Regulations for Administration on Human Organ Bank

1. Promulgated by the Executive Yuan, the Department of Health Order Wei-Shu-Yi No. 0980205329, on February 2, 2009; The Regulations shall be effective on the day of the promulgation.
2. Amended by the Executive Yuan, the Department of Health Order Shu-Shou-Shi No. 1011100225, on October 2, 2012.

Article 1

These Regulations are promulgated pursuant to the authority of Paragraph 2, Article 14 of the Human Organ Transplant Act.

Article 2

Those engage in the processing or preservation of human organs (including human tissues and cells) and derivatives for the purpose of transplantation shall apply for establishment of a human organ bank (referred to as "organ bank" hereunder) in accordance with these Regulations.

The preservation of reproductive cells shall be handled in accordance with the Artificial Reproduction Act.

Article 3

Juristic persons, medical care institutions and research institutions (collectively referred to as "institutions" hereunder) may apply for the establishment of an organ bank.

An institution in the preceding paragraph that has established an organ bank shall appoint a medical director and a quality director.

Article 4

The medical director of an organ bank must be a physician with at least one year of practice experience in transplantation, basic or clinical immunology, organ bank, blood bank or other related field. The responsibilities of the medical director are as follows:

1. Review the eligibility of organ donors.
2. Review the release of human organs.
3. Validate the medical and technical standard operating procedures for organ preservation.
4. Review and evaluate adverse events related to organ transplant.
5. Review other medical matters related to organ bank.

A medical director may not act concurrently as a medical director of another organ bank of institution.

Article 5

The quality director of an organ bank must be a physician, or a medical technician or a person with a degree in biology related field with at least one year of practical experience in organ bank, blood bank or related field. The responsibilities of the quality director are as follows:

1. Establish and maintain the quality management system of the organ bank.
2. Set up medical and technical standard operating procedures for organ preservation.
3. Investigate adverse events related to organ transplant.
4. Handle other matters related to the quality assurance of organ bank.

A quality director may not act concurrently as a medical director or a quality director of another organ bank.

Article 6

An institution shall establish its organ bank in an independent and demarcated area and equip the organ bank with its own preservation equipment.

Article 7 The following testing for pathogen infection must be completed before a human organ is preserved:

1. Human immunodeficiency virus (HIV).
2. Hepatitis B virus (HBV).
3. Hepatitis C virus (HCV).
4. Treponema pallidum (syphilis).

Article 8

An organ bank shall prepare the following documents and retain them along with the human organ it preserves:

1. A letter of consent from the donor, except for one of the following circumstances:

(1) In case of an organ transfer, a permit certificate from the recovery organ bank has been presented.

(2) In case of an imported organ, a donor consent certificate from the source institution has been presented.

2. A eligibility certificate of the donor.
3. In case of an imported organ, a document to prove its approval of importation.
4. A report for the result of tests and other necessary processing prescribed in the preceding article.
5. A description or record on the preservation status of the human organ.

Where a human organ is transferred to another organ bank, a copy of the documents mentioned in the preceding paragraph shall be transferred concurrently.

An organ bank shall retain the documents mentioned in the preceding paragraph 1 and 2, for at least another ten (10) years after the human organ concerned has been destroyed or if there is no leftover or derivative of the human organ being preserved after its use.

Article 9

An institution that plans to establish an organ bank shall submit the following documents when applying to the central health authority for approval:

1. Establishment plan, which shall include descriptions of the responsible person of the institution, and address of the institution and the proposed organ bank, type of organ bank, estimated storage space, medical director, quality director, progress of establishment, quality management system, organization and staff, operating procedures, facilities and premises, environmental control and monitoring, equipment, label control, recovery, storage, delivery, receiving, tracking and destruction of organs.
2. Documents evidencing the qualifications of the medical director and the quality director.
3. A simple layout of the operational and storage premises.

Article 10

After the application referred to in the preceding article has been approved following the document review, an institution shall complete

the establishment and trial run of the organ bank, and request the central health authority to conduct onsite inspection within six (6) months.

Article 11

The central health authority will issue a three-year permit to an organ bank that has passed the onsite inspection.

The permit mentioned in the preceding paragraph shall contain the following information:

1. Name and address of the institution.
2. The representative or responsible person of the institution.
3. The type of organ bank.
4. The location of the organ bank.
5. The names of medical director and quality director.

When there is change to the item mentioned in subparagraph 1, 2 or 5 of the preceding paragraph, an institution shall, within thirty (30) days after the occurrence of fact, apply for change of registration; when there is change to the item mentioned in subparagraph 3 or 4 of the preceding paragraph, an institution shall reapply for approval.

An institution may, within three (3) months before the current permit for its organ bank expires, apply to the central health authority for extension of permit. An institution that has passed the review will receive a permit extension of up to three (3) years.

Article 12

The establishment and operation of an organ bank shall comply with the rules of Good Human Organ, Tissue and Cell Practice (as attached).

Article 13

The personnels of an institution and organ bank are obligated to to maintain the confidentiality of a third party's private information known or obtained while practicing, and shall not disclose it without reason.

Article 14

The central competent health authority may conduct examination of the organ bank of an institution and review relevant records and documents, to which, the institution and its personnel shall not evade, interfere or refuse.

In the case of the necessity to examine an organ bank set up in a foreign country, the central competent health authority may require cooperation of inspection from the institution that store human organs in a foreign organ bank to provide the related documents of import source. The required documents shall apply mutatis mutandis to the rules of sub-paragraphs of Article 9.

Article 15

An organ bank that plans to cease operation shall submit a proposed action plan three (3) months in advance to the central health authority for prior approval.

Article 16

An institution shall not post advertisements that make exaggerated and untruthful claims.

Article 17

When an organ bank has any incident that apparently would adversely affect the function or safety of the preserved organs, the organ bank shall immediately make report to the central health authority and take prompt and appropriate actions.

Article 18

An institution whose organ bank permit has been revoked or annulled by the central health authority due to violation of these Regulations is barred from applying for the establishment of an organ bank within one (1) year.

Article 19

When an institution apply for permit of establishment, changes, and extension of an organ bank or to examine an organ bank set up in a foreign country, a fees shall be charged for the application; The charge item and fees shall apply to rules of the Fee-charging Standards for Human Organ Bank Review.

Article 20

The central health authority may appoint or mandate another agency or juristic person or organization to handle the following matters:

1. Document review and onsite inspection related to permit application for organ bank establishment as provided in Article 9, Article 10 and Paragraph 3 of Article 11 herein.
2. Review related to the application for change of registration and extension of permit extension as provided in Paragraphs 3 and 4 of Article 11 herein.

3. Examination related matters as provided in Article 14 herein.

Article 21 (Deleted)

Article 22

These Regulations shall be implemented on the date of promulgation.