RESEARCH ETHICS JAPAN

Summary of 2022 Revised Ethical Guidelines for Life and Medical Sciences

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Life Science and Medical Guidelines

Development history of the Guidelines

Source/modification) Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and Ministry of Economy, Trade and Industry. Revision of Life Science and Medical Guidelines Associated with Amendment of the Act on the Protection of Personal Information in 2020 and 2021. March 2022.

"Ethical Guidelines for Human Genome/Gene Analysis Research"
(Notification No. 1 of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and Ministry of Economy, Trade and Industry, March 2001)

Fully revised
Enforced in April 2005

Fully revised
Enforced in April 2013

"Ethical Guidelines for Epidemiological Research"
(Notification No. 2 of Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare, 2002)

Fully revised
Enforced in April 2005

Fully revised
Enforced in November 2007

"Ethical Guidelines for Clinical Research"
(Notification No. 255 of Ministry of Health, Labour and Welfare, 2003)

Fully revised
Enforced in April 2005

Fully revised
Enforced in April 2009

Enacted in 2003
Act on the Protection of Personal Information

Integrated

Integrated

"Ethical Guidelines for Medical Research Involving Humans"
(Notification No. 3 of Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare, 2014)

2015 Revised Act on the Protection of Personal Information
(Thereafter reviewed every 3 years)

Promulgated on March 23, 2021
Enforced on June 30, 2021

"Ethical Guidelines for Life Science and Medical Research Involving Humans"
(Notification No. 1 of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and Ministry of Economy, Trade and Industry, 2021)

Pre-revision
Life Science and Medical Guidelines

Subject of the former genome guidelines
+
The scope has newly included research in the physical anthropology area such as human genetics and in the humanities area using human genome/gene information.

+

The scope has newly included research in the medical field using AI.

2020/2021 Revised Act on the Protection of Personal Information

Enforced on April 1, 2022,
2022 revised Life Science and Medical Guidelines

Before Revision Summary of Revisions in the Life Science and Medical Guidelines

1. Change in guideline structure

- Provisions that existed only in the genome guidelines (e.g., genetic counseling, handling of genome cohort studies) were moved and integrated into the former medical guidelines, and procedural provisions were simplified.
- Many of the provisions remain largely unchanged from the two former guidelines before integration. However, the responsibilities of the principal investigator/research representative and their duties were greatly expanded.

2. Newly introduced contents

[1] "**Research cooperative institutions**" that do not require REC review (they play the role to newly collect samples/information within the range of minor invasion and to provide the samples/information only to the research institution. They cannot provide explanation/obtain IC.)

[2] Principles of "**one research, one review**" (however, each conventional REC review is also accepted)

[3] "**IC by electromagnetic means** (e-consent)"

[4] "**Reporting items**" that require only REC's confirmation, not requiring review

< What is electronic IC? >

[1] To obtain informed consent **using a digital device**.

[2] To obtain informed consent **via the network**.

Before Revision Summary of Revisions in the Life Science and Medical Guidelines

3. Major changes from the former medical guidelines

[1] Concept change for factors to consider when in weighing risk-benefit comparison

[2] Expansion of the concept of "human genome/gene" analysis research

[3] Note added on the need for consideration in "research that may reveal unique characteristics of local residents, etc."

[4] Change of the concept of "minors" ⇒ Civil Code amendment enforced on April 1, 2022

[5] The administrative responsibility related to “referral to the ethics review committee" was changed from "head of research institution" to "principal investigator/representative investigator".

[6] Expansion of the scope of registration to jRCT (MHLW/clinical trial registration DB)

[7] Expansion of the items to be described in "handling of results, etc. obtained from research" in the research protocol, and relocation and inclusion of the same explanatory provision.

[8] Expansion of the scope of research which should include “reponses to be taken in the event of serious adverse events" in the research protocol.

[2] Expansion of the concept of "human genome/gene" analysis research

"Human genome/gene" analysis research covered by the former genome guidelines did not include research on somatic mutations such as cancer and gene expression or research on protein structure/function.

The new Guidelines include all the use of “samples and information of human origin to obtain knowledge about the human genome, gene structure or function, and gene mutation or expression," including from somatic mutations to epigenomics and omics analysis.

[3] Addition of the need for consideration in "research that may reveal unique characteristics of local residents, etc."

The former genome guidelines refer only to "genetic" characteristics.

⇒ Special consideration is required in research that is not limited to genetic traits, but can affect "unique traits" (including values) of a particular population

- Genetic characteristics
- Characteristics due to environmental factors
- Characteristics due to social factors, etc.

Example) Research in indigenous people; research in a population that believes in a religion or brief; research on a group sharing a mythological world; human genetic research using excavated human bones and remains

[6] Expansion of the types of research subject to "jRCT registration"

Under the former guidelines, registration was mandatory only for "interventional researches".

Non-interventional research also required "that the outline of the research should be registered prior to the conduct of the research and that this should be updated according to change in the research protocol and the progress of the research" and "that efforts must be made to register the results of the research".

[7] Expansion of the contents of the items to be described in "Handling of results, etc. obtained from research", and relocation and inclusion of the same explanatory provision.

"Explanation of results, etc." in the former genome guidelines applies only to the contents related to genetic information.

In all researches, the explanation policy on "results, etc. obtained from the research" has to be specified in the research protocol.

+

- The explanation policy for results, etc. should be "explained and understood" at the time of obtaining IC.

(including the policy when relatives request explanations on research results, etc. individually, etc.)

- It is also required to establish a consultation/counseling system based on the results, etc.

[8] Expansion of the scope of research which should describe "responses in case of serious adverse events" in the research protocol

The former guidelines excluded research within the range of "minor invasion" from the subjects to be described.

"(Excluding minor invasion.) " was deleted, and this description is required for all "invasive research".

Detailed explanation of
Former genomic guidelines + Former medical guidelines
⇒ the pre-revision Life Science and Medical Guidelines
can be viewed from the following
"Introduction to ICR Clinical Research" page:

https://www.icrweb.jp/course/view.php?id=464

Before Revision: What was said in establishing Life Science and Medical Guidelines...

- This Act on the Protection of Personal Information, in particular the revision in 2021, is mainly focused on the unification of the world of personal information protection, including academic research and medical field. So **in the future, we basically just have to handle personal information in accordance with the new Act on the Protection of Personal Information**. However, as shown in page 26 of the document, which I mentioned earlier, there are still exceptions for academic research. As I have introduced earlier, the law sets forth the obligation to make efforts as the responsibility of academic research institutions, etc. in Article 59, and therefore we expect guidelines to fulfill the part.
- For the handling of personal information in the medical and academic fields, ethical guidelines and guidance explaining them have been prepared. Regarding how to sort out their positioning from the Act on the Protection of Personal Information and guidelines, etc. stipulated by the Personal Information Protection Commission, we consider two points: we presumably **needs to think separately of the parts to which the law applies and the parts to which the law does not apply**.

(Joint Meeting on Handling of Personal Information in Life Science and Medical Research, etc. (1st), minutes of May 7, 2021)

Summary of Revisions in 2022 Revised Life Science and Medical Guidelines

Life Science and Medical Guidelines

Structure of guidelines (2022 Notification)

Preamble
Chapter 1 General provisions — General remarks
Section 1 Purpose and basic policy
Section 2 Definitions of terms
Section 3 Scope of application

Chapter 2 Responsibilities of researchers, etc. — Responsibilities
Section 4 Basic responsibilities of researchers, etc.
Section 5 Responsibilities, etc. of the head of research institution

Chapter 3 Appropriate conduct of the research, etc. — Procedures
Section 6 Procedures concerning research protocol
Section 7 Description of the research protocol

Chapter 4 Informed consent, etc.
Section 8 Procedures, etc. for obtaining informed consent
Section 9 Procedures, etc. for obtaining informed consent from Proxy Consenters

Chapter 5 Handling of results, etc. obtained from research
Section 10 Explanation of results, etc. obtained from research

Chapter 6 Ensuring Credibility of research
Section 11 Appropriate responses and reporting
Section 12 Management of conflicts of interest
Section 13 Storage of samples and information for research
Section 14 Monitoring and audit

Chapter 7 Responses to serious adverse events
Section 15 Responses to serious adverse events

Chapter 8 Ethics review committee — Ethical review
Section 16 Establishment, etc. of ethics review committee
Section 17 Roles, responsibilities, etc. of ethics review committee

Chapter 9 Basic responsibilities for personal information, etc., samples, and samples/information of a dead person — Protection of personal information
Section 18 Protection of personal information, etc.

Chapter 1	The concept of guidelines in general and definition of terms are specified.
Chapter 2	The responsibilities and concepts to be observed in conducting the research are specified.
Chapters 3 - 7	Specific procedures, etc. to be performed by researchers, etc. in conducting the research are specified.
Chapter 8	Provisions concerning ethics review committee
Chapter 9	Provisions for protection of personal information, etc.

Source) Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and Ministry of Economy, Trade and Industry. Revision of Life Science and Medical Guidelines Associated with Amendment of the Act on the Protection of Personal Information in 2020 and 2021. March 2022.

Hereafter, cited government materials are from the above document unless otherwise noted.

Background of 2022 Revision: 2020/2021 Revision of Act on the Protection of Personal Information

Revisions of the Act on the Protection of Personal Information in FY 2020 and 2021

2020 revision
Fully enforced in April 2022

Revision based on so-called review every 3 years

Expansion of suspension of use, deletion, etc., prohibition of improper use, enhancement of provision of information related to cross-border transfers, establishment of "pseudonymously processed information", etc.

- ✓ Strengthen the protection and utilization of personal rights and benefits
- ✓ Cope with new risks associated with increased circulation of cross-border data
- ✓ Respond to the era of AI/big data, etc.

2021 revision
Partially enforced in April 2022
(regional parts to be enforced around spring of 2023)

Unification of public and private sectors for the personal information protection system

- ✓ Strengthen the protection and utilization of personal information through public and private sectors
- ✓ Unify regulations in medical and academic fields
- ✓ Review exclusion provisions for academic research, etc.

Source: 1st Joint Meeting on Handling of Personal Information in Life Science and Medical Research, etc. Material 3-2 (explanatory material from secretariat of Personal Information Protection Commission), partially modified

II. Major Revision of Life Science and Medical Guidelines

1. Organization of terms [Guideline No. 2]

[1] Terms concerning **information about living individuals** in the guidelines were **aligned with the terms of the revised Act on the Protection of Personal Information**.

[2] No definition was placed for terms concerning information on deceased persons. For research using information on deceased persons, a provision stating that the research should be handled in the same manner as that with information on living individuals was included.

[3] The terms **"anonymization"** and **"correspondence table"** are not used.

2. Review of the scope of guidelines [Guideline Section 3-1]

Along with the new establishment of pseudonymously processed information under the revised Act on the Protection of Personal Information, information, etc. corresponding to "pseudonymously processed information that is not personal information" is to be newly included in the scope of the guidelines.

3. Main management entity of personal information [Section 5-2/Part 13, Section 8-1(4)]

The main management entity of personal information is to be **the head of the research institution*** **or the head of the institution to which the person who provides only existing samples/information belongs**.

* Head of research institution

Refers to the representative of the corporation conducting the research, the head of the administrative agency, or the sole proprietor conducting the research. The head of the research institution may delegate the authority or affairs specified in these guidelines to an appropriate person within the research institution in accordance with the provisions specified at the research institution.

II. Major Revision of Life Science and Medical Guidelines

4. Procedures, etc. for obtaining informed consent (IC) [Guideline Section 8]

1) When research is conducted by obtaining new samples/information from research subjects [Guideline Part 8-1(1)]

[1] Research using samples: No change

[2] Research not using samples

< When special care-required personal information is obtained >

- The procedures for obtaining IC, etc. (IC procedures) may be **simplified** in an appropriate manner if the exceptional requirements stipulated in the revised Act on the Protection of Personal Information are met and all of the following requirements are satisfied:
  a. An opportunity for research subjects, etc. to refuse the conduct, etc. of the research is guaranteed.
  b. The simplification will not be disadvantageous to research subjects.
  c. Absence of simplification makes it difficult to conduct the research or significantly impairs the value of the research.

< When information other than special care-required personal information is obtained >

- For the IC procedures when information newly obtained from research subjects (excluding special care-required personal information) is provided to a collaborative research institution, **the IC procedures when existing information** (excluding special care-required personal information) **is provided to other research institutions shall apply mutatis mutandis**.

II. Major Revision of Life Science and Medical Guidelines

2) When research is conducted using existing samples/information possessed by the institution [Guideline Part 8-1(2)]

The existing samples/information that **can be used without IC procedures** are as follows:

- **Samples** already controlled to **prevent identification of specific individuals** (when no personal information is obtained from the samples)
- **Existing pseudonymously processed information**
- **Anonymously processed information** (for research using samples, only when it is difficult to obtain IC)
- **Personal-related information**

< Research using samples >

For researches of high social importance, use of existing samples/information is allowed in the following cases:
- Appropriate consent is obtained after necessary notification is given to research subjects, etc.
- **Opt-out** is implemented (only **when the exceptional requirements** stipulated in **the revised Act on the Protection of Personal Information are met**.)

< Research not using samples >

Use of existing samples/information is allowed in the following cases:
- Appropriate consent is obtained after necessary notification is given to research subjects, etc.
- **Opt-out** is implemented (only **when the exceptional requirements** stipulated in **the revised Act on the Protection of Personal Information are met**.)

II. Major Revision of Life Science and Medical Guidelines

3) When existing samples/information is provided to other research institutions [Guideline Part 8-1(3)]

[1] The cases were divided according to the types of existing samples/information provided.

- When **samples or special care-required personal information** is provided: **IC** is required **in principle**.
- When **information (excluding special care-required personal information)** is provided: **Appropriate consent** is required **in principle**.

[2] The existing samples/information that **can be provided without IC procedures** are as follows:

- **Samples** controlled to **prevent identification of specific individuals** (when IC procedures are difficult and no personal information is obtained from the samples)
- **Individual-related information** (when the recipient is not expected to obtain as personal information)
- **Individual-related information** (when the recipient is expected to obtain as personal information and the exceptional requirements stipulated in the revised Act on the Protection of Personal Information are met)
- **Anonymously processed information** (when obtaining appropriate consent is difficult)

When obtaining IC or appropriate consent is difficult ...

[3] **Simplification** of IC procedures is allowed if the following requirements are satisfied (it is necessary to make efforts to give an opportunity for research subjects, etc. to refuse as much as possible).

- **The exceptional requirements stipulated in the revised Act on the Protection of Personal Information** are met.
- **All the requirements specified in Part 8-9(1)** are met.

[4] The provision by **opt-out** is permitted if **the exceptional requirements stipulated in the revised Act on the Protection of Personal Information** are met.

* Based on the contents of the revised Act on the Protection of Personal Information, matters which require notification, etc. when providing existing samples/information by opt-out were also reviewed.

II. Major Revision of Life Science and Medical Guidelines

4) When research is conducted with the provision of existing samples/information [Guideline Part 8-1(5)]

○ The researchers, etc. who conduct the **research in response to** the provision of **personal-related information** (only when expected to be obtained as personal information) shall, when conducting the research, **take procedures in accordance with** the provisions of IC in conducting the research using the existing information held at their institution (**Part 8-1(2) B**).

5) When samples/information is provided to a third party in a foreign country [Guideline Part 8-1(6)]

○ Even if the exceptional requirements stipulated in the revised Act on the Protection of Personal Information are met, appropriate consent continues to be required in principle, and samples/information is provided only when the following apply:

(A) Appropriate consent has been obtained from research subjects, etc.
(B) Samples/information is provided to a person who has established a system conforming to the standards specified by the Personal Information Protection Commission.
(C) Samples/information is provided to a person whose country has a personal information protection system of the same level as that in Japan.

○ The following procedures are to be required **even if the exceptional requirements** stipulated in the revised Act on the Protection of Personal Information **are met**:

- In the case of (A), it is necessary **to provide the research subject with information such as name of the foreign country, etc. at the time of informed consent**.
- In the case of (B), it is necessary to take actions required to **ensure continuous implementation of corresponding measures** and to **provide the research subject with information on the necessary measures upon request** of the subject.
- **Opt-out was allowed** when (B) and (C) are not met and obtaining consent is difficult **after hearing the opinion of the ethics review committee**.

Newly Established and Introduced "Pseudonymously Processed Information" and "Individual-Related Information"

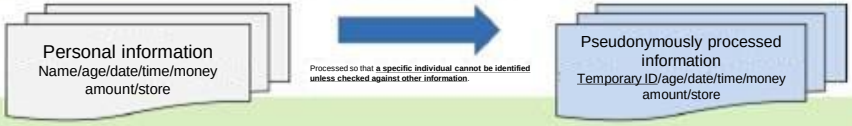
Establishment of pseudonymously processed information and individual-related information

Pseudonymously processed information

- **Information about an individual obtained by processing personal information in accordance with standards established by the Personal Information Protection Commission so that a specific individual cannot be identified unless checked against other information.**

  *Established with the following background: pseudonymously processed information maintains the usefulness of data at the same level as pre-processing personal information while ensuring a certain level of safety; thus, there is an increasing need to utilize pseudonymously processed information because it allows more detailed analysis with relatively simple processing methods than anonymously processed information.

- **In the use of "pseudonymously processed information", obligations, such as responding to a request for disclosure/suspension of use, were relaxed on the condition that the use was limited to internal analyses.**



(Reference) Examples of expected uses

1. Internal analyses for **a purpose that is not included in the initial purposes of use** or for **a new purpose for which it is difficult to judge whether it is included**.
   [1] **Research in the medical/pharmaceutical field, etc.**
   [2] Learning of machine learning models such as fraud detection and sales forecasting
2. Personal information for which the purpose of use has been achieved may be **used for statistical analysis** in the future. This personal information is stored after **processed as pseudonymously processed information**.

Individual-related information

- **Information about a living individual that does not fall under any of personal information, pseudonymously processed information, or anonymously processed information.**

  * Established with the following background: a scheme to evade the intent of the provisions of Article 27 of the Act on the Protection of Personal Information (Restriction of provision to a third party) is spreading widely; in this scheme, personal data are provided to a third party as non-personal information while knowing in advance that the data are collected as personal data by the recipient as a result of the development and spread of technologies that accumulate a large amount of user data and instantaneously match them to make personal data; and there is a concern for spread of the method to collect personal information without involving the principal.

- When **information provision to a third party** falls under **the provision of "individual-related information" to a third party** and the information **does not correspond to personal data at the provider** but **is expected to be personal data at the recipient**, **confirmation that the principal's consent has been obtained** is **mandatory**.

Source: 1st Joint Meeting on Handling of Personal Information in Life Science and Medical Research, etc. Material 3-2 (explanatory material from secretariat of Personal Information Protection Commission), partially modified

Relationship Between the Guidelines and Act on the Protection of Personal Information: Related to Personal Information and Consent

2020/2021 Revised Act on the Protection of Personal Information

Including information that identifies an individual such as name and address as well as information on telephone number, e-mail address, occupation, and family structure

Personal information: "**information about individuals**" "who are living" [1] **that can identify a specific individual** (not only the information alone but also information that allows easy cross-checking) or [2] that contains **individual identification codes** (genomic information, etc.)

Non-personal information

- **Already having a certain level of academic values/widely used/generally available samples and information**
- **Already prepared anonymously processed information**

- **Anonymously processed information**
- Pseudonymously processed information
- **Individual-related information**
  (Cookies, browsing history, location information, etc.)

- Anonymously processed information: intentionally processed in accordance with processing standards
- **Pseudonymously processed information**: intentionally processed in accordance with processing standards
- Personal-related information (on the recipient side)
- **Deleted information, etc.**
- **Special care-required personal information**

- **Information on the individual deceased**
- **Samples**
- **Existing samples**
- **Existing samples whose use will not serve to obtain personal information**
  (Non-gene/non-genomic samples)

- **Opt-out when providing special care-required personal information to a third party**
  (Notification to Personal Information Protection Commission)

- **Academic exceptions for provision to a third party** (Act Article 27, Paragraph 1, Item 5/6/7; Act Article 28, Paragraph 1)
- **Public health exceptions for provision to a third party** (Act Article 27, Paragraph 3; Act Article 28, Paragraph 1)

- **Appropriate consent**

"Anonymization"

- **Informed consent**
- **Opt-out procedures according the Guidelines**
- **Requirements for simplification of IC procedures, etc.** (minimally invasive/social importance, etc.) **and measures** (publicity/post-hoc explanation to the target population, making known to the society)
- **Rules for "already prepared pseudonymously processed information" by handling methods**

2022 revised Life Science and Medical Guidelines

"Pseudonymously Processed Information" for the Guidelines

- At first glance, physical replacement to the part "the anonymized (limited to those that cannot identify a specific individual)" in the former guidelines.
- On the other hand, the operation of "anonymization" performed is mostly the same in nature as "linkable anonymization" and "the anonymized (only those processed or controlled so as to prevent immediate identification of which research subject is the owner of the samples/information)" under the former guidelines.
- However, "pseudonymously processed information" is **not fully equivalent** to these.

[Key points]

- Can be used without consent, but ...
- **Almost meaningless and unusable except for internal use only**
- It only results in a situation violating the law or incapable of developmental collaborative research or use inadvertently.

"Pseudonymously Processed Information" for the Guidelines

Source) Kenji Matsui. 3.2 Research Ethics, Protection of Personal Information, and Anonymization. "Introduction to Health Data Science" planned in 2023.

Table 1. Definition of pseudonymously processed information and restrictions in the Act on the Protection of Personal Information

	Pseudonymously processed information **Applicable to personal information**	**Pseudonymously processed information** **Not applicable to personal information**
Definition	Personal information processed in accordance with processing standards so that the information alone cannot identify a specific individual. However, a specific individual may be identified when collating with deleted information, etc. generated in the processing process.	Information that arises at an institution (the recipient institution: in this case, not applicable to a third party) to which only pseudonymously processed information has been provided (i.e. without provision of deleted information, etc.) in association with outsourcing based on a contract, business succession, or shared use with a specific person.
Use beyond the specified purpose of use (use for purposes other than the intended purpose)	**Prohibited unless required by law**. However, the purpose can be changed freely to the extent reasonably considered to have a relationship (publication is required for each change).	No limitation.
Provision to a third party (including provision to a third party in a foreign country)	**Prohibited unless required by law**. ***Also applied to academic research institutions, etc.** ***Prohibited even if the consent of the person in question is obtained.**	Prohibited unless required by law. *Also applied to academic research institutions, etc. *Prohibited even if the principal's consent is obtained.
Collation with other information	**Collation** to identify individuals in relation to personal information **is prohibited**. ***Also applied to academic research institutions, etc.**	Collation to identify individuals in relation to personal information is prohibited (including acquisition of deleted information, etc.).
Use for contacting the person in question	**Prohibited**. ***Also applied to academic research institutions, etc.**	Prohibited. *Also applied to academic research institutions, etc.

2022 revised Guidelines Chapter 4 Section 8-1(2)

(2) When using existing samples/information possessed by the researcher's own research institution for research

Researchers, etc. shall perform the following procedures (A) or (B).

A Research using samples

Researchers, etc. are not always required to obtain informed consent in writing. However, if they do not obtain written informed consent, they must obtain oral informed consent for the matters to be explained pursuant to the provision 5 and prepare records on the method and contents of explanation and the details of consent received. However, if any of the following applies, these procedures are not required.

(A) All of the existing samples/information fall under any of the following:

[1] If the existing samples already cannot serve to identify a specific individual, personal information will not be obtained by using these existing samples.

[2] The information used in the research is pseudonymously processed information (limited to information that has already been prepared).

[3] Obtaining informed consent is difficult and the information to be used in the research is anonymously processed information.

[4] The information used in the research is personal-related information.

B Research not using samples

Researchers, etc. are not always required to obtain informed consent. However, if they do not obtain informed consent, any of the following must be met:

(A) The information used in the research is pseudonymously processed information (limited to information that has already been prepared), anonymously processed information, or personal-related information.

Appearing at these two places only. In addition, these are only for "already prepared", and preparation from now on is not accepted.

Precautions for "Cross-Border Transfer" (provision to overseas/foreign researchers, etc.)

2022 revised Guidelines Chapter 4 Part 8-1(6)

(6) Handling when samples/information is provided to a person in a foreign country

A When samples/information is provided to a person (excluding those who have a system in place that complies with the standards set forth in Article 16 of the Enforcement Rules of the Act on the Protection of Personal Information. The same shall apply to A and B below) in a foreign country (excluding those designated by the Personal Information Protection Commission as foreign countries that satisfy all items of Article 15, Paragraph 1 of the Enforcement Rules of the Act on the Protection of Personal Information. The same shall apply hereinafter) (including cases where all or part of the handling of such samples/information is outsourced to a person in a foreign country), the appropriate consent of the research subjects, etc. must be obtained for the provision of samples/information to such a person. However, this shall not apply to any of the following cases:

- When providing to researchers, etc. in the excluded countries according to the provision of the Act on the Protection of Personal Information, the rule of "a person in a foreign country" in the Guidelines shall not apply and the rule for provision to other research institutions in Japan (Part 8-1(3)) shall apply in the same way.
- Currently excluded countries are limited to:

[1] EU countries, [2] the United Kingdom

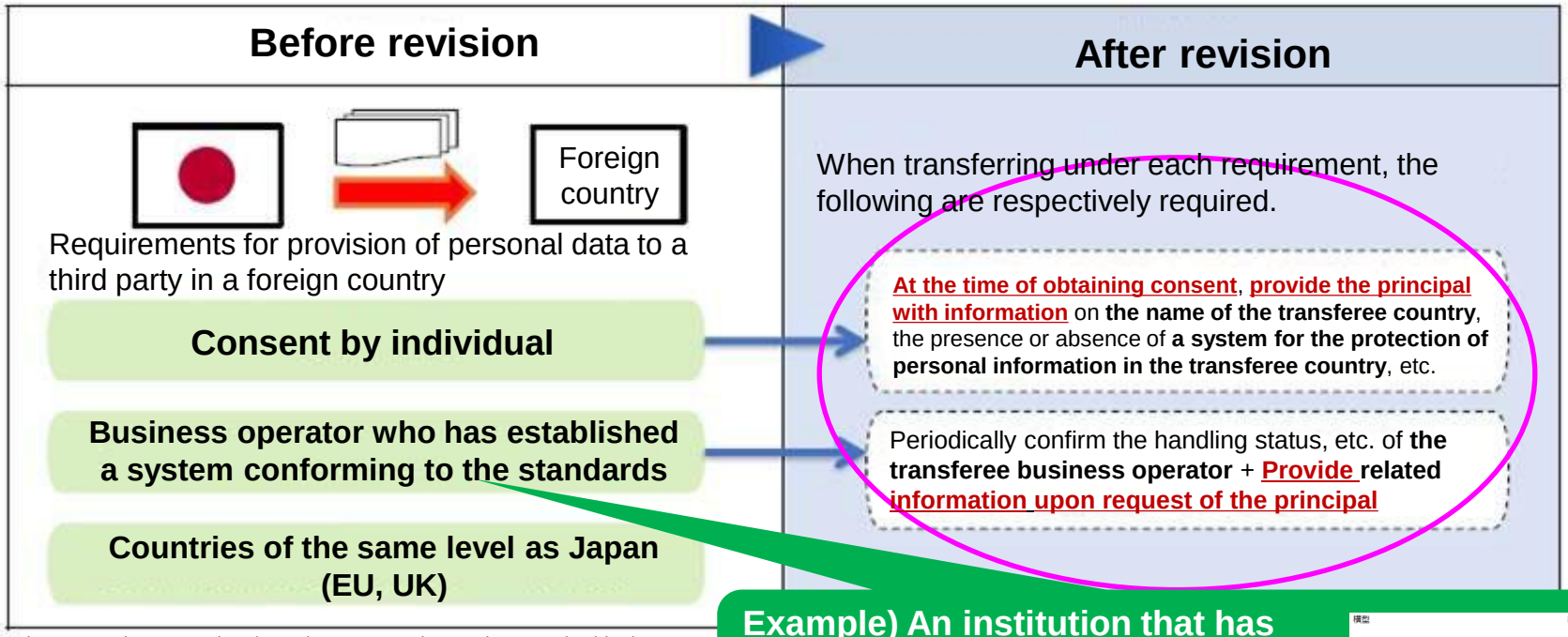
*The United States should become a country of exclusion soon as it reached an agreement with the EU on March 25, 2022 and the new ***Privacy Shield 2.0*** received the **GDPR adequacy decision** (currently not accepted). The Asian area, etc. are out of the discussion.

Provision to a Third Party in a Foreign Country

Enhancement of provision of information related to cross-border transfers

○ When providing personal data to a third party in a foreign country, the transferee business operator is request to enhance the provision of information to the principal regarding the handling of personal information.

[Background] In recent years, some countries have introduced regulations controlled by government. As opportunities for cross-border transfers of personal information have expanded, differences in systems among countries and regions make predictability of individuals or business operators who handle data unstable, and a concern arises from the viewpoint of protection of personal rights and benefits.



*There are other exceptional requirements such as "when required by law".

*The above is an explanation of the rule of the private sector.

Source: 1st Joint Meeting on Handling of Personal Information in Life Science and Medical Research, etc. Material 3-2 (explanatory material from secretariat of Personal Information Protection Commission), partially modified

Provision to "a person in a foreign country" in the Guidelines

2022 revised Guidelines
Chapter 4 Section 8-1(6)

Cases where provision is allowed without consent:

[1] The recipient is a person/organization located in the EU or UK.

[2] The recipient is a person/organization who has received APEC/CBPR certification.

[3] Not falling under the category of "third party" as defined in the law.

[4] Required by laws and regulations.

Academic exceptions where it is necessary to protect human life, body, and property and obtaining consent is difficult

Special reasons (public health exceptions)

However, it is necessary to meet additional requirements according to the Guidelines.
([3]⇒Response by opt-out; [4]⇒1(6), 9(1) + 9(2), etc.)

When the recipient is neither in the EU/UK nor a CBPR-certified organization

B A person who provides samples/information to a person in a foreign country shall provide the following information to the research subject, etc. in advance when seeking appropriate consent of the research subject, etc. in accordance with A.

[1] Name of the foreign country
[2] Information on the system for protection of personal information in the foreign country obtained by a proper and reasonable method
[3] Information on measures taken by the said person to protect personal information

横型 APECCBPRs JIPDEC, Japan 縦型 APECCBPRs JIPDEC, Japan

C A person who provides samples/information to a person in a foreign country (limited to those who have established a system conforming to the standards specified in Article 16 of the Enforcement Rules of the Act on the Protection of Personal Information) shall, when providing samples/information to the said person without receiving appropriate consent of the research subject, etc., take necessary measures required under Article 28, Paragraph 3 of the Act on the Protection of Personal Information with respect to the handling of the personal information, and provide the research subject, etc. with information on the necessary measures upon request of the research subject, etc.

3 The personal information handling business operator shall, when providing personal data to a third party who is located in a foreign country (limited to those who have established the system stipulated in Paragraph 1), take necessary measures to ensure continuous implementation of the corresponding measures by the third party, and shall provide the information on the necessary measures to the principal at his/her request, as stipulated in the Rules of the Personal Information Protection Commission.

Enforcement Rules for the Act on the Protection of Personal Information (Enforced on April 1, 2022)

(Measures, etc. necessary to ensure continuous implementation of corresponding measures by a third party in a foreign country)

Article 18 Measures necessary to ensure continuous implementation of corresponding measures by a third party in a foreign country pursuant to the provisions of Article 28, Paragraph 3 of the Act (including as applied mutatis mutandis following a replacement of terms pursuant to Article 31, Paragraph 2 of the Act), shall be as follows:

(1) Periodically confirm, in an appropriate and reasonable manner, the implementation status of the corresponding measures by the third party, the presence or absence of a system in the foreign country that may affect the implementation of the corresponding measures, and their details.

(2) Take necessary and appropriate measures if it becomes difficult for the third party to take corresponding measures. In addition, suspend the provision of personal data (personal-related information when applying mutatis mutandis following a replacement of terms pursuant to Article 31, Paragraph 2 of the act) to the third party if it becomes difficult to secure the continuous implementation of the corresponding measures.

2 The method to provide information pursuant to the provisions of Article 28, Paragraph 3 of the Act shall be the method by providing electromagnetic records, method by issuing documents, or other appropriate methods.

3 The personal information handling business operator shall, upon request pursuant to the provisions of Article 28, Paragraph 3 of the Act, provide the principal with the following information without delay. However, if provision of information may markedly hinder the proper business operations of the personal information handling business operator, the whole or part of the information may not be provided.

(1) Method to arrange the system stipulated in Article 28, Paragraph 1 of the Act by the third party

(2) Summary of corresponding measures taken by the third party

(3) Frequency and method of confirmation pursuant to the provision of Paragraph 1, Item 1

(4) Name of the foreign country

(5) Presence or absence of a system in the foreign country that may affect the implementation of corresponding measures by the third party and its summary

(6) Presence or absence of interference with the implementation of corresponding measures by the third party and its summary

(7) Summary of measures to be taken by the personal information handling business operator pursuant to the provisions of Paragraph 1, Item 2 with respect to the interference referred to in the preceding item

The Act on the Protection of Personal Information has some measures to avoid the applicability to "a third party" in the provision to other institutions, including "cross-border transfers" (⇒ The Guidelines have also introduced them at least).

- Provision based on an "outsourcing" contract
- Provision based on a "business succession" contract
- Provision based on a "shared use" contract

- **Identification of sharing users (clarification)**
- **Identification of personal data items for shared use**
- **Purpose of use of each user**
- **Name and address of each data manager (in the case of a corporation, also the name of the representative)**

⇒ It is necessary to notify the individual in advance or keep him/her able to easily know.

2022 revised Guidelines, Guidance Part 8-1(3) Commentary 2

Note that in the case of provision in association with shared use, the recipient research institution needs to handle samples/information only within the scope of the purpose of use specified [in the contract].

In the case of a multicenter research, ... Basically, ... provision to a third party based on Article 27, Paragraph 1 of the Act is considered, but [2] the provision of samples/information in association with shared use is not prevented.

Exclusion from Application for "Academic Research" ("Academic Exceptions")

The former Act on the Protection of Personal Information, Article 76 (Exclusion from Application):

For the personal information handling business operators, etc. who are listed in any of the following items, if all or part of the purposes of handling the personal information, etc. are those respectively specified in each of these items, the provisions of Chapter 4 [Obligations, etc. of a Personal Information Handling Business Operator] shall not apply.

***Not applicable to medical associations, etc.**

1. [Omitted]
2. [Omitted]
3. University and other **institutions** or **organizations** for the purpose of academic research or **persons belonging** to them Purpose of use for academic research
4. [Omitted]
5. [Omitted]

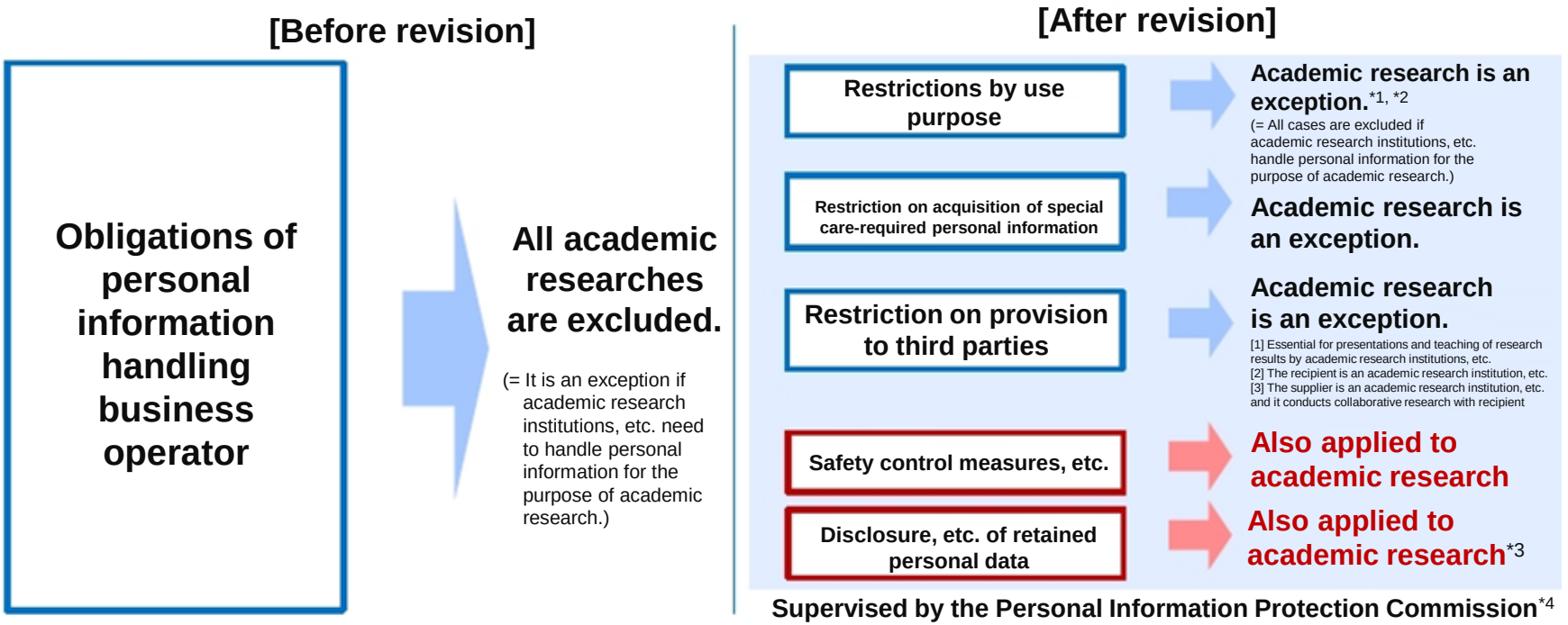
Organization: Academic societies, study societies (*)
Members: Staff, members of academic societies, members of study societies

Same in the 2020/2021 revised law

"Academic research" under the Act on the Protection of Personal Information = "Academic research institutions, etc." × "Scientific research purpose"
(Principal requirement) (Purpose requirement)

Refinement of Academic Exceptions [1]

- Unvarying exclusion provisions related to academic research are reviewed on the occasion of unification, and **the exceptions related to academic research are refined for each individual obligation provision**.
- From the viewpoint of respecting the autonomy of academic research institutions, etc. including autonomy of universities, **academic research institutions, etc. are requested to formulate and publicize the self-imposed rule concerning the proper conduct of research using personal information**, based on the purpose of Article 146, Paragraph 1 of the Act on the Protection of Personal Information. Then, the Personal Information Protection Commission **shall not exercise its supervisory authority** in principle **with regard to the handling of personal information in accordance with the self-imposed rule**.

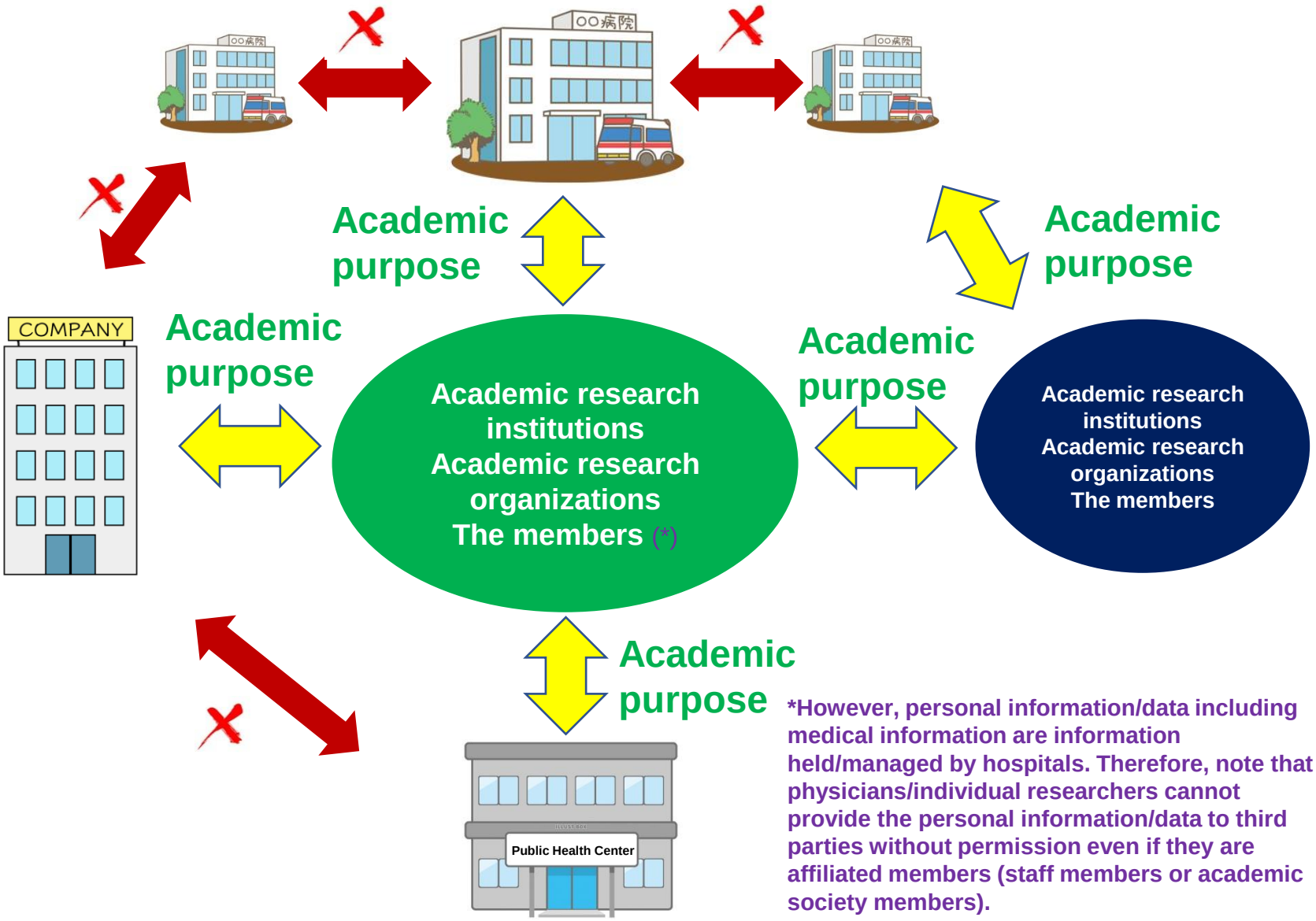


*1 Academic research institutions, etc.: universities (private universities, **national and public universities**), academic societies, **National Research and Development Agencies** (mainly for academic research), etc. (**underlines** indicate those added this time)
*2 Excluding cases in which there is a risk of unjustified infringement on the rights and benefits of individuals (e.g., cases in which an injunction request is accepted due to a tort under the Civil Code)
*3 For national and public universities and National Research and Development Agencies, the same rules as those for administrative agencies shall apply with respect to disclosure, etc. of retained personal information.
*4 Identification/publication of purposes of use, prohibition of improper use/acquisition, and reporting of leakage are also applied.

*The above is an explanation of the rule of the private sector.

Source: 1st Joint Meeting on Handling of Personal Information in Life Science and Medical Research, etc. Material 3-2 (explanatory material from secretariat of Personal Information Protection Commission), partially modified

Relationship Diagram for Application of "Academic Exception"



*However, personal information/data including medical information are information held/managed by hospitals. Therefore, note that physicians/individual researchers cannot provide the personal information/data to third parties without permission even if they are affiliated members (staff members or academic society members).

2022 revised Guidelines
Chapter 4 Section 8-1

(1) When conducting research by obtaining new samples/information

Not much different from the former guidelines:

Guarantee of an opportunity to refuse + Publicity for target population/post-hoc explanation or making known to the society

\+

[1] Invasion is not involved in the conduct of the study (excluding minor invasion)
[2] Simplification of the procedures specified in 1 and 4 will not be disadvantageous to research subjects.
[3] Absence of simplifying the procedures specified in 1 and 4 makes it difficult to conduct the research or significantly impairs the value of the research.

[2] Research not using samples

(i) When special care-required personal information is obtained

Researchers, etc. are not always required to obtain informed consent. However, if they do not obtain informed consent, they must obtain appropriate consent from research subjects, etc. in principle. However, in the case where the opportunity for research subjects, etc. to refuse the conduct or continuation of the research is guaranteed while meeting the requirements of 9 (1) [1] to [3] and satisfying any of the following requirements, acquisition and use of special care-required personal information are allowed by taking appropriate measures among those listed in 9 (2) [1] to [3]

a A research institution corresponding to an academic research institution, etc. needs to obtain the special care-required personal information for academic research purposes and there is no risk of unjustifiable infringement of the rights and benefits of research subjects.

(2) When using existing samples/information possessed by the researcher's own research institution for research

(C) When both (A) and (B) are not met, the existing samples/information is used in a socially very important research, and appropriate consent is obtained after notifying the research subjects, etc. of the matters in 6 [1], [2], and [6] to [9] or all of the requirements in the following [1] to [3] are met

[1] Any of the following requirements is met.

(i) A research institution corresponding to an academic research institution, etc. needs to handle the existing samples/information for academic research purposes and there is no risk of unjustifiable infringement of the rights and benefits of research subjects.

Scope of application more limited than the former guidelines':

Socially very important

+

Conventional opt-out

(Notification/keep able to easily know + Guarantee of an opportunity to refuse)

(3) When the existing samples/information is to be provided to other research institutions

Greatly changed from the former guidelines:

Obligation to make efforts to guarantee an opportunity to refuse + Publicity for target population/ post-hoc explanation or making known to the society

\+

[1] Invasion is not involved in the conduct of the study (excluding minor invasion)
[2] Simplification of the procedures specified in 1 and 4 will not be disadvantageous to research subjects.
[3] Absence of simplifying the procedures specified in 1 and 4 makes it difficult to conduct the research or significantly impairs the value of the research.
[4] The research is considered to be socially very important

(B) When (A) is not met, efforts are made to give an opportunity for the research subjects, etc. to refuse the provision of the existing samples and special care-required personal information, any of the following requirements is met, all of the requirements in 9 (1) are met, and appropriate measures stipulated in 9 (2) are taken

[1] A research institution corresponding to an academic research institution, etc. needs to provide the existing samples and special care-required personal information to a collaborative research institution for academic research purposes and there is no risk of unjustifiable infringement of the rights and benefits of research subjects.

[2] The existing samples and special care-required personal information is to be provided to a research institution corresponding to an academic research institution, etc. the research institution needs to handle them for academic research purposes and there is no risk of unjustifiable infringement of the rights and benefits of research subjects.

Appearance of Two Types of "Research Institutions"

"Research institution corresponding to an academic research institution, etc." *vs.* just "research institution"

(1) When conducting research by obtaining new samples/information

B Non-invasive research

(B) Non-interventional research

[2] Research not using samples

(i) When special care-required personal information is obtained

Researchers, etc. are not always required to obtain informed consent. However, if they do not obtain informed consent, they must obtain appropriate consent from research subjects, etc. in principle. However, in the case where the opportunity for research subjects, etc. to refuse the conduct or continuation of the research is guaranteed while meeting the requirements of 9 (1) [1] to [3] and satisfying any of the following requirements, acquisition and use of special care-required personal information are allowed by taking appropriate measures among those listed in 9 (2) [1] to [3].

a A research institution corresponding to an academic research institution, etc. needs to obtain the special care-required personal information for academic research purposes and there is no risk of unjustifiable infringement of the rights and benefits of research subjects

b There is a special reason for the research institution to conduct the research by obtaining the special care-required personal information and it is difficult to obtain the informed consent and appropriate consent from the research subjects, etc.

2022 revised Guidelines Chapter 4 Part 8-1(1)

Another Exception: "Public Health Exceptions" of the Act.

Article 27, Paragraph 1 of the Act: A personal information handling business operator shall not provide personal data to a third party without prior consent of the individual, except for the following cases.

[...]

3 **It is particularly necessary for the improvement of public health ...** and it is difficult to obtain the principal's consent.

"Public health exceptions" of the Act ⊂≒ "Exceptions for special reasons" of the Guidelines

Guidance Part 8-1(3) Commentary 8 for the 2022 revised Guidelines

"In the case of special reasons ..." means the cases stipulated in Article 27, Paragraph 1, Item 2 [Life/Property Protection Exceptions], Item 3 [Public Health Exceptions], and Item 4 [National/Administrative Exceptions] of the Act on the Protection of Personal Information.

"Public health exceptions" of the Act ⊂≒ "Exceptions for special reasons" of the Guidelines

Conditions under which "Public Health Exceptions" apply in provision to a third party under the Guidelines:

(Method A)

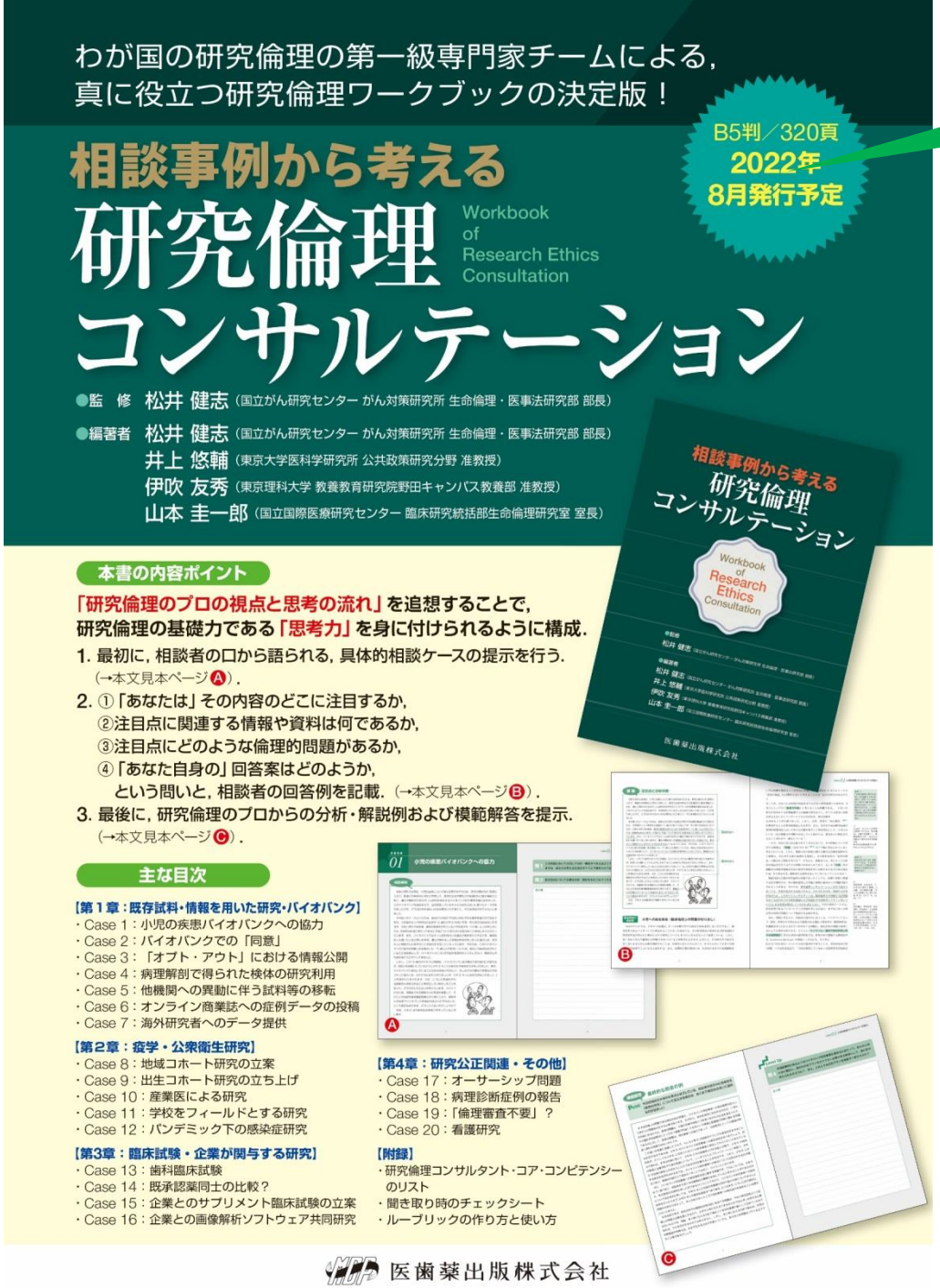
1. **There is a special reason.**
2. IC procedures are difficult + Obtaining appropriate consent is also difficult.
3. All **9 (1) requirements** are met.
4. Implementation of any of **9 (2) measures** + **Securing an opportunity to refuse** (obligation to make efforts)

[1] No invasion (excluding minor invasion)
[2] Simplification does not cause any disadvantage
[3] Research is difficult/damaged without simplification
[4] Research of high social importance

[1] Publicity for the group including research subjects, etc.
[2] Post-Hoc explanation to research subjects, etc.
[3] Publicity + Making known to the society

(Method B)

1. **There is a special reason.**
2. IC procedures are difficult + Obtaining appropriate consent is also difficult.
3. **Opt-out** (notification to the principal/keep him/her able to easily know + Guarantee of an opportunity to refuse)



B5 size, 424 pages
Scheduled to be published in October 2022

- Already responded to both the 2020/2021 revised Act on the Protection of Personal Information and the 2022 revised Life Science and Medical Guidelines.
- This should cover about 80% of problems commonly bothering many researchers and leading to consultations on research ethics (although just a personal thought ...).
- Open consultation is accepted. If you wish, please contact the following.

(The details of consultation may be used as educational materials while paying attention to confidential information.)

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