Title: Administrative Regulations on the Establishment of Human Biobank
Amended Date: 2011.01.31
Category: Ministry of Health and Welfare

Article 1 This set of Regulations is formulated in accordance with regulations of Paragraph 2, Article 4 of the Human Biobank Management Act (hereafter referred to as the Act).

Article 2 Institutions meet one of the following qualifications and have set up a bio-medical director and an information director shall apply for a biobank establishment to the central competent authority after approved by the Ethics Committee specified in Paragraph 1 of Article 5 (hereafter referred to as the Ethics Committee):
1. Government agencies of justice, health, bio-technology industries or scientific development-related;
2. Hospitals who have passed the accreditation of teaching hospitals;
3. Public/Private technological academies or above; or
4. Central government-associated institutions or national incorporated foundations and judicial associations that have been set up for life science research.

Article 3 Applicants involved in the previous article shall submit flowing documents to the competent authority for approval:
1. Setting proposal that contains following matters:
(1) Representatives of the institution and the Biobank;
(2) Addresses of the institution and the Biobank;
(3)Types, quantities and related data and information of biological specimens planned to be collected and preserved;
(4) Planned setting schedule;
(5) Staff, organization and operating processes of the Biobank;
(6) A simplified representation of facilities, equipments and the planned preservation place of the Biobank as well as related environmental control and monitoring;
(7)Contents of informed consent and the measures of participant's rights and interests protection;
(8) Operating procedures of dealing with biological specimens and related data and information.
2. Organization and membership list of the Ethics Committee;
3. Names of the bio-medical director and the information director as

well as photocopies of their qualification certificates;
4. Management provisions on information security set by the operator;
5. Rules of notification mechanisms and remedies applicable when participants' biological specimens or related data and information are stolen, leaked, altered or suffer from other violations;
6. Rules related to benefits or feedbacks from commercial use and received by the operator;
7. Relevant measures to be taken so that collected biological specimens and related data and information will not be destroyed in the event that the corrective action may not be completed due to the death or incapacity of the participant as specified in the supplementary provisions in Article 30 of the Act.

Article 4 Qualifications and responsibilities of the bio-medical director and the information director of the Biobank are as follows:
1. The bio-medical director: holds a Physician Certificate, Medical Technologist License or Master's degree in biology-related subject and has practical experience of more than three years in bio-medical related fields; responsible for supervision and maintenance of the quality management of collections, preservation, application and destruction of biological specimens of the Biobank and for other matters related to biomedicine of the Biobank;
2. The information director: holds a Master's degree in an information-related subject and has practical experience of more than three years in information-related fields; responsible for supervision and maintenance of the safety management of data and information in the Biobank and for other matters related to information safety of the Biobank.
When a Biobank has more than 2 places for biospecimens preservation, one bio-medical director shall be set for each address.

Article 5 Competent authority should examine and approve applications for setting up of a Biobank based on following standards:
1. Completeness and feasibility of the proposal;
2. Considerateness of guarantee of participants' rights and interests;
3. Appropriateness of the review process carried out by the Ethics Committee.

Article 6 A Permission Certificate with a valid period of three years will be issued after the application for the setting up of a Biobank which has been reviewed and approved by competent authority.
In the Permission Certificate, following information shall be clearly stated:
1. Name and address of the Biobank;
2. Name and representative of the operator;
3. Address of the operator;
4. Preservation address of the biological specimens.

Article 7 The operator should submit following documents to the competent authority for applying an extension to the permission certificate for setting up of a Biobank three months before its expiration:
1. A copy of the original permission certificate;
2. An explanation regarding collection, preservation status and application of the biological specimens within the current period of validity, which shall be signed by the bio-medical director;
3. Explanation of implementation related to information security within the current period of validity, which shall be signed by the information director;
4. Explanation of matters to be added or altered within the next period of validity.
Each extension to the permission certificate is limited to three years after the previous application has passed the examination.

Article 8 Within the period of validity of the permission certificate, should there be any alternation of matters handled or staff that causes inconsistency with the original plan or with document descriptions submitted during application for extension to period of validity, operator should report it to competent authority for approval within one month from the date of making the alternation.

Article 9 Operator should submit relevant plans as well as documents reviewed and approved by the Ethics Committee to the competent authority for approval in order to apply for overseas transport or export of derivatives of biological specimens.

Article 10 Operators who have seriously violated provisions in Article 23, 24 or 28 of the Act and have been revoked permission certificates by the competent authority shall stop operation immediately and submit

follow-up disposal plans to the competent authority for approval within three months from the date of revocation.

Article 11 Institutions shall apply provisions in Articles 2 to 5 when partial or complete transfer of Biobank according to provisions in Paragraph 1 of Article 14 in the Act, or correcting relevant procedures according to provisions in Article 30 in the Act.

Article 12 Operator and relevant personnel should not evade, obstruct or refuse regular checks of the Biobank or reading of related documents carried out by the competent authority.

Article 13 This Administrative Regulations shall come into effect on the date of the promulgation.