

## The Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998)

Date of Royal Seal and Publication:

2055.10.21 (4 Feb, 1999)

### Amending Act:

		Date of authentication and publication
<sup>1</sup> 1.	The Republic Strengthening and Some Nepal Laws Amending Act, 2066 (2010)	2066.10.7 (21 Jan, 2004)

Act number 20 of the year 2055(1998)

<sup>2</sup> .....

### An Act made to provide for the transplantation of human body organ

**Preamble:** Whereas, it is expedient to make provisions regulating the activities pertaining to the extraction of an organ from the human body for the purpose of treating a disease in a systematic manner in accordance with the modern medical treatment and extraction of an organ from the body of a human being and transplantation of that organ into the body of another human being and preventing activities relating to the purchase and sale of human body organ and use of the same in other purposes;

<sup>1</sup> This Act came into force on 14 Jyestha 2065(28 May, 2008).

<sup>2</sup> Deleted by the Republic Strengthening and Some Nepal Laws Amending Act, 2066 (2010).



  
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Now, therefore, be it enacted by Parliament in the twenty seventh reign of His Majesty King Birendra Bir Bikram Shah Dev.

## Chapter-1

### Short title and commencement

1. **Short title and commencement:** (1) This Act may be called the “Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055(---).”

(2)<sup>3</sup> This Act shall commence on such date as the Government of Nepal may appoint, by a notification in the Nepal Gazette.

2. **Definitions:** Unless the subject or the context otherwise requires, in this Act:

(a) "human body" means the body of any alive or dead human being,

(b) "organ" means any organ of the human body and this term includes a tissue of the human body,

(c) “organ transplantation” means the transplantation of an organ of one human body into another human body for the purpose of treating a disease in a managed manner in accordance with the modern medical system,

(d) “activity relating to organ transplantation” means an activity to extract an organ from the human body for the purpose of treating a disease in a managed manner in accordance with the modern medical system, to safely store the organ so extracted or transplant it into another human body by following the scientific technology and method,

<sup>3</sup> This Act came into force on 2058 (10.22 (4 Feb, 2002) vide a notification in the Nepal Gazette.



  
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- (e) “health institution” means a health institution having obtained the permit to operate the activity relating to organ transplantation pursuant to this Act,
- (f) “permit” means the permit to be issued pursuant to Section 5 to operate the activity relating to organ transplantation,
- (g) “private license” means the license to be issued pursuant to sub-section (1) of Section 8 to operate the activity relating to the transplantation of an organ,
- (h) “doctor” means a doctor in possession of the qualification as referred to in sub-section (2) of Section 8,
- (i) "committee" means an organ transplantation coordination committee constituted pursuant to Section 12,
- (j) “donor” means a person who gives consent in writing to donate an organ pursuant to Section 15 for the purposes of Section 14,
- (k) “organ receiving person” means a person who receives the organ donated by a donor pursuant to this Act,
- (l) “close relative”, in respect of any person, means that person’s son, daughter, mother, father, brother, sister, uncle, nephew, niece, grand-father, grand-mother from the father’s side, grand-son, grand-daughter from the son’s side, grand-son, grad-daughter from the daughter’s side, and includes husband, wife, adopted son, adopted daughter, step mother, step father, father-in-law, mother-in-law, which whom relationship has constantly existed since two years ago, and
- (m) “prescribed” or “as prescribed” means prescribed or as prescribe in the rules framed under this Act.

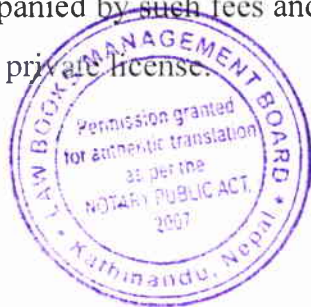


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## Chapter-2

### Permit relating to organ transplantation and private license

3. **Prohibition on operation of activity relating to organ transplantation without obtaining permit:** No person shall operate, or cause to be operated, any activity relating to the organ transplantation without obtaining the permit pursuant to this Act.
4. **Application for permit:** Any person, other than a governmental hospital prescribed by the Government of Nepal by a notification in the Nepal Gazette, has to make an application, accompanied by such fees and in such a form as prescribed, to the committee, to operate the activity relating to organ transplantation.
5. **Issuance of permit:** (1) Where an application is made pursuant to Section 4, the committee shall complete the prescribed procedures and issue the permit to the applicant in the prescribed format.  
  
(2) Such physical means, human resource and other necessary services as required to be arranged by the concerned applicant in order to obtain the permit pursuant to sub-section (1) shall be as prescribed.
6. **Prohibition on operation of activity relating to organ transplantation without obtaining private license:** No person shall operate the activity relating to organ transplantation without obtaining the private license pursuant to this Act.
7. **Application for private license:** A doctor who intends to operate the activity relating to organ transplantation has to make an application, accompanied by such fees and in such a form as prescribed, to the committee for the private license.



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8. **Issuance of private license:** (1) Where an application is made pursuant to Section 7, the committee shall complete the prescribed procedures and issue the private license to the applicant in the prescribed form.

(2) Such qualification as required to be possessed by the doctor in order to obtain the private license pursuant to sub-section (1) shall be as prescribed.

9. **Term and renewal of permit:** (1) Except where the permit is revoked earlier pursuant to Section 10, the term of the permit shall remain valid for a period of two years.

(2) Prior to the expiration of the term of permit, an application, accompanied by such fees and in such form as prescribed, has to be made by the concerned health institution to the committee for the renewal of the permit.

(3) Where an application is made pursuant to sub-section (2), the committee shall complete the prescribed procedures and renew the term of permit for up to two years each time.

(4) The permit which is not renewed pursuant to sub-section (3) shall *ipso facto* be revoked.

10. **Revocation and suspension of permit and private license:** (1) If a health institution or private license holder doctor acts in contravention of this Act or the rules framed under this Act or fails to carry out the order and directive issued by the committee pursuant to Section 29, the committee may revoke or suspend the permit of such a health institution or the private license of such a doctor for a period not exceeding six months.

(2) Prior to the revocation or suspension of the permit or private license pursuant to sub-section (1), the committee shall give a reasonable



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opportunity to the concerned health institution or doctor to furnish explanation in defense.

**11. Appeal:** (1) The health institution or doctor who is not satisfied with the order issued by the committee pursuant to sub-section (1) of Section 10 may make an appeal to the Ministry of Health and Population and Population of the Government of Nepal within thirty five days after the issue of such an order.

(2) A decision made by the Ministry of Health and Population and Population of the Government of Nepal on the appeal made pursuant to sub-section (1) shall be final.

### Chapter-3

#### Organ transplantation coordination committee

**12. Organ transplantation coordination committee:** (1) There shall be formed an organ transplantation coordination committee consisting of the chairperson and member as follows, in order to formulate policies, plans and programs on organ transplantation and submit the same to the Government of Nepal, in addition to the performance and exercise of the other functions, duties and powers contained in this Act:

(a)	A senior doctor nominated by the Government of Nepal	-Chairperson
(b)	Three doctors nominated by the Government of Nepal	-Member
(c)	Representative, Joint Secretary level, Ministry of Health and Population and Population	



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		-Member
(d)	Representative, Ministry of Law and Justice	-Member
(e)	Representative, Nepal Medical Council	-Member
(f)	Representative, Nepal Medical Association	-Member
(g)	Director General, Department of Health Services	-Member secretary

(2) The term of office of the chairperson and members nominated pursuant to clauses (a) and (b) of sub-section (1) shall be two years, and, after expiration of their term, they may be re-nominated.

(3) The Government of Nepal may, if it so considers necessary, make necessary alteration or change in respect of the members of the committee as referred to in sub-section (1).

(4) The committee may, if it so considers necessary, invite any expert or advisor to attend its meeting, as an observer.

(5) The procedures relating to the meetings of the committee shall be as determined by the committee itself.

(6) The Government of Nepal shall provide such budget as may be required for the committee.

(7) The meeting allowance and other facilities of the chairperson and members of the committee shall be as prescribed.

(8) The secretariat of the committee shall be located at the Department of Health Services of the Government of Nepal.

#### Chapter-4

#### Activity relating to organ transplantation



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13. **Prohibition on operating activity relating to organ transplantation:** No person shall operate an activity relating to organ transplantation for the purpose of the sale and purchase of an organ or similar other acts.
14. **Extraction of organ and transplantation of organ can be done:** Subject to the other provisions contained in this Act, an organ can be extracted from the human body and an organ can be extracted from the body of a human being and transplanted into the body of another human being only for the purpose of treating a disease in a managed manner in accordance with the modern medical treatment system.
15. **Organ can be extracted from body of alive person:**
- (1) Subject to the other conditions mentioned in this Act, an organ may be extracted from the body of an alive person (donor) and such an organ may be transplanted into the body of a close relative of that donor, only in the following circumstances:
- (a) Where it is certified by at least two concerned doctors that a bodily organ of any patient is deformed to be unworkable and it is necessary to transplant another organ in lieu of his or her deformed bodily organ in order to save the life of such a patient,
- (b) Where a close relative (donor) of the patient as referred to in clause (a) has voluntarily given consent in writing to donate the organ, along with the concurrence of at least two of his or her relatives,

Provided, however, that if any donor has no two close relatives, consent in writing may be given voluntarily to donate the organ, along with the concurrence of even one close



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(c) Where the donor giving consent voluntarily to donate the organ pursuant to clause (b) has completed the age of eighteen years,

(d) Where it is certified by at least two concerned doctors that the donor giving consent to donate an organ pursuant to clause (b) will neither die immediately and nor become disabled or incapacitated permanently as a result of extraction of any organ out of the twin organs of the body of that donor,

(e) Where it is certified by at least two concerned doctors that the tissue intended to be extracted from the body of the donor can re-grow.

(2) Subject to the other provisions contained in this Act, where it is certified by at least two concerned doctors that any tissue can re-grow in the body of a person who has not completed the age of eighteen years, this Section shall not be deemed to bar the extracting of that tissue from the body of such a person.

(3) This Section shall not be deemed to bar the extracting of any unworkable organ from the body of any person and throwing away of such an organ, in the course of treatment.

(4) The procedures of giving consent and concurrence pursuant to clause (b) of sub-section (1) shall be as prescribed.

(5) If the donor so wishes, he or she may withdraw the consent given pursuant to clause (b) of sub-section (1).

(6) If the donor withdraws the consent pursuant to sub-section (5), the person receiving the organ shall not be entitled to claim any kind of compensation against the donor.

**16. Organ can be extracted from body of the deceased:** (1) Subject to the other provisions contained in this Act, an organ may be extracted from the



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body of a deceased or the organ so extracted may be transplanted into the body of another person only in the following circumstances:

- (a) Where it is certified by at least two concerned doctors that the person from whose body the organ is to be extracted has already died a brain death,
- (b) Where the person who wishes to donate his or her organ after death, for the purposes of Section 14, has voluntarily given an informed consent in writing.

(2) The other procedures on giving consent and concurrence pursuant to clause (b) of sub-section (1) shall be as prescribed.

**17. Prohibition on transplantation of bodily organ of deceased:**

Notwithstanding anything contained in Section 16, no organ shall be extracted from the body of any deceased and transplanted into another human body in such a manner as to affect the post mortem of that person who died as a result of murder or suicide or in a doubtful circumstance.

Provided, however, that this Section shall not be deemed to bar the extracting of an organ for the post mortem of such a deceased or for any other research purpose.

**18. To make aware about possible risk:** While extracting and transplanting an organ pursuant to this Act, the doctor shall examine the health of the donor and the recipient of organ and inform both parties about the possible effects and risks that can be caused therefrom on or to their health.

**19. Requirement of consent of recipient of organ:** (1) In transplanting an organ pursuant to this Act, the consent of the recipient of organ shall also be required.



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(2) Where the recipient of organ is a minor and incapacitated to make decision, the close relative may give such consent on behalf of such a recipient.

**20. Transplantation organ without consent:** Notwithstanding anything contained in Section 19, an organ may be transplanted even without consent of the recipient of organ in the following circumstances:

- (a) Where the recipient of organ is not claimed by any one,
- (b) Where it is not possible to inform the close relative of the recipient of organ and obtain consent in due time,
- (c) Where it is possible that such a person can die if the organ is not transplanted immediately in the circumstances as referred to in clauses (a) and (b).

**21. Cost expenditure and service charge:** In transplanting an organ pursuant to this Act, a health institution may collect the cost expenditure and service charge from the recipient of organ.

Provided, however, that:

- (a) The rate of such service charge has to be approved by the committee.
- (b) The rate of such service charge has to be published as directed by the committee.
- (c) The rate of such service charge has to be proper and reasonable.

**22. Technical matters to be followed in extracting or transplanting organ:** The technical matters relating to modern medical sciences required to be followed in extracting an organ or safely storing an extracted organ or transplanting an organ pursuant to this Act shall be as prescribed.



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## Chapter-5

### Offense and Punishment

**23. Offense relating to organ transplantation:** If a person extracts any organ of another person or transplant the organ so extracted into another person or uses it in another work or is directly involved in such act in contravention of the provisions contained in Sections 13, 14, 15, 16 and 17, such a person shall be deemed to have committed the offense as referred to in this Act.

**24. Punishment:** (1) A person who commits an offense as referred to in Section 23 shall be punished with imprisonment for a term not exceeding five years and a fine not exceeding five hundred thousand rupees.

(2) A person who commits an offense as referred to in Section 23 in any place other than a health institution shall be punished with imprisonment for a term not exceeding one year and a fine not exceeding one hundred thousand rupees, in addition to the punishment to be imposed pursuant to sub-section (1).

(3) Where a person who has not got the private license commits an offense as referred to in Section 23 in any place other than a health institution, such a person shall be punished with imprisonment for a term not exceeding two years and a fine not exceeding two hundred thousand rupees, in addition to the punishment to be imposed pursuant to sub-section (1).

(4) Where an offense as referred to in Section 23 is committed and the person from whom an organ has been extracted dies as a result of that wound or pain within three months, the person who commits such offense



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shall be punished with imprisonment for life, along with the confiscation of entire property.

(5) A person who does an activity relating to organ transplantation in contravention of the provisions contained in this Act other than sub-sections (1), (2), (3) and (4) or the rules framed under this Act shall be punished with imprisonment for a term not exceeding one year and a fine not exceeding one hundred thousand rupees.

**25. Punishment for attempt:** Where all preparation has been made to commit an offense as referred to in Section 23 but the offense has not yet been committed, it shall be deemed an attempt to commit such offense, and the person makes such an attempt shall be punished with half the punishment as referred to in Section 24.

**26. Punishment for accomplice:** A person who aids in the commission of an offense as referred to in Section 23, other than a person who is directly involved in the commission of the offense, shall be deemed to be an accomplice, and the accomplice shall be punished with half the punishment to be imposed on the accused.

**27. Prohibition on advertisement and publicity:** (1) No one shall make, or cause to be made, advertisement and publicity, directly or indirectly, through communication media as to that an organ can be provided or is necessary.

Provided, however, that this Section shall not be deemed to bar the disseminating of related information with a view to providing technical knowledge about organ transplantation.

(2) Any communication agency, publisher and editor, broadcasting institution and transmitter making advertisement and publicity in contravention of sub-section (1) may be punished by the prescribed authority



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(3) One who is not satisfied with the fine imposed by the prescribed authority pursuant to sub-section (2) may make an appeal to the Appellate Court within thirty five days after the date of knowledge of imposition of such fine.

## Chapter-6

### Miscellaneous

**28. Inspection:** (1) The authority authorized by the committee may inspect as to whether the health institutions and doctors holding the private license have observed this Act or the rules framed under this Act and the orders and directions given pursuant to Section 29 in operating activities relating to organ transplantation.

(3) The authority who carries out inspection pursuant to sub-section (1) shall have to submit a report on inspection carried out by him or her to the committee.

**29. Powers to give order and direction:** (1) Where the competent authority has carried out inspection pursuant to Section 28 or in any other situation whatsoever, the committee may give necessary order and direction to the health institutions and doctors having obtained the private license in respect of the operation of activities relating to organ transplantation.

(2) In giving necessary direction and order pursuant to sub-section (1), the committee shall do so particularly on the following matters:

(a) Technical matters required to be followed in transplanting organs in accordance with the principles of medical sciences.

(b) Such physical means, resources and human resources as required in transplanting organs.



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- (c) Safely storing an organ extracted from a human body for organ transplantation in accordance with scientific technique and method.
- (d) Minimum safety provisions required to be followed in transplanting organs.
- (e) Dissemination of information on technical matters relating to organ transplantation.

(3) It shall be the duty of the concerned health institution and doctor having obtained the private license to carry out, or cause to be carried out, the order and direction given by the committee pursuant to sub-section (2).

**30. Not to be compelled to make deposition:** The health institution or doctor having obtained the private license or any person related with such institution or doctor shall not be compelled to make deposition before any one other than the authority authorized by the laws in force in respect of activities relating to organ transplantation operated by such an institution or doctor or person pursuant to this Act.


**30. Annual report:** (1) Every health institution shall prepare description of the acts done pursuant to this Act in respect of activities relating to organ transplantation in the prescribed form and submit the same to the committee every year.

(2) The committee shall, every year, submit to the Government of Nepal a report, along with its evaluation as to the report submitted by the health institution pursuant to sub-section (1) and the policies and programs to be adopted by the Government of Nepal in respect thereof.



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32. **To be state case:** The cases under this Act shall be filed as state cases; and these cases shall be deemed to be included in Schedule-1 of the State Cases Act, 2049(1993).
34. **Powers to frame rules:** The Government of Nepal may frame necessary rules in order to accomplish the objectives of this Act.

  
Jan. 25, 2011

