

**Title:** Human Biobank Management Act

**Amended Date:** 2012.08.08

**Category:** Ministry of Health and Welfare

## Chapter 1 General Provisions

**Article 1** The Human Biobank Management Act (hereinafter “Human Biobank Act”) is specifically stipulated to regulate the establishment, management, and applications of the human biobank (hereinafter “Biobank”), ensure the rights and benefits of biological database participants, and promote medical development and public welfare.

**Article 2** The “competent authority” (hereinafter “Competent Authority”) as referred to herein means the Department of Health of the Executive Yuan

**Article 3** Definitions:

1. Biological specimen: This term refers to derivatives, such as the cells, tissues, organs, or body fluids, which are collected from a human body or produced by experimental operations and are sufficient to provide adequate information for identifying the participant’s biometrics.

2. Participant: This term refers to any natural person who provides his/her biological specimens, personal information, and other related data and information to the Biobank.

3. Biomedical research: This term refers to medical research on basic biometrics, such as genes.

4. Biobank: For the purpose of biomedical research, the Biobank contains participants’ biological specimens, natural persons’ information and other related data and information based on human population or specific groups. These biological specimens, derivatives, or relevant data are stored in the Biobank without delinking websites for the need of follow-up applications.

5. Coding: Codes are used to substitute for the participant’s personal information, such as name, ID card number, and medical records number, to protect his/her privacy and identity.

6. Encryption: This term refers to the process of making the participant’s personal data and information unidentifiable.

7. Delinkage: This term refers to the operation of permanently

disabling encoded biological specimens, data, and information from being linked to or matching them with the participant's personal data or information.

8.Operator: This term refers to a person that establishes and manages the Biobank.

9.Transfer: This term refers to the process where an operator transfers the Biobank and the rights and obligations between the operator and the participant to a third party.

## Chapter 2 Establishment of Biobank

Article 4 A Biobank Operator must be a governmental agency, medical or academic institution, research institution, or legal person (hereinafter collectively referred to as "Organization") and shall apply to the Competent Authority for a permit.

The Competent Authority shall stipulate rules and regulations to govern matters related to the permit applications mentioned in the preceding paragraph, such as applicant qualifications, application procedures, conditions for the establishment approval, review standards, regular inspections, relevant managerial matters, and other matters of compliance.

Article 5 A Biobank Operator shall establish an ethics committee to review and supervise matters relating to the management of the Biobank.

There shall be between nine (9) to fifteen (15) commissioners in an ethics committee mentioned in the preceding paragraph, of which more than one half (1/2) shall be legal experts, social workers, and other disinterested community members; and at least two thirds (2/3) of the commissioners shall not be the personnel of the Organization.

Any matters related to the applications of data and information contained in the Biobank shall be drafted as a plan to be submitted to the ethics committee for approval, after which the plan shall be submitted to the Competent Authority who will further invite legal experts, social workers, and other disinterested community members to conduct a review on the plan. Only upon the final approval should the plan be enforced.

The number of each type of professionals mentioned in the preceding paragraph shall be no less than one fourth (1/4) of the

total seats; and the professionals of the same gender shall not amount to less than one third (1/3) of the total seats.

The Competent Authority may commission private professional agencies (organizations) or groups to process the reviews set forth in Paragraph 3.

The reviewers referred to in Paragraphs 2 and 3 shall be recused to avoid conflicts of interest if necessary.

### Chapter 3 Biological Specimens Collection and Participant Protection

Article 6 Collections of biological specimens shall be conducted in compliance with medical and research ethics. Participants shall be informed of related matters in a clearly comprehensible manner. Such matters shall be specified in an agreement of consent. Any collection may only be undertaken after the participant's written consent is obtained.

The Participant referred to in the preceding Paragraph must be at least twenty (20) years of age and have the legal capacity.

However, a participant of the biobank on specific population groups is not subjected to this rule.

In the event that a participant of the biobank on specific population groups set forth in the proviso in the preceding Paragraph is under seven (7) years of age or is subject to a declaration of guardianship, the Operator shall obtain the consent of the participant's legal representative. In the event that a minor participant is seven (7) years of age or older or subject to a declaration of assistance, consent shall be obtained from the participant and his/her legal representative.

The content of the agreement of consent mentioned in Paragraph 1 shall be submitted to the Competent Authority for records after being approved by the ethics committee of the concerned operator.

Article 7 As set forth in the preceding Article, a participant shall be informed of the following matters:

- 1.The legal authorities and their contents governing the establishment of the Biobank.
- 2.The identity of the Biobank Operator.
- 3.Information regarding the identity and the service unit of the biological specimen collectors.

- 4.The reasons why a particular participant was selected.
- 5.The rights and direct benefits to which the participant is entitled pursuant to the Human Biobank Act.
- 6.The purposes of collection and the range and duration of the use of the collected biological specimens; collection methods; types and quantities of specimens to be collected; and regions where specimens are collected.
- 7.Any complications and hazards that might possibly occur during and as a result of a collection(s).
- 8.Any possible impacts of the genetic information derived from the biological specimens on the participant, and his/her relatives or an ethnic group.
- 9.Any reasonable risks or inconvenience which the participant may anticipate.
- 10.The rights which are excluded by these Human Biobank Act.
- 11.The mechanism designed to safeguard personal privacy and other rights and benefits of the participant.
- 12.The Operator’s organizational structure and operating principles.
- 13.Specific type of health information of the participant that is expected to be linked in the future.
- 14.Relevant regulations governing the applications of the Biobank.
- 15.Anticipated commercial applications.
- 16.The participant may choose whether upon his/her death or incapacity, his/her biological specimens and related data and information will continue to be stored and used.
- 17.Other important matters related to the Biobank.

Article 8

A Participant may make a request to cease providing any biological specimen, withdraw, or change the scope of the use, which the Operator shall not refuse.

Should any participant withdraw from the program, the Operator shall destroy the biological specimens and related data and information provided by the participant. In the event that such materials have been provided to a third party, the third party shall destroy same upon receiving the notification from the Operator. However, this rule shall be inapplicable if one of the following circumstances occurs:

- 1.The Participant agrees in writing to the continuous use of

certain materials.

2. Materials have already been delinked.

3. The preservation of documents such as the agreement of consent is necessary for the purpose of inspections and approved by the ethics committee.

Article 9 In the event of a participant's death or incapacity, except as otherwise agreed herein, the Biobank may, in accordance with the original agreement, continue the storage and use of the biological specimens and related data and information.

Article 10 A Participant shall not request to view, duplicate, add, or correct data or information related to collections or processing of their biological specimens, or data or information with regard to the collection and process of the biological specimens, data, or information pursuant to Human Biobank Act. However, the restriction shall not apply to the personal information that can identify the participant.

#### Chapter 4 Biobank Management

Article 11 In the event that the biological specimens, data, or information is stolen, leaked, tampered with, or otherwise infringed, an Operator shall immediately investigate the matter, report same to the Competent Authority, and notify relevant participants in an appropriate manner.

An Operator shall stipulate emergency response measures in relation to matters mentioned in the preceding Paragraph, and submit same to the Competent Authority for approval.

Article 12 Personnel engaged in the collections, processing, storage, or use of biological specimens shall not disclose any confidences or other personal data or information of the participant, that is known or obtained as a result of their work.

Article 13 An Operator shall stipulate and disclose its own rules on information security management pursuant to the Biobank information security regulations promulgated by the Competent Authority.

Such rules mentioned in the preceding Paragraph shall be submitted to the Competent Authority for records after being approved by the ethics committee.

Article 14 An Operator shall not transfer part or entire Biobank to another, unless the transfer is reviewed and approved by the Competent Authority.

In conducting the review mentioned in the preceding Paragraph, the Competent Authority shall consider the following:

- 1.the rights and interests of the participants.
- 2.the nature of the concerned Operator and its transferee(s).
- 3.the transferee’s ability to protect the rights and interest of the participants.
- 4.the intention of the participants as expressed or may be inferred.

In the event that an Operator plans to cease the operation of the Biobank, a follow-up plan therefor shall be submitted one (1) year in advance to the Competent Authority for approval before such a plan can be enforced.

Article 15 Biological specimens of the Biobank, other than the derivatives, shall not be exported.

Any international transmission of Biobank data or the export of any derivatives mentioned in the preceding Paragraph shall be submitted to the Competent Authority for approval.

In the event that the use of the Biobank is provided to a third party, the rules set forth in the preceding two paragraphs shall be specified in the contract of use with such third party.

#### Chapter 5 Biobank Applications

Article 16 Any biomedical research being based on human population groups or specific population groups shall not use any materials obtained from a Biobank the establishment of which is not authorized.

Where an Operator uses or provides to any third party the biological specimens, and related data and information, such use and the provision shall be conducted pursuant to the scope, duration, and method as agreed to by the Participant.

Article 17 In the event that a Biobank that is established for the purpose of public interests or subsidized by the government should provide its biological specimens and relevant data and information to a third party, the principle of fairness and equality shall apply.

- Article 18 Any storage, use, or disclosure of the concerned operator's entire biological specimens and related data and information shall be encoded, encrypted, delinked, or transformed so that the participant's identity is unable to be determined.
- An Operator shall encrypt and independently administer information that can determine the identity of an individual participant, such as his/her name, identification number, and date of birth. An Operator shall establish a review and control procedure for cross referencing the aforesaid personal information with the biological specimens and relevant data and information. Such information shall be restored immediately after each necessary use.
- When an Operator cross references data or information of different sources, the Operator shall comply with Paragraph 1 hereof and restore the information immediately after the cross-reference is complete.
- Documents that are unable to be separated from the information which can determine the identity of a participant, such as the agreement of consent and declarations of participation termination, are not subject to the rules set forth in the preceding three paragraphs. Nevertheless, the Operator shall adopt other necessary measures to maintain the confidentiality.
- Article 5, Paragraph 3 hereof shall apply to the cross reference and application procedures referred to in Paragraphs 2 and 3.
- Article 19 An Operator's staff and interested parties shall recuse themselves in the event of conflict of interests.
- Article 20 Any use of biological specimens, derivatives and relevant data and information in the Biobank shall not be used for purposes other than biomedical research. Medical research approved in accordance with Article 5, Paragraph 3 hereof shall not be subject to this rule.
- Article 21 Any profits derived from the commercial use and received by an Operator and Biobank shall be given back to the human population groups or specific population groups to which the respective participants belong.
- The Competent Authority shall stipulate regulations governing the distribution of profits mentioned in the preceding Paragraph.

Article 22 An Operator shall regularly publish studies and research results of using the Biobank.

#### Chapter 6 Penalties

Article 23 Violations of Article 4, Paragraph 1 hereof by establishing any Biobank without an approval from the Competent Authority shall be subject to a fine of no less than two million New Taiwan Dollars (NT\$ 2,000,000) and no more than ten million New Taiwan Dollars (NT\$ 10,000,000). Any and all biological specimens and other data and information stored in such a Biobank shall be destroyed. However, in the event that the qualification and condition requirements for the establishment set for in Article 4, paragraph 2 hereof are met and that other relevant procedures may be supplemented or corrected, the violator may be first ordered to make such supplement or correction within a prescribed deadline. Violations of Article 14, Paragraph 1 hereof or Article 14, Paragraph 3 by failing to submit a follow-up plan to the competent authority for a prior approval with regard to of any future cessation of Biobank operation within the time specified; or by failing to comply with the approved follow-up plan shall be subject to a fine of no less than two million New Taiwan Dollars (NT\$ 2,000,000) and no more than ten million New Taiwan Dollars (NT\$ 10,000,000). Violations of Article 15, Paragraph 1 or Paragraph 2 by failing to apply to the Competent Authority for approval shall be subject a fine of no less than two million New Taiwan Dollars (NT\$ 2,000,000) and no more than ten million New Taiwan Dollars (NT\$ 10,000,000). Any exported biological specimens and related data and information shall be immediately destroyed. Violations of Article 30 by failing to destroy any biological specimens and related data and information as required by law shall be subject to a fine of no less than two million New Taiwan Dollars (NT\$ 2,000,000) and no more than ten million New Taiwan Dollars (NT\$ 10,000,000). Where the circumstances set forth in the preceding four paragraphs constitute a serious offense, the Competent Authority may also revoke the establishment permit of the violator.

Article 24

When engaging in any of the following violations, an Operator shall be subject to a fine of no less than five hundred thousand New Taiwan Dollars (NT\$ 500,000) and no more than two million and five hundred thousand New Taiwan Dollars (NT\$ 2,500,000); and may be ordered to undertake timely corrective actions. An Operator who fails to timely undertake such corrective actions shall be subject to an additional fine imposed for each failure:

- 1.violating Article 5, Paragraph 1 or 3 by failing to establish an ethics committee, or failing to submit the management and application matters of the Biobank to the ethics committee for review and supervision, or failing to submit same to the Competent Authority for approval; violating Article 5, Paragraph 2 by allowing unlawful composition of the ethics committee; or violating Article 5, Paragraph 6 by failing to recuse from a conflict of interests.
- 2.violating Article 6, Paragraphs 1-3 or Article 7 by collecting biological specimens; or violating Article 6, Paragraph 4 by failing to submit the agreement of consent to the ethics committee for review and approval.
- 3.violating Article 12 by disclosing any confidences or other personal data or information of a participant that is known or obtained as a result of the work.
- 4.violating Article 13, Paragraph 1 by failing to stipulate or disclose rules regarding information security, or for the reason that the management of biological specimens and related data and information violates any information security regulations; or failing to comply with Article 13, Paragraph 2 requiring that the information security rules pass the review of the concerned ethics committee or submitted to the Competent Authority for records.
- 5.violating Article 18, Paragraph 1 by failing to process the biological specimens and related data and information so that the participant ' s identity is unable to be determined; or violating Article 18, Paragraph 4 by failing to adopt necessary measures to maintain the confidentiality of information contained in the documents that are unable to be separated from the information which can determine the identity of a participant; or violating Article 18, Paragraph 5.
- 6.violating Article 18, Paragraph 2 by failing to encrypt and

independently administer information that can determine the identity of an individual participant, failing to establish a review and control procedure for cross referencing the personal information with the biological specimens and relevant data and information, or failing to immediately restore such information after each necessary use; or violating Article 18, Paragraph 3 by failing to cross reference data with information by means that the participant's identity is unable to be determined, or by failing to immediately restore such information after cross reference.

7. violating Article 20 by using biological specimens, derivatives, and related data and information for the purposes other than biomedical research.

In the event of any of the violations set forth in the preceding paragraphs, the Competent Authority may order a temporary cessation of the operation of the Biobank pending timely corrective actions; where the circumstances constitute a serious offense, the Competent Authority may also revoke the establishment licensure of the violator.

Article 25 When engaging in any of the following violations, a Operator shall be subject to a fine of no less than two hundred thousand New Taiwan Dollars (NT\$ 200,000) and no more than two million and one million New Taiwan Dollars (NT\$ 1,000,000); and may be ordered to undertake timely corrective actions. An Operator who fails to timely undertake such corrective actions shall be subject to an additional fine imposed for each failure:

1. violating Article 8, Paragraph 1 for refusing a Participant's requests; or violating Article 8, Paragraph 2 by failing to destroy or notify the concerned third party to destroy biological specimens and related data and information provided by a withdrawing Participant.

2. violating Article 16, Paragraph 2 by failing to use or provide to any third party the biological specimens and related data and information pursuant to the scope, duration, and method as agreed to by the Participant.

3. violating the regulations stipulated pursuant to Article 21, Paragraph 2.

4. violating Article 22 by failing to regularly publish biomedical studies and results.

Violations of Article 29 by collecting or using biological specimens in biomedical research being not based on the population groups or specific population groups shall be subject to fines a fine of no less than two hundred thousand New Taiwan Dollars (NT\$ 200,000) and no more than two million and one million New Taiwan Dollars (NT\$ 1,000,000). The violators may be ordered to undertake timely corrective actions. An Operator who fails to timely undertake such corrective actions shall be subject to an additional fine imposed for each failure.

Article 26 When engaging in any of the following violations, a person shall be subject to a fine of no less than sixty thousand New Taiwan Dollars (NT\$ 60,000) and no more than two million and three hundred thousand New Taiwan Dollars (NT\$ 300,000); and may be ordered to undertake timely corrective actions. The person who fails to timely undertake such corrective actions shall be subject to an additional fine imposed for each failure:

1. where any person other than an Operator violates Article 5, Paragraph 3.
2. where an Operator violates Article 6, Paragraph 4 by failing to submit the agreement of consent to the Competent Authority for records.
3. violating Article 11, Paragraph 1 by failing to report to the Competent Authority the infringement on the biological specimens, or related data or information, or where an Operator fails to immediately investigate the situations and notify the relevant participants in an appropriate manner; or violating Paragraph 2 of the same Article.
4. where any person other than an Operator violates Article 12 by divulging any confidence or other personal data or information of a Participant that is known or held by him/her as a result of his/her work.
5. violating Article 16, Paragraph 1 by obtaining materials that are used for biomedical research being based on population groups or specific population groups from a Biobank whose establishment has not been approved.

Article 27 With regard to the sanctions set forth in the preceding four articles, the Operation who actually committed the act of violation shall be subject to a fine of no less than thirty thousand New

Taiwan Dollars (NT\$ 30,000) and no more than three hundred thousand New Taiwan Dollars (NT\$ 300,000).

In the event that an individual violator referred to in the preceding Paragraph is a licensed healthcare worker, he/she shall also be punished in accordance with laws and regulations governing healthcare professionals.

- Article 28 In the event that the establishment of a Biobank is in violation of the regulations stipulated by the Competent Authority pursuant to Article 4, Paragraph 2, in addition to the penalties set forth herein, the Competent Authority may order a timely corrective action. If necessary, the Operator may be ordered to cease operations pending the correction actions. Where the nature of the offense is serious, the establishment permit of the violator may be revoked.

#### Chapter 7 Supplementary Provisions

- Article 29 (deleted)
- Article 30 For any Biobank established prior to the enforcement of Human Biobank Act, its Operator shall, within no later than February 5, 2012, complete all necessary corrective actions to conform to Human Biobank Act. Those who fail to undertake complete corrective actions within the time specified shall destroy and may not re-use any and all biological specimens and related data and information. However, in the event that the corrective action may not be completed due to the death or incapacity of the Participant, the biological specimens and related data and information may be preserved with the approval of the ethics committee and the Competent Authority.
- Article 31 The Human Biobank Act shall become effective as of the day of promulgation.