

Biobank Japan Project for Genomic and Clinical Research
**“Operation and Management of Japan’s Disease Biobank Intended for Utilization of Samples,
Clinical Information and Genome Data”**

ELSI Committee
Outline of Establishment

Established on March 15, 2024

Office of BioBank Japan

BioBank Japan Project for Genomic and Clinical Research

“Operation and Management of Japan’s Disease Biobank Intended for Utilization of Samples,
Clinical Information and Genome Data”

1. Establishment

The Ethical, Legal and Social Issues (ELSI) Committee (hereinafter referred to as the “Committee”) shall be established under the BioBank Japan Project for Genomic and Clinical Research’s “Operation and Management of Japan’s Disease Biobank Intended for Utilization of Samples, Clinical Information and Genome Data” of the Japan Agency for Medical Research and Development (hereinafter referred to as the “Project”) as an organization for providing advice and recommendations from a standpoint independent from the promotion of the Project.

2. Purpose

The Committee shall aim to provide advice and recommendations concerning ELSI to ensure the proper operation of the Project.

3. Composition

- (1) The Project representative shall commission an expert in a position independent from the promotion of the Project to serve as a Committee member.
- (2) Committee members may serve concurrently on the Advisory Board and/or the Sample and Data Utilization Review Committee of the Project.
- (3) The chairperson shall be co-opted from among the Committee members.
- (4) The chairperson shall propose to the Office of BioBank Japan (hereinafter referred to as the “Office”) the invitation or presence of an expert other than the Committee members if the person is deemed necessary for the Committee’s discussion. The Office shall discuss the proposal with the Project representative and take the required steps.
- (5) Persons in charge of the Project shall attend the Committee meetings.

4. Quorum

The quorum for a Committee meeting shall be a majority of the Committee members.

5. Procedural Steps

(1) Upon receiving a report and/or request for consultation from the Project, the Committee shall provide advice and/or recommendations with regard to how ELSI should be handled under the Project.

(2) The Committee shall provide advice and/or recommendations to ELSI that are deemed necessary by its members (including the chairperson) and that have been approved by the Committee.

(3) In the event that an ELSI matter deemed urgent by the Committee has arisen under the Project, the Project representative shall promptly address the matter.

6. Term

The Committee shall be in place as long as the Project continues unless exceptional circumstances arise, and the term of office of Committee members shall continue until the end date of the Project (scheduled to be March 31, 2028).

7. Duty of Confidentiality

Committee members shall not divulge any information obtained in the course of their duties to external parties without good reason. This shall continue to apply notwithstanding the expiration or termination of their term of office as Committee members.

8. Disclosure of Information

The Project shall strive to disclose information about the Committee's activities.

9. Other Matters

(1) All matters necessary to operate the Committee shall be determined upon discussion between the Project and the Committee.

(2) General affairs of the Committee shall be handled by the Office.

Revision History

March 15, 2024 Version 1