

Basic Policy Regarding Handling of R&D Data at AMED

November 2021

Japan Agency for Medical Research and Development (AMED)

1. Purpose

The Japan Agency for Medical Research and Development (AMED) hereby establishes this Basic Policy with the aim of contributing, by further promoting the creation and utilization of the “R&D Data” defined in paragraph 2 below, to not only to the development of research and development in the field of medicine, but also to the creation of new value in society and, in turn, helping the people to live ever more healthy and cultured lives.

2. Scope

This Basic Policy governs the handling of data that is generated, obtained or collected through R&D services conducted under an R&D Services Agreement with AMED, a supported project, or a program otherwise supported by AMED, and data generated by processing such data (“R&D Data”).

3. Basic Approach Regarding Utilization of R&D Data

There is a need to promote the outstanding research results and innovation generated through the utilization of data which is produced from R&D carried out with public funds. In the medical field in particular, in order to deliver results for patients and their families more quickly, there is a demand for new diagnostic methods and new therapies which are developed by not only research institutes, but also by private companies and other organizations, through secondary utilization of clinical information and genomic information.

In light of this demand, AMED intends to actively promote the utilization of R&D Data by developing the systems necessary for appropriate management and utilization of R&D Data.

The promotion of utilization of R&D Data must be carried out with the purpose provided in paragraph 1 above, in compliance with the guidelines on medical research, while taking into consideration the intentions of research institutions on the premise of reasonable and appropriate data utilization according to the characteristics of the data, and the intentions and privacy of patients and other persons who cooperate in such research (“research participants”).

4. Publication and Sharing of R&D Data

With regard to the methods of publication and sharing of R&D Data, each research institute, pursuant to the R&D Services Agreement concluded between itself and AMED, must select one of the following methods as set forth in the “Guidelines on AMED Research Data Utilization” (“**AMED Guidelines**”): (i) Unrestricted Open Sharing, (ii) Restricted Open Sharing, (iii) Restricted Closed Sharing, and (iv) Unshared, for each set of R&D Data depending on the status and nature, etc. of individual data item, and, upon obtaining AMED’s approval, shall publish and share the data in accordance with the method selected.

5. AMED Guidelines and Data Sharing Policy

- (1) This Basic Policy sets forth the basic matters regarding the handling of R&D Data at AMED, and the specific details of such matters are stipulated by the AMED Guidelines.
- (2) In addition to this Basic Policy and the AMED Guidelines, AMED may formulate individual data sharing policies for each research field, research theme, or research subject, etc. taking into consideration the unique circumstances of each such field, theme or subject (hereinafter referred to as “Data Sharing Policies”) based on this Basic Policy and the AMED Guidelines.

6 . Utilization of R&D Data

Persons who receive and use R&D Data shall use such R&D Data pursuant to the conditions of use set forth in this Basic Policy, the AMED Guidelines and the Data Sharing Policy, etc.

7. Personal Information and Privacy

AMED is fully aware that R&D Data may include personal information and private information of research participants and other persons. In using R&D Data, AMED will give sufficient consideration to the privacy of research participants and other persons, with regard to personal information contained in R&D Data, in compliance with applicable laws and regulations, guidelines and other rules concerning the protection of personal information, and rules for the protection of personal information stipulated by AMED.

8. Management of R&D Data

When managing R&D Data by itself or through a third party, AMED will strive to manage the same

with sufficient and appropriate security, in accordance with the information security policy established by AMED.

9. Date of Application

This Basic Policy is applicable from April 1, 2022.

Specifically, all R&D Services Agreements concluded with AMED on or after April 1, 2022, as well as the projects supported by AMED for which grant decisions are made on or after such date, will be subject to this Basic Policy.