Guidelines on AMED Research Data Utilization
Ver. 2.0

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Japan Agency for Medical Research and Development (AMED)

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Chapter 1. Purpose of these Guidelines

Since its establishment in April 2015, the Japan Agency for Medical Research and Development ("**AMED**") has been promoting medical R&D with a mission of delivering the results of research where AMED is the client to patients and their families as soon as possible by practical utilization. The importance of utilizing the results of R&D, including R&D Data, to fulfilling said goal continues to grow.

It is our country's fundamental stance in promoting open science that the results of R&D including R&D Data must not only be used by universities, research institutes, companies, and other organizations, separately and independently but must also be further promoted and expanded by a number of players beyond the frameworks of institutions or specialized field. In particular, it is considered important to implement data sharing of R&D Data beyond the boundaries of institutions and areas of expertise and to not let R&D Data be scattered randomly across numerous locations: from the perspective of efficiency meaning, for example, avoiding duplicate measurement and acquisition of the same data; as well as from the perspective of effectiveness so as to, for example, gain important and innovative insights through data analysis performed by other persons.

However, we also need to be aware of the fact that data sharing of some R&D Data is conducted in a manner not necessarily appropriate, such as cases where R&D Data is provided to third parties in or outside of Japan for a price and on terms that do not appropriately reflect its value, or in a manner which is not consistent with the initial purpose of the R&D services, and the fact that there are researchers who free ride on the results of R&D accomplished by other persons despite their unwillingness to conduct data sharing themselves (so-called research parasites). From the perspective of balancing incentives to conduct research and development for each of universities, research institutes, companies, and other organizations and the national interest, as well as an open and closed strategy, it is important to allow some R&D Data to not be shared at least for a certain period of time. Moreover, the data generated as the result of R&D supported (by outsourcing or financially) by AMED may contain patients' personal information, meaning that such data must be shared with appropriate protections for personal information and privacy under the related laws and regulations and ethical guidelines in place.

Therefore, AMED believes that it is important, for improving the health of Japanese citizens and overcoming diseases, and for the advancement of R&D in the field of medicine in and outside of Japan, to promote the utilization of R&D Data generated, obtained or collected in the process of publicly funded R&D services through data sharing. For the purpose of achieving that goal, these Guidelines apply without exception to all R&D Services Agreements executed from April 2020 onward where AMED is a client[1], and in principle obligate the service providers of such agreements to share data in accordance with these Guidelines.

In November 2021, AMED also drafted a basic policy regarding the handling of data generated, obtained or collected in connection with research supported (by outsourcing or financially) by AMED and data generated by processing the foregoing data ("**R&D Data**" as further defined below) ("Basic Policy Regarding Handling of R&D Data at AMED"; the "**Basic Policy**"). The Basic Policy sets forth basic matters related to AMED's handling of R&D Data and stipulates that the details of handling shall be "as specified in the Guidelines on AMED Research Data Utilization" (Article 6.1 of the Basic

[1] Version 2.0 of these Guidelines will apply to all R&D Services Agreements executed from April 2022 onward without exception.

Policy), and it is pursuant to this provision based on which these Guidelines are established.

AMED has also established a “Data Sharing Policy for the Realization of Genomic Medicine” with respect to genomic information. These Guidelines also apply to genomic information to the extent that it is considered R&D Data, as defined below, but with respect to matters not covered by these Guidelines and matters which are different from those specified herein, the Realization of Genomic Medicine shall prevail over these Guidelines.

Chapter 2. Data subject to these Guidelines

1. Types of data subject to these Guidelines

These Guidelines govern the handling of data that is generated, obtained or collected through R&D services conducted under a R&D Services Agreement with AMED, a supported program, or a program otherwise supported by AMED, and data generated by processing such data ("**R&D Data**").

As stated below, R&D Services Agreements where AMED is the client include definitions of "Target Data" and "Derived Data"; and "R&D Data" includes both of said Target Data and Derived Data.

While the scope of R&D Data referred to here is broad, Table 1 presents specific examples of data that may be considered as R&D Data. It should be noted that inclusion in Table 1 does not automatically mean that the data is considered to be R&D Data subject to these Guidelines, but rather whether or not the data is R&D Data depends upon the relevant agreement that is applicable to such data. This is because the content of "Target Data" and "Derived Data" varies depending on the substance of the R&D services conducted under a R&D Services Agreement with AMED, a supported program, or program otherwise supported by AMED.

R&D Data also includes data that is collected in the course of R&D services but which, when analyzed, does not yield results useful for the goal of such R&D services (so-called "negative data").

Table 1. 1Specific Examples of R&D Data

Category	Examples
Individuals (research participants and data derived from human samples)	• Images (including pathology), genome (germline, DNA base sequence, genome modifications, etc.), medical records (age, disease name, images, test sample report, medical examination data, etc.), biological information, data collected from mobile apps (number of steps, activity tracking, etc.), epidemiological surveys (lifestyle habits, socioeconomic questionnaires, etc.), administrative records (medical insurance, nursing-care insurance, medical checkups, vaccinations, demographic data, etc.), phenotype. • Implant-related registries. • Statistical data aggregated, tabulated, or statistically processed; individual-level aggregate data including PHR. • Data related to the measurement conditions of medical information (including measurement data obtained from medical devices, information that identifies the medical device from which the data was obtained, settings of the medical device at the time the data was obtained, operation records of the medical device at the time the data was obtained, and information related to the person performing the

	measurement with the medical device).
Data derived from organisms other than humans	• Bioresources (cells, fungi, bacterial flora, viruses, etc.). • Data regarding organisms other than humans (animal data, microbes). • Data regarding plants.
Other data	• Structure, physical properties, bioactivity, and toxicity of chemical substances. • Data regarding physical phenomena.

2. Definition of "Data" in the R&D Services Agreement

(1) Target Data

Data that is generated, obtained or collected in relation with a program subject to a R&D Services Agreement where AMED is the client (including processed data to the extent it is recognized as identical to Target Data) is defined as "Target Data" (for example, former part of Article 1(15) of the R&D Services Agreement).

It is expressly provided here that processed data is included in the definition of "Target Data" to the extent it is recognized as identical to Target Data to prevent a situation in which a compressed file (such as a zip file) of Target Data which is exactly the same as the "Target Data" when decompressed, would be treated as Derived Data referred to below and not as Target Data.

"Process" here includes processing, analyzing, editing or combining Target Data.

Data which is "recognized as identical" here means any data having identical content and nature as Target Data from a physical or economical perspective. For example, any data that cannot be physically restored to Target Data such as statistical information (information obtained by extracting items related to common factors from information provided by a number of persons and aggregating such information by category) cannot be recognized as identical to Target Data, and even if it were physically restorable to Target Data, any data set that has its own economic value that is independent from Target Data, such as a training data set prepared by adding annotations, cannot be recognized as identical to Target Data.

Target Data may also include individual parts of data that in aggregate form a database.

(2) Derived Data

Under a R&D Services Agreement where AMED is the client, Derived Data is defined as data generated by performing processing, analysis, editing or combination, etc. on Target Data so that the Target Data is not technically restorable, and which cannot be recognized as identical to "Target Data" (for example, the latter part of Article 1(15) of the R&D Services Agreement).

Derived Data includes, for example, statistical information obtained by extracting items related to common factors and aggregating such information by category by processing Target Data, and data sets for learning prepared by processing Target Data, and other types of data.

Chapter 3. Authorization to Use R&D Data

In terms of specific methods of utilizing R&D Data, there are various possible methods depending on the R&D topic. We have adopted the policy that it is necessary to make widely available to third parties, in an appropriate manner, various types of R&D Data generated, obtained or collected in the process of R&D services publicly funded by AMED conducted under a R&D Services Agreement with AMED, a supported program or a program otherwise supported by AMED, as being one kind of "public property," after a certain period.

On the other hand, it is also important to preserve incentives to perform R&D (including product development, publication of articles and patent applications) for the service providers of R&D services including universities, research institutes, companies and other organizations, and to protect the rights and statutory interests of research participants who provide samples and clinical information and other materials and information. Therefore, it is necessary to determine on a case-by-case basis the timing, scope and method and other conditions of publication of R&D Data under the R&D Services Agreement in light of the nature, etc. of the relevant R&D topic.

From the foregoing perspective, the disclosure and transfer to third parties of any and all R&D Data generated, obtained or collected in relation to R&D services is prohibited in principle under the R&D Services Agreement that is commonly applied to R&D services publicly funded by AMED, and disclosure and transfer to third parties is only allowed in cases that are approved under Chapter 4 of Guidelines on AMED Research Data Utilization or where AMED has given its prior consent (for example, Article 12-2.2 of the R&D Services Agreement). In keeping with such provisions, these Guidelines allow service providers to disclose or transfer R&D Data to third parties only in the following cases:

(i) When disclosing R&D Data in accordance with the disclosure method designated in the Data Management Plan for each individual R&D topic.

(ii) When data sharing R&D Data with third parties after separately obtaining the consent of AMED.

In other words, please note that, for instance, it constitutes a breach of Article 12-2.2 of the R&D Services Agreement (breach of agreement in the relationship with AMED) to disclose or transfer R&D Data to a third party in any cases other than (1) or (2) above regardless of the purpose thereof.

This is because we are planning a clarification in writing a framework that enables the case-by-case basis determination of the timing, scope and method, etc. of data sharing of an individual R&D topic based on a general policy which balances the protection of the rights and statutory interests of research participants and the preservation of incentives for universities, research institutes, companies and other organizations as the service providers performing research and development, and the promotion of research in the relevant area through data sharing.

It is also provided in the R&D Services Agreement that a service provider shall not use R&D Data for any purpose other than the R&D services unless it separately obtains consent from AMED (Article 12-2.2 of the R&D Services Agreement). Therefore, even if a service provider uses its own R&D Data, it constitutes a breach of Article 12-2.2 of the R&D Services Agreement (breach of agreement in the relationship with AMED) to use the same for any purpose other than for the R&D services from which such R&D Data has been generated, obtained or collected. However, the act of disclosing or

transferring R&D Data to third parties in accordance with the respective Data Management Plan (discussed in Chapter 5 below) to be prepared in accordance with these Guidelines does not constitute a breach of such restriction on use.

In the case where a university, research institution or company, etc. which is the service provider discloses or provides R&D Data to a specific third party with the method of (2) above, they are expected to use the "Data License Agreement"2 template published by AMED alongside these Guidelines. The template warrants to the data recipient that the provider of data (service provider of R&D services) has obtained the consent of AMED with respect to such disclosure or provision of data (Article 5.1(ii) of said agreement). This provision is included to alert the recipient of data to the fact that the provider of data (service provider of R&D services) requires AMED's consent in order to disclose or provide data to the recipient.

[2] https://www.amed.go.jp/koubo/datamanagement.html

Chapter 4. Data Sharing

1. Disclosure of Data Catalogue

From the perspective of promoting the sharing and appropriate utilization of R&D Data, as a premise, it is important for both the service provider side, namely universities, research institutes, companies and other organizations and the client side, namely AMED, to identify what type of R&D Data will be generated, obtained or collected and how it is scheduled to be utilized in each case of R&D services outsourced by AMED.

For this purpose, each applicant for a R&D services program is requested to state in the Data Management Plan (to be described in Chapter 5 below) to be submitted by each such applicant the type, description, volume and other information of R&D Data scheduled to be generated, obtained or collected in the course of the program as well as the method of utilization of such R&D Data, as specifically as possible.

From the perspective of utilization of R&D Data by data sharing, it is also important to openly disclose or share the existence of R&D Data with related parties, and to make such data available to external third parties to a certain appropriate extent.

Consequently, AMED intends to prepare and publish on its website a data catalogue which will present information on R&D Data generated, obtained or collected in relation to R&D programs which state in their Data Management Plan that "Data which may be utilized for purposes other than this R&D topic exists" for the purpose of introducing such R&D Data to universities, companies and other research institutes which may wish to utilize said data.

The data catalogues is intended to contain information necessary to the extent of openly disclosing or sharing the existence of R&D Data with related parties, but there are no plans to include R&D Data itself in the catalogue. AMED may request service providers to describe in the Data Management Plan or otherwise provide the information necessary for preparing the data catalogue[3].

2. Data Sharing Method

As mentioned above, AMED considers it necessary to make widely available to third parties, in an appropriate manner, R&D Data as being one kind of "public property," after a certain period.

There are the following three methods for disclosing or sharing R&D Data with third parties.

(1) Restricted Closed Sharing

- In Restricted Closed Sharing, the service provider may provide R&D Data only to those researchers specified in the Data Management Plan and researchers individually approved by AMED ("Approved Researchers").
- For Restricted Closed Sharing, the service provider must, on the premise that it is sharing data, take appropriate measures necessary to prevent loss and dispersion of R&D Data (for instance, by creating backups of the R&D Data itself, or by registering with a third party database which uses appropriate backup measures).
- The service provider may provide R&D Data only to Approved Researchers

[3] This may include, for instance, the database name, database URL, and data ID, etc.

under individual agreements (service providers are expected to use the "Data License Agreement" template[4]) with each Approved Researcher, or by way of database registration or by other methods which AMED recognizes as appropriate.

- In addition to internal personnel[5], external parties[6] may also be included in Approved Researchers. In the Data Management Plan, the former are described under "Sharing with Internal Personnel", and the latter under "Sharing with External Parties".

(2) Restricted Open Sharing

- In Restricted Open Sharing, the service provider must, pursuant to the Data Management Plan, register R&D Data in a database appropriate for Restricted Open Sharing.
- A "database appropriate for Restricted Open Sharing" means a database which allows third parties to obtain and use R&D Data registered in such database in accordance with the database's terms of use upon the third party clearly stating its purpose and method of use of such R&D Data and the operator of the database giving its approval for such use by the third party.

(3) Unrestricted Open Sharing

- In Unrestricted Open Sharing, the service provider must, pursuant to the Data Management Plan, register R&D Data in a database appropriate for Unrestricted Open Sharing.
- A "database appropriate for Unrestricted Open Sharing" means a database which allows any third party to use the data therein, in accordance with the database's terms of use, without access restrictions.

3. Determining and Changing the Method of Implementing Data Sharing

(1) Determination at the time of commencing R&D services

At the time of commencing R&D services, the service provider must make an application to AMED with one of the following methods as the method of data sharing R&D Data during the R&D period[7] pursuant to the Data Management Plan, and obtain AMED's

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4 *See* the final paragraph of Chapter 3 and footnote 2.

5 Meaning persons for whom an application has been made to AMED as researchers, etc. engaged in the R&D services of the relevant R&D topic and who have been authorized by AMED, regardless of whether they belong to the same university or research institute, etc.

6 Meaning any third parties other than internal related parties described in Note 5, including researchers, universities, research institutes, etc. or companies that perform joint research/joint development, etc. with the university or research institute, etc. which is the service provider of the relevant R&D topic.

7 Meaning the "R&D period" defined in Article 1 (ix) of the R&D Services Agreement, or in other words, the period during which R&D services are conducted under the R&D Services Agreement (if the R&D services are suspended, until the time of such suspension), which is different from the term of the R&D Services Agreement also stipulated therein.

approval:

(i) Unshared[8]

(ii) Restricted Closed Sharing

(iii) Restricted Open Sharing

(iv) Unrestricted Open Sharing

Having done so, the service provider must promptly share any R&D Data generated, obtained or collected during the R&D period by the data sharing method approved by AMED, and continue to share such data by the data sharing method for the duration of the R&D period.

Even if (i) Unshared or (ii) Restricted Closed Sharing is selected, the service provider must prevent the loss and dispersion of R&D Data, such as by making appropriate backups.

Adoption of (i) through (iv) above with respect to the data sharing method for R&D Data does not have to be determined uniformly for each program, but rather one of the data sharing methods can be specified for each obtained data set based on the class, type and characteristics, etc.

If (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing is selected, the R&D Data will be shared widely upon its registration into the database, and therefore it will be necessary to consider whether the data is of a nature or can be processed into a form suitable for such open data sharing.

Processing into a form suitable for open data sharing means, for example, that if raw data is not suited for (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing due to privacy issues, changing to a format suitable for open data sharing by performing the necessary processing in consideration of privacy.

In relation to this, if the database operator is a person other than the service provider, then the database operator is a third party from the perspective of a data subject whose personal information is contained in R&D Data, and as such the service provider must in principle obtain the data subject's (research participant's) consent to providing the R&D Data to the database operator.

(2) Additions and changes during the R&D period of the R&D services

In order to make additions or changes to the data sharing method of R&D Data during the R&D period, the service provider must resubmit the Data Management Plan to AMED and obtain AMED's consent. These could include, for instance, adding a new data sharing method if new R&D Data is generated and no sharing method is specified in the Data Management Plan for such data, or changing the sharing method into a different method of (i) through (iv) from the method previously specified.

In principle, AMED requires service providers to submit a Data Management Plan for each year, and it is sufficient to apply and obtain consent for additions or changes to the R&D Data sharing method at the time of the annual submission. However, if changes are necessary mid-year, the service provider should separately discuss their handling with

[8] Unshared data includes data the publication of which would be problematic for ethical or security reasons, but based on the purpose stated in Chapter 1, the scope of unshared data should be limited, and classification as unshared cannot be accepted without careful consideration.

AMED.

(3) Handling after expiration of the R&D period of the R&D services

General Rule: Restricted Open Sharing or Unrestricted Open Sharing except where inappropriate based on the nature of the R&D Data

When the R&D period of R&D services expires, the service provider must submit a Data Management Plan to AMED and, in principle, select (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing of R&D Data, and obtain AMED's approval. Having obtained AMED's approval, the service provider must promptly share data using the selected method ((iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing), and report to AMED the necessary information specified by AMED[9].

However, if the nature of the R&D Data is such that it is not suited for (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing, then service provider must submit a Data Management Plan to AMED at the time of expiration of the R&D period of R&D services which contains:

(a) Selection of either (i) Unshared or (ii) Restricted Closed Sharing of R&D Data.

(b) Reasonable reason for the selection made in (a) (such as that the R&D Data is of a nature unsuitable for (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing, and if selecting (i) Unshared, the reason why (ii) Restricted Closed Sharing cannot be selected).

The service provider may use the sharing methods of (i) Unshared and (ii) Restricted Closed Sharing of R&D Data after the expiration of the R&D period of R&D services only upon receiving AMED's approval.

It should be noted that even if the nature of the R&D Data is such that it is not suited for (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing, it will not be considered unsuited for data sharing if it is possible to process such data to be anonymized (whether or not a specific individual can be identified) so as to be suited for data sharing. In such case, the service provider must select either (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing as the data sharing method, and perform the necessary processing and share the data using the selected method promptly after receiving AMED's approval. In such a case, the service provider may be required to include the data sharing method of the unprocessed R&D Data (either (i) Unshared or (ii) Restricted Closed Sharing) in the Data Management Plan.

Exception: Grace period

As stated above, when the R&D period of the R&D services expires, the service provider must submit a Data Management Plan to AMED and, as a general rule, select either (iii) Restricted Open Sharing or (iv) Unrestricted Open Sharing as the data sharing method and obtain AMED's approval. However, the service provider may, by submitting a Data Management Plan to AMED and obtaining AMED's approval, continue using the data

[9] The "database name, database URL, data ID, etc." described in footnote 3 falls under "necessary information".

sharing method selected during the R&D period of R&D services until the earlier of [10]

(A) two years after the expiration of the R&D period; or
(B) publication date of the results of R&D (meaning the day on which the research paper is accepted or the patent application laid open; hereinafter the same shall apply).

If (B) does not occur but (A) two years have passed since the expiration of the R&D period, the service provider may submit a Data Management Plan to AMED and apply to continue using the data sharing method selected during the R&D period of R&D services until four years have passed from the expiration of the R&D period (application for extension of period), and if AMED approves such application, the service provider may continue using the data sharing method selected during the R&D period of R&D services until four years have passed from the expiration of the R&D period. However, if (B) above occurs during such extension period, the service provider may not continue using the data sharing method selected during the R&D period of R&D services, and instead must proceed in accordance with the handling specified in "*After the expiration of grace period*" below.

After the expiration of the grace period

As stated above, upon the occurrence of the earlier of (A) (including an extension to four years) or (B) above, a service provider must submit a Data Management Plan to AMED and, upon obtaining AMED's approval, proceed in accordance with the "*Principle: Restricted Open Sharing or Unrestricted Open Sharing except where inappropriate based on the nature of the R&D Data*".

It is necessary to determine the appropriate data sharing method on a case-by-case basis, but examples of data suited for Unrestricted Open Sharing include data which does not include personal information, data where personal information has been "anonymously processed" in accordance with Act on the Protection of Personal Information, and statistical data. Examples of data suited for Restricted Open Sharing include data which needs to be combined with personal information held by a service provider (clinical information, etc.), data which misunderstanding, misuse or abuse by non-experts must be avoided, and data not suited for secondary distribution. Data where Restricted Closed Sharing is appropriate even after the expiration of the grace period includes data whereby individuals are likely to be identified, data which may result in discrimination or prejudice, data which cannot be published for policy reasons, and other data which is not suited for Unrestricted Open Sharing or Restricted Closed Sharing in light of its nature or expected purpose of use.

A service provider must make an application to AMED using the Data Management Plan, can only share data by the method approved by AMED, and if AMED requests to hold discussions regarding the sharing method, the service provider must discuss in good faith and in accordance with the spirit of these Guidelines.

[10] However, if the earlier of (A) or (B) arrives, but it is demonstrated that an article scheduled for publication is being reviewed or a follow-up study is being conducted regarding the results of R&D, or AMED otherwise determines that it is not appropriate to openly share such data, then until the time when such situation is resolved.

4. Service providers' Compliance with Laws and Regulations, etc.

When a service provider shares R&D Data in accordance with these Guidelines, the service provider should pay careful attention not to violate or breach applicable ethical guidelines, etc., laws and regulations related to the protection of personal information, or agreements with third parties (including confidentiality provisions) (with respect to the APPI, see, for example, Articles 12-2.3 and 12-2.4 of the R&D Services Agreement).

Also, when universities, research institutions and companies, etc. that are service providers of R&D services obtain or collect data, including personal information of research participants, it is advisable to obtain the advance consent of such research participants (relevant individuals) to the third party transfer of such data. AMED plans to provide a template/standard form "Consent Letter regarding Third-Party Transfer of Personal Information in this Research. " For contracts related to R&D services where AMED is a client, AMED recommends, as a general rule, that the universities, research institutes, companies and other organizations, which are the service providers of such R&D services, when obtaining or collecting data, including personal information, from research participants (relevant individuals), in addition to obtaining consent for research participation, also obtain, with the same consent form, explicit consent for third-party transfer of personal information from the research participants (related individuals). AMED plans to require reports on the use of the consent form and the status of obtaining consent.

5. Utilization of R&D Data by AMED

Just as described in "Chapter 1. Purpose of these Guidelines", AMED aims to put data generated as the result of R&D to practical use soon by wide data sharing in an appropriate manner. For this reason, AMED has the authority to use data created, obtained, or collected through R&D services, a support project, or a program otherwise supported by AMED conducted under a R&D Services Agreement with AMED, or data generated by processing such data (including Target Data and Derived Data), and may take necessary measures so that R&D Data will be utilized appropriately.

For example, if a service provider does not share data appropriately in accordance with "3. How to Implement Data Sharing" above, AMED may share data on behalf of the service provider (as a general rule, expenses therefor is to be borne by the service provider).

AMED may request that data which is subject to data sharing in accordance with "2. Data Sharing Method" above be uploaded to the database designated by AMED. Data which AMED requests to be registered in a database may also include data which is not necessarily expected to be shared at the time of such request. For example, even in the case of data which is not expected to be disclosed to or shared with a third party at the time it is generated, AMED may separately request registration in a database as Restricted Closed Shared Data from the perspective of preventing the dispersion or falsification of data.

6. Intellectual Property Rights

AMED encourages protection of intellectual property rights for the purpose of promoting R&D in the field of medicine and the smooth application to practice of the results thereof[11], and researchers may acquire intellectual property rights based on data obtained

[11] *See* AMED Intellectual Property Policy (April 1, 2016; 2016 Regulation, No. 58)

through funding by AMED. However, in order to conduct secondary research utilizing R&D Data and to increase the opportunities for practical use of the results thereof, AMED promotes appropriate use and exercise of the intellectual property rights in accordance with the spirit of these Guidelines.

Chapter 5. Data Management Plan (DMP)

1. What is a Data Management Plan (DMP)?

Results of R&D, including data created, acquired, or collected through R&D services, a supported project, or a project otherwise supported by AMED conducted under a R&D Services Agreement with AMED, as well as R&D Data generated by processing such data is one kind of "public property." In particular, as the importance of R&D Data is growing, R&D Data's appropriate management and use is profoundly important in terms of maximizing the results of R&D. Therefore, in order to promote the appropriate and fair implementation of these policies, AMED has made it mandatory, at the time of execution of the R&D Services Agreement, to submit a "Data Management Plan (DMP)" ("**DMP**") describing the type, storage location and other information of the R&D Data, the data management supervisor, and policies for data sharing and other data utilization in the R&D services conducted under a R&D Services Agreement, a partially supported project designated by AMED, and in a project otherwise supported by AMED[12].

AMED requires DMPs to describe what kind of data is generated, obtained or collected and by whom and where it is retained under a R&D Services Agreement where AMED is the client.

2. Roles and Functions of the Data Management Plan (DMP)

Upon receiving DMPs, by being aware of data utilization policies regarding the types of R&D Data, repository, data management supervisor, and policies and other information for data sharing and other data utilization, AMED has strengthened its management functions and catalyst functions and, as much as possible, has helped facilitate interactions among different R&D topics and prevented duplication of R&D. Hereafter, AMED will manage DMPs in more detail than before and will appropriately and fairly collect, assure quality of, give meaning to, retain and utilize R&D Data generated, obtained or collected as a result of AMED's R&D.

In addition, submitting DMPs has a significant meaning for service providers as well. As described in "Chapter 3 Authorization to Use R&D Data", under a R&D Services Agreement, submission of a DMP is a premise for permitting data sharing and any other data utilization by the service provider within the scope of purpose of services. In particular, a service provider may freely carry out data sharing or any other data utilization within the scope described in a DMP and approved by AMED under the R&D Services Agreement. On the other hand, any data utilization not specified in a DMP or deviating from that described in the DMP requires AMED's separate prior approval. Therefore, it is very important to set out as specific and detailed content in a DMP as possible for a service provider to secure a discretionary scope in R&D. Although there may be cases where the scope and details, etc. of data utilization need to be revised due to the progress of R&D or changes in the external environment, service providers may review and revise DMPs as appropriate, in principle, at the time of entering into an agreement each fiscal year or when need for revision arises, and AMED may approve such revisions upon giving advice as necessary.

Data sharing to a certain extent is mandatory for certain AMED programs related to genomic medicine under the Genome Data Sharing Policy, regardless of the descriptions

[12] https://www.amed.go.jp/koubo/datamanagement.html

in their DMPs. This is because such programs aim to carry out prompt, extensive and appropriate data sharing of genomic data associated with the results of R&D as well as genome information including clinical information and the results of analysis and interpretation. Therefore, in the case of such program, whether or not the details of the DMP are compliant with the Genome Data Sharing Policy may be the subject of prior/interim/ex-post evaluation of such program.

3. Key Elements of the Data Management Plan (DMP)

Key elements of the DMP include the following. The form of DMP shall be as specified in the Exhibit attached hereto, which will be revised from time to time by AMED.

- Program name
- R&D topic
- Name, title and affiliation of the R&D principal investigator
- Regarding R&D Data in which the data may be used for purposes other than this R&D topic
  - Name of data
  - Data class
  - Explanation of data
  - Summary of data volume
  - Access rights
  - Reason for and term of being unshared
  - Planned date of publication
  - Whether there is individual consent (IC)
  - Scope of matters consented
  - Repository information
  - Repository URL, DOI link
  - Whether the clinical research information is registered
  - Clinical research registration information
- R&D Data management supervisor
  - Data management organization
  - Data manager
- Names and affiliations of the personnel related to R&D Data, and whether their names can be published

End of document

Meeting for Exchange of Opinions regarding the Handling of Data Related to the Results of R&D at AMED.

Working Group Members (First edition drafted March 2020)

Attorney at Law, Makoto Uchida
Associate Professor, Chiaki Sato
Attorney at Law, Keiji Tonomura
Japan Telemedicine Society, Takashi Hasegawa

(Exhibit) Data Management Plan Form

日本医療研究開発機構（AMED） データマネジメントプラン 様式 Ver4.0			
（記載上の注意点） ①研究開発データが複数の場合、適宜、行を複写追加して記入して頂いて結構ですが、それ以外のフォーマットを変更しないようにお願いします。 ②緑色箇所、備考欄に【公開】と記載がある箇所は、研究開発終了後にカタログとして公開される部分となります。公開可能な情報を記載して下さい。			
作成日		令和4年　　月　　日	備考欄
AMED課題管理番号　（AMED記載）			AMED記載
1．プロジェクト情報			
事業名			
研究開発課題名			【公開】
研究開発代表者	所属		大学の場合「○○学部、大学院△△研究科」まで、企業等の場合「○○部」まで記載してください。
	役職		
	氏名		名字とお名前の間に全角１文字分のスペースを入れてください。（例：研究　一郎）
2．本研究開発によって取得・収集される研究開発データについて			
本研究開発課題以外での利活用の可能性が考えられるデータの有無		選択してください	※該当するものを選択してください。研究開発代表者自身のみならず、第三者による二次的な利活用の可能性が考えられる場合も含め、該当するものを選択してください。原則、AMEDが委託者となる委託研究開発契約によって得られた成果（データ）については、研究開発データの公開・提供方針に係わらず、全て記載するようお願いします。 「あり」の場合は３の各項目を記載してください。
（上記で「あり」を選択した場合のみ） ３を記載しない場合、その理由			「利活用の可能性が考えられるデータはあるが、３を記載しない」意向の場合は、その理由を記載してください。 （なお、原則として、該当するデータがあれば、全て記載していただく必要があります。）
3．個々の研究開発データについて			
研究開発データ① ＊複数の場合、適宜、行を複写追加して記入してください。	データの名称		【公開】 例）○○の非臨床試験、臨床研究、治験、遺伝子/ゲノム、医薬品開発、医療機器等開発、レギュレーション策定　等
	データの種別①	選択してください	※該当するものを選択してください。【公開】 （ヒト個人（研究参加者及びヒト試料由来のデータ）　ヒト以外の生物由来のデータ　その他のデータ）
	データの種別②		※上記データの種別①を選択後、該当するものを選択してください。【公開】
	データの説明		【公開】 例）○○の薬効を確認するために○○に投与した結果得られた○○データ、○○に有用な△△のメカニズムの解明するための○○試験で得られたデータ。
	概略データ量	選択してください	※該当するものを選択してください。【公開】 （1GB 未満　1GB 以上10GB 未満　10GB 以上100GB 未満　100GB以上）
	アクセス権	選択してください	※該当するものを選択してください。【公開】 （公開　外部関係者と共有　内部関係者と共有　非公開　その他（未定など）
	（上記で「外部関係者と共有」を選択した場合のみ）外部関係者の情報		外部関係者を具体的に記載してください。 例）○○会社、○○大学○○科○○先生） ※企業名等秘密情報については明示できない旨を記載してください。 例）製薬企業へデータを提供する（秘密情報のため、企業名については記載不可）
	（上記で「非公開」を選択した場合のみ）非公開の理由とその期間		上記で「非公開」を選択した場合のみ、その理由と期間について記載してください。 （「非公開」以外を選択した場合は、記載は不要です。）
	公開予定日		ガイドライン等に従い、公開予定日を記載してください。【公開】
	個人同意（IC）の有無	選択してください	※個人情報保護法に準拠した第三者提供への同意が取得できている、あるいは同意を取得予定である場合は、「あり」を選択してください（参考：個人情報保護法ガイドライン（通則編）2-12「本人の同意」）。 例）個人情報を含む当該研究開発データが学術研究目的以外（民間企業の単独利用を含む製品開発や商用利用等）にも利用される可能性の同意が取得されている。
	（上記で「あり」を選択した場合のみ）同意事項の範囲	選択してください	※上記で「あり」を選択した場合に、同意事項として当てはまるものを選択してください。 （ＡＭＥＤが提供している「本研究における個人情報の第三者提供に関する同意書ひな型」を使用　ＡＭＥＤが提供している「本研究における個人情報の第三者提供に関する同意書ひな型」を使用していないが、個人情報を含む当該研究開発データが学術研究目的以外（民間企業の単独利用を含む製品開発や商用利用等）で、第三者提供する可能性の同意が入った同意書を使用
	リポジトリ情報	選択してください	※現在のリポジトリ情報、あるいはプロジェクト後のリポジトリ情報として、該当するものを選択してください。【公開】 （個人のPC　研究室のPC・サーバー　学内等の自組織のデータセンター等 他の外部機関（インターネットアクセスなし） 外部のリポジトリあるいはデータベース等（インターネットアクセス可）　その他　）
	（上記リポジトリのURLがある場合のみ）リポジトリURL、DOIリンク		上記リポジトリのURL、DOIリンクを記載してください（複数ある場合、カンマ（,）で区切ってください）。【公開】 例）https://xxx/xxx/, https://yyy/yyy/
	臨床研究情報の登録の有無（jRCT、UMIN-CTR等）	選択してください	※該当するものを選択してください。【公開】
	（上記で「あり」を選択した場合のみ）登録情報（URLなど）		上記で「あり」を選択した場合のみ、臨床研究登録情報が掲載されているURLを記載してください。【公開】
4．研究開発データ管理に関わった人材			本研究課題で取得・収集されたデータに関与した人材について回答してください。データ関連人材について、すべて人を漏れなく記載してください。
4－1.研究開発データの管理責任			
(1)データ管理機関			データを管理する研究開発を行う機関のe-Radに登録された法人名を記載してください。【公開】
(2)データ管理者	氏名		データ管理機関において、各管理対象データを管理する担当者の名前を記載してください。 名字と名前の間に全角１文字分のスペースを入力してください。（例：研究　一郎）
	連絡先		データ管理者の所属機関の住所や電話番号、メールアドレス等を記載してください。【公開】
4－2.研究開発データ関連人材の詳細			
データ関連人材① ＊複数名の場合、適宜、行を複写追加して記入してください。	所属		大学の場合「○○学部、大学院△△研究科」まで、企業等の場合「○○部」まで記載してください。【公開可であれば公開】
	氏名		名字と名前の間に全角１文字分のスペースを入力してください。（例：研究　一郎）【公開可であれば公開】
	所属・氏名の公表の可否	選択してください	※該当するものを選択してください。