

## BioBank Japan Sample and Data Access Committee Review Criteria

Established on October 10, 2018

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" (hereinafter referred to as the "Project"), BioBank Japan (BBJ), which was established for the Project at The Institute of Medical Science, The University of Tokyo (hereinafter referred to as "IMSUT"), shall provide external research institutions with samples (meaning DNA, serum, plasma, tissues and the like; the same applies hereinafter) and data (meaning clinical information, SNP data, DNA sequence data, cause of death and the like; the same applies hereinafter) it stores and manages (hereinafter such samples and such data shall be referred to collectively as "Samples, etc.") and shall accept Samples, etc. from external bodies for storage. The Review Criteria, based on which the BBJ Sample and Data Utilization Review Committee (hereinafter referred to as the "Committee") reviews the applications for provision and acceptance of Samples, etc., shall be prescribed as follows. The Committee shall conduct a review of the research project concerned pursuant to the items below so as to examine whether it is appropriate to provide or accept Samples, etc. under the Project.

### [Review Criteria]

1. Upon receipt of an application for provision or acceptance of Samples, etc., the Committee shall conduct a review from the following perspectives.
  - (1) Validity of the subject matter of the planned research project
    - The utilization of samples and the like provided by a public biobank is a precondition of the research project.
    - The research project is a feasible project aimed at scientific verification of a hypothesis.
  - (2) Technological capability of the applicant requesting provision or acceptance of Samples, etc.
    - In pursuing the research project, the research institution concerned (including joint research institutes and external analysis organizations) has adequate facilities and human resources.
  - (3) Research track record of the applicant requesting provision or acceptance of Samples, etc.
    - The applicant has a track record of research related to the research project concerned.
2. The Committee shall review the validity of research projects. However, in the event there is a clear lack of ethical considerations given in the research project under review, the Committee shall be entitled to state its opinion.

### [Supplementary rules]

1. The above Review Criteria shall be formulated by the Committee and promptly reported to the

Office of BioBank Japan upon formulation.

2. If the Review Criteria need to be revised, the Committee shall revise them upon discussion. The revision shall be promptly reported to the Office of BioBank Japan.