instead a symbol or a number that has no relevance to the person. When it is impossible to identify a specific person only through a certain piece of information included in materials and information but it is possible to identify the person, etc. by combining information available elsewhere, such as in some list, “anonymization” shall mean to remove, in part or in whole, the information that is necessary to complete such combination and to make it impossible to identify the person.

(8) Linkable Anonymization
The term “linkable anonymization” shall mean anonymization based on a method where an index table of symbols or numbers attached to individuals is maintained so that individuals may be identified as necessary.

(9) Unlinkable Anonymization
The term “unlinkable anonymization” shall mean anonymization based on a method where no index table of symbols or numbers attached to individuals is maintained so that individuals cannot be identified.

(10) Researcher, etc.
The term “researcher, etc.” shall mean a person involved in conducting epidemiological research, such as a research director or a director of a research institution (excluding persons who provide existing materials and information to researchers, etc. and who have no further involvement in epidemiological research).

(11) Research Director
The term “research director” shall mean a person at a research institution who carries out epidemiological research as well as supervises the operations related to the epidemiological research.

(12) Research Institution
The term “research institution” shall mean an institution that conducts epidemiological research (excluding those organizations to which persons who provide existing materials and information to researchers, etc. and who have no further involvement in epidemiological research belong).

(13) Organization Conducting Research
The term “organization conducting research” shall mean a business operator or organization, such as a juridical person or administrative organ (meaning an administrative organ as prescribed in Article 2 of the Act on the Protection of Personal Information Held by Administrative Organs) that has a research institution.

(14) Director of an Organization Conducting Research
The term “director of an organization conducting research” shall mean the representative of a business operator or organization, such as the head of an administrative organ, or the representative of a juridical person corresponding to an organization conducting research.

(15) Collaborative Research Institution
The term “collaborative research institution” shall mean a research institution that collaboratively conducts human epidemiological research described in a research protocol.

(16) Ethics Review Committee
The term “ethics review committee” shall mean a council-type body established as an advisory board to the director of a research institution for the purposes of investigation and discussion of the propriety of conducting epidemiological research and other necessary matters concerning epidemiological research, from such ethical and scientific viewpoints as respecting the personal dignity and human rights of research subjects.

(17) Informed Consent
The term “informed consent” shall mean consent regarding becoming a research subject and regarding the handling of materials and information, which a person, who has been requested to act as a research subject, gives on the basis of his/her free will after receiving adequate prior explanations from a researcher, etc. with regard to epidemiological research and understanding the significance, objectives and method of the research, the expected results and the disadvantages.

(18) Existing Materials and Information
The term “existing materials and information” shall mean materials and information that falls under either of the following:
(i) Materials and information that already existed at the time a research protocol for epidemiological research was prepared
(ii) Materials and information that has been collected since the time a research protocol for epidemiological research was prepared, and which was not intended to be used in the said epidemiological research at the time of collection

PART VI: DETAILED REGULATIONS

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

PART VII: REVISION

These Guidelines shall be revised, as required or approximately five years after they come into force, upon conducting an examination of the entire contents.

PART VIII: EFFECTIVE DATE

These Guidelines shall come into effect as of November 1, 2007.