

Human MRI Data Sharing Policy
in Strategic International Brain Science Research Promotion Program
(March 2021)

For the purposes of integrating, registering, managing, closed sharing and openly sharing human MRI image data and any accompanying metadata of research subjects (“Target Data”) in AMED Strategic International Brain Science Research Promotion Program (“Brain/MINDS Beyond”) research project, it is required to set forth a data sharing policy (this “Policy”), and all the researchers participating in Brain/MINDS Beyond are required to comply with this Policy.

1. Scope of application of this Policy

This Policy applies to any researchers who obtained Target Data collected in a research project funded by Brain/MINDS Beyond in Brain/MINDS Beyond research projects, any co-researchers in the research project funded by Brain/MINDS Beyond who belong to the same research institutions as said researchers and who shared the workload on the research items with the research representatives in the R&D plans (hereinafter, such researchers and co-researchers are collectively referred to as “Institute Researchers”), and any researchers who belong to any institutions other than those of the Institute Researchers and are permitted to use the Target Data under an agreement with the Institute Researchers and listed in the Data Management Plan or any other researchers individually approved by AMED (“Approved Researchers”).

2. Unrestricted Openly Shared Data, Restricted Openly Shared Data, Restricted Closed Shared Data

Unrestricted Openly Shared Data, Restricted Openly Shared Data and Restricted Closed Shared Data are as described below. However, the details are as specified in the Guidelines on AMED Research Data Utilization¹⁾.

(1) Unrestricted Openly Shared Data

Any data that becomes available, by registration in the database under the Data Management Plan to be submitted to AMED, for anyone without access restrictions subject to observance of the terms of use, etc. of such database (with anonymization, without any correspondence table, and not containing any facial information (*)). However, the database to which such data is registered must be limited to one that is offered to the database registrants who use the registered data for research purposes under the terms of use thereof.

*Facial information means “any brain MRI image and any other medical image, which is not an actual photograph of a face but an image through which a face can be reconstructed using such image (but the relevant individual cannot be identified based on facial information).”

(2) Restricted Openly Shared Data

Any data that becomes available, by registration in the database under the Data Management Plan to be submitted to AMED, for such researchers, etc. whose data access applications are approved upon specifying the purposes and method of use, etc. in accordance with the terms of use, etc. of such database (with anonymization, with correspondence table (only subject to appropriate management), and not containing any facial information as a rule, but facial information can be provided for individual research with the approval of the ethics review committee of each institution).

(3) Restricted Closed Shared Data

Any data that becomes available only for such researchers, etc. listed in the Data Management Plan to be submitted to AMED or individually approved by AMED, for database browsing, etc. or use in any other manner (with anonymization, with correspondence table (only subject to appropriate management), and containing facial information).

3. Basic policy for data sharing

(1) All the Institute Researchers and Approved Researchers participating in Brain/MINDS Beyond must consent to the registration of Target Data to the Brain/MINDS Beyond database as well as intra-project sharing and unrestricted openly sharing thereof through the Brain/MINDS Beyond portal site. Further, the following data must be treated as Unrestricted Openly Shared Data unless there are special circumstances: Human brain MRI image data, as well as the following data regarding research subjects: age, sex, diagnosis, method used in diagnosis, handedness, educational attainment, (premorbid) estimated IQ, name of the representative symptom evaluation scale for such disease and the total points, and assessment of sleepiness at the time of resting state fMRI.

(2) Any data obtained by Institute Researchers and Approved Researchers in other research, etc. before the commencement of this project (“Existing Data”) may be registered, openly shared and used only if the relevant individuals pertaining to the Existing Data have consented to the descriptions of the Brain/MINDS Beyond research project and the data sharing as set forth in this Policy.

(3) Since the Target Data may be transferred to third parties through the Brain/MINDS Beyond database, Institute Researchers and Approved Researchers must give necessary explanations to the research subjects, and take necessary procedures including obtaining appropriate consents from the research subjects to the transfer of personal information to third parties.

(4) The Brain/MINDS Beyond database refers to the set of A, B and C as described below:

A MRI image data and any accompanying clinical index data obtained by the institutions participating

in Brain/MINDS Beyond and integrated on the servers and backup servers located at the University of Tokyo, Advanced Telecommunications Research Institute International, National Center of Neurology and Psychiatry and RIKEN, and such data stored in a cloud system for restricted closed sharing and restricted openly sharing.

B Data integrated as A above and preprocessed data, which is stored on a distribution server for unrestricted openly sharing.

C Portal site that informs external researchers of the existence of data set forth in B and serves as an entry point to access such data.

4. Method of data sharing for each category of data

(1) Unrestricted Openly Shared Data

After obtaining Target Data which is Unrestricted Openly Shared Data, Institute Researchers and Approved Researchers must, unless otherwise provided in the Data Management Plan, register such Target Data on the Brain/MINDS Beyond database and openly share the same by the earlier of “two years from the completion of R&D services” or “when the results of R&D are disclosed to the public (the day on which the relevant article is published, or application for patent is disclosed to the public; hereinafter the same shall apply)” as set forth in the Guidelines on AMED Research Data Utilization.

Any user may use the registered Target Data without restrictions upon registering his/her name and the institution to which he/she belongs conditional upon his/her observance of the terms of use, etc. of the Brain/MINDS Beyond database. The basic method of data sharing shall be as specified in the Guidelines on AMED Research Data Utilization. The terms of use of the Brain/MINDS Beyond database will provide that the purpose of use of Unrestricted Openly Shared Data should be limited to research purposes (including research for profit by private companies).

(2) Restricted Openly Shared Data

After obtaining Target Data which is Restricted Openly Shared Data, Institute Researchers and Approved Researchers must promptly register such Target Data on the Brain/MINDS Beyond database and openly share the same.

Any user may use the registered data if his/her data access application is approved upon specifying the purpose and method of use etc. of registered Target Data in accordance with the terms of use, etc. of the Brain/MINDS Beyond database.

(3) Restricted Closed Shared Data

After obtaining Target Data which is Restricted Closed Shared Data, Institute Researchers and Approved

Researchers must promptly register such Target Data on the Brain/MINDS Beyond database.

Target Data which is Restricted Closed Shared Data may be used only by such researchers, etc. listed in the Data Management Plan to be submitted to AMED or individually approved by AMED.

5. Preparation of Data Management Plan

In accordance with Chapter 5, paragraphs 1, 2 and 3 of the “Guidelines on AMED Research Data Utilization”¹⁾, a Data Management Plan setting forth the handling of Target Data (policies for the registration, storage, closed sharing and openly sharing of information) must be prepared, and data must be managed based on the same.

6. Protection of personal information and ethical considerations

(1) If any Target Data is processed or managed such as by deleting information that can identify research subjects, such as names and date of birth, so that the research subjects pertaining to such Target Data are not readily identifiable, such Target Data can be, as a rule, treated as information that cannot identify specific individuals. However, if the Institute Researchers have the correspondence table, unless it is appropriately managed, such Target Data cannot be treated as information that cannot identify specific individuals.

(2) When registering, openly sharing and closed sharing any Target Data, all the laws and regulations related to protection of personal information and related ethical guidelines, etc. such as the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects”²⁾ must be complied with.

(3) When carrying out any research as part of the Brain/MINDS Beyond research project, the human rights and privacy of research subjects must be protected.

7. Intellectual property

Any intellectual property rights arising from the results of research utilizing Target Data and any database based on Target Data belongs to the research institution (including any research institution of a private company) or the researchers that conducted such research. However, considerations must be paid so that the sharing of Target Data will not be excessively hindered by such intellectual property rights in order to increase the opportunities to conduct secondary research and to put the results obtained therefrom to practical use.

References

1. “Guidelines on AMED Research Data Utilization” <https://www.amed.go.jp/content/000073342.pdf>, Japan Agency for Medical Research and Development, March 2020
2. “Ethical Guidelines for Medical and Biological Research Involving Human Subjects” <https://www.mhlw.go.jp/content/000757566.pdf>, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, March 23, 2021