Japanese Society of Tissue Transplantation

GUIDELINE ON ETHICAL ISSUES IN APPLICATION OF HUMAN TISSUE TO MEDICAL PRACTICE

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CONTENTS

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INTRODUCTION

The primary mission served by those involved in the field of transplantation medicine is protecting lives and contributing to the improvement of quality of life (QOL) through highly specialized medical transplantation procedures. Many years have now passed since groundbreaking surgical methods for kidney, heart, lung, liver, pancreas, cornea, skin, bone/ligament, bone marrow, and heart valve transplantation have taken hold, both internationally and in Japan.

In addition to the ethical issues of ordinary medical care, transplantation medicine has the special characteristics of requiring an organ/tissue donor, so that the ethical considerations for both donor and recipient sides is indispensable. Regarding organs, various ethical and legal issues related to organ transplantation, including necessary processes for that are mentioned in the "the Organ Transplant Law". However, there are currently no official guidelines concerning ethical issues related to the tissue transplantation, thus signifying the urgent need to prepare and standardize such guidelines. Starting from these perspectives, the Japanese Society of Tissue Transplantation (JSTT) has now drafted the ethical guidelines for the transplantation of human tissue donated from a deceased donor. Fortunately, there is a transcript of a tentative draft drawn up by the Special Subcommittee (Tissue Transplantation Section) of the Public Health Council of the former Ministry of Health and Welfare (MHW) (Chairman: Prof. Kikuo Nomoto, Dept. of Immunology, Kyushu University) held in fiscal 1999, in which the ethical policy for tissue transplantation has been described. In developing our guidelines, JSTT has taken the former MHW's policy draft as our basis and reflected changes of social conditions made since then.

Then in 2009, "the Organ Transplant Law " was revised, and the "Regulation for Enforcement of the Organ Transplantation Law" and "Guidelines to Application of the Organ Transplantation Law (Guideline)" were also revised. Along with this, the legal and medical requirements for organ donation after death, the consent procedures, and the procedures leading up to organ recovery have been revised. In 2014, the "Act on Securing Safety of Regenerative Medicine", "Regulation for Enforcement of Act on Securing Safety of Regenerative Medicine" and "Order for Enforcement of the Act on Securing Safety of Regenerative Medicine" were enacted, and allogeneic pancreatic islets transplantation falls under Type 1 Regenerative Medicine (in the case of autologous pancreatic islets transplantation, under Type 3 Regenerative Medicine).

In 2010, JSTT established a system for diversion of tissues stored in the tissue bank to the research and “Appropriate Use Review Committee”, and formulated "Guidelines on Tissue Use for Research" and "Guidance on Tissue Supply for Research". Furthermore, several emerging infectious diseases that may be transmitted by transplantation have also been reported since the 1st edition of this guideline was published. In the context of these circumstances, this guideline has been revised in order to respond to the aforementioned situational changes, both inside and outside the country.

This guideline is primarily applied to JSTT members. However, JSTT expects not only JSTT members, but also researchers at universities and laboratories, to observe and strictly abide by this guideline, as it was formulated with due consideration to Notification No. 1314 of the “Ensuring the Quality and Safety of Pharmaceutical Products Manufactured from Human/Animal-Derived Materials” issued by the Pharmaceutical and Medical Safety Bureau of the former MHW.

At present, skin, heart valves, blood vessels, bones, ligaments, pancreatic islets, trachea/bronchi, corneas and amnion are procured and stored for medical application in Japan. Several tissue banks for managing the storage and distribution of donated tissue have been established, and the banking system is now organized. However, there is currently no law regulating the tissue transplantation, but Article 5 of “the Organ Transplant Law” and Article 1 of its “Regulation for Enforcement of the Organ Transplantation Law” only deal with organs for the transplantation.
Regarding the transplantation of human tissues in this law, only the basic policy is shown in the "Guidelines to Application of the Organ Transplantation Law" (Guideline, Nortification No. 712001), saying that "It is permissible when it is performed as a medical act with the consent of the person or the bereaved family, and when it is deemed to be appropriate from a medical point of view and from a social point of view.”(Article 14).
It should be noted that the "Act on Securing Safety of Regenerative Medicine" stipulates that the transplantation of allogeneic pancreatic islets is Type 1 Regenerative Medicine (in cases of autologous pancreatic islets transplantation, it corresponds to Type 3 Regenerative Medicine).

This guideline establishes certain guiding principles regarding issues related to the ethical validity and safety of tissue use, and also conditions for the donated human tissue to be used for medical treatment and research are included. In tissue banks organized

for the purpose of transplanting human tissue or using it for research, full transparency and public awareness of its operation must be taken into consideration, and ethical validity and concrete safety must be strictly ensured (Reference: JSTT Guideline on the Safety, Storage, and Application of Human Tissues in Medical Practice). Regarding the use of human tissues for institutional and corporate research, education, training, and other purposes, tissues provided by a JSTT-certified tissue bank are targeted.

In the future, it is expected that tissue banks will be properly operated in strict accordance with this guideline, and that society, as a whole, will broaden and deepen their understanding and overall trust in the use of human tissue for the betterment of healthcare.

1. BASIC POLICY

This guideline, in principle, presents ethical issues for persons engaged in the tissue transplantation or its research, general researchers and research institutes (including research institutes such as companies), and when handling human tissues, on the premise of respect for human dignity and protection of human rights, the public nature and transparency of banking work must be ensured, and at the same time, the safety of those engaged in the work must be ensured.

2. TISSUES SUBJECT TO THIS GUIDELINE

Human tissues subject to this guideline are skin, heart valves, blood vessels, bones, ligaments, pancreatic islets, trachea, bronchi, and corneas donated in good will from deceased donors. Tissues retrieved from living donors such as skin, bones, ligaments, heart valves, blood vessels, amnion, and pancreatic islets are also included in the guideline.

3. COMPLIANCE WITH THE BASIC PRINCIPLES IN APPLICATION OF HUMAN TISSUE

When using human tissue, the following seven principles must be strictly observed to fully ensure ethical validity and safety.

3-1. Ensuring voluntariness regarding the donation of human tissue.

The donation of human tissues should be based on the free will of the donor and family members (in the case of donation from the living, the donor himself/herself, but in the case of minors, the family (parental authority, legal guardian), and in the case of donation from the deceased, the family (including the bereaved family) who respect the will of the donor himself/herself). And there should be no pressure on the donor side in the donation decision-making process.

3-2. Informed consent of the donor/recipient.

The donor and/or family must receive sufficient information of the process of donation, as well as the procedures of tissue retrieval and how the tissue would be used, before making the decision to donate. The recipient and his/her family must be given sufficient information of the efficacy and potential risks of human tissue transplantation before deciding to undergo the transplantation.

3-3. Retaining social/public responsibilities and ensuring the dignity of the donor.

The donation of human tissues is a sublime act done under good will for the benefit of society. Tissue banks and transplant facilities that receive donations must ensure the dignity of the donor and treat the tissue with respect for the donor's free will and goodwill toward society.

3-4. Donation should be done on a non-profit basis

Donation of human tissues is to be carried out without any dompensation. Financial reward must not be offered for the donation of tissues. Operating as a non-profit organization, a tissue bank cannot claim or receive financial gain for the distribution of human tissues. In addition, after the donation is made, the donor side cannot claim the right to be provided with financial reward, property, or other benefits for the donated human tissue.

3-5. Ensuring the safety and efficacy of donated human tissues.

In view of that those engaged in the banking and transplantation of human tissue must be fully aware of the purpose of human tissue donation, which is solely for the treatment and benefit of the recipient, the safety and efficacy in retrieval, processing, storage, and transplantation of human tissues must be strictly maintained. The related parties should also be made fully aware of the potential risks of transmittable infection that can occur through transplantation, and must therefore endeavor to collect the detailed information of such risks. For that specific purpose, it is vital to establish a prompt and

close communication system between the organ/tissue donation facilities, the organ/tissue transplant facilities, the Japan Organ Transplant Network, the Japan Society for Transplantation, the JSTT and the tissue banks.

3-6. Protection of personal information.

All personal information must be protected for donor and recipient confidentiality. Those involved in the organ/tissue donation and the tissue banking shall strictly manage information that identifies the donor side or recipient side, and information that they do not want to be known, and such information must not be leaked. Information about the donor side and information about the recipient side must not be transmitted to each other. For this purpose, it is necessary to appoint an information manager. The official JSTT basic policy for the handling of personal information is shown below. It is desirable that the official basic policy be posted both inside and outside the facility at each tissue bank so that it can be clearly informed.

3-6-1. Basic Policy for Handling Personal Information in the Tissue Bank.

Based on the Personal Information Protection Law and Research Ethics Guidelines, JSTT has now formulated the "Basic Policy for Handling Personal Information in Tissue Banks" to comply the law:

3-6-1-1. The tissue bank clarifies the purpose of use of personal information, and handle it only to the extent necessary to achieve that purpose.

3-6-1-2. The tissue bank will only acquire the personal information needed for the course of its operation in a legal and appropriate manner.

3-6-1-3. The tissue bank will retain the personal information, handle it accurately and appropriately, and keep it up-to-date to the extent necessary to achieve the purpose of its use.

3-6-1-4. When handling personal information, the tissue bank will take all necessary and appropriate measures to prevent leakage, loss, or damage in order to ensure safe and proper management of the information.

3-6-1-5. The tissue bank will respond in good faith to all complaints and other offers regarding the personal information of all persons involved with the bank.

3-7. Disclosure of the information.

As a social and public organization, a tissue bank must establish the system to disclose information about all of its activities to the general public, while adequately protecting

all personal information.

4. THE BASIC PRINCIPLES IN HUMAN TISSUE RECOVERY.

The recovery of human tissue must comply with the following fundamental principles to ensure complete adequacy of the safety and ethical issues.

4-1. Informed Consent Required for Human Tissue Recovery.

4-1-1. On the occasion of human tissue recovery for transplantation and other purposes, the information must be given with sufficient consideration for the donor. Prior to the tissue recovery, a written consent of donation issued voluntarily by the donor/the bereaved must be obtained. More specifically, after fully explaining the following contents, the document containing the contents of the explanation must be shown and delivered to the donor side.

4-1-1-1. The process of donation, the procedures used for the tissue recovery, and the state of the donor after the tissue recovery.

4-1-1-2. Explanation that the primary purpose of tissue donation is for the transplantation. And explanations on how handle the cases that are not used for the transplantation (i.e., used for research, education, training at a universities or research institutes, companies or otherwise incinerated).

4-1-1-3. Disclosure of donor screening tests results: The results of donor screening tests are to be disclosed to the donor's next-of-kin upon request.

4-1-1-4. Handling of human tissue after its recovery. Recovered tissue is not to be returned to the donor's next-of-kin, except in the case that the procedure is duly approved by the ethical committee, etc.

4-1-2. When explaining tissue donation to the donor's next-of-kin and obtaining their consent, full voluntariness of the donor side must be ensured, and if at any time the donor side refuses to continue with the explanation, that intention must be fully respected. In particular, if it is shortly after death, the bereaved family must be given a sufficient explanation in consideration of the circumstances and feelings of the bereaved family. In the explanation, it must be clearly explained to the donor's next-of-kin that they have the right to refuse consent, and that if refused, no disadvantages will be accrued.

4-1-3. The explanation to the donor side should be given by a person directly associated

with the organization bank, such as the tissue transplant coordinator, in order to fully maintain neutrality of the required explanation. If the explanation to the next-of-kin can't be given by them, then it should be given by someone other than the person who was in charge of treating the donor.

4-2. Procedures in the Recovery of Human Tissues.

4-2-1. In principle, and as described above (4-1), the recovery of human tissues for the transplantation is allowed only after the donor party has been fully informed and the following requirements have been met.
4-2-1-1. The person (himself/herself) has not indicated his/her intention to refuse to donate his/her tissue in his/her lifetime, and full written consent has been obtained from his/her next-of-kin for the tissue donation and subsequent handling of the donated tissue.
4-2-1-2. Sufficient respect for the deceased is maintained, sufficient consideration for living donors is paid, and the recovery of donor tissues is considered to be appropriate from a social aspect.

4-2-2. If the person (himself/herself) has indicated his/her intention to refuse to provide his/her tissue in his/her lifetime, the tissue should not be retrieved, even with the consent of his/her family.

4-2-3. The recovery of human tissues should be performed by a licensed doctor. Special care should be taken not to lose courtesy and gratitude for the deceased throughout the process, and in the case of living donors, not to lose consideration for the donor.

4-2-4. The recovery of human tissues should be performed under aseptic conditions, as much as possible, in order to prevent contamination by any infectious microorganisms and/or other substances during the retrieval process.

4-2-5. Those who are engaged in human tissue banking must not supply, apply for, or promise any profit to the donor party in return for the donation of human tissues.

4-2-6. Those engaged in the tissue bank should strictly manage such information that identifies the donor side or that the donor side does not want to be disclosed, and should strictly adhere to the policy that said information must not be leaked to anyone other than those involved in the tissue bank.

4-3. Donor Exclusion Criteria and Requirements in Donor Screening Tests.

Tissues should not be recovered if the donor candidate meets the exclusion criteria, and also should not be used for the transplantation if found that the exclusion criteria are met after the tissue recovery. It is necessary to conduct a detailed interview, inspection, and palpation with the donor, as much as possible. Interviewing the donor's next-of-kin to obtain the medical/social history of the donor is also required with a full review of the medical record. If pathological (autopsy) findings are available, the results should also be used as a reference. In regard to the various inspection methods, the method deemed most appropriate at that specific time should be adopted. In addition, items such as interviews and tests, and their associated methods, should be reviewed as needed in view of the newest knowledge about infectious diseases and related academic and technological advancements. For that, it is desirable that expert organizations such as the specific related academic societies will cooperate and participate in the review of the criteria, collection, and evaluation of the infectious disease information related to the transplantation.

5. PROVIDING HUMAN TISSUES AND ITS USE FOR THE TRANSPLANTATION

5-1. When a tissue bank supplies human tissues to a transplant facility, it must be conducted fairly based on a written standard. At that time, care should be taken to maintain the fairness of transplantation opportunities in regard to the selection of recipients.

5-2. When the tissue bank supplies human tissue to a transplant facility, it should provide information on the items of the specific donor-screening test performed, the method used for testing and the results.

5-3. In the tissue bank, records related to the supply of human tissues to transplant facilities are to be stored in order to secure the traceability, and properly managed with strict attention to the protection of privacy. Moreover, it is required that a system is established to confirm the information on the donor, the processing method/preservation process, and the recipient records, as necessary. In addition, each record shall be retained for a minimum period of 20 years, however, the records should be retained as long as possible after the 20-year expiration period.

5-4. Before using human tissue for transplantation at a transplant facility, written consent of the recipient is to be obtained. In order to obtain consent, the doctor in charge of the facility should fully explain to the recipient's side the safety, as well as the potential risks related to the transplantation of the human tissue and the expected efficacy of the transplantation.

5-5. When the human tissue is used for transplantation at a transplant facility, it is required to record the tissue bank name and the human tissue identification number in the medical records, and establish a system that enables retrospective surveys and follow-up surveys to be conducted, as necessary.

5-6. In the tissue bank and transplant facility, the information that leads to the identification of the recipient side and that the recipient side does not want to be disclosed, is to be strictly controlled, and such information must not be leaked. For this purpose, an information manager who manages the recipient information described in [7-4] must be assigned. A representative of the tissue bank should preferably act as the information manager.

5-7. The tissue bank, a non-profit/public institution, must not receive any profits from the transplant facilities or from patients as compensation, other than necessary actual expenses, and must not make any request of, or promise to, the patients or transplant facilities. However, administrative expenses related to communication, coordination, recovery, inspection, preservation, and transportation, etc., that are normally required for normal tissue-bank activities will not be considered "compensation".

6. USE OF HUMAN TISSUES FOR RESEARCH, EDUCATION, TRAINING AND OTHER USES.

Article 9 of the "the Organ Transplant Law" states that "Organs removed from corpses pursuant to the provision of Article 6 and not used for the transplantation must be treated in accordance with Regulation for Enforcement of the Organ Transplantation Law (MHLW Ordinance)". And Article 4 of Regulation for Enforcement of the Organ Transplantation Law stipulates that "The organs under Article 9 of the Law (refers to the organs specified in Article 5 of the Law) must be disposed of by incineration".

In case that an eyeball (which is defined as an organ by Article 5 of the Law) is removed for the purpose of corneal transplantation, it must be disposed of by incineration if not used for transplantation, and it cannot be diverted to research, etc. However, corneas that are initially provided for the purpose of research can be used for that research with written consent.

Regarding pancreatic islets, if a pancreas provided for the purpose of transplantation is not used due to it being deemed not suitable for transplantation, it is generally considered that the use of that pancreas for islets transplantation is thought to be inconsistent with the original purpose of Article 9 of the Law. However, it is permissible to use it for islets transplantation, because the purpose of pancreas transplantation and islets transplantation are equivalent. In this case, if it is not used for islets transplantation, it cannot be diverted for the research. However, if it was provided for the purpose of pancreatic islets transplantation from the beginning, it can be used for the research with written consent when not used for the transplantation.

6-1. Accredited tissue banks are provided with human tissues primarily for the use for the transplantation. However, if that tissue cannot be used for the transplantation, or if the family wants it to be used for purposes other than transplantation, it shall be possible to use for the purpose of research/education/training upon obtaining written consent of the family.

6-2. The research refers to the medical research conducted by general researchers of the research institutes such as universities, medical institutions or companies (hereinafter referred to as research institutes/companies), and medical research contributing to disease treatments in cooperation with said persons. And the education and training are for the purpose of research related to human tissue processing technology and for the purpose of the acquisition and improvement of technology of tissue bank engineers.

6-3. When the accredited tissue bank supplies the donated human tissue to research institutes related to transplant medicine or research institutes/companies for research purposes, the “Appropriate Use Review Committee of JSTT” will review the eligibility of the research institution/company and the validity of the research, and then decide whether or not to supply the tissue. In that case, the "Guidelines on Tissue Use for Research" and "Guidance on Tissue Supply for Research" must be strictly observed. In addition, at the research institutes/companies, the ethics committee specified in [7-8]

should confirm the validity of the content of the research and clarify the judgment process.

6-4. Research institutes/companies that receive human tissue supplied from a tissue bank for the purpose of research/education/training are limited to those that manufacture biological medical products. Furthermore, the research institutes and companies must meet the requirements set forth in [6-8]. When tissue is supplied, the ethics committee stipulated in [7-8] should confirm the validity of the content, decide whether or not to supply, and clarify the process.

6-5. When receiving human tissue from an accredited tissue bank and using it at research institutes/companies, the research institutes/companies must record the date of receipt, the source bank name, and the purpose of use, and preserve such records and information.

6-6. When the accredited tissue bank supplies the collected human tissue to research institutes, companies, etc., the ethics committee stipulated in [7-8] should confirm the validity of the purpose of use, decide whether or not to supply it, and prepare and save the record of the notice of the human tissue supply (Form 1-2).
The shipment of the human tissue and information specified in the notice of the human tissue supply (Form 1-2) to research institutions and companies, must be conducted in accordance with ”the revised Act on the Protection of Personal Information" and "Ethical Guidelines for Life Science/Medical Research (8th 1 (3) / (4))".
【Reference】
Personal-related information and special care-required personal information included in the notice of the human tissue supply of the Appropriate Use Review Committee will be provided as pseudonym processing information, which basically does not require informed consent procedures.
In the ”Regarding the revision of the Life and Medical Guidelines for 2nd and 3rd years of Reiwa” accompanied by the revision of “the Act on the Protection of Personal Information", however, it is possible to provide by opt-out if the exception requirements stipulated in “the Act on the Protection of Personal Information” are met.

6-7. The accredited tissue bank is a non-profit and public organization, as stipulated in [5-7] and [7-10], and when supplying human tissues to research institutes/companies, must not charge so-called "compensation" other than the necessary expenses stipulated

in [5-7].

6-8. Requirements for the research institutes/companies

6-8-1. Research institutes/companies must meet the requirements stated in this JSTT Guideline on the Safety, Storage, and Application of Human Tissues in Medical Practice. In addition, research institutes/companies must be approved by the Appropriate Use Review Committee of JSTT, and be approved for the supply of human tissues.

6-8-2. Research institutes/companies must ensure that operations are carried out in full compliance with the provisions of the “Principle in Handling and Use of Tissue/cell derived Medical Materials" (issued by former Ministry of Health and Welfare Pharmaceutical Safety Bureau, December 26, 2000).

6-8-3. Research institutes/companies must comply with the "Guidelines on Tissue Use for Research" and the "Guidance on Tissue Supply for Research".

6-8-4. Research institutes/companies must be a member of JSTT.

6-9. Review by the Appropriate Use Review Committee of JSTT

6-9-1. When supplying human tissue retrieved for the above purpose, it is premised that it has been reviewed and approved by the Appropriate Use Review Committee of the Japan Society for Tissue Transplantation.

6-9-2. When supplying human tissues, it is required that it complies with this guideline, the "Guideline on the Safety, Storage and Application of Human Tissue in Medical Practice", the "Guidelines on Tissue Utilization for Research", and the "Guidance on Tissue Supply for Research".

7. TISSUE BANK MANAGEMENT

In operating a tissue bank, it is necessary to establish a system that will responsibly, stably, and promptly supply human tissues donated to society in good faith, while paying strict attention to ensuring safety and fairness in transplantation. In specific, the following points should be prepared.

7-1. The representative of the tissue bank must be clear, and the system must be responsible for operations as a non-profit/public institution. In particular, when multiple medical institutions cooperate to set up and operate the tissue bank, there is an agreement among all the medical institutions that they cooperate, and the organization bank must operate in an integrated and responsible manner.

7-2. It is required that the framework for the operation of the tissue bank is clarified, such as the operation and implementation guidelines being prepared in writing.

7-3. A system must be established to ensure appropriateness when retrieving human tissues, and in particular, the following points are required.

7-3-1. The ethical committee specified in [7-8] below has examined and approved the ethical validity and safety of human tissue procurement in advance. In addition, when procuring human tissue at an institution other than the medical institution that establishes and operates the tissue bank, sufficient understanding and cooperation of the medical institution where the tissue procurement is conducted must be obtained.

7-3-2. A record of the procedures related to the recovery of the human tissue must be created and stored at the tissue bank, with its content being confirmed regularly by the internal or external ethics committee specified in [7-8] below.

7-4. A personal information manager must be set up to protect the personal information of the donors and recipients, with a clarified method established for the management of that information.

7-5. The tissue bank that provides the donated tissue used for the transplantation shall be responsible for collecting and managing the follow-up information of each transplant patient that receives the specific selected tissue.

7-6. The tissue bank shall set up a person in charge of quality control for procurement, processing, and storage of the donated human tissues. In additionally, in cooperation with the related organizations and institutions, the tissue bank should regularly educate and train technicians involved in the processing and preservation of human tissues.

7-7. The tissue bank must ensure the transparency of the management. In specific, the implementation status and results of the tissue bank project (i.e., the type, volume, storage status, and usage status, etc., of the tissues procured) must be kept in writing and disclosed upon request.

7-8. In the operation of the tissue bank, the tissue bank is required to set up various committees such as the ethics committee by itself and to establish an institution to make decisions for the entire entity. Alternatively, if the medical institution that establishes and operates the tissue bank has an existing ethics committee, it can be utilized to evaluate the procedures for tissue procurement. In addition, when the donated human tissue is not used for transplantation, a verification of validity related to the use for research, education, training (specified in [6-4]) must be conducted.

7-9. The ethics committee stipulated in [7-8] above should set ethical standards for matters related to the overall operation of the tissue bank, and those involved in the operation of the tissue bank must be thoroughly informed of those pre-set ethical standards.

7-10. A tissue bank as a non-profit/public institution must not receive, request, or promise any profit from transplant facilities or patients, etc., as compensation other than necessary expenses. However, actual administrative expenses (i.e., those related to travel expenses, communication, coordination, and personnel expenses) and actual bank expenses (i.e., those related to the procurement of human tissues, various inspections, preservation, and transportation) normally necessary for conducting activities as a tissue bank will not be considered "compensation".

Since the general public is involved in the donation and use of human tissues through tissue banks, the understanding of society as a whole is essential for the proper establishment of that system. To this end, it is important that all parties concerned, including the tissue bank, must strictly comply with the requirements and standards presented in this guideline, and ensure ethical validity and safety regarding the use of human tissue. JSTT will take strict measures if this guideline is violated in any manner.

CLOSING REMARKS

This guideline is written with a focus on the use of human donor tissue for transplantation purposes, which has already been carried out based on clinical needs, and also presents the official guidelines that must be observed for facilities that are planning to start a tissue bank in the near future through voluntary efforts. In addition with the progress and development of regenerative engineering technology, it is expected that the use of human donor tissues will change significantly, not only in transplantation, but also from the aspect that the use of human tissue may lead to industrial applications in the future and research results using human tissues may be widely and effectively used. With a view to the above, the creation of rules is also mentioned in this guideline.