

BASIC STANDARDS FOR OPERATING A HUMAN TISSUE BANK

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Tissue Bank Quality Assessment Form

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I. INTRODUCTION

The Guideline Committee of JSTT has composed “Guideline on the Safety, Storage & Application of Human Tissue in Medical Practice,” in which JSTT has described its current thinking on the medical application of human tissue from the viewpoint of scientific association. Every organization that belongs to JSTT or that stores human tissue is recommended to be in conformity to this Guideline for the practice of a fair, reliable and transparent operation. Meanwhile, it is advisable to note that, including this document, an official guideline with legally enforceable responsibilities for a tissue-banking institution or its operations has not yet been established.

On 26 December 2000, the Pharmaceutical Safety Bureau of the former Ministry of Health and Welfare (present Ministry of Health, Labour and Welfare) issued Notice No. 1314 “Guideline for safety and quality in medical products manufactured from human/animal derived materials.” The notice has been issued for commercial manufacturing/companies, but JSTT recognizes that tissue banks belonging to JSTT are also recommended to comply with this Guideline. In addition to this notice, in 2002 the Japanese government has enforced stricter regulations for medical products made from animals, such as bovine-derived material, to be on the alert for infections like BSE. These regulations are part of the so-called “Revised Pharmaceutical Law.” The revised law demands relevant organizations to secure quality control with high accuracy and to establish Standard Operating Procedures (SOP). In view of the legal environment of today, the Registration Committee of JSTT has drawn up this Basic Standard from “Guideline on the Safety, Storage & Application of Human Tissue in Medical Practice” prepared by the JSTT Guideline Committee, to present criteria for starting up and operating a tissue bank. JSTT expects the Basic Standard will help every tissue bank to maintain high quality operations.

II. PURPOSE OF THE STANDARD OPERATING PROCEDURES FOR A HUMAN TISSUE BANK

The purpose of the SOP is to guarantee safe and efficient operations and to secure the ethical and technological correctness of tissue banks in Japan. Every tissue bank is expected to obtain these qualities by complying with “Guideline on the Safety, Storage & Application of Human Tissue in Medical Practice” prepared by the JSTT Guideline Committee.

III. PRINCIPLES OF A TISSUE BANK

Observance of the following fundamental principles is essential to secure the ethical adequacy in utilizing human tissues for transplantation.

A. Thorough Practice of Informed Consent

It is required to obtain informed consent through providing sufficient information about retrieval of tissue to the donor party and about transplantation of human tissue to the recipient party.

B. Securing of Respect for the Donor

Donation of human tissue is a sublime act for society with goodwill. When handling donated human tissues, a tissue bank and transplant organization must keep the respect for the dignity, intention and good faith of the donor party.

- C. **Guarantee of the Free Will Decision for the Donor**
The potential donor has no obligation to donate human tissue and may also refuse to receive or to accept information or interview about it. The free will and intention of the donor (or the bereaved family of a deceased donor) should be given the first priority, and no unjust pressure should be given to the donor party in their decision-making process.
- D. **Donation Must be Done on a Non-profit Basis**
Donation of human tissue is a sublime and public act for society with goodwill, and due to this characteristic, it is necessary to make sure that there is no financial consideration given or claimed over donation. However, a tissue bank can claim reasonable amount of actual expenses (e.g., cost for retrieval, storage, distribution, personnel, transportation, etc.), which are not deemed as financial consideration. As a non-profit organization/institution, a tissue bank should not quote an unfair amount greater than the actual cost in order to produce profits.
- E. **Protection of Personal Data**
In the management of a tissue bank, personal data, such as name, age, etc., of the donor and recipient must be protected as confidential information.
- F. **Fulfilment of the Donor's Good Intentions**
In handling donated human tissues, an organization or institute should make the best effort to fulfill the wish of the donor, and to secure the ethical appropriateness and respect for the good intentions of the donor.
- G. **Provision of Information**
As a social and public organization, a tissue bank is obliged to make its activities public, while adequately protecting personal and confidential data.

IV. ORGANIZATIONAL OR INSTITUTIONAL REQUIREMENTS FOR A TISSUE BANK

To operate a tissue-banking organization or institution, the following requirements need to be fulfilled.

1. It is clearly defined who is the chief director of the organization, being in charge of its overall management.
2. The organizational operation and implementation guidance should be prepared and documented
3. Meetings to discuss the tissue bank's operation policy must be regularly held, and minutes of each meeting should be kept.
4. Accounting records of a tissue bank should be accurately kept in written form. It is necessary to have an established system of accounting, and receive regular audits. The accounting records should be available for disclosure when requested. Where the bank is operated on research expenditure, clear records must be maintained of the settlement balance.
5. The organization of the bank must be clearly structured and systemized.

6. A system to protect personal and confidential information should be established. (i.e., a tissue bank needs to have a manager of confidential data and an established system for data storage/administration in written form)
7. Clear indication of each managerial responsibility in retrieval, storage, and distribution of human tissues.
8. Inspection by a neutral party must be conducted to assess the fairness in distribution and techniques in retrieval and preservation of human tissue.

V. CRITERIA FOR INFORMED CONSENT

Prior to the retrieval of human tissue for transplantation, informed consent must be obtained in conformity with the following requirements.

1. Prior to retrieval of tissues, written consent must be obtained from the donor or his/her next-of-kin (when donation is made after the donor is deceased).
2. As described in (III-C), the donor party should be guaranteed complete disclosure about donation, and they have no obligation to donate or to accept information or interviews about it. When met by a rejection from the donor party, the session to provide information should be immediately discontinued. It must also be made clear that the donor party holds the right to refuse or to undo previous decisions without any disadvantage caused to them.
3. In order to keep an objective standpoint, a neutral person, such as a coordinator should give the donor party the information about donation. In case such option is unavailable, the physician of the procuring tissue may provide the donor party with information, with the witness of a third party. (e.g., other physician, doctor of the procuring hospital, nurses, etc.)

VI. CRITERIA FOR AN ELIGIBLE DONOR

When a specific disease or condition is observed in a donor, cells or tissue of such donor should not be procured or used. It is necessary to conduct the interview, inspection and palpation of donors, in as much detail as possible. Interviewing the donor's bereaved family or next-of-kin is also required as well as studying the donor's medical records. The parameters, criteria and methods of interview and inspections need to be regularly reviewed for updating.

1. Criteria to judge donor's eligibility must be collected and checked from results of interviews and medical records. Serological and bacteriological tests must be performed on procuring tissue. Where a pathological autopsy is planned, the findings of it should be also taken into account.
2. If the donor died from an adventitious cause, an autopsy conducted by a police surgeon or an inspection doctor must be completed in advance.
3. Appropriate screening tests need to be performed for each kind of tissue.
4. When performing each test, the latest method at that time must be employed.
5. All donors must meet the donor suitability requirements presented in "Guideline on the Safety, Storage & Application of Human Tissue in Medical Practice" and be reviewed in advance.

VII. RETRIEVAL OF HUMAN TISSUE

A tissue bank should have an organized system for proper and appropriate processing and techniques.

1. A physician and an organization that procures human tissue should obtain advance approval from the institutional ethical committee or its equivalent on the proceedings and method of retrieval. The organization should also have an established system for retrieval.
2. Sufficient level of medical technology and respect for the dead must be both observed when procuring human tissues.
3. Proper equipment/device and technique must be utilized to procure human tissue.
4. The recipient organization is not responsible for inferior quality of equipment/device used in retrieval.
5. Documentation proving the recovery room environment as aseptic as possible must be obtained, and pre-processing cultures must be performed during the retrieval procedure.
6. Proper consent and written agreement from the recovery hospital must be obtained prior to human tissue retrieval.
7. A tissue bank or a relevant network must be in charge of storage and management of retrieval records.

VIII. SAFE AND EFFICIENT STORAGE OF PROCURED HUMAN TISSUES

Prompt preservation to retain quality of procured tissue is as important as preventing contamination, and eliminating bacteria in the procedure.

1. Utmost effort must be made to prevent microbial contamination during the preservation process of procured tissue.
2. Appropriate microbial review and screening tests must be performed at each stage of the preservation process.
3. Validation of room cleaning protocol to avoid cross-contamination of tissues during processing and preservation of tissues must be maintained.
4. A tissue bank must have an established system to retain optimal quality of stored human tissue.
5. Storage records must be kept and archived. Such records should be available to disclose whenever requested.
6. Storage and Transplant records must be kept for 20 years.
7. Expiration date should be determined for all tissues. Expired tissue should not be used for transplantation.

IX. DISTRIBUTION OF HUMAN TISSUE TO A TRANSPLANT INSTITUTION

Quality control and fair allocation are essential in the distribution of human tissue.

1. When a tissue bank distributes human tissues to a transplant organization, the allocation of tissues must be made fairly and impartially. Selection of a recipient must be done carefully based on demand.

2. A tissue bank must provide information to the transplant organization about the criteria, method, and results of donor screening tests as well as the processing procedures of procured tissues.
3. A tissue bank must keep, maintain confidentiality and archive records of each donation and distribution. Samples of tissues or serum should be retained. Allograft transplant records about recipients and procedures in processing and preservation must be available.
4. A transplant organization must maintain a log of adverse reaction of recipients.
5. A system that provides traceability of records must be established.

X. CLOSING REMARKS

When activities of tissue banks gain more credibility and greater acceptance from our society, both basic and clinical research in Japan will pick up momentum, and that will lead to a general advancement and improvement of clinical technology with human tissue. JSTT believes that fair and impartial operation of tissue banks complying with this Basic Standard will pave the way for a thriving future of transplant medicine in Japan.

Appendix 1

Tissue Bank

Quality Assessment Form

Name of organization inspected

Name of inspector(s)

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2. Organizational or institutional requirements for a tissue bank

2-1. Is there an organized system with clear indication of the chief director, who is responsible for overall management of the organization?

Notes [Yes No]

2-2. Is there a written description of organizational operation and implementation guideline?

Notes [Yes No]

2-3. Are sessions of the operational committee and ethical committee regularly held? Are minutes of each meeting properly kept?

Notes [Yes No]

2-4. Is accounting of the organization correctly administrated?

Notes [Yes No]

2-5. Are the activities plan and the revenue and expenditure budget prepared in order to keep a sustainable management of the organization?

Notes [Yes No]

2-6. Are there written records kept to present the tissue banking operations and the financial condition?

Notes [Yes No]

2-7. Is the secretariat of the tissue bank clearly structured and systemized?

Notes [Yes No]

2-8. A tissue bank can claim reasonable amount of actual expenses (processing fee) of human tissue to other organizations. (i.e., cost for retrieval, storage, distribution, personnel, transportation, etc.) As a non-profit organization, a tissue bank should not quote an amount greater than the actual cost in order to produce profits. Compliant?

Notes [Yes No]

2-9. Is there an established system to protect confidentiality of personal data? (i.e., there is a person in charge of managing confidential data, or the storage/management operation being described and kept in written form, etc.)

Notes [Yes No]

2-10. Is there clear indication of each managerial responsibility in retrieval, storage, and distribution of human tissue?

Notes [Yes No]

2-11. Does the organization receive regular inspections conducted by a neutral party for the evaluation of fairness in distribution and for the assessment of techniques in retrieval and preservation of human tissues?

Notes [Yes No]

3. Informed Consent

3-1. Prior to retrieval, is a written consent obtained from the donor or (when the donor is deceased) the donor's next-of-kin?

Notes [Yes No]

3-2. If it is clear from an objective point of view that the donor is incapable of giving consent by him/herself, a representative of the donor (next-of-kin, etc.) may give consent on behalf of the donor. In such case, does the representative receive sufficient information in written form before granting consent?

Notes [Yes No]

3-3. On providing the donor party with information about human tissue donation, it must be performed in conformity to what is described in above 1-3, and the freewill of the donor party must be prioritised and considered. Are there any unjust verbal pressure observed to oblige the donor party to accept the information against their will, or to give consent to donation?

Notes [Yes No]

3-4. When the donor party wishes to discontinue the explanation of the donation process, is it responded by an immediate cease?

Notes [Yes No]

3-5. When explanation and information to be provided after cardiac arrest of the donor, is sufficient care and consideration made to respect the feelings of the donor's next-of-kin?

Notes [Yes No]

3-6. The donor party has the right to refuse or to undo previous decisions about donation, without any disadvantage caused to them by doing so. Are these points made clear in the explanation process?

Notes [Yes No]

3-7. In order to keep a neutral ground, does the coordinator provide explanation and information?

Notes [Yes No]

3-8. Where a coordinator or its equivalent is unavailable, a physician who procures tissue may provide the donor party with explanation. In such case, is there a witness (e.g. other physician or doctor of procuring hospital, nurses, etc.) present?

Notes [Yes No]

4. Donor's Eligibility

4-1. Are parameters to determine donor's eligibility, such as medical/social interviews and medical records, collected and reviewed?

Notes [Yes No]

4-2. Are serological and bacteriological tests performed on the donor and recovered tissue(s) ?

Notes [Yes No]

4-3. If a pathological autopsy is available, are results reviewed in the evaluation of donor suitability?

Notes [Yes No]

4-4. Is there a letter of consent in which shows the donor did not object to donation of human tissues during his/her life? Or, for a deceased donor, is there a written consent granted by the donor's next-of-kin in which they agree to human tissue donation?

Notes [Yes No]

4-5. If the donor was deceased from an external cause, the autopsy by a police surgeon or an pathologist must be performed and completed. Is this checked before retrieval?

Notes [Yes No]

4-6. Are appropriate screening tests performed for each kind of tissue?

Notes [Yes No]

4-7. Are screening tests performed with latest approved methods?

Notes [Yes No]

4-8. Is the donor's suitability presented in "Guideline for the safety, storage and application of human tissue in medical practice" evaluated by a medical doctor?

Notes [Yes No]

5. Retrieval of human tissue

5-1. A physician and an organization that procures human tissue should obtain advance approval from the internal ethical committee or its equivalent on the proceedings and method of retrieval. An established cooperative system in procuring human tissue is also necessary within the relevant organization.

Notes [Yes No]

5-2. Medically and ethically proper technique and sense of respect for the dead must be maintained in retrieval of human tissue. Compliant?

Notes [Yes No]

5-3. Are proper equipment/device and technique prepared in order to maintain the quality of human tissue procured?

Notes [Yes No]

5-4. The quality of equipment/devices used in retrieval must be as good as not to cause any trouble to the organization being granted procured tissues. Compliant?

Notes [Yes No]

5-5. Is procuring room environment kept as aseptic as possible? Is bacteria clearance performed as thoroughly as possible during the retrieval?

Notes [Yes No]

5-6. Is permission obtained or is there a written agreement for recovery from the director the donor hospital/organization prior to the human tissue retrieval?

Notes [Yes No]

5-7. Does the organization or a relevant network maintain and securely store retrieval records?

Notes [Yes No]

6. Safe and efficient storage of procured human tissue

6-1. Is utmost effort made to prevent microbial contamination during the preserving process of procured tissue?

Notes [Yes No]

6-2. As well as practicing appropriate microbial sterilization, are screening tests performed at each stage of the preservation process?

Notes [Yes No]

6-3. Is sufficient level of cleanliness validated to prevent cross-contamination in the room for processing and preservation of tissue?

Notes [Yes No]

6-4. Does the organization perform regular audits of the room environment?

Notes [Yes No]

6-5. Is there an established system, with clear indication of responsibility, for maintaining the quality of human tissue stored at the organization?

Notes [Yes No]

6-6. Are storage records of human tissue appropriately kept and archived so that they are available for review?

Notes [Yes No]

6-7. Is a valid date given to tissues procured, and are expired tissues (not to be used in transplantation) appropriately discarded?

Notes [Yes No]

7. Distribution of human tissue to a transplant organization

7-1. Is a fair distribution of human tissue practiced?

Notes [Yes No]

7-2. Is selection of recipient practiced carefully (based on equal opportunity)?

Notes [Yes No]

7-3. Does the (distributing) organization appropriately provide information to a transplant organization about the criteria, procedures, and results of donor screening tests?

Notes [Yes No]

7-4. Does the organization appropriately keep and archive records of its distribution with sufficient care to protect personal data?

Notes [Yes No]

7-5. Does the organization retain samples of tissues or serum for future review?

Notes [Yes No]

7-6. Are records of donor, recipient and procedures of processing/preservation kept and available for review at any time?

Notes [Yes No]

7-7. Does the tissue bank review prognostic records of recipient and adverse reaction of transplantation.

Notes [Yes No]

7-8. Is there an established system that can provide traceability in transplantation when necessary?

Notes [Yes No]