

# **Kidney Transplantation (Regulation and Prohibition) Rules, 2058 (2002)**

Date of publication in Nepal Gazette

2058.10.22 (4 Feb. 2002)

In exercise of the powers conferred by Section 34 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055(1998), the Government of Nepal has framed the following Rules.

1. **Short title and commencement:** (1) These Rules may be called as the “Kidney Transplantation (Regulation and Prohibition) Rules, 2058 (2002).”

(2) These Rules shall come into force on the date on which the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) comes into force.<sup>1</sup>

2. **Definitions:** Unless the subject or the context otherwise requires, in these Rules:

(a) “Act” means the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055(1998).

(b) “Kidney” means the kidney of a human body.

3. **Permit:** (1) A health institution which intends to provide the kidney transplantation service pursuant to Section 4 of the Act shall submit an application, accompanied by the fees as referred to in Schedule-1, to the committee in a format as referred to in Schedule-2, for the permit to carry out activities pertaining thereto.

---

<sup>1</sup> These Rules commence from 2058.10.22 (4 Feb. 2002) as per the Notification of Nepal Gazette of same date.

(2) Upon receiving an application pursuant to Sub-rule (1), the committee shall make necessary inquiry as to whether there is arrangement of physical means (facilities), human resources and other necessary facilities as referred to in Schedule-3 in the applicant health institution and whether such human resource has obtained the qualification as referred to in Schedules 4 and 5 or not; and where such arrangement is found on such inquiry, the committee shall issue a permit to operate the kidney transplantation service to such health institution in a format as referred to in Schedule-6.

4. **Application for private license:** (1) A doctor (medical practitioner) who intends to provide the kidney transplantation service, for purposes of Section 7 of the Act, shall submit an application, accompanied by the fees as referred to in Schedule-1 and a certified copy of the certificate of qualification as referred to in Schedule - 4, to the committee in a format as referred to in Schedule-7, for the private license.

(2) Upon receiving an application pursuant to Sub-rule (1), the committee shall, if such doctor appears to have obtained the qualification as referred to in Schedule-4 upon holding necessary inquiry, issue the private license to provide the kidney transplantation service to such doctor in the format as referred to in Schedule-8, for purposes of Section 8 of the Act.

5. **Renewal of permit and fees:** (1) Prior to at least Thirty Five days of the expiration of the period of the permit prescribed pursuant to Sub-section (1) of Section 9 of the Act, the institution having obtained permit shall submit an application, accompanied by Fifty percent amount of the fees prescribed pursuant to Sub-rule (1) of Rule 3 for

the renewal of permit, to the committee in a format as referred to in Schedule-9, for the renewal of permit.

(2) Upon receiving an application pursuant to Sub-rule (1), if the concerned health institution is found to have regularly arranged the physical means, human resources and other necessary services and facilities and have observed the orders and directives given from time to time pursuant to Section 29 of the Act, the committee shall renew the permit received by such health institution to operate the kidney transplantation service and give the certificate in a format as referred to in Schedule-10.

6. **Brain death:** For purposes of Clause (a) of Sub-section (1) of Section 16 of the Act, brain death means the state where the receptive and responsive activity of the brain (including brain stem) of any person has so stopped that it cannot be restored and, as well as, where the eye movement, corneal reflection, swallowing and motor activity have also stopped.
7. **Format of document to be certified by concerned doctor:** The format of document to be certified by the concerned doctor for purposes of the following Sections of the Act shall be as follows:
  - (a) As referred to in Schedule-11 for purposes of Clause (a) of Sub-section (1) of Section 15,
  - (b) As referred to in Schedule-12 for purposes of Clause (d) of Sub-section (1) of Section 15.
8. **Format of deed of consent:** The format of the following deed of consent shall be as follows:
  - (a) As referred to in Schedule-13 for purposes of Clause (b) of Sub-section (1) of Section 15,

- (b) As referred to in Schedule-14 for purposes of Clause (b) of Sub-section (1) of Section 16,
  - (c) As referred to in Schedule-15, in the case of a deed of consent to be given by the close relative of a donor giving deed of consent pursuant to Clause (b) after his/her death to extract the kidney from his/her body,
  - (d) As referred to in Schedule-16 for purposes of Sub-section (1) of Section 19,
9. **Document to be provided:** The health institution having obtained permit shall submit a copy of the documents received by it pursuant to Rules 7 and 8 in the course of operation of the kidney transplantation service to the committee each time within Seven days within the date of completion of such service.
10. **Prescription of authority:** The committee has been prescribed as the authority for purposes of Sub-section (2) of Section 27 of the Act.
11. **Meeting allowance:** The chairperson, member of the committee and observer shall get the meeting allowance as mentioned in Schedule-17 for taking part in the meeting of the committee.
12. **Powers to frame Manual:** The committee may frame necessary Manuals for purpose of Section 29 of the Act.
13. **Power to alter schedule:** The Government of Nepal may, by a notification published in the Nepal Gazette, make necessary alteration on the Schedule of this Rules.

## **Schedule-1**

(Relating to Sub-rule (1) of Rule 3 and Sub-rule (1) of Rule 4)

### **Permit and private license fees**

- (a) Ten Thousand Rupees for a permit to operate the kidney transplantation service,
- (b) One Thousand Rupees for the private license.

## **Schedule-2**

(Relating to Sub-rule (1) of Rule 3)

### **Application for permit to operate kidney transplantation service**

The Organ Transplantation Coordination Committee,  
*Kathmandu.*

**Subject: Request for permit**

Whereas, I need the permit to operate the kidney transplantation service;

Now, therefore, I have made this application, accompanied by the necessary fees, and setting out the following details, for purposes of Section 4 of the Act and Sub-rule (1) of Rule 3 of the Rules.

Applicant health institution's:

Name:

Address:

Office issuing the health institution registration certificate:

Registration number:

Date of registration:

If the renewal of health institution is required, date of expiration of term:

A description of such physical means, human resource and other necessary services and facilities as existing in this health institution for providing the organ transplantation service is attached herewith.

The above-mentioned contents and the description attached herewith are true and correct, if proved false, I shall bear and pay according to law.

Seal of health institution:

Applicant on behalf of health institution:

Name:

Signature:

Designation:

Date:

### Schedule-3

(Relating to Sub-rule (2) of Rule 3)

**Physical means, human resource and other necessary services  
and facilities required to be arranged by health institution**

**(a) Physical means:**

- (1) Hemodialysis machines in running condition including reverse osmosis (at least two),
- (2) Necessary tools and equipment related with anesthesia,
- (3) Necessary tools and equipment to carry out operation of both the donor and the recipient for the purpose of transplantation of kidney,
- (4) Ventilator (at least two),
- (5) Monitor (at least two),
- (6) Hemodialysis machine in running condition for a highly infected disease,
- (7) Colordoplor.

**(b) Human resource:**

**Number**

- |   |              |
|---|--------------|
| (1) Nephrologists   | At least one |
| (2) Kidney transplantation surgeon                                      | At least one |
| (3) Anesthesiologist  | At least two |
| (4) Radiologist   | At least one |
| (5) Pathologist   | At least one |
| (6) Cardiologist, neurologist, psychiatrist and dental surgery service. |              |



**(c) Other necessary services and facilities:**

- (1) Hemodialysis machine equipped with facilities,
- (2) Surgical intensive care unit equipped with facilities,
- (3) Pathology laboratory (round the clock service with provision of urea, criatinine, electro-light) equipped with facilities,
- (4) Operation theater equipped with facilities,
- (5) Post operative ward equipped with facilities,
- (6) HLA (human leukocyte antigen) laboratory equipped with facilities,
- (7) Blood gas analysis service.

Even though the concerned health institution does not have the physical means as referred to in paragraphs (6) and (7) of Clause (a), human resource as referred to in paragraph (6) of Clause (b) and the services and facilities as referred to in paragraphs (6) and (7) of Clause (c), it will meet the requirement if an agreement concluded with any other health institution or specialist that such physical means, human resource, service and facilities can be made available at any time as and when required through such other institution or specialist is submitted.

## **Schedule-4**

(Relating to Sub-rule (2) of Rule 3)

### **Qualification and experience of doctor to obtain private license for providing kidney transplantation service**

A doctor who intends to obtain the private license to operate the kidney transplantation service, for purposes of Section 8 of the Act and Sub-rule (1) of Rule 4, shall gain at least Six months of experience in kidney transplantation work after having obtained master's degree in urology/uro surgery, or at least Two years of experiences in kidney transplantation work after having obtained master's degree in general surgery, for obtaining the private license.

## Schedule-5

(Relating to Sub-rule (2) of Rule 3)

**Required qualification and experience of other doctor to be engaged in health institution providing kidney transplantation service**

The qualification of other doctor to be engaged in a health institution providing kidney transplantation service shall be prescribed as follows:

	<b>Doctor</b>	<b>Required qualification</b>
(a)	Nephrologist	Having obtained at least master's degree in nephrology  or  Having obtained master's diploma degree in nephrology after obtaining master's degree in internal medicine  or  Having gained at least Five years of experience in a central level hospital or foreign hospital prescribed by the committee in hemodialysis works after having taken at least six months of training in nephrology following obtaining master's degree in

		internal medicine.
(b)	Anesthesiologist	Having gained at least Five years of experience in a central level hospital or foreign hospital prescribed by the committee in anesthesia works after obtaining master's degree in anesthesia.  or  Having gained at least Seven years of experience in a central level hospital or foreign hospital prescribed by the committee in anesthesia works after obtaining master's diploma degree in anesthesia.
(c)	Radiologist	Having gained at least Five years of experience in a central level hospital or foreign hospital prescribed by the committee in radiology works after obtaining master's degree in radiology.  or  Having gained at least Seven years of experience in a central level hospital or foreign hospital prescribed by the committee in radiology works after obtaining master's diploma degree in radiology.
(d)	Pathologist	Having gained at least Five years of experience in a central level hospital or foreign hospital prescribed by the committee

		<p>in pathology works after obtaining master's degree in pathology.</p> <p>or</p> <p>Having gained at least Seven years of experience in a central level hospital or foreign hospital prescribed by the committee in pathology works after obtaining master's diploma degree in pathology.</p>
--	--	--

**Explanation:**

For purposes of experience as referred to in this Schedule, "central level hospital" means the following hospital:

- (a) Bir Hospital,
- (b) Paropakar Indra Rajya Laxmi Maternity Home,
- (c) Kanti Children Hospital,
- (d) Shukraraj Tropical and Communicable Disease Hospital,
- (e) Tribhuvan University, Teaching Hospital,
- (f) Patan Hospital.

## Schedule-6

(Relating to Sub-rule (2) of Rule 3)

**Organ Transplantation Coordination Committee, Kathmandu**

### **Permit to operate kidney transplantation service**

To, .....

.....

Whereas, necessary inquiry has been made into the application made by that institution on..... (date) for the permit to operate the kidney transplantation service, and it has been submitted to the meeting of the Organ Transplantation Coordination Committee; and it has been decided on.....(date) to issue the permit to operate the kidney transplantation service to that institution;

Now, therefore, this permit is hereby issued pursuant to Sub-section (1) of Section 5 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Sub-rule (2) of Rule 3 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

This Permit shall remain valid for a period of up to Two years.

Permit issuing authority's:

Name:

Signature:

Date:

Designation: Member secretary

Organ Transplantation Coordination Committee

## **Schedule-7**

(Relating to Sub-rule (1) of Rule 4)

### **Application for private license to operate kidney transplantation service**

Passport size photograph of applicant recently taken, with two ears being visible
---

The Organ Transplantation Coordination Committee,  
Kathmandu.

**Subject: Request for private license.**

Whereas, I need the private license to operate the kidney transplantation service;

Now, therefore, I have made this application, accompanied by the necessary fees, and setting out the following details, pursuant to Section 7 of the Act and Sub-rule (1) of Rule 4 of the Rules.

The certified copy of the following educational degree and certificate of experience obtained by me is attached herewith.

SN	Educational degree or training obtained	Period of study	Name and address of institution providing degree	Class	Date of degree	Remarks

The above-mentioned contents and the description attached herewith are true and correct, if proved false, I shall bear and pay according to law.

Thumb impressions

Right      Left

Applicant doctor's:

Name:

Signature:

Date:

Registration number and date of  
Nepal Medical Council  
registration number:

Address:



**Format of certification of experience**

(a) In the case of work in the central level hospital:

I hereby certify that Mr./Mrs./Miss....., age of ..... years, a resident of....., son/daughter/wife of Mr..... has worked in the following post in this hospital for the following period:-

Name of hospital	Name of post held	Class or level	Permanent, temporary, contract	Date of appointment or service	Date until when service has been done in that post	Whether in service till now	Main details of works of that post	Remarks

Of the chief of hospital certifying that the above details are true and correct:

Name:

Signature:

Date:

Designation:

Name of Hospital:

Seal of Hospital:

Concerned doctor's:

Signature:

Name:

- (b) The committee shall make certification based on the documents submitted by the concerned applicant in respect of experience of works in a foreign hospital.

## Schedule-8

(Relating to Sub-rule (2) of Rule 4)

**Organ Transplantation Coordination Committee, Kathmandu**

### **Private license to operate kidney transplantation service**

To .....

.....

Whereas, necessary inquiry has been made into the application submitted by you on..... (date) for the private license to operate the kidney transplantation service, and it has been submitted to the meeting of the Organ Transplantation Coordination Committee; and decision has been made on..... (date) to issue the private license to operate the kidney transplantation service to you;

Now, therefore, this private license is, hereby, issued pursuant to Section 8 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Sub-rule (2) of Rule 4 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

Private license issuing authority's:

Name:

Signature:

Date:

Designation: Member secretary

Organ Transplantation Coordination Committee

## **Schedule-9**

(Relating to Sub-rule (1) of Rule 5)

### **Application for the renewal of permit**

The Organ Transplantation Coordination Committee,

*Kathmandu.*

**Subject: Request for renewal of permit.**

Whereas, I need to have renewed the permit issued by that committee to operate the kidney transplantation service;

Now, therefore, I submit this application, accompanied by the necessary fees, pursuant to Sub-section (2) of Section 9 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Sub-rule (1) of Rule 5 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

Seal of health institution

Applicant on behalf of health institution:

Name:

Signature:

Designation:

Date:

## **Schedule-10**

(Relating to Sub-rule (2) of Rule 5)

**Organ Transplantation Coordination Committee, Kathmandu**

### **Certificate of renewal of permit**

To.....,

.....

Whereas, the application submitted by that institution on.....  
(date) for the renewal of the permit to operate the kidney transplantation  
service has been submitted to the meeting of the Organ Transplantation  
Coordination Committee dated.....; and decision has been made  
on.....(date) to renew the permit to operate the kidney transplantation  
service to that institution for a period from..... to.....;

Now, therefore, this certificate is, hereby, issued pursuant to Sub-  
section (3) of Section 9 of the Human Body Organ Transplantation  
(Regulation and Prohibition) Act, 2055 (1998) and Sub-rule (2) of Rule 5 of  
the Human Body Organ Transplantation (Regulation and Prohibition) Rules,  
2058 (2002).

Permit renewing authority's:

Name:

Signature:

Date:

Designation: Member secretary

Organ Transplantation Coordination Committee

## **Schedule-11**

(Relating to Clause (a) of Rule 7)

### **Contents to be certified by the concerned doctor** **that organ transplantation is necessary**

We hereby certify, pursuant to Clause (a) of Sub-section (1) of Section 15 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Clause (a) of Rule 7 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002), that we have examined the health of Mr/Mrs/Ms.....(name of patient), age of ..... years, a resident of ....., and found that his/her both kidneys in his/her body are non-functional and that it is necessary to transplant one kidney in lieu of the destroyed kidneys in his/body in order to save his/her life.

Certifying nephrologist's:

1. Full name and surname:

Signature:

Date:

Registration number of Nepal Medical Council:

Name of health institution being engaged in:

Seal of health institution being engaged in:

2. Full name and surname:

Signature:

Date:

Registration number of Nepal Medical Council:

Name of health institution being engaged in:

Seal of health institution being engaged in:

## Schedule-12

(Relating to Clause (b) of Rule 7)

**Contents to be certified by the concerned doctor**  
**that donor of kidney will have no physical effects**

Whereas, certification has been made on..... (date) by nephrologists Mr/Mrs/Ms..... and Mr/Mrs/Ms..... that they have examined the health of Mr/Mrs/Ms..... (name of patient), age of ..... years, a resident of ....., and found that his/her both kidneys in his/her body are non-functional and that it is necessary to transplant one kidney in lieu of the destroyed kidneys in his/body in order to save his/her life; and

Whereas, on..... (date), Mr/Mrs/Ms..... (name of donor), age of..... years, a resident of ..... years, has, for the transplantation of kidney into the body of patient, executed a deed of consent to extract one kidney out of his/her twin kidneys in his/her body and transplant the kidney into the body of the patient;

Now, therefore, pursuant to Clause (d) of Sub-section (1) of Section 15 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Clause (b) of Rule 7 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002), we hereby certify that the donor so giving consent to donate the organ will neither die immediately nor become disabled or incapacitated in a permanent manner as a result of extraction of any organ out of the twin organs of the body of that donor.

1. Certifying nephrologist's:

Full name and surname:

Signature:

Date:

Registration number of Nepal Medical Council:

Name of health institution being engaged in:

Seal of health institution being engaged in:

2. Certifying surgeon's:

Full name and surname:

Signature:

Date:

Registration number of Nepal Medical Council:

Name of health institution being engaged in:

Seal of health institution being engaged in:



## Schedule-13

(Relating to Clause (a) of Rule 8)

### **Deed of consent to be given by alive person to donate kidney**

Whereas, for purposes of Section 15 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998), I ..... and my near relative ..... by relation ..... have agreed and concurred to extract one kidney from my body and transplant it into the body of my close relative ..... who is my ..... by relation;

Now, therefore, I have given this deed of consent, pursuant to Clause (b) of Sub-section (1) of Section 15 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Clause (a) of Rule 7 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

Donor of kidney:

Recipient of kidney:

Name:

Name:

Grand-father's name:

Grand-father's name:

Father's name:

Father's name:

If married,

If married,

husband's or wife's name:

husband's or wife's name:

Age:

Age:

Address:

Address:

Signature:

Signature:

Recently taken passport  
size photograph  
with two ears being visible

Recently taken passport  
size photograph  
with two ears being visible

Thumb impressions  
Right Left

Close relative of donor of kidney:

(a) Name:  
Age:  
Address:  
Relation:  
Signature:

Thumb impressions:  
Right Left

(b) Name:  
Age:  
Address:  
Relation:  
Signature:

Thumb impressions:  
Right Left

## Schedule-14

(Relating to Clause (b) of Rule 8)

### Deed of consent to be given by person to donate kidney after death

Recently taken  
passport size  
photograph of  
donor with two  
ears being visible.

Whereas, I consent to extract the kidney from my body after my death and transplant the same into the body of any patient who is in need of kidney;

Now, therefore, I have knowingly and voluntarily given this deed of consent, pursuant to Clause (b) of Sub-section (1) of Section 16 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Clause (b) of Rule 8 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

Donor of kidney after death:

Name:

Grand-father's name:

Father's name:

If married,

husband's or wife's name:

Age:

Address:

Right Left

Thumb impressions

Signature:

## Schedule-15

(Relating to Clause (c) of Rule 8)

### **Deed of consent to be given by close relative of deceased to extract kidney after death**

To.....,

.....

Whereas, my/our close relative deceased ..... has, for purposes of Section 14 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998), knowingly and voluntarily given consent to extract kidney from his/her body after his/her death and transplant the same in the body of any person whosoever and executed a deed of consent on ..... (date), pursuant to Clause (b) of Sub-section (1) of Section 16 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Clause (b) of Rule 8 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002), and now he/she has died; and

Whereas, I/we, the below-mentioned close relative/relatives, concur to extract kidney from his/her body as per his/her will;

Now, therefore, I/we have executed this deed of consent pursuant to Clause (c) of Rule 8 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002).

Close relative giving consent to donate kidney of deceased:

Name:

Name:

Signature:

Signature:

Grand-father's name:

Grand-father's name:

Father's name:

Father's name:

If married,

If married,

husband's or wife's name:

husband's or wife's name:

Age:

Age:

Relationship with deceased:

Relationship with deceased:

Address:

Address:

Date:

Date:

Thumb impressions

Thumb impressions

Right Left

Right Left

## Schedule-16

(Relating to Clause (d) of Rule 8)

### **Deed of consent to be executed by recipient of kidney or person on behalf of such person**

To.....,

.....

Whereas, I/he/she ..... , age of ..... years, a resident of Ward No....., VDC/Municipality ....., District, have/has been suffering from kidney related ..... disease, I/he/she have/has got my/his/her health checked up by the concerned doctor; and the doctor has certified that both kidneys in my/his/her bodies have been deformed to be unworkable and it is necessary to transplant one kidney in lieu of such deformed kidney for the safety of my/his/her life; and

Whereas, the donor ..... has given consent on ..... (date) to extract kidney from his/her body during his/her life/after death and transplant the same into my/his/her body or body of any person whosoever for purposes of my/his/her medical treatment; and I/he/she agree/agrees to receive the kidney of the said donor through transplantation pursuant to Sub-section (1) of Section 19 of the Human Body Organ Transplantation (Regulation and Prohibition) Act, 2055 (1998) and Rule 12 of the Human Body Organ Transplantation (Regulation and Prohibition) Rules, 2058 (2002);

Now, therefore, I have executed this deed of consent to that effect.

Person consenting to receive kidney:

Name:

Signature:

www.lawcommission.gov.np

Date:

Grand-father's name:

Father's name:

Relationship with patient:

Address:

Date:

Thumb impressions

Right Left

Thumb impressions

Right Left

## **Schedule-17**

(Relating to Rule 11)

### **Rate of meeting allowance**

The meeting allowance receivable by the chairperson, member of the committee and observer for having taken part in the meeting of the committee shall be Three Hundred Rupees per meeting.