

Article

Legal Aspects Of Organ Donation And Transplantation In India

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INTRODUCTION

After years of exploitative practices in living unrelated transplants the Transplantation of Human Organs Act was passed in India in 1994 to put a stop to commercial dealings in organs. It also accepted the concept of brain-stem death and deceased organ donation and transplantation. Living unrelated donation is still permissible under the Act, but it has to be established that such a donation is altruistic in nature.

This article summarises the points relevant to deceased organ donation in the Transplantation of Human Organs Act, 1994, Transplantation of Human Organs Rules, 1995 (amended 2008), Transplantation of Human Organs and Tissues Act, 2011 (Amendment) and the Transplantation of Human Organs and Tissues Rules, 2014.

The Act itself lays down the broad legal framework, while the Rules are about the practical working of the Act (the required 'Forms' and other documents). Since Health is a state subject, each state has to adopt the Act by passing legislation. Government Orders/Resolutions have also been brought out by some state governments for clarity on procedures to be followed.

TRANSPLANTATION OF HUMAN ORGANS ACT, 1994 & TRANSPLANTATION OF HUMAN ORGANS RULES, 1995 (amended 2008)

KEY POINTS

- To regulate removal, storage and transplantation of human organs for therapeutic purposes.
- Prevent commercial dealings in organs.
- Brain-stem death defined – Stage at which all functions of the brain stem have permanently and irreversibly ceased.
- Procedure for brain-stem death certification laid out.
- Consent for deceased organ donation:
 - Self when alive, 2 witnesses (Form 5 – “Donor card”)
 - Person in lawful possession of body (Form 6)-

Parents, in case of minors (Form 9)

- Unclaimed bodies, > 48 hours, hospital / prison in-charge
 - Regulatory / Enforcement bodies:
 - Appropriate Authority: State appointed for granting and renewing hospital transplant license, monitoring of hospitals
 - Authorisation Committee: clearance of unrelated living donor transplants
 - Board of Medical Experts (panel comprising four doctors for certifying brain death)
 - Hospital medical administrator
 - Independent specialist from panel authorised by Appropriate Authority (Doctor No. 2)
 - Neurologist / Neurosurgeon (Doctor No. 3)
 - Treating medical officer Doctors No. 2 and No. 3 will be co by the Administrator in-charge of the hospital from the panel of experts approved by the Appropriate Authority.
 - Brain-stem death certification - The format for brain-stem death certification is laid out in Form 8 (Brain-stem death certificate). Two independent certifications have to be carried out at least six hours apart. While the brain-stem death certificate requires the doctors to document the results of testing for brain-stem reflexes and the apnoea test, there are no guidelines in the Rules about how the apnoea test should be done.
 - Transplant coordinator - The of Human Organs Rules, 2008 made it mandatory for a hospital to nominate a transplant coordinator before it was registered.

TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) ACT, 2011 & TRANSPLANTATION OF HUMAN ORGANS AND TISSUES RULES, 2014

KEY POINTS

- Tissues also included (except blood).

- Human Organ Retrieval Centre defined. This is a hospital which has adequate facilities for treating seriously ill patients who can be potential donors of organs in the event of death. These hospitals need to be registered for retrieval of human organs and tissues (Form 13 –Application for registration of hospital to carry out organ/tissue retrieval other than eye/cornea retrieval).
- Transplant coordinator defined. This is a person appointed by the hospital for coordinating all matters relating to removal or transplantation of human organs or tissues.
- Required request – It is the duty of the registered medical practitioner (RMP) in consultation with the transplant coordinator if available to make known to the family of a brain-stem dead person the option of organ and tissue donation. Whether donation is authorized or declined it needs to be documented in Form 8 (Declaration cum consent Form).
- Expansion of brain-stem death certification panel – Anaesthetist /Intensivist nominated by the head of the hospital and duly empanelled by the Appropriate Authority may certify brain death as a member of the Board of Medical Experts.
- Brain-stem death certificate is Form 10 as per the Rules of 2014. It is the same as Form 8 of the Rules of 2008 with two additions – i) an Anaesthetist or Intensivist can be a part of the panel. ii) In case of children 6 to 12 years of age, 1 to 5 years of age and infants, the time interval between the first and second testing shall increase depending on the opinion of the panel of experts.
- Deceased donor maintenance cost –Can be borne by recipient, institution, government or NGO/Society.
- Procedure for donation of organ or tissue in medicolegal cases – After the authority for removal of organs or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the RMP of the hospital shall make a request to the Station House Officer or Superintendent of the area either directly or through the police post located in the hospital to facilitate timely removal of organs or tissue from the donor and a copy of such a request should also be sent to the postdoctor of the area simultaneously.

STATE GOVERNMENT ORDERS AND RESOLUTIONS

- The Governments of Tamil Nadu and Kerala have brought out Government Orders (GOs) laying down the procedure for brain-stem death certification. This includes the Brain-stem death certificate (Form 8 as per the Rules 2008) and, in addition, the guidelines for Apnoea test. The Tamil Nadu GO mentions that Intensivists can be a part of the panel certifying brain death, while the Kerala GO does not.
- The Tamil Nadu GO No. 75 is given at the end of the article with Form 8 as Annexure -1 and Guidelines for Apnoea test as Annexure-2.
- The Government of Andhra Pradesh's GO and the Government of Maharashtra's Resolution both say that Intensivists can be a part of the panel certifying brain death. Form 8 is used for brain-stem death certification. There are no guidelines for test.
- For more details on the GOs – Tamil Nadu (www.dmrhs.org/tnos), Kerala (www.knos.org.in), Telangana (www.jeevandan.gov.in), Maharashtra (www.ztccmumbai.org)