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Data Use Regulations

Hirosaki University COI Data Management Committee

1 Purpose

These regulations aim to ensure the smooth operation of the management of the handling of data related to research and development, including analysis, use, and publication, by the Hirosaki University COI Data Management Committee (hereinafter referred to as the "Data Management Committee").

2 Definition and Scope of Resident Data

As a general rule, the data managed by the Data Management Committee refers to pseudonymized information obtained from health surveys conducted by Hirosaki University. For the types and handling of resident data, refer to "5 Types and Handling of Resident Data."

・The handling of genomic data and personally identifiable information shall follow the "Guidelines for the Handling of Genomic Data and Personally Identifiable Information."

・The data items of "5.1 Iwaki Project Health Checkup Data," "5.2 Iki-Iki Health Checkup Data," and "5.3 QOL Health Checkup Data" are classified into the following three categories for use:

Category	Application Category	Examples of Items
1	Common Data	Personal records, health questionnaires, blood, urine, body composition, physical fitness measurements, etc.
2	Semi-Common Data	Genes, microbiota
3	Proprietary Data	Data obtained by specific institutions in cooperation with Hirosaki University

3 Persons Eligible to Apply for the Use of Resident Data

The following individuals shall be eligible to apply for the use of resident data: individuals recognized as co-researchers through the ethical review of the relevant health survey; individuals recognized as co-researchers in studies utilizing data from the relevant health survey; external co-researchers affiliated with institutions that have entered into joint research agreements or joint research course establishment agreements; and other persons specifically approved by the Data Management Committee.

4 Procedures for Data Use

4.1 Prior Consultation

Users wishing to analyze resident data (hereinafter referred to as “Applicants”) shall provisionally submit a written application (Form 1) to confirm data availability with the Data Management Committee and obtain preliminary approval from the Chair. In cases where external researchers from corporations or research institutions initiate new studies, or where questions arise regarding the submission, the Applicant may be required to provide a prior oral explanation, either in person or online, to the Chair.

4.2 Prior Consent for Proprietary Data

If the requested dataset includes Category 3 (Proprietary) data obtained by other institutions, the Applicant shall contact the relevant institution in advance and obtain formal consent using Form 7 and Form 8.

4.3 Submission of Application Documents

4.3.1 Principal Investigator

In joint research between internal researchers and external corporate researchers, the external researcher shall, in principle, be responsible for submitting the application documents.

4.3.2 Details to Be Included in Submitted Documents

Applicants shall submit Form 1 to the Data Management Committee, including all mandatory information: purpose and methods of analysis, analysis period and location, specific resident data requested, names of data analysts, and details regarding dedicated analysis terminals and storage media. For applications involving genomic data, the Applicant must also specify the information management officer and include the application checklist and required attachments.

4.3.3 Application for Changes

If any changes occur to the approved application details, the Applicant shall submit a revised Data Analysis Application (Form 1) along with a Change Application Checklist (Form 3) reflecting the modifications.

4.3.4 Applicable Period for Applications

The data analysis period shall, in principle, not exceed three years (see Section 6.2 for hypothesis-generating research). This period must fall within the timeframe approved by the relevant ethics committee and, for external researchers, within the duration of the applicable

joint research agreement or joint research course. Extensions shall be requested using Form 1. An extension of the general analysis period shall automatically extend the approval for Category 3 data without requiring renewed consent from the providing institution.

4.3.5 Timing of Submission of Applications, and Review and Decision by the Data Management Committee

The Data Management Committee shall review applications to determine the feasibility of the request and the scope of data to be provided.

Studies involving the COI-NEXT Ethics Committee (Iwaki Project data with a corporate Principal Investigator):

a) Before Ethical Review: The Applicant shall formally submit Form 1 to the Data Management Committee. If the Committee determines the analysis is feasible, it shall issue a conditional approval notice. The Applicant shall then proceed with the ethical review by the COI-NEXT Ethics Committee using this notice.

b) After Ethical Review Approval: The Data Management Committee shall issue a formal approval notice upon receipt of the ethical review results.

All other cases:

a) Before Ethical Review: Ethical review (new or modified) shall be conducted by the Ethics Committee as necessary.

b) After Ethical Review Approval: The Applicant shall formally submit Form 1 to the Data Management Committee. This submission must reflect any revisions or requirements resulting from the ethical review process. If the Committee determines through review that analysis is feasible, it shall issue an approval notice.

4.4 Transfer of Data and Responsibilities of Data Analysts

4.4.1 Transfer of Data

Upon approval, data analysts shall submit a written confirmation of receipt (Form 2) to the Data Management Committee when the resident data is transferred.

4.4.2 Location of Data Analysis

Data analysis shall, in principle, be conducted within Hirosaki University facilities. Analysis at other institutions or via remote systems requires specific approval by the Data Management Committee. Remote analysis must comply with the “Guidelines for the Use of the Hirosaki University COI Remote Analysis System” and requires the submission of Form 9.

4.4.3 Responsibilities of Data Analysts

The duplication of resident data and the transfer, use, lending, or sharing of such data with individuals other than the authorized data analysts are prohibited.

Data analysts shall exercise the due care of a prudent manager in the management of resident data. They shall implement reasonable security measures to prevent unauthorized access, destruction, loss, or leakage of information processing systems containing resident data. Data analysts shall not outsource the analysis of resident data to third parties.

4.5 Reporting of Data Analysis Results

When results are obtained through analysis (including methodologies, datasets, and findings), data analysts shall submit these results to the Data Management Committee. Even during ongoing analysis, Applicants shall submit a mandatory annual progress report (Form 4) by the end of each fiscal year.

4.6 Completion of Data Analysis

Upon completion of the analysis, data analysts shall submit a completion report (Form 5). After providing the final analysis dataset to the Committee, the analyst shall delete all resident data except for basic information (reception number, age, sex, height, and weight) and data that their own institution originally obtained. Deletion shall be performed using dedicated software, and the analyst shall submit Form 10, specifying the date, person responsible, and method of deletion.

Analysts shall comply with any additional or separate instructions provided by the Data Management Committee regarding data retention or disposal.

4.7 Prior Notification and Reporting of External Disclosure of Research Results

4.7.1 Prior Notification of External Disclosure of Research Results

Data analysts shall notify the Data Management Committee in writing approximately 30 days prior to any external disclosure, such as conference abstract submissions, manuscript submissions, or media interviews. If the research results involve inventions, the feasibility of patent applications shall be discussed separately. External disclosure includes conference presentations, journal submissions, publicly disclosed funding reports, and press releases. The Committee shall review the submission to approve or deny the disclosure.

4.7.2 Reporting After Publication of Submitted Papers

Following the acceptance of a submitted paper, analysts shall promptly report the author names, DOI, and paper URL to the Data Management Committee.

5 Types and Handling of Resident Data

5.1 Iwaki Project Health Checkup Data

This refers to pseudonymized data from the Iwaki Health Promotion Project conducted by Hirosaki University and Hirosaki City since 2005.

- **UMIN Registration:** UMIN000040459 (Core components from 2014 onward).
- **Acknowledgement Requirements:** Publications and presentations must cite the Iwaki Health Promotion Project and include the following grant numbers: JPMJCE1302, JPMJCA2201, and JPMJPF2210. For research using data from fiscal year 2025 onward, the Moonshot grant JPMJMS2021 must also be included.

5.2 Iki-Iki Health Checkup Data

This consists of pseudonymized data from the "Iki-Iki Health Checkups," a combined program involving the JST COI Program and AMED/JPSC-AD dementia research projects. The Committee handles only data obtained at the Hirosaki site.

- **Compliance:** Research shall comply with JPSC-AD Basic Regulations. Progress and results shall be reported to JPSC-AD via the Data Management Committee twice a year (by the end of May and December). Research outputs will be published on the JPSC-AD website.
- **Acknowledgement Requirements:** Grant numbers JP16dk0207025 (FY2016–2020) and JP21dk0207053 (FY2021 onward) shall be included in the Acknowledgements section regardless of the data usage year.

5.3 QOL Health Checkup Data

The QOL Health Checkups involve same-day feedback and health education. Data includes questionnaires, examination results, and daily self-monitoring records.

5.3.1 QOL Health Checkup Data Conducted by Hirosaki University

Hirosaki University is the primary implementing organization. Data is classified as Category 1 and Category 2. Acknowledgements shall include grant numbers JPMJCE1302, JPMJCA2201, and JPMJPF2210.

5.3.2 QOL Health Checkup Data Conducted by the Healthy Living Promotion Center

The Healthy Living Promotion Center is the primary implementing organization. Data is classified as Category 1 and Category 2. Acknowledgements shall include grant numbers JPMJCE1302, JPMJCA2201, and JPMJPF2210.

5.3.3 MY-version QOL Health Checkup Data Conducted by Meiji Yasuda

Meiji Yasuda is the primary implementing organization. Data is handled as Category 3 (Proprietary). Acknowledgements shall include grant numbers JPMJCE1302, JPMJCA2201, and JPMJPF2210.

5.4 Data to Be Handled by the Data Management Committee in the Future

5.4.1 Health Survey Data Conducted by Hirosaki University

Data obtained through joint research between Hirosaki University and COI participating companies will be managed by the Committee as data preparation is finalized.

5.4.2 Health Survey Data Conducted by Data Collaboration Universities

Pseudonymized data from collaboration universities shall be accepted for application and jointly managed in accordance with specific inter-university agreements.

6 Terminology

6.1 Hypothesis-Testing Research

Research designed to verify a predefined hypothesis. This includes studies where the Applicant's proprietary data is used as the dependent variable.

6.2 Hypothesis-Generating Research

Data-driven research aimed at identifying potential dependent or explanatory variables. The maximum analysis period is one year, extendable via change application.

Applicants shall report progress using Form 4. The initial report is due within six months of final approval, with subsequent reports required every three months. If hypothesis verification becomes necessary, a new research project must be initiated via new ethical and data applications.

In the event of content overlap during publication or transition, existing hypothesis-testing research projects shall take priority.

7. Governing Language

This document is an English translation provided for convenience only. In the event of any inconsistency or discrepancy between the Japanese version and the English version, the Japanese version shall prevail.

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Associated Guidelines and Forms

- Guidelines for the Use of the Remote Analysis System
- Guidelines for the Handling of Genomic Data and Personally Identifiable Information
- Form 1: Data Analysis Application (New/Change)
- Form 2: Confirmation of Data Receipt
- Form 3: Change Application Checklist
- Form 4: Data Analysis Progress Report
- Form 5: Data Analysis Completion Report
- Form 7: Request for Prior Consent for Data Analysis Application
- Form 8: Notice of Result of Request for Prior Consent
- Form 9: Remote Analysis Use Application (New/Renewal/Change)
- Form 10: Pledge of Data Deletion/Disposal