Guidelines Pertaining to Using Anonymized Data (Provisional translation)

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June 30, 2016 Ministry of Health, Labour and Welfare

Part 1 Definition of Terms

The terms used in these Guidelines are defined as follows:

- The term **"anonymized data"** means questionnaire information (individual sheets) that the Ministry of Health, Labour and Welfare (hereinafter referred to as the "MHLW") has processed in a manner in which no particular individual, corporation or other organization can be identified (including by way of collating it with other information), pursuant to Article 35 of the Statistics Act (Act No. 53 of 2007; hereinafter referred to as the "Act").
- The term "requester" means the person who requests the provision of anonymized data.
- The term "user" means the person who receives and actually uses anonymized data.
- The term "**agent**" means the person to whom the requester issues a document evidencing his/her authority of representation such as a power of attorney and who is authorized to conduct request procedures for the provision of anonymized data on behalf of the requester. For the purpose of these procedures, an act conducted by the agent will be deemed as an act conducted by the requester.

Part 2 Requirements for Use

<u>1. Requirement of use purpose</u>

The use of anonymized data may be permitted when it is found that the use will contribute to the development of academic research or higher education, or the promotion of Japan's interest in the international community and the development of a sound international economy and society, provided that the use satisfies all the following requirements.

[Academic research purpose or higher education purpose]

- 1. Anonymized data are to be used only for the purpose of producing statistics or statistical research.
- 2. Anonymized data are to be used directly for the purpose of academic research or higher education (meaning the education in a university or a technical college as defined in Article 1 of the School Education Act (Act No. 26 of 1947).
- 3. The results of the relevant academic research or higher education are to be published and shared for the common good.
- 4. Anonymized data are to be controlled in an appropriate manner.

[Purpose of use under a project to promote the use of international comparative statistics]

- 1. Anonymized data are to be used only for the production of statistics that are necessary for international comparison.
- 2. Anonymized data are to be used by an international organization that Japan has joined, or the use of anonymized data satisfies all the following requirements.
 - (i) Statistics or statistical research results that are necessary for international comparison will be provided to a public institution, foreign government, etc. (meaning a foreign government, international institution or any other organization equivalent to these; the same applies hereinafter), or provided to a person/entity engaging in academic research or higher education with such statistics or statistical research results.
 - (ii) It is found that questionnaire information or other similar information that is necessary for the production of statistics has been provided or will certainly be provided by two or more foreign governments, etc., and that some support, including the dispatch of personnel or the provision of funds, buildings or other facilities, has been provided or will certainly be provided by a public organization or one or more foreign governments, etc.
- 3. The following contents are to be published.
 - (i) In the case of an international organization that Japan has joined: Results of international comparison conducted by using anonymized data
 - (ii) In the case of a person/entity other than international organizations that Japan has joined: The provision status of international comparison, etc., conducted with anonymized data
- 4. Anonymized data are to be controlled in an appropriate manner.

2. Requirements of the place of use

If anonymized data are to be used outside Japan, such use may be permitted on the condition that one of the following three requirements is met.

- 1. A request for provision is made by an organization, etc., which is recognized, without being subject to examination, as sufficiently reliable in terms of information control, since such organization, etc., has received questionnaire information or other similar information from two or more foreign governments, etc., and some support, including the dispatch of personnel or the provision of funds, etc., from a Japanese public organization or one or more foreign governments, etc., and has received the above-mentioned information and support for the last five consecutive years.
- 2. Personnel of the Japanese government are temporarily transferred to the organization to which the requester belongs, and it is possible to ask the personnel to check the status of the requester's use of anonymized data.
- 3. The requester or agent (limited to agents who fall within the scope of users) will be able to visit the MHLW during the period of use of anonymized data (such visit must take place within one year from the start date of provision of the anonymized data) and to attend a hearing conducted by the MHLW in the Japanese language with respect to the status of use, etc.

3. Scope of requesters or users

The following persons/entities are examples of the requesters who satisfy the requirements for use described above.

[Academic research purpose or higher education purpose]

- O Researchers who belong to universities or other institutions having the purpose of academic research, or such institutions
- O Persons who engage in academic research at think tanks or other similar organizations, or such organizations
- O Persons who do not belong to an institution but nevertheless engage in academic research
- O Instructors who provide lectures or other education at higher education institutions such as universities, or such institutions

[Purpose of use under a project to promote the use of international comparative statistics]

- O International organizations that Japan has joined
- O Non-profit organizations that receive questionnaire information, funds, etc., from multiple foreign governments, etc.

The scope of requesters and users at a university is as follows:

[Academic research purpose]

O When graduate students or undergraduate students (hereinafter collectively referred to as "students") engage as assistants in research using anonymized data under the instructions of an instructor:

 \Rightarrow The instructor will be the requester, and the instructor and the students will be the users.

- O When an instructor and students engage in joint research:
 - \Rightarrow The instructor will be the requester, and the instructor and the students will be the users.
- O When a graduate student, etc., engages, as an individual, in research with anonymized data:
 - \Rightarrow The graduate student, etc., will be the requester and user.

[Higher education purpose]

- O When students use anonymized data in a lecture or seminar (including in the process of writing up a dissertation or graduation thesis) under the instructions of an instructor:
 - \Rightarrow The instructor will be the requester, and the instructor and all the persons who will use such data in the lecture, seminar, etc., will be the users.
- O When an instructor prepares materials for his/her lecture, etc., by using anonymized data and distributes such materials to students:

 \Rightarrow The instructor will be the requester and user.

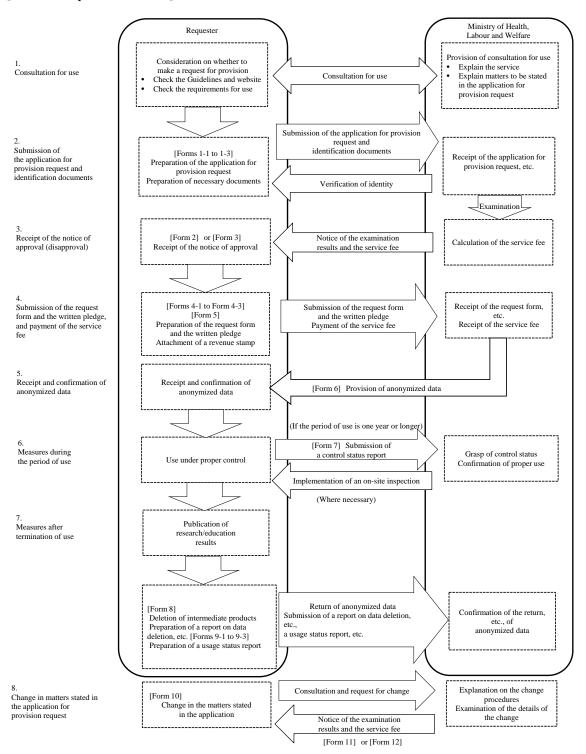
* If anonymized data are to be used for the purpose of higher education, the instructor concerned must, in advance, provide the students who will be the users with ethics education in relation to the use of statistics (including education concerning the service, the obligation of proper control, the prohibition on provision to third parties, matters to be complied with, and penalties) in order to ensure that the students will properly use anonymized data.

Part 3 Request Procedures

The administrative procedures for a request are as follows:

- 1. Consultation for use
- 2. Submission of the application for provision request and identification documents
- 3. Receipt of the notice of approval (disapproval)
- 4. Submission of the request form and written pledge, and payment of the service fee
- 5. Receipt and confirmation of anonymized data
- 6. Measures during the period of use
- 7. Measures after termination of use
- 8. Change in matters stated in the application for provision request

[Flow of Request Procedures]



<u>1.</u> Consultation for use

The website below explains the objective of this service, the titles and years of surveys available for anonymized data provided by the MHLW, the requirements for use of such data, and other relevant information. Please make sure that you check the website before you consult us concerning the use of the service.

On the website, you can also find various forms necessary for service request procedures; you can download and use such forms as appropriate.

The website of the Ministry of Health, Labour and Welfare:

(http://www.mhlw.go.jp/toukei/itaku/tokumei.html)

(Top page of the Ministry of Health, Labour and Welfare \rightarrow Statistical information/White papers \rightarrow Various statistical surveys \rightarrow For statistical information users \rightarrow Custom-Made Aggregation/Provision of anonymized data \rightarrow Provision of anonymized data)

When you intend to make a request for the provision of anonymized data, consult us in advance in order to avoid any inadequacy in documents or non-compliance with requirements for use and to expedite an examination and other procedures pertaining to the necessary documents. Japanese is the only language you can use for consultations.

[Contact Information]				
Room No. 15, 21F, Central Government Building No. 5,				
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916				
Examination and Analysis Office				
to the Director-General for Statistics and Information Policy,				
Ministry of Health, Labour and Welfare, Japan				
(Tel) 03-5253-1111 (Extension: 7392)				
(Fax) 03-3595-1608				
(email) n <u>ijitekiriyou@mhlw.go.jp</u>				
Business hours: 9:30–12:00, 13:00–18:15				
(excluding Saturdays, Sundays, holidays, and year-end and New Year holidays)				

When you consult us on use of the service, we will check with you the following matters and necessary documents.

- O Confirmation of your proper understanding of contents posted on the website and the objective of the service
- O How to enter information in necessary documents, and provision procedures
- O Requirements pertaining to the purpose of use and users
- O Conditions that must be accepted, and matters that must be observed by the users
- O Amount of the service fee and its payment method
- O Places of use and storage, usage environment, control method, and other matters related to proper control
- O Result publication schedule
- O Hearing on the details of the request, and the request's compatibility with the agreed standards

2. Submission of the application for provision request and identification documents

(1) Documents necessary for the application for provision request

Enter necessary information in the "application for provision request for anonymized data" (Forms No. 1-1 to 1-3; hereinafter referred to as the "application") and submit the application to the responsible office together with the applicable "identification document" (see (3) on p. 12) and a "return-mail envelope" (see (4) on p. 13), and "if you are affiliated with or enrolled at an organization, a document evidencing the affiliation or enrollment (e.g., certificate of employment, school certificate, or school identification card)" (see (xiii) on p. 11). (A return-mail envelope is not required if you would like to receive your notice of approval (disapproval) by email.)

If the application is made through an agent, attach a power of attorney to the application. When submitting the application, please attach to it, if any, documents evidencing any public interest in your purpose of use and/or any entrustment contract, etc., under which aggregation processes are outsourced (see p. 9).

- (2) How to enter information in the application
 - (i) The affiliation/job title, name, date of birth, address, telephone number, and e-mail address of the requester

Provide the address and telephone number that will allow us to get in touch with you in the daytime.

(ii) The titles, years, and number of files of anonymized data

Check the titles and years of statistical surveys whose availability for the provision of anonymized data is announced on the website of the MHLW, and enter the titles and years of the relevant statistical surveys in the application.

From the viewpoint of clarifying management responsibility, when making a copy of anonymized data provided upon request, only one copy may be created for each file of the anonymized data.

When you enter the number of files in the application, please bear in mind that in principle, one user is supposed to use one file on one computer; take into account the number of users and the place of use.

For example, if you would like to allow one user to use the same anonymized data on multiple computers, you should apply for the same number of files as the number of computers.

On the contrary, if you would like to copy one file of anonymized data to one computer so as to allow multiple users to use the same computer in turns, you only have to apply for one file.

(iii) The purposes of use of anonymized data, and other relevant items

A. Direct purpose of use

Higher education: Enter the names of the university and graduate school, department or faculty that will use anonymized date.

International comparison: Check (/ mark) the item that applies.

When you choose "Other," please provide the details.

(a) Title and implementation duration

Academic research:

Enter the title (such as "Research related to $\circ\circ$ ") and duration of the academic research concerned.

Higher education:

Enter the title of the course subject (such as "Seminar [III] on $\circ\circ$ ") and schedule (including the day and hour).

International comparison:

Enter the title of the project to promote the use of international comparative statistics (such as "International comparison project related to $\circ\circ$ "), and the project schedule.

(b) Objective and necessity

Academic research:

Describe the necessity of the academic research, such as the significance of the academic research within a specific research field or the society.

Higher education:

Enter the general objective (such as "learning the basic theory of regression analysis of statistics and its practical applications") and necessity of the course subject.

International comparison:

Describe the usefulness of the relevant project to promote the use of international comparative statistics, including the significance of the project in international society and the vitalization of international research through such project.

(c) Contents and necessity of anonymized data and how to use it

Academic research:

Describe the specific contents of the research concerned, the necessity to use anonymized data, and how such data will be used.

Higher education:

Specifically describe the contents of the course subject concerned, and the necessity to use anonymized data in the course subject (e.g., "In a computer room exclusively used for seminars, each student will be provided with one computer and will aggregate anonymized data by using spreadsheet software").

International comparison:

Describe the specific contents of the project, including the form of the project, the use or non-use of an external subcontractor, and how anonymized data will be used.

Describe the scope of persons/entities that will receive international comparison statistics produced under the project to promote the use of international comparative statistics.

(d) Contents of statistics produced from anonymized data, or those of statistical research

Describe an outline, analysis methods and other details of statistical charts to be produced, or those of the statistical research concerned.

(e) Contents of questionnaire information or other information provided by foreign governments, etc. (when the purpose of use is international comparison and the requester is a person/entity other than international organizations that Japan has joined)

Describe the contents of specific items to be published, including questionnaire information that has been received or will be certainly received for the purpose of the relevant project to promote the use of international comparison statistics, and the names of the foreign governments, etc., which are or will be the providers of such information.

(f) Contents of support provided by public organizations or foreign governments, etc., and the names of the supporting organizations/governments (when the purpose of use is international comparison and the requester is a person/entity other than international organizations that Japan has joined)

Describe the contents of the specific support that has been provided by Japanese public organizations or foreign governments, etc., for the purpose of the relevant project to promote the use of international comparison statistics, and the names of such supporting organizations/governments.

Furthermore, attach copies of agreements executed with foreign governments, etc., for the provision of questionnaire information or support.

B. Other purposes of use

Describe all secondary purposes of use, which are other than the publication methods described in "Direct purpose of use" or "Result publication schedule and method."

Academic research: If research results are to be published as printed material, or to be used for other ancillary research, enter such publication or use as a purpose of use.

If you cannot specifically list the seminars, workshops, research conferences, or other meetings that are held periodically or non-periodically at universities, academic societies, etc., and in which you will report the progress of the relevant academic research, list those meetings, etc., at which your attendance is expected at the time you submit the application.

Higher education:

If the contents of higher education are to be secondarily used for academic research, state such use as a purpose of use.

International comparison:

If the results of the relevant project to promote the use of international comparison statistics are to be published as printed material, or to be used for other ancillary research, also state such publication or use as a purpose of use.

C. Result publication schedule and method

Check (\checkmark mark) all that apply.

Enter the scheduled time of publication for each planned publication.

Academic research:

List the names and activities of academic societies and conferences at which publication is planned to take place (limited to cases of general academic research), and the names of academic journals, organizational papers, specialized magazines, etc., in which publication is planned to take place (limited to commonly available journals).

Higher education:

Enter such a statement as, "the fact that a lecture was conducted with the relevant thesis or statistical product will be announced on the website of the university, relevant laboratory, etc., or in a publicly available business report of the university, etc."

International comparison:

State the publication schedule for the results of use of anonymized data for international comparison (in the case of an international organization that Japan has joined), or the publication schedule for the implementation status of the project to promote the use of international comparison statistics (in the case of a person/entity other than international organizations that Japan has joined).

(iv) Preferred date for receiving anonymized data

Enter the month and year in which you wish to receive anonymized data.

(v) Places of use and storage, usage environment, and control method with regard to anonymized data

Specifically describe the places of use and storage so that each item concerning the control method can be substantiated.

Check (\checkmark mark) all that applies in each item concerning the usage environment and control methods.

If aggregation is to be outsourced and anonymized data are to be used or stored by an external subcontractor, enter information concerning such subcontracting.

(vi) Period of use of anonymized data

The period of use must be a maximum of two years, and must be kept to the minimum necessary.

(vii) Persons to handle anonymized data

Enter the names and affiliations/job titles of persons who will actually handle anonymized data, their place of use and number of files, and the total number of computers and files to be used by such persons. If you cannot enter all the information because there are many users, use separate sheets.

- O If the requester is to use anonymized data:
 - \Rightarrow Enter information concerning the requester.
- O If any process is to be outsourced:
 - \Rightarrow Enter information concerning the persons who will handle anonymized data at an external subcontractor.
- O If anonymized data are to be used for the purpose of higher education:

- \Rightarrow Enter information concerning the instructor and students who will use anonymized data in a class, etc.
- (viii) Questionnaire information and other anonymized data that you have already received or that you will request in the future

List each piece of information/data whose period of use overlaps with the period of use under this application, including information/data related to statistical surveys under the jurisdiction of other ministries, etc.

(ix) Method of receiving anonymized data, etc.

Select a medium on which you would like your anonymized data to be stored for provision, by checking (\checkmark mark) one of the available options.

For the delivery method, check (\checkmark mark) either method that you prefer: by mail or delivery by hand.

If you choose mail, we will use registered mail with return receipt requested.

(x) Past records of provision

Check (✓ mark) the applicable box, according to whether or not you received in the past any anonymized data, Custom-Made Aggregation or questionnaire information; if you received any of the above services in the past, enter the name of the ministries, etc., that provided you with the service, and the titles of the relevant statistical surveys.

Check (\checkmark mark) the applicable box, according to whether or not you received in the past any penalty under the Statistics Act or other related regulations, or any ban on receipt of relevant services due to a contractual breach, etc.

(xi) If anonymized data are to be used outside Japan

Check (✓ mark) the conditions that apply and enter necessary details.

(xii) If anonymized data are for a project to promote the use of international comparison statistics, and the requester is a person/entity other than international organizations that Japan has joined

Attach copies of agreements executed with foreign governments, etc., for the provision of questionnaire information, support, etc.

(xiii) Other necessary matters

If there is any document evidencing any public interest in the purpose of use, or any entrustment contract, etc., under which aggregation processes are to be outsourced, state the name of such document/contract and attach a copy of it to the application.

[Examples of Attached Documents]

- If you are affiliated with or enrolled at an organization, a document evidencing the affiliation or enrollment (e.g., certificate of employment, school certificate, or student identification card)
- Notice of decision on the granting of a research subsidy (e.g., the Science Research Subsidy from the Ministry of Education, Culture, Sports, Science and Technology, and the Science Research Subsidy from the Ministry of Health, Labour and Welfare)
- List of books and papers written by the requester and users (only those in Japanese)
- Educational program (syllabus)
- Letter of recommendation from an instructor, university, relevant academic society, etc.
- Any agreement exchanged with a foreign government, etc., when questionnaire information or support was provided
- Entrustment contract etc.

(3) Identification document

When the application is made, your identity will be verified; please submit to the responsible office the applicable identification document of the requester. If an agent makes the application, the applicable identification documents for both the requester and the agent will be required. If the original of an identification document is presented, the responsible office will make a copy of it.

(i) If the requester is an individual

If the requester is an individual whose domicile is in Japan, he/she is required to submit, on the application date, (a) document(s) issued by one of the government authorities and by which his/her name, date of birth, and address can be confirmed (hereinafter referred to as an "identification document"); such document, which must be prior to its expiration date, includes "driver's license," "health insurance card," "individual number card" (including the basic resident register card), "residence card," and "special permanent resident certificate."

If the requester's domicile is outside Japan, submit the "passport" or "driver's license" issued by the relevant foreign government, etc.

A. When you submit the application by directly visiting the responsible office:

Bring with you one identification document by which the name, date of birth, and address can be confirmed (limited to an identification document with a photo of the face).

B. When you submit the application by mail:

Submit copies of two or more types of identification documents.

If you are unable to submit two or more types of identification documents, you may instead submit one identification document and a copy of your residence certificate (prepared within six months before the application date), only if the application is made within Japan.

(ii) If the requester is a corporation or other organization

If the requester is a "corporation or other organization" (hereinafter referred to as a "corporation, etc.") located in Japan, a "certificate of registered matters" or "certificate of registered seal" prepared with respect to the corporation, etc., within six months before the application date must be submitted, together with the documents listed in (i) above pertaining to the representative or administrator of the corporation, etc. (if a representative or administrator has been designated). If a corporation, etc., located outside Japan makes the application, it must submit a copy of a document issued by one of the government authorities of the country in which the corporation, etc., is located, and by which the status of the corporation, etc., can be confirmed in the same manner as the Japanese "certificate of corporate registered matters."

			Documents Necessary for Application	Remarks
Address is in Japan	By visit	Individual	Identification document (1 type)	With a photo of the face of the individual
		v visit Corporation	The following (i) and (ii):	For (i), with a photo of the face of the representative/administrator
			(i) Identification document (1 type) of the representative or administrator(ii) Certificate of registered matters of the corporation, etc.	For (ii), a copy is acceptable.
	By mail	Individual	Either of the following (i) or (ii): (i) Identification documents (2 types) (ii) Identification document (1 type) and a copy of the residence certificate	For both (i) and (ii), copies are acceptable.
		Corporation	The following (i) and (ii): (i) Identification documents (2 types) of the representative or administrator (ii) Certificate of registered matters of the corporation, etc.	For both (i) and (ii), copies are acceptable.
Address is outside Japan		Individual	Identification document (1 type)	With a photo of the face of the individual
	By visit	Corporation	The following (i) and (ii): (i) Identification document (1 type) of the representative or administrator (ii) An alternative document to the certificate of registered matters	For (i), with a photo of the face of the representative/administrator For (ii), a copy is acceptable.
	By mail	Individual	Identification documents (2 types)	A copy is acceptable.
		Corporation	The following (i) and (ii): (i) Identification documents (2 types) of the representative or administrator (ii) An alternative document to the certificate of registered matters	For both (i) and (ii), copies are acceptable.

* In the case of the agent's visit, an identification document of the agent (one type with a photo of his/her face on it) and a power of attorney (must be the original) are also required.

(4) Return-mail envelope

Together with the "application," submit a return-mail envelope that will be used by the MHLW to send you the "notice of approval of request for provision of anonymized data" (Form No. 2; hereinafter referred to as the "notice of approval") or "notice of disapproval of request for provision of anonymized data" (Form No. 3; hereinafter referred to as the "notice of disapproval"); write the name and address of the requester or agent on the envelope and affix a sufficient Japanese postage stamp to it.

If anonymized data will be used outside Japan and it is difficult to obtain a Japanese postage stamp, enclose the necessary number of the international postal reply coupons (do not put the "international postal reply coupons" on the return-mail envelope, as the responsible office will exchange the coupons with a "Japanese postal stamp").

You can receive your notice of approval, etc., by email. If you wish to do so, please let us know.

In this case, a return-mail envelope is not necessary.

(5) Handling of user information

The application and related documents will be kept at the MHLW for the purpose of managing users, and will be reported by the MHLW to the Minister of Internal Affairs and Communications pursuant to Article 55 of the Act.

When the penalty described in "Part 4 Measures against improper use" (see p. 23) is imposed, related information will be shared among relevant ministries and agencies.

3. Receipt of the notice of approval/disapproval

Based on the application and related documents submitted by the requester, the MHLW will examine the application. The requester will be notified of the result of this examination through the "notice of approval" or "notice of disapproval" within 14 days from the date on which the MHLW accepted the application in the case of an application from within Japan, or within the period agreed between the MHLW and the requester in the case of an application from outside Japan

(if you request, you can be notified by email).

(1) If the application is approved:

Through the "notice of approval," the MHLW will notify the requester of the amount of the service fee, the scheduled time of provision, the use expiration date, the payment due date for the service fee, and the submission deadline date for the request form.

With the aforesaid notice, the "request form," the "written pledge on use of anonymized data" (Form No. 5; hereinafter referred to as the "written pledge"), and the "terms and conditions for provision of anonymized data" (Appendix of Form No. 5; hereinafter referred to as the "terms and conditions") will also be enclosed.

Take a note of the "application number" specified in the "notice of approval," as it will be used for future communications with the responsible office and for confirmation of the submission of documents.

(2) If the application is disapproved:

The MHLW will send to the requester the "notice of disapproval" stating the reason for disapproval.

The Administrative Appeal Act (Act No. 160 of 1962) does not apply to the service described in these Guidelines.

4. Submission of the request form and written pledge, and payment of the service fee

(1) Submission of the request form, etc.

When the requester receives the notice of approval and wishes to request the provision of anonymized data, he/she is required to prepare the "request form" (Forms No. 4-1 to 4-3) and the "written pledge," and submit these documents to the responsible office no later than the due date indicated in the "notice of approval," in accordance with in (i) to (iii) below.

Note that if the "request form" or "written pledge" is not submitted or the service fee is not paid by using a revenue stamp no later than the due date, the "notice of approval" will become invalid.

(i) Request form

Since the form is different for each purpose of use, enter the necessary details in the form that is appropriate for your purpose of use.

(ii) Written pledge

When placing the name and seal on the written pledge, each user is required to carefully read and understand the matters to be complied with, stated therein.

The requester is required to submit to the responsible office the "written pledge" to which all the users have affixed their respective names and seals (in the case where the number of users exceeds three, please add User columns as appropriate).

(iii) Payment of the service fee

Please put a revenue stamp in the amount specified in the "notice of approval" on the designated space of the "request form" prepared under (i) above. Do not place a cancellation mark on this revenue stamp. The service fee cannot be paid in cash.

[Reference: How to calculate the service fee]

- The total of (i) to (iv) will be the service fee.
- (i) Basic fee per application: 1,850 yen
- (ii) Number of anonymized data files to be provided \times 8,500 yen
- (iii) Storage media

CD-R: 100 yen per disk \times Necessary quantity

DVD-R: 120 yen per disk × Necessary quantity

(iv) Postage, if sent by mail (*)

The postage for registered mail with the fee for return receipt added thereto

*: No postage will be charged if you are to come to the office to receive the data.

(2) Cancellation of the application

If it becomes necessary for you to cancel the application after your submission of the "request form," inform the responsible office accordingly.

(3) Cancellation of approval of request for provision, due to a reason attributable to the requester's fault

If the MHLW finds that it is appropriate to cancel its approval due to any false statement made in the "application," etc., or any dishonest act or other fault on the part of the requester, the Ministry will cancel the approval.

5. Receipt and confirmation of anonymized data

The MHLW will provide the "notice of provision of anonymized data" (Form No. 6), "anonymized data," a "code book," and a "data layout," no later than the scheduled time of provision specified in the "notice of approval" (the "control number" specified in the "notice of provision of anonymized data" will be used when the use of the anonymized data has been completed and subsequently the data are to be returned to the MHLW).

If the provision is likely to be delayed due to a natural disaster or other unavoidable reasons, the responsible office will immediately notify the requester. Both the parties should then discuss and determine how to handle the situation.

(1) Receipt

The requester will receive anonymized data stored on the medium described, and through the method described, in "8. Method of receiving anonymized data, etc." in the "application." If you requested the provision method of mailing but have not received anonymized data after the scheduled time of provision, immediately contact the responsible office.

(2) Decoding

Anonymized data are protected by encryption and with a password and other measures; please decode the data before use. The password will be sent to the requester's email address stated in the application.

(3) Inspection

If you have problems such as it is not possible to read data on the storage medium or decode an encrypted file, please inform the responsible office within 14 days from the receipt of the anonymized data.

Further, if you find any error in, or have doubts as to, the anonymized data that you received, immediately stop using the data and contact the responsible office.

6. Measures during the period of use

(1) Proper control of anonymized data

The following provisions of the Act will apply to the requester who has received anonymized data, users of such data, and persons who have accepted an entrustment in relation to such data:

- (i) Obligation to manage anonymized data in an appropriate manner (Item 2 of Paragraph 1 of Article 42 and Paragraph 2 of the Act)
- (ii) Prohibition on improper use by themselves, improper provision to any third party, or plagiarism (Paragraph 2 of Article 43 of the Act)
- (iii) Penalty for improper use by themselves, improper provision to any third party, or plagiarism (Item 3 of Article 61 of the Act)
- (2) Specific measures for proper control

Until the provided anonymized data are returned to the MHLW, the requester and users must properly control the anonymized data according to the control method stated in the application and on the basis of which the MHLW's approval has been given.

- (i) The place of use of anonymized data (including the storage of anonymized data files) must be limited to a lockable physical place so that anonymized data will not be brought outside.
- (ii) Anonymized data must not be brought outside the place of use, for example, by transferring the data to a detachable external storage device, etc.
- (iii) Anonymized data must be stored in specifically designated media, which must be kept in a lockable cabinet, etc.
- (iv) When anonymized data are being used, there must be a restriction on who can be at the place of use, or an identity check of some kind.
- (v) When anonymized data are being used, the computer environment must not be connected to external networks such as the Internet.
- (vi) All measures against unauthorized use, including measures against computer viruses and security holes, ID/password authentication, and screen lock, must be introduced into the computer on which anonymized data are used.
- (vii) Appropriate measures must be taken to ensure that anonymized data and intermediate products will not remain on computers that may potentially connect with external networks and computers to be used by persons other than the users of such data.

The environment must be controlled to prevent persons other than the users of anonymized data from accessing computers on which such data and/or intermediate products are stored.

(viii) In order to prevent any accidental leakage of anonymized data provided as well as intermediate products and waste materials generated through aggregation operations and containing such data, appropriate control measures must be taken.

< If any aggregation operation or storage is outsourced to an external subcontractor >

(ix) The compliance with the requirements described in (i) to (viii) above must be stipulated in the entrustment contract concerned and the requester must give the subcontractor proper instructions.

< If anonymized data are used for the purpose of higher education >

- (x) The requester must provide the students who will be the users of anonymized data with ethical education concerning the use of statistics and guidance with respect to the provisions of the Act, the objective of the service, requirements for use, specific measures for proper control, other matters to be complied with, penalties, etc.
- (xi) Anonymized data must be kept and controlled by the instructor and must not be kept or controlled by students.
- (3) Making copies of anonymized data

If you intend to copy anonymized data to another computer, etc.^(*1), you are allowed to make only one $copy^{(*2)}$ during the same period. Unless you delete the copy made on that computer, you are not allowed to make a new further copy and store it on a different computer.

The same rule applies to intermediate products created through processing or aggregation of anonymized data, as long as any individual piece of information of anonymized data can be identified from such intermediate products.

Further, storing anonymized data on one server to allow multiple users to use the data concurrently is not permitted. If you wish to concurrently use anonymized data on multiple computers, you are required to request the same number of anonymized data files as the number of computer units on which such anonymized data are to be used. When anonymized data provided to the requester is copied to one computer that will be used by multiple users in turns to use the same anonymized data, the receipt of only one file is sufficient.

*1: External storage devices and other media such as DVD-RWs are included.

*2: Copying includes any conversion of anonymized data into a dataset for statistical analysis software.

- (4) Matters to be heeded with regard to use of anonymized data
 - (i) The anonymized data that you will receive must not be used to identify specific individuals or business operators, or to establish data linkage that may enable identification of individual subjects.
 - (ii) Confidentiality measures are implemented for the anonymized data that you will receive so that the subjects of surveys will not be identified. Thus, aggregated results will not always be consistent with the statistics published by the MHLW.
 - (iii) As anonymized data provided are based on answers from the subjects of surveys, logical consistency may not be found between items.
 - (iv) You are not allowed to use statistics or results of statistical research unless you publish them by using the method stated in the "application."
 - (v) The MHLW will not respond to inquiries related to such matters as how to aggregate anonymized data, how to interpret analysis results, and how to operate statistical analysis software.

- (5) Submission of control status reports
 - (i) Periodical report

If the period of use of anonymized data exceeds one year, submit a "control status report" (Form No. 7) to the responsible office annually within one month from each anniversary of the date on which the anonymized data was provided.

(ii) Interim report

Other than periodical reports, the MHLW may require that the requester submit a "control status report" during the period of use of anonymized data. If required, please submit a "control status report" by the date designated by the responsible office.

If there are two or more places of use or storage, a "control status report" is required to be prepared for each place.

(6) On-site inspection

During and after the period of use, the MHLW may dispatch its personnel to the place of use or other places deemed necessary and conduct an on-site inspection. If any improper use is found as a result of such inspection, immediately return the provided anonymized data and delete copies of the anonymized data and intermediate products.

Subsequently, the MHLW will take measures based on (3) of "4. Submission of the request form and written pledge, and payment of the service fee" (p. 15) and "Part 4 Measures against Improper Use" (p. 23), which include cancellation of approval.

(7) Publication of results

According to the schedule and method of publication stated in the "application," publish the results or the academic research, or the contents of the higher education or the project to promote the use of international comparison statistics, which was conducted by using anonymized data. In publishing such results, clearly indicate the following two facts:

- (i) the fact that anonymized data provided by the MHLW under Article 36 of the Act were used (clearly use the term "anonymized data," and avoid indicating that you received "micro data" or "individual sheets"); and
- (ii) the fact that results obtained by using anonymized data are statistics, etc., produced and processed independently by users on the basis of such data, and that these results are different from those produced and published by the MHLW.

(Example: The results obtained by using anonymized data are statistics independently produced and processed on the basis of the anonymized data related to " $\circ\circ$ Survey" and provided by the MHLW.)

7. Measures after termination of use

The requester must submit the data/documents listed in (i) to (iii) below immediately after the expiration of the period of use.

- (i) The anonymized data that the requester has received
- (ii) A "report on data deletion, etc." (Form No. 8)
- (iii) A "usage status report" (Forms No. 9-1 to 9-3)

After giving advance notice to the responsible office, the data/documents listed in (i) to (iii) above must be submitted together, by directly bringing them to the office or by registered mail.

(1) Deletion of intermediate products, and submission of a "report on data deletion, etc."

Delete anonymized data and intermediate products copied to computers and external storage devices, prepare a "report on data deletion, etc.," and submit it to the responsible office together with the provided anonymized data.

The control number that is required to be entered in the "report on data deletion, etc." can be found in the "notice of provision of anonymized data" issued upon the provision of anonymized data.

- (2) Submission of usage status reports
 - (i) Upon the expiration of the period of use

Submit to the responsible office a "usage status report" stating an outline of research results as well as the status and schedule of publication in the case of use for academic research purposes, stating the implementation status of education in the case of use for higher education purposes, or stating the results of use of, and the status of provision of, international comparison statistics in the case of use for international comparison.

(ii) Submission of an additional report after the expiration of the period of use

If there is any future publication plan as at the time of submission of the report under (i) above, submit to the responsible office an additional "usage status report" on such publication within three months after completion of the publication.

 (iii) Action to take where it is not possible to show the results of research, or the contents and results of education or of the project to promote the use of international comparison statistics

If it is not possible to show the results of research, or the contents and results of education or of the project to promote the use of international comparison statistics, due to an unavoidable reason such as death, the dissolution of the relevant corporation, or the termination of the relevant research project, the requester or user must submit to the responsible office a "usage status report" stating the reason for not being able to show such results/contents.

(iv) Publication of the contents of usage status reports

Note that the MHLW may publish on its website, etc., the information (such as the affiliation and name of the requester) stated in the submitted usage status reports

(Article 19 of the Ordinance for Enforcement of the Statistics Act (Ordinance of the Ministry of Internal Affairs and Communications No. 145 of 2008; hereinafter referred to as the "Enforcement Ordinance")).

8. Change in matters stated in the application for provision request

If, due to the requester's own circumstance, there is any change in matters stated in the "application," etc., implement the following procedures.

(1) Non-substantial change

If change related to the requester and/or user only falls within any of the following categories, notify the responsible office of such change in writing (the use of email and facsimile is also acceptable); in so doing, state the application number specified in the "notice of approval" (no particular form is designated for this notice of change).

- O Change of the name of the requester's/user's organization due to organizational change, consolidation, or other similar reasons
- O Change of the affiliation of a user due to personnel relocation/transfer
- O (See (2) (iii) A, if users themselves are to be changed)
- O Change of a job title due to promotion or advancement
- O Change of address or contact information
- O Change of the requester's/a user's family name

When making the following application, submit a return-mail envelope (see (4) on p. 13) together with the necessary documents (except for the case of (2)(i)). (This return-mail envelope is not required if you would like to

receive the notice of approval or disapproval of the change by email.)

(2) Addition of a purpose of use, or change of users, the place of use, etc.

In the case of any change in stated matters other than those described in (1) above, contact the responsible office and take the following procedures according to the time when such change arises.

(i) If change is made before the MHLW gives approval:

Contact the responsible office and submit the "application" and documents required by the MHLW.

(ii) If change is made after the MHLW has issued the notice of approval

(and before submitting the "request form" to the responsible office and paying the service fee):

If change is made after the MHLW has issued the notice of approval of the application and prior to the submission of the "request form" to the responsible office and the payment of the service fee, contact the responsible office and implement procedures for addition or change by using the "application for change in stated matters, etc." (Form No. 10; hereinafter referred to as the "application for change, etc.").

If the MHLW approves the application for change, it will issue to the requester the "notice of approval of change of stated matters, etc." (Form No. 11; hereinafter referred to as the "notice of approval of change, etc."). Then, the requester is required to affix a revenue stamp in the amount specified in the above notice to the "request form," and submit this form to the responsible office.

If the MHLW disapproves the application for change, it will issue to the requester the "notice of disapproval of change in stated matters, etc." (Form No. 12; hereinafter referred to as the "notice of disapproval of change, etc.") stating the reason for disapproval.

(iii) If change is made after the MHLW has received the "request form":

If change is required in the matters stated in the application, etc., after the MHLW has received the "request form," contact the responsible office and take required procedures.

For changing the matters listed below, the applicable procedures for change are as follows:

A. If you wish to change users:

If an anonymized data user is required to be changed due to personnel relocation/transfer, contact the responsible office and submit the "application for change, etc."

If the MHLW approves the change of the user, it will issue to the requester the "notice of approval of change, etc."; if it disapproves, it will issue the "notice of disapproval of change, etc." to the requester. Upon receiving the approval, the new user must submit his/her "written pledge" to the responsible office.

B. If you wish to request an extension of the period of use:

Extension of the period of use may be permitted only once; if you wish to request an extension, contact the responsible office and submit the "application for change, etc."

If the MHLW approves an extension of the period of use, it will issue to the requester the "notice of approval of change, etc."; if it disapproves, it will issue the "notice of disapproval of change, etc." to the requester.

In the case of disapproval, return the anonymized data and take other necessary measures immediately after the expiration of the period of use (see "7. Measures after termination of use" (p. 20)).

An extension of the period of use is permitted when all the following requirements are satisfied:

- O The rational ground for why an extension is considered inevitable is specified.
- O Except for change in the period of use, there will be no change in any other matter such as the purpose of use, the scope of users, the place of use, or the control method.
- O The duration of the extension is limited to the minimum extent required.
- O The application for extension is made for the first time.

C. If a publication method is to be changed:

If all the publication methods stated in the "application" become unavailable for use (such as when the planned publication of an article in an academic journal is not taking place because the article could not pass peer review), and therefore a new publication method is to be used, contact the responsible office and submit the "application for change, etc."

If the MHLW approves the new publication method, it will issue to the requester the "notice of approval of change, etc."; if it disapproves, it will issue the "notice of disapproval of change, etc." to the requester. Upon receiving the MHLW's approval, the requester must publish results by using the new publication method.

Part 4 Measures against Improper Use

1. Penalty provision under the Statistics Act

The provision of Item 3 of Article 61 of the Act stipulates that when a person having received the provision of anonymized data or having accepted an entrustment of business concerning the handling of anonymized data, etc., provided or misappropriated such anonymized data for the purpose of acquiring a wrongful gain for himself/herself or for a third party, he/she will be punished by a fine of not more than 500,000 yen.

2. Penalty for violations

If it is found that a user of anonymized data or a party concerned therewith has committed any violation of Paragraph 2 of Article 13 of the Enforcement Ordinance or other contractual breach, they will be required to take corrective measures and will be subject to a penalty with respect to future applications (prohibition of service use for a certain period of time). For details, see the "terms and conditions."

Anonymized data, although they are processed to remain anonymous, are information reported from the subjects of statistical surveys. It is important that each user uses anonymized data with a high awareness of information security, and publishes and shares with society the results of such use, in order to avoid undermining public confidence in statistical surveys and to enable this service to be widely understood. Users are requested to fully understand the objective of this service and, on the basis of this understanding, to ensure thorough information control and publish research results, etc.