

「Regulations on Human Organ Transplantation」

[Regulation, 2007.3.21., Adopted]

(Adopted at the 171st Executive Meeting of the State Council on March 21, 2007, promulgated by Decree No. 491 of the State Council of the People's Republic of China on March 31, 2007, and effective as of May 1, 2007)

Chapter I General Provisions

Article 1 These Regulations are formulated for the purpose of standardizing transplantation of human organs, ensuring the quality of medical treatment, safeguarding human health and protecting the lawful rights and interests of citizens.

Article 2 These Regulations apply to transplantation of human organs conducted within the territory of the People's Republic of China, but do not apply to transplantation of human cells and such human tissues as corneas and bone marrow.

The term “human organ transplantation” in these Regulations means

the process involved in the removal of part or all of an organ with a specific function, such as the heart, lung, liver, kidney or pancreas, from a donor, and its implantation into a recipient to replace his diseased or impaired organ.

Article 3 No organization or individual may, in any form, trade in human organs or engage in any activities related to such trade.

Article 4 The competent health department of the State Council is responsible for supervision and administration of human organ transplantation nationwide. The competent health department of the local people's government at or above the county level is responsible for supervision and administration of human organ transplantation within its own administrative area.

The Red Cross Societies at various levels participate in accordance with law in publicizing the need for donation of human organs and in other related work.

Article 5 Any organization or individual has the right to report to the competent health department or the relevant departments on any

violation of these Regulations, and has the right to report to the people's government at the same level or the relevant department of the people's government at a higher level on any failure of the competent health department or the relevant department to perform its duties of supervision and administration in accordance with law. The people's government, the competent health department or the relevant department which receives the report shall verify and handle the report in a timely manner, and inform the reporting person of the results.

Article 6 The State establishes a working system for human organ transplantation to publicize and promote the donation of human organs, work out a list of persons waiting for transplantation of human organs, organize and coordinate the utilization of human organs.

Chapter II Donation of Human Organs

Article 7 Donation of human organs shall follow the principles of voluntariness and gratuitousness.

A citizen has the right to donate or not to donate his organ. No organization or individual may force, deceive or entice a person into donating his organ.

Article 8 A citizen who donates his organ shall have full capacity for civil conduct. For donation of his organ, a citizen shall give written consent to the donation and he shall have the right to withdraw such expressed consent.

Where a citizen, during his lifetime, expresses an objection to the donation of his organ, no organization or individual may donate or remove his organ. Where a citizen, during his lifetime, does not express an objection to the donation of his organ, his spouse, children of full age and parents may, after his death, jointly give consent to the donation of his organ in written form.

Article 9 No organization or individual may remove a living organ for transplantation from a citizen who has not reached the age of 18.

Article 10 The recipient of a living organ shall only include the donor's spouse, lineal relatives, collateral relatives by blood up to the

third degree of kinship, and a person for whom there is evidence to prove that he has developed a kinship with the donor due to his supporting or other reasons.

Chapter III Human Organ Transplantation

Article 11 A medical institution that is to engage in human organ transplantation shall, in accordance with the provisions of the Regulations on Administration of Medical Institutions, apply for registration of a clinical department related to human organ transplantation with the competent health department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located.

A medical institution that is to engage in human organ transplantation shall meet the following conditions:

(1) having licensed doctors and other medical personnel who are suitable for engaging in human organ transplantation;

(2) having equipment and facilities needed for human organ transplantation;

(3) having a committee on clinical application and ethics of human organ transplantation, which shall be composed of experts in medicine, law, ethics and other fields, among whom the number of medical experts engaged in human organ transplantation shall account for not more than one quarter of the committee members; and

(4) having sound administration systems for human organ transplantation, such as a system of quality surveillance and control.

Article 12 When registering a clinical department related to human organ transplantation, the competent health department of the people's government of a province, autonomous region, or municipality directly under the Central Government shall, apart from taking the conditions prescribed in Article 11 of these Regulations as basis, take into consideration the medical demand for human organ transplantation and the lawful sources of human organs within its administrative area.

The competent health department of the people's government of a province, autonomous region, or municipality directly under the Central Government shall, in a timely manner, make public the list of the medical institutions that have registered a clinical department related to human organ transplantation.

Article 13 When a medical institution that has registered a clinical department related to human organ transplantation no longer meets the conditions prescribed in Article 11 of these Regulations, it shall cease to engage in human organ transplantation and report the matter to the registration department. The registration department shall, within two days from the date of receipt of the report, revoke registration of the clinical department related to human organ transplantation and make such revocation public.

Article 14 The competent health department of the people's government at or above the provincial level shall, on the basis of the success rate of human organ transplantation operations and the long-term survival rate of the transplanted organs and recipients, arrange for experts to regularly assess the medical institutions in terms of their clinical application of human organ transplantation, and make public the results of such assessment in a timely manner. Where a

medical institution fails the assessment, the registration department shall cancel registration of the clinical department related to human organ transplantation. The specific measures therefor shall be formulated by the competent health department of the State Council.

Article 15 A medical institution and its medical personnel shall, in engaging in human organ transplantation, comply with ethical principles and technical rules for administration of human organ transplantation.

Article 16 A medical institution performing a human organ transplantation operation and its medical personnel shall carry out a medical examination on the donor of a human organ to assess the risks of transmission of disease to the recipient due to the transplantation, and take measures to minimize such risks.

Article 17 Before removing a living organ or before the death of a deceased donor, the licensed doctor responsible for human organ transplantation shall apply to the committee on clinical application and ethics of human organ transplantation of the medical institution where he works for examination of the removal of the human organ.

Where the committee on clinical application and ethics of human organ transplantation denies the removal of a human organ, the medical institution shall not make a decision on removing the human organ and its medical personnel shall not conduct the removal.

Article 18 Upon receipt of an application for examination of the removal of a human organ, the committee on clinical application and ethics of human organ transplantation shall make an examination of the following matters and give a written opinion on consenting or denying the removal:

(1) whether the consent of the donor is true;

(2) whether trade in human organs or such trade in a disguised form is involved; and

(3) whether the matching of the human organ and the indications of the recipient conform to ethical principles and technical rules for administration of human organ transplantation.

The committee on clinical application and ethics of human organ transplantation may give its written consent to the removal of a human organ only when two-thirds or more of the members of the committee consent to the removal.

Article 19 Before removing a living organ, the medical institution engaged in human organ transplantation and its medical personnel shall fulfill the following duties:

(1) inform the donor of the risks of the operation, matters needing attention after the operation, possible complications and preventive measures therefor, and sign an instrument of informed consent with the donor;

(2) examine the written consent given by the donor to the donation of his organ and the materials proving that the donor and the recipient have a relationship prescribed in Article 10 of these Regulations; and

(3) confirm that the normal physical functions of the donor will not

be impaired except for the direct effect from the removal of the organ.

The medical institution engaged in human organ transplantation shall keep the medical records of the donors of living organs and offer the donors medical follow up.

Article 20 The removal of an organ from a deceased donor can only be conducted after the donor has been determined dead in accordance with law. The medical personnel engaged in human organ transplantation may not participate in determining the death of a donor.

A medical institution engaged in human organ transplantation and its medical personnel shall respect the dignity of the deceased; the cadaver from which an organ has been removed shall be medically treated in an ethical manner and restored to its original appearance except for the organ removed for transplantation.

Article 21 A medical institution engaged in human organ transplantation, which performs a human organ transplantation

operation, may not charge the recipient for the transplanted organ or do so in a disguised form, except for the fees as follows:

(1) operation fees for the removal and implantation of the human organ;

(2) fees for the preservation and transport of the human organ; and

(3) fees incurred by medicines, tests and medical materials consumed for the removal and implantation of the human organ.

The charging rates for the fees prescribed in the preceding paragraph shall be set in accordance with the relevant provisions of laws and administrative regulations and made public.

Article 22 The order of the patients applying for human organ transplantation operations shall be arranged in conformity with medical needs and in adherence to the principles of fairness, impartiality and openness. The specific measures therefor shall be formulated by the competent health department of the State Council.

Article 23 The medical personnel engaged in human organ transplantation shall maintain confidentiality of the personal information of the donors and recipients as well as the patients applying for human organ transplantation operations.

Article 24 A medical institution engaged in human organ transplantation shall, at regular intervals, report on human organ transplantation to the competent health department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located. The specific measures therefor shall be formulated by the competent health department of the State Council.

Chapter IV Legal Liability

Article 25 Where the provisions of these Regulations are violated under any of the following circumstances and a crime is thus constituted, criminal liability shall be investigated for in accordance with law:

(1) removal of a citizen's living organ without his consent;

(2) removal of an organ from the cadaver of a citizen who has, during his lifetime, expressed an objection to the donation of his organ; or

(3) removal of a living organ from a citizen who has not reached the age of 18.

Article 26 Where, in violation of the provisions of these Regulations, trade in human organs or any activity related to such trade is conducted, the competent health department of the local people's government at or above the level of a city divided into districts shall, in accordance with its functions and duties, confiscate illegal income and impose a fine of not less than eight times but not more than ten times the volume of trade conducted. If a medical institution participates in the aforesaid activity, the person in charge with accountability and other persons with competent accountability shall be given a sanction in accordance with law, the registration department shall cancel registration of its clinical department related to human organ transplantation and, within three years, the medical institution may not apply for registration of a clinical department related to human organ transplantation. If any of medical personnel

participates in the aforesaid activity, his practice certificate shall be revoked by the department that issued the certificate.

Where a State functionary participates in the trade in human organs or any activity related to such trade, the relevant State organ shall, in accordance with its functions and powers, remove him from office or discharge him from public employment by way of a sanction in accordance with law.

Article 27 Where a medical institution engages in human organ transplantation without registering a clinical department related to human organ transplantation, it shall be penalized in accordance with the provisions of the Regulations on Administration of Medical Institutions.

Where a medical institution performing a human organ transplantation operation and its medical personnel, in violation of the provisions of these Regulations, fail to carry out a medical examination on the donor of a human organ or to take measures, thus resulting in transmission of disease to the recipient due to a human organ transplantation operation, they shall be penalized in accordance with the provisions of the Regulations on Handling Medical Accidents.

Where any of the medical personnel engaged in human organ transplantation, in violation of the provisions of these Regulations, divulges the personal information of a donor or recipient of a human organ, or of a patient who applies for a human organ transplantation operation, he shall be penalized in accordance with the Law on Licensed Doctors or the relevant provisions of the State on administration of nurses.

Where any damage is caused to another person for violation of the provisions of these Regulations, civil liability shall be assumed in accordance with law.

Where any fees are charged in violation of the provisions of Article 21 of these Regulations, a penalty shall be imposed in accordance with the provisions of the laws and administrative regulations on pricing.

Article 28 Where any of medical personnel is found in any of the following circumstances, he shall be given a sanction in accordance with law; if the circumstances are serious, the competent health

department of the local people's government at or above the county level shall suspend his practice of medicine for a period of not less than six months but not more than one year in accordance with its functions and duties; and if the circumstances are especially serious, his practice certificate shall be revoked by the department that issued the certificate:

(1) removing a human organ without consent given upon examination by the committee on clinical application and ethics of human organ transplantation;

(2) failing to fulfill the duties of information, examination and confirmation in accordance with the provisions of Article 19 of these Regulations before removing a living organ; or

(3) failing to medically treat a cadaver in an ethical manner after removing an organ therefrom and to restore it to its original appearance.

Article 29 Where a medical institution is found in any of the following circumstances, the person in charge with accountability and

other persons with competent accountability shall be given a sanction in accordance with law; if the circumstances are serious, the registration department shall cancel registration of its clinical department related to human organ transplantation and the medical institution may not apply for registration of a clinical department related to human organ transplantation within three years:

(1) continuing to engage in human organ transplantation when it no longer meets the conditions prescribed in Article 11 of these Regulations;

(2) making a decision on removing a human organ without consent given upon examination by the committee on clinical application and ethics of human organ transplantation, or coercing its medical personnel into removing a human organ in violation of the provisions of these Regulations; or

(3) in the circumstances prescribed in subparagraph (2) or (3) of Article 28 of these Regulations.

Where a medical institution fails to report, at regular intervals, on

human organ transplantation to the competent health department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located, the said department shall order it to make corrections within a specified time limit; if no correction is made within the specified time limit, the person in charge with accountability and other persons with competent accountability shall be given a sanction in accordance with law.

Article 30 Where any of the medical personnel engaged in human organ transplantation participates in determining the death of a deceased donor, the competent health department of the local people's government at or above the county level shall suspend his practice of medicine for a period of not less than six months but not more than one year in accordance with its functions and duties; if the circumstances are serious, his practice certificate shall be revoked by the department that issued the certificate.

Article 31 Any staff member of a State organ who abuses his power, neglects his duty, or commits illegalities for personal gain or by fraudulent means in supervising and administering human organ transplantation, and thus commits a crime, shall be investigated for

criminal liability in accordance with law or, if no crime is committed, shall be given a sanction in accordance with law.

Chapter V Supplementary Provision

Article 32 These Regulations shall be effective as of May 1, 2007.