

BioBank Japan Sample and Data Access Committee Operating Rules

Established on September 14, 2018

Revised on April 1, 2019

Japan Agency for Medical Research and Development's
BioBank Japan Project for Genomic and Clinical Research
“Operation and Management of Japan's Disease BioBank Intended for Utilization”

Article 1 (Establishment)

The Sample and Data Access Committee (hereinafter referred to as the “Committee”) shall be established under the BioBank Japan Project for Genomic and Clinical Research “Operation and Management of Japan's Disease BioBank Intended for Utilization” of the Japan Agency for Medical Research and Development (hereinafter referred to as the “Project”) in connection with: (i) the provision of samples (meaning DNA, serum, plasma, tissues and the like; the same applies hereinafter) and data (meaning clinical information, genomic data, prognosis information, regional information and the like; the same applies hereinafter) (hereinafter such samples and such data shall be referred to collectively as “Samples, etc.”) stored and managed at BioBank Japan, which was established for the Project at the Institute of Medical Science, The University of Tokyo (hereinafter referred to as “IMSUT”), to domestic researchers who have been engaged in related research (i.e., persons who are attached to a university, public research institution, private company or the like and who have a history of being engaged in related research); and (ii) the acceptance of Samples, etc. by BioBank Japan from external bodies.

Article 2 (Purpose)

The Committee shall review the provision and acceptance of Samples, etc. and shall discuss matters related to such review in order to ensure the proper and effective utilization of Samples, etc. provided by BioBank Japan.

Article 3 (Roles)

Upon receipt of an application for provision or acceptance of Samples, etc., the Committee shall, in order to promote the appropriate utilization of Samples, etc. in line with the purpose of the Project, conduct a review in an unbiased and fair manner pursuant to the prescribed Review Criteria and shall provide a written report of the results of such review to the Office of BioBank Japan (hereinafter referred to as the “Office”) at the Institute of Medical Science, The University of Tokyo.

Article 4 (Committee Chair)

The Committee shall have a chair, who shall be appointed by the representative of the Project at the Institute of Medical Science, The University of Tokyo.

Article 5 (Committee Members)

The members of the Committee shall consist of the following persons in addition to a chair:

- (1) One expert attached to the Institute of Medical Science, The University of Tokyo.
 - (2) A few experts attached to any of the cooperating medical institutions for the former “Tailor-made Medical Treatment Program.”
 - (3) A few external experts who are not involved in the promotion of the Project.
 - (4) A few other experts who are deemed necessary by the chair.
2. All Committee members other than the chair shall be appointed by the chair.
 3. Committee members may serve concurrently on the Advisory Board and/or the ELSI Committee of the Project.
 4. All Committee members shall be commissioned by the Institute of Medical Science, The University of Tokyo.
 5. The term of office of Committee members shall continue until the end date of the Project unless exceptional circumstances arise; provided, however, that the term of office of a Committee member appointed to fill a vacancy shall be the remaining term of office of his/her predecessor.
 6. The chair shall preside over meetings of the Committee and shall supervise the affairs of the Committee. Where necessary, the chair may appoint a co-chair from among members of the Committee and may request the co-chair to conduct the proceedings of meetings.
 7. If deemed necessary by the chair, the Committee may request experts other than its members to attend or make comments at Committee meetings.
 8. The 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.

Article 6 (Holding of Committee Meetings)

Committee meetings shall be convened by the chair and may be held at any time when deemed necessary by the chair.

2. Except as set forth in Article 9, the proceedings of a meeting may be commenced only if the following requirements are met:
 - (1) The Committee members listed in article 5, paragraph 1, items (1) through (3) are present at the meeting.
 - (2) A majority of the Committee members are present at the meeting; provided, however, that any Committee member who is absent may be deemed to be present if the Committee member has submitted a power of attorney or equivalent to the Office.

Article 7 (Procedure for Review of Application for Utilization of Samples, etc.)

The chair shall decide whether a review of utilization or acceptance of Samples, etc. will be conducted by electronic review (i.e., a review procedure in which the review is conducted by using an electronic review system or email and responses submitted by Committee members are summarized to form the Committee's resolution) or assembly review (i.e., a review procedure in which Committee members meet together).

2. If a question, etc. is submitted by any Committee member as to a decision to use electronic review, the Office shall conduct coordination and the chair shall update his/her decision on the review procedure. The Office shall inform all Committee members of the updated decision together with the background and reason therefor.

Article 8 (Resolution on Review of Application for Utilization of Samples, etc.)

In the case of an electronic review, if a majority of all Committee members give a response of "approval," the application reviewed shall be deemed approved. If any questions and/or negative opinions on the subject matter of the application are received, a decision shall be made based on Committee members' responses received after the Office informs all Committee members of such questions and/or negative opinions and requests all Committee members to reconsider the application.

2. In the case of an assembly review, the application reviewed shall be deemed approved if a majority of all Committee members give approval.

3. Particulars of review shall be specified separately by the Office.

Article 9 (Expedited Review)

In the case of a review of an application for which the chair deems it unnecessary to hold a meeting, such as in the case of an application for an extension of the research period of, or a minor change in the number of specimens requested for, a project for which an application has been made, or in the case of an application by a research organization whose similar application was approved in the past, the Committee may adopt a resolution based on the results of an expedited review conducted by Committee members appointed by the chair.

2. The Office shall inform all Committee members of the results of any expedited review conducted under the preceding paragraph.

Article 10 (Monitoring of Utilization; Judgment on Misconduct)

The Committee shall conduct checks regarding the appropriate utilization of Samples, etc. based on annual reports, etc. of users of Samples, etc., including users whose research subjects were approved by the former Sample and Data Access Committee. In the event of a suspected breach by a user of Samples, etc. of the BBJ Sample and Data Utilization Guidelines or the BBJ Data Handling Security Guidelines

(for Users), BioBank Japan shall conduct an investigation into the alleged misconduct and the Committee shall judge whether or not the alleged misconduct occurred based on the results of such investigation. If a judgment is made that the alleged misconduct did occur, the Committee shall decide on a suspension of utilization by the user or any other measures to be taken.

Article 11 (Utilization of Samples Subject to Special Agreements)

Of the Samples, etc. stored and managed by BioBank Japan, those subject to a special agreement executed in advance between the organization that provided the Samples, etc. and BioBank Japan may be provided for utilization without a resolution of the Committee.

Article 12 (Exclusion of Interested Persons)

Persons interested in a review shall be those who have a close connection with the applicant and the subject matter of the application or who are deemed by the Office of BioBank Japan to be interested persons. No such interested persons shall be eligible to vote on the resolution on the review. If the chair is an interested person, a deputy chair shall be appointed from among the Committee members.

Article 13 (Secrecy of Committee Meetings)

All Committee meetings shall be held in private in order to maintain, among other things, the creativity of research and the protection of intellectual property rights and personal information.

Article 14 (Attendance at and Sitting in on Committee Meetings)

If deemed necessary by the chair, the Committee shall not preclude persons from any of the organizations involved in the Project from sitting in on a Committee meeting.

2. If deemed necessary by the chair, the Committee may request the applicant to attend a Committee meeting and to provide the Committee with an explanation of the subject matter of the application.

Article 15 (Disclosure of Information on Committee)

The Office shall publish the list of Committee members and summaries of proceedings of meetings that are not related to the details of specific reviews.

2. All other information shall be handled upon consultation with the chair on a case-by-case basis.

Article 16 (General Affairs)

General affairs of the Committee shall be handled by the Office of BioBank Japan.

Article 18 (Other Matters)

All matters necessary to enforce these rules other than as set forth herein shall be determined by the

Committee.

Revision History

September 14, 2018 Version 1

April 1, 2019 Version 2

- The procedure for monitoring of access and for judgment on misconduct was added as Article 10.