

# **THE TRANSPLANTATION OF HUMAN ORGANS RULES, 1995**

**(GSR NO. 51(E), dt. 4-2-1995)**

**[As amended vide GSR 571(E), dt.31-7-2008]**

*In exercise of the powers conferred by sub-section (1) of section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely:-*

- 1. Short title and commencement**
- 2. Definitions**
- 3. Authority for removal of human organ**
- 4. Duties of the Medical Practitioner**
- 5. Preservation of organs**
- 6. Composition of Authorisation Committees**
- 7. Registration of hospital**
- 8. Renewal of registration**
- 9. Conditions for grant of certificate of registration**
- 10. Appeal**

## **1. Short title and commencement**

These rules may be called the Transplantation of Human Organs Rules, 1995.

They shall come into force on the date<sup>1</sup> of their publication in the Official Gazette.

## **2. Definitions**

"Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);

"Form" means a form annexed to these Rules;

"Section" means a section of the Act;

<sup>2</sup>["National Accreditation Board for Laboratories" (NABL) means a Board set up by the Quality Council of India (set up by the Government of India) for undertaking assessment and accreditation of testing and calibration of laboratories in accordance with the international standard ISO/IEC/17025 and ISO 15189;

the Registered Medical Practitioner, as defined in clause (n) of section 2 of Transplantation of Human Organs Act, 1994 includes an allopathic doctor with MBBS or equivalent degree under the Medical Council of India Act.]

Words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

## **3. Authority for removal of human organ**

Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and so such conditions as specified in 4[Forms 1(A), 1(B) and 1(C)].

## **4. Duties of the Medical Practitioner**

A registered medical practitioner shall, before removing a human organ from the body of a donor before his death, satisfy himself-

that the donor has given his authorization in Form 1(A) or 1(B) or 1(C).

that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.

That the donor is a near relative of the recipient as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary documents as prescribed and medical tests, if required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant center.

That in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provision of sub-rule (2) of rule 4A.

In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.

A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself-

(a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had

subsequently revoked the authority aforesaid; 1[(b) that then person lawfully in possession of the dead body has signed a certificate as specified in Form 6.]

A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself- that a certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act; that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

#### **4A. Authorisation committee**

The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation committee constituted under the provision of clauses (a) and (b) of sub-section (4) of section 9 of the Act.

Where the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e. Incharge of transplant center must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. Are kept for records along with the information on the number of age of children and family photograph depicting the entire immediately family, birth certificate of children containing particulars of parents.

When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committees shall consider all such requests.

When the proposed donor and the recipient are not "near relatives", as defined under clause (i) of section 2 of the Act, the Authorisation Committee shall evaluate that,-

there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;

the following shall specifically be assessed by the Authorisation Committee:-

an explanation of the link between them and the circumstances which led to the offer being made;

reasons why the donor wished to donate;

documentary evidence of the link, e.g. proof that they have lived together, etc;

old photographs showing the donor and recipient together;

that there is no middleman or tout involved;

that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;

that the donor is not a drug addict or known person with criminal record;

that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection such kin shall also be recorded and taken note of.