

Facts for the Family to Understand about Organ Donation

About the Japan Organ Transplant Network

The Japan Organ Transplant Network, a public interest incorporated association, is the sole organization in Japan that serves as an organization to ensure that organs are allocated to patients who wish to receive organ transplants (“recipients”) based on the will and consent of the person who wish to donate organs after death (“donors”) and their families.

○ Mission Statement

[Our Mission]

We will contribute to the advancement of transplant medicine through legitimate organ procurement.

[Our Values]

- Fairness and Equity

We will respect the four rights (right to donate organs, not to donate organs, to receive an organ transplant, and not to receive an organ transplant) in a fair and equitable manner.

- Transparency

We will ensure transparency by providing appropriate information.

- Sincerity

We will establish a reassuring environment and behave with sincerity and cordiality.

- Cooperation

We will develop highly professional human resources to cooperate in a multidisciplinary approach.

- Pride

We will make efforts so that all people can retain pride and passion together.

[Our Vision]

Through the advancement of transplant medicine, we will pursue a society that respects the life of each individual person.

Facts for the Family to Understand about Organ Donation

1. Donating organs

Organ donation is one of the choices that can be made after death, based on the decision of the patient and the consent from the patient's family. Organ transplantation is medical care made possible by the altruism of organ donation.

There is no obligation to listen to our explanation until the end, and feel free to tell us that you no longer wish to at any time. If you wish to be informed again or have any questions, we will always be available. Non-family members may be included in the explanation if the family wishes.

After being informed, please thoroughly discuss with your family before making a final decision. We will respect the patient's and family's decision.

Please feel free to tell us if a change in the decision for organ donation occurs within the family after you have given consent and wish to withdraw from organ donation. It is possible to withdraw consent at any time as long as it is before the organ recovery surgery.

2. What is organ donation?

The organs donated are transplanted to patients with severe impairment or loss of organ functions due to congenital or acquired disease. After receiving the transplant, such patients can recover from life-threatening situations or improve their quality of life.

At the same time, it should be understood that organ transplantation, varying with such factors as the function of the organs and the condition of recipients, may not necessarily go well even using current medical technology.

3. The Decision of the Patient and Organ Donation

Under law, organ donation from a deceased person is permitted in either of the following conditions:

- The individual possesses a documented decision to donate organs, and the family has given consent for organ donation.
- The individual has not expressed a refusal to donate organs, and the family has given consent for organ donation.

If the individual has not refused to be tested for brain death and the family has given consent for the brain death diagnosis, brain death diagnosis is performed twice as required by law. The time at which brain death is diagnosed becomes the time of death, which afterwards the heart, lungs, liver, kidneys, pancreas, small intestine, and eyes (cornea) can be donated.

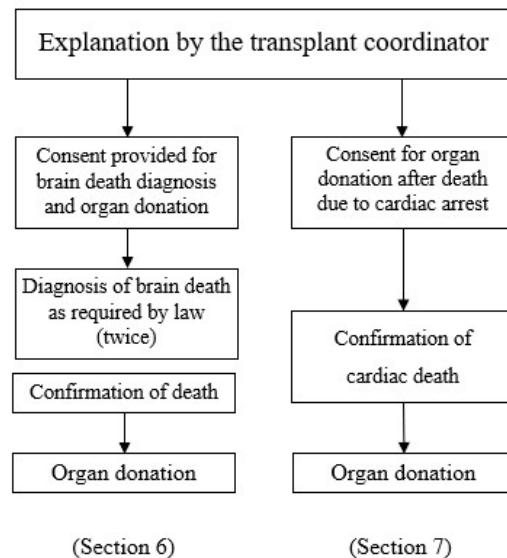
After confirmation of death by circulatory cessation, the kidneys, pancreas, and eyes (corneas) can be donated.

When the individual has a documented decision to donate organs and additionally has a documented decision to donate organs to relatives, relatives who are registered recipients with the Japan Organ Transplant Network will have priority to receive the organs (see page 8 Appendix).

When the individual has expressed the intention not to donate organs either in writing or verbally, organ donation cannot be permitted. The family members should again confirm whether the patient does not have a decision not to donate organs based on daily words and/or actions.

Organ donation is not permitted from an individual who is considered to have difficulty in expressing a valid decision to donate organs.

<Flow from explanation to organ donation>



4. Consent from the Family

The full understanding and consent of all members of the family is necessary for organ donation. If any family member disagrees, please discuss thoroughly before making a conclusion.

If all family members reach a conclusion to donate, a representative of the family must sign the consent form.

Organ donation after brain death and organ donation after death declared by circulatory cessation are described in Sections 6 and 7 below, respectively.

5. The Procedures Following Consent for Organ Donation

To determine whether the donated organs will work in the body of the recipient, medical information (such as medical charts and diagnostic images) about the donor is reviewed. In addition, tests, examinations, or preoperative procedures, as described below, are necessary after consent is

given. Although these procedures are not intended for treatment of the donor, please understand the necessity of these procedures for donation.

(1) About Access to Medical Information and Examinations

A procurement coordinator will obtain the patient's medical information and treatments provided to the patient from hospital admission up to the present. This includes the medical chart and diagnostic images, such as CAT scans, ultrasound images, and X-ray images.

In addition, please acknowledge that organ recovery and transplant physicians will perform examinations and review medical information to assess the function of the organs donated.

The medical information obtained will be communicated to the facilities where the transplantation may be performed to determine whether or not transplantation is possible. In addition, medical information is retained for future treatment of the recipients. Please acknowledge that the information obtained will be utilized after statistical processing for the development of medicine.

(2) Regarding Tests and Procedures

Laboratory blood tests and other necessary tests will be performed as needed. In addition, samples (such as blood samples and pathological tissue samples) are collected and stored as needed. You may be notified of the results of the individual tests upon request.

To perform the following tests, blood samples are collected at the time the consent form is signed:

(i) Test for infections and (ii) histocompatibility test (HLA test) and lymphocyte crossmatch test.

(i) Test for Infections

If the donated organs have any bacteria or virus infection, they may cause the recipient to develop a risk of infection. Therefore, a blood test is performed to determine the presence or absence of infections.

Virus tests: HBs antigen, HCV antibody, HIV antibody, HTLV-1 antibody, West Nile Virus (in the presence of a travel history within four weeks), etc.

(ii) Histocompatibility Test (HLA test) and Lymphocyte Crossmatch Test

For kidney and pancreas transplants, the priority of recipient selection is based on the results of donor histocompatibility tests. This histocompatibility test is assessed by white blood cell (HLA) typing.

Additionally, tests to assess the compatibility between the donor and recipient (a lymphocyte crossmatch test) is also performed by utilizing blood samples of both the donor and the recipient.

(iii) Procedures

To stabilize blood pressure and urine volume or prevent infection, procedures such as intravenous fluids or blood transfusions (including blood products) are performed as needed. These procedures are continued until organ recovery.

All the above steps are performed after receiving approval from the attending physician.

6. Brain Death Diagnosis and Organ Donation

(1) Brain Death and the Diagnosis of Brain Death

Brain death is a condition in which the function of the entire brain, including the brain stem which controls respiration, are irreversibly lost. When brain death occurs, consciousness is completely lost, response to pain or external stimuli does not occur, and breathing on one's own is not possible. With the assist of respirators, heartbeat can be temporarily maintained, but eventually the heart will stop beating.

To confirm brain death, the diagnosis of brain death is performed. The method of testing the diagnosis of brain death for organ transplant is strictly specified by law.

- Deep coma
- Pupils that are fixed and dilated beyond a certain level
- Loss of brain stem reflex to stimuli
- Flat brain waves
- Loss of spontaneous respiration

Two or more experienced physicians who are independent from organ transplant confirm the above set of tests and again confirm the same set of tests at least 6 hours apart (at least 24 hours apart for children under 6 years).

One set of the brain death diagnosis usually takes about 2 hours. If injury to the cornea precludes any of the tests, the diagnosis of brain death may be not be able to be made.

In addition, brain death cannot be diagnosed in individuals with unknown causes of brain death, low body temperatures, acute drug poisonings, or metabolic and endocrine diseases, such as hepatic comas and diabetic comas.

After the brain death diagnosis is performed, the family will be notified of the results. In addition, the family may witness the process of brain death diagnosis if desired. Please tell us if you wish to witness the process.

When brain death is diagnosed through the process of the legal diagnosis of brain death for organ donation, death is legally pronounced, and the time at which the second diagnosis of brain death has been completed becomes the time of death.

After completion of the brain death diagnosis for organ donation, the time of death cannot be changed even if the consent for organ donation is withdrawn, if organs cannot be donated for reasons described in Section 8 below, or any other reasons.

(2) Regarding the Organ Recovery Operation

Family members are to say farewells with the patient in the hospital room before the operation. If you have any requests when doing so, please tell us. The start time of the operation needs to be coordinated with the persons involved and will be notified once it has been determined.

The organ recovery operation will be performed in the operating room by a specialized physician. Although an operative scar is necessary in the chest and abdomen, such scars will be sutured neatly and covered with gauze or tape after the operation so that they are not directly visible.

When donating the eyes, eye prostheses are used, and the eyelids are closed after donation. For the organ recovery, surrounding tissues (such as blood vessels, ureters, lymph nodes, and spleen [see page 8 Appendix]) accompanying the organs must be recovered.

Although the time required for the operation varies with the organs donated, the operation takes approximately four to five hours. The time from the start of operation to the return of the donor's body to the family is expected to be five to six hours. If other tissues are recovered, more time will be needed in the operating room.

7. Organ Donation after Death Declared by Circulatory Cessation

(1) Regarding Procedures (Insertion of Catheters and Injection of Heparin) Before Circulatory Cessation

The following procedures are performed with the family's consent after brain death is diagnosed:

(i) Insertion of Catheters

If there is no blood flow to the kidney after circulator cessation, its function rapidly deteriorates. As a result, the kidney may not be utilized for transplantation even when it is donated.

For this reason, catheters (tubes for medical use) are inserted at the time when circulatory cessation is expected to occur soon. Placing catheters in the femoral artery and vein (the artery and vein at the base of the legs) before cardiac arrest and injection of a medical solution into these catheters immediately after death declared by circulatory cessation cools the kidneys from the inside to preserve function. When this procedure is performed will be determined by the attending physician, the recovery physician, and the coordinator and communicated to the family before proceeding. This procedure usually takes approximately one and a half hours. Prolonged catheter placement may deteriorate the blood flow to the legs and cause discoloration of the legs.

(ii) Injection of Heparin

Cessation of blood flow after cardiac standstill causes blood to coagulate in the kidneys, therefore not being able to be transplanted. For this reason, a drug called heparin is injected immediately before circulatory cessation to prevent blood coagulation. The use of heparin makes blood less likely to coagulate, but if bleeding occurs it may be less likely to stop.

When it is medically difficult to perform or not possible to obtain consent from the family for the above procedures, heparin will be injected immediately after death declared by circulatory cessation, and the patient will be transferred immediately with cardiac massage to the operating room to undergo the recovery operation. In this situation, time to send out the patient to the

operating room will be shortened.

(2) Regarding the Organ Recovery Operation

After circulatory cessation and the confirmation of death, the organ recovery operation will be performed in the operating room by a specialized physician; therefore, family members are to part with the patient before the operation. Although an operative scar is necessary in the abdomen, such scars will be sutured neatly and covered with gauze or tape after the operation so that they are not directly visible. It will take approximately three hours performing the recovery operation and cleaning the body to return to the family. For the organ recovery, surrounding tissues (such as blood vessels and the ureters [see page 8 Appendix]) accompanying the kidneys must be recovered.

When donating the eyes, eye prostheses are used, and the eyelids are closed after donation.

If other tissues are recovered, more time will be needed in the operating room.

(3) Regarding Pancreas Donation

Pancreas donation is possible when the fulfillment of certain strict conditions as the procedures described above in (1), and additionally must have absence of persistent hypotension immediately before circulatory cessation.

8. Circumstances in which the Organs Cannot be Donated

(1) When there are Medical Conditions

If tests show evidence of bacterial or viral infection, impairment of organ function, or complications that pose a problem during transplant, organs may be unable to be donated.

In addition, organs may be found to be ineligible for transplant during or after the recovery operation.

When the general condition of a potential donor is unstable, we cannot expect when and what will happen. An abrupt change in the condition may occur to make organ donation impossible.

(2) When Forensic or Administrative Autopsy is Necessary

In the case of death due to causes other than disease, such as an accident, a postmortem inspection by the police is required before the recovery operation. Although a postmortem inspection itself does not preclude organ donation, a forensic or administrative autopsy may be given priority over organ donation, making organ donation impossible in some cases.

(3) When the Individual's Decision not to Donate Organs has been Expressed

When the individual's decision not to donate organs has been expressed or registered with the Japan Organ Transplant Network, organ donation cannot be made even if the family wishes to.

To confirm the deceased's decision, we would like you to understand that we will check the Japan Organ Transplant Network Registry. In addition, we would like to ask the family to confirm that the individual's decision not to donate organs has not been expressed on their own health insurance card or driver's license.

9. Fees Related to Organ Donation

There are no additional fees charged to the patient or family for organ donation. Neither are there any financial support, such as a subsidy for funeral expenses, provided as organ donation is purely an act of altruism.

10. Regarding Recipient Selection

Patients who wish to receive transplants are registered to the Japan Organ Transplant Network. Recipients are strictly selected from registered patients who wish to receive a transplant according to organ-specific selection criteria.

11. After Organ Donation

As a rule in transplantation, neither the family of the organ donor nor the recipient can be informed of personally identifiable information regarding each other. The assigned transplant coordinator will report the outcome of the transplants in a manner consistent with the wishes of the family.

The family is requested not to reveal specific information of donation through social media or mass media to avoid communication to other sides. When afterwards you wish to reveal about the organ donation, we request you to give consideration not to disclose personally identifiable information.

12. Freedom to Withdraw Consent from Organ Donation

Please feel free to tell us if a change in the decision for organ donation occurs within the family after you have given consent and wish to withdraw from organ donation. It is possible to withdraw consent at any time as long as it is before the organ recovery surgery.

13. Disclosure of Information

The Japan Organ Transplant Network, which gives top priority to protect privacy, will not disclose any personally identifiable information.

However, in cases of organ donation after brain death, it is necessary to disclose information regarding organ donation and transplant by society to ensure information disclosure and transparency. The family will be informed in advance regarding the information and timing of disclosure, and only the content permitted by the family will be disclosed. If a press conference needs to be held by the Japan Organ Transplant Network, the family will be fully informed in advance.

14. Handling of Information

The Japan Organ Transplant Network collects information on organ donations and transplants for proper organ procurement and exercises extreme caution in handling the information according to the rules of our organization based on laws, regulations, and ethical guidelines.

As a social responsibility of our organization, we develop basic materials for maintaining and improving our activities to provide education, training, or research to enhance the quality of transplant medicine and may utilize collected information for these purposes. In those circumstances, data processed so that specific individuals cannot be identified (anonymously processed information) may be provided to universities, other research institutions, or scientific societies with extreme precaution to the protection of personal information. Personal information is anonymized (data processed so that specific individuals cannot be identified) and will not be personally identifiable.

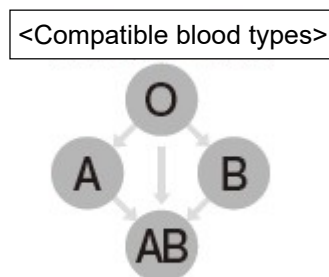
If you have any questions, concerns, or wishes, please tell us at any time.

Public Interest Incorporated Association
Japan Organ Transplant Network
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Priority Donation to Relatives

If a donor has a documented decision to donate organs with a documented wish to prioritize donation to relatives, the organs may be prioritized for donation to relatives who are registered on the recipient wait list according to the following requirements:

- (1) The relatives who can become recipients are the donor's spouse (the marriage must be registered which does not include common-law marriage), children, and parents (including biological parents and children, and adopted parents and children under the special adoption system).
- (2) The kinship must be confirmed by official certificates (such as a family register indicating the relationship).
- (3) For medical reasons, organ donation may not always be necessarily made to relatives. For example, organ transplantation is possible when blood types are matching (e.g., from blood type A to blood type A) or compatible (e.g., from blood type A to blood type AB), but is not possible when incompatible.
- (4) If organs cannot be transplanted to relatives, recipients are strictly selected by the usual selection criteria from the registered patients who wish to receive organ transplants.
- (5) Even if the name of relatives to whom organs will be donated on a priority basis has been designated (written), this is regarded as the intention for priority donation to relatives as specified in (1).
- (6) If the intention to restrict organ donation to a specified recipient (e.g., "I want to donate my organs only to X") has been expressed in writing, the organs cannot be donated.
- (7) When the cause of death is suicide for an individual who has expressed the intention for priority donation to relatives, donation to relatives cannot be prioritized.



Surrounding Tissues Accompanying Organs to be Recovered

Heart: The heart is recovered along with blood vessels accompanying the heart (pulmonary artery, pulmonary vein, superior vena cava, inferior vena cava, and ascending aorta).

Lung: Both lungs are recovered along with the trachea, main pulmonary artery, pulmonary vein (including a part of the left atrial wall), a part of the pericardium, and tissues surrounding the lungs. A part of the thoracic aorta and a part of the thoracic esophagus may also be recovered.

Liver: The liver is recovered along with the hepatic artery (including a part of the abdominal aorta), hepatic vein, and a part of the inferior vena cava, portal veins, bladder, bile duct, a part of the adrenal glands, a part of the diaphragm, and surrounding tissues.

Kidney: Both kidneys are recovered along with the renal artery (including a part of the abdominal aorta), renal vein (including a part of the inferior vena cava), ureters, both adrenal glands or a part of them, and surrounding adipose tissue.

Pancreas: The pancreas is recovered along with part of the duodenum and jejunum, spleen, blood vessels accompanying the pancreas, a part of the bile duct, and a part and surrounding tissues of the mesentery.

Small intestine: The intestinal tract up to the jejunum, ileum, and ascending colon is recovered along with the root or main trunk of the superior mesenteric artery and vein and a part of the mesentery. In addition, part of the adjacent stomach, large intestine, or abdominal wall may also be recovered.

- Additional remarks:**
1. A part of the spleen and lymph nodes may be recovered for a lymphocyte crossmatch test and post-operative immunological tests.
 2. For pancreas, kidney, liver, and small intestine transplants, the common iliac artery and vein and part of the internal and external iliac artery and vein, internal carotid artery and vein, and brachiocephalic artery may be recovered for forming blood vessels accompanying the relevant organs.
 3. Organs that have not been transplanted after being recovered for organ transplant are handled as required by law.