

ANNEXURE-A TO THE SUB-COMMITTEE-II REPORT
(PROPOSED AMENDMENTS IN TOHO ACT & RULES)

<p>Existing Transplantation of Human Organs Rules, 1995</p> <p>(Rules 3, 4(1), 6 and 9)</p>	<p>Proposed Transplantation of Human Organs Rules, 1995</p> <p>(Rules 3, 4(1), 6 and 9 with additional Rules 6A, proposed to be inserted between Rule 6 and 7 of the existing rules.</p>
<p>3. Authority for Removal of Human Organ.- Any donor may authorize the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in Form I.</p>	<p>3. Authority for Removal of Human Organ.- Any donor may authorize the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in <i>Forms 1(A), 1(B) and 1(C), as may be applicable to the donor.</i></p>
<p>4. Duties of the Medical Practitioner.- (1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death, satisfy himself –</p> <p>(a) that the donor has given his authorization in Form 1;</p> <p>(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate as specified in Form 2.</p> <p>(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form 3 after carrying out the following tests on the</p>	<p>4. Duties of the Medical Practitioner.- (1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death, satisfy himself –</p> <p>(a) that the donor has given his authorization in <i>appropriate Form 1(A) or 1(B) or 1(C).</i></p> <p>(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate as specified in Form 2.</p> <p>(c) That the donor is a near relative of the recipient, as certified in Form 3, <i>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</i></p>

donor and the recipient, namely:-

i) tests for the antigenic products of the Human Major Histocompatibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;

ii) tests to establish HLA-DR beta and HLADQ beta gene restriction fragment length polymorphism;

iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;

iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphisms using at least five single locus polymorphic probes.

d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that they are so related and shall sign a certificate in Form 4.

by the authorisation committee/committees of competent jurisdiction(s) and that the necessary medical tests to determine the factum of near relationship, have been performed to the satisfaction of the authorisation committees of competent jurisdiction(s). The tests are as follows:-

(vi) The tests for HLA, HLA-B alleles to be performed by the serological and/or PCR based DNA methods.

(vii) Test for HLA-DR beta genes to be performed using the PCR based DNA methods.

(viii) Where the tests referred to in (i) and (ii) above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on both or at least one parent. If parents are not available, same tests to be performed on such relatives of donor and recipient as are available and are willing to be tested.

(ix) Where the tests referred to in (iii) above do not establish a genetic relationship between the donor and the recipient, tests for DNA fingerprinting using single locus/multilocus polymorphic probes to be performed.

Test mentioned in (iv) above is likely to be required in rare cases and therefore may be dispensed with in cases where there is urgency on medical grounds rendering inexpedient and impractical to wait for the result of the test, the Authorization Committee may consider the case without the test in (iv) above.

d) that in case the recipient is spouse of the donor, the donor to give 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 authorization committee.

e) 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

	<p>permission from the Authorisation Committee for the said donation has been obtained.</p>
<p>6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10.</p>	<p>6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10. The Authorisation Committee shall take a decision on such application in accordance with the guidelines in Rule 6A.</p> <p><u>6A. GUIDELINES FOR WORKING OF THE AUTHORISATION COMMITTEE</u></p> <p><i>1. Secretariat of the Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee at least three days before ordinary meetings and at least a day before the date of emergent meeting. Such applications should be circulated along with all annexures, which may have been filed along with the applications. At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the office of the jurisdictional DM/ADM/SDM or through any other competent officer, or relevant ministry, who shall ensure that such fact or information is gathered or verified from the relevant original source whether the same falls within the jurisdiction of the said district or outside the district falling under the jurisdiction of the Authorisation Committee. In case such information/fact needs verification from place outside the jurisdiction of the DM/ADM/SDM, it shall be the responsibility of the DM/ADM/SDM to use his official channel to contact his counterpart in the relevant district or any other authority to provide him the necessary information.</i></p> <p><i>2. In the course of determining eligibility of the</i></p>

applicant to donate, the applicant should be personally interviewed by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should preferably be videographed. The Authorisation Committee must focus its attention on the following :-

a) Where the proposed transplant is between persons related genetically, (e.g. Brother, Sister, Mother, Father, Children above the age of 18 years)

The authorisation committee must evaluate :-

v) results of tissue typing and other basic tests.

vi) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;

vii) documentary evidence of identity and residence of the proposed donor e.g. Ration Card/Voters identity Card/Passport/ Driving License/ PAN Card/Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative.

viii) If in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests as prescribed in Rule 4(1).

b) Where the proposed transplant is between a married couple :

The authorisation committee must evaluate all available evidence to establish the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph is placed before the committee along with the information on the number and age of children and a family photograph depicting the entire immediate

family, birth certificate of children containing the particulars of parents.

c) Where the proposed transplant is between persons who are related genetically but whose relationship cannot be established in accordance with rules:-

iv) results of tissue typing and other tests with the name of the HLA laboratory and if possible the statistical estimation of the probability of a genetic relationship;

v) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;

vi) documentary evidence of identity and residence of the proposed donor e.g. Ration Card/Voters identity Card/Passport/ Driving License/ PAN Card/Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative.

d) Where the proposed transplant is between individuals who are not “near relatives”. The authorization committee must evaluate:

vii) That there is no commercial transaction between the recipient and the donor. That no payment of money or moneys worth as referred to in the Sections of the Act, has been made to the donor or promised to be made to the donor or any other person.

viii) that the following is specifically assessed by the Authorisation Committee :-

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

f) Reasons why the donor wishes to

donate?

g) Documentary evidence of the link e.g. proof that they have lived together etc.

h) Old photographs showing the donor and the recipient together.

ix) that there is no middleman/tout involved;

x) 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.

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

xii) that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his/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/ disagreement/objection of such kin may also be recorded and taken note of; and

e) When the proposed donor or the Recipient or Both are foreigners:

i. A senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient or where they are not related the reasons as to why the proposed donor is desirous of donating his organ to the proposed recipient.

ii. Authorisation Committee shall examine the cases of Indian donors consenting to donate organs to a foreign national, including a foreign national of Indian origin, with greater caution. Such cases should be considered rarely on case to case basis.

3. *In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed/verified by a person other than the recipient. Any document with regard to the proof of residence/ domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Authorisation Committee may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.*

4. *In all cases of non-near relatives, the interview of the donor should specifically deal with the aspect of affection/attachment/ other special reason, in order to rule out commercial considerations.*

5. *Further all donors should specifically be interviewed to rule out any element of coercion, undue influence, fraud or misrepresentation in the proposal of donation. The Authorisation Committee should state in writing its reason for rejecting/approving the application of the proposed donor and all approvals should be subject to the following conditions:-*

i) that the approved proposed donor has been and would mandatorily be subjected to all such medical tests as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question and

ii) further that the psychiatrist clearance would also be mandatory to certify his mental condition, awareness, absence of any overt or latent psychiatric disease and ability to give free consent.

iii) All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.

6) *The Authorisation Committee should employ a Secretariat comprising of adequate number of*

	<p><i>employees to help it in receiving the applications and circulating it to members, informing the applicants to complete any deficiency in the application either in terms of information or in terms of supporting documents, which may be required to be submitted; to assist the Chairperson in sending notices to the members of the Authorisation Committee; to prepare minutes of the interview and providing secretarial services for dictating agenda of meetings and speaking orders.</i></p> <p><i>7). The authorisation committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires immediate transplantation.</i></p>
<p>9. Conditions for grant of Certificate of Registration. – No hospital shall be granted a certificate of registration under this Act unless it fulfils the following requirement of manpower, equipment, specialized services and facilities as laid down below:-</p> <p>General Requirement</p> <ol style="list-style-type: none"> 1. Surgical Staff 2. Cardiology Staff 3. Nursing Staff 4. Communication System 5. Intensivist 6. Medical Social Worker 7. Perfusionist 8. Ophthalmologist 9. Corneal Surgeons. 	<p>9. Conditions for grant of Certificate of Registration. – <i>No hospital shall be granted a certificate of registration under this Act unless it fulfils the following requirement of manpower, equipment, specialized services and facilities as laid down below:-</i></p> <p>General Manpower Requirement Specialised Services and Facilities</p> <ol style="list-style-type: none"> <i>1. 24 hours availability of medical and surgical, (senior and junior) staff.</i> <i>2. 24 hours availability of nursing staff, (general and speciality trained).</i> <i>3. 24 hours availability of Intensive Care Units with adequate equipments, staff and support system, including specialists in anaesthesiology, intensive care, physiotherapy.</i> <i>4. 24 hours availability of laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology and Hematology and Radiology departments with trained staff.</i> <i>5. 24 hours availability of Operation Theater facilities (OT facilities) for planned and emergency</i>

<p>Various Departments</p> <ol style="list-style-type: none"> 1. Microbiology 2. Mycology 3. Pathology 4. Virology 5. Nephrology 6. Neurology 7. Psychology 8. G.I. Surgery 9. Anaesthesiology 10. Imaging Facilities 11. Paediatrics 12. Physiotherapy 13. Immunology 14. Haematology 15. Blood Bank 16. Clinical Chemistry 17. Cardiology 18. Department of Ophthalmology 	<p><i>procedures with adequate staff, support system and equipments.</i></p> <p><i>6. 24 hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone systems, fax, computers and paper photo-imaging machine .</i></p> <p><i>7. Experts (Other than the experts required for the relevant transplantation) of relevant and associated specialities including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, paediatrics, gynaecology immunology and cardiology etc. should be available to the transplantation centre.</i></p> <p style="text-align: center;">Equipments</p> <p><i>Equipments as per current and expected scientific requirements specific to organ/organs being transplanted. The transplant centre should ensure the availability of the accessories, spare-parts and back-up/maintenance/service support system in relation to all relevant equipments.</i></p> <p>Experts</p> <p><i>(A) Kidney Transplantation</i></p> <p>M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognized center in India or abroad and having attended to adequate number of renal transplantation as an active member of team.</p> <p><i>(B) Transplantation of liver and other abdominal organs</i></p>
<p>Non-transplantation Programme Team</p> <ol style="list-style-type: none"> 1. Neurologist 2. Neurosurgeon 	<p>M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with a reasonable experience of performing liver transplantation as an active member of team.</p> <p><i>(C) Cardiac, Pulmonary, Cardio-Pulmonary</i></p>

<p>3. Medical Superintendent</p> <p>4. And Other Hospital Staff</p> <p>5. Eye Donation Counsellor/Grief Counsellor.</p> <p>Basic Equipment</p> <p>1. Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.</p> <p>2. Slit Lamp</p> <p>3. Special Microscope</p> <p>4. Operating Microscope</p> <p>Additional Equipment Required for Transplantation Programme</p> <p>1. Cell Saver</p> <p>2. Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric operated.</p> <p>3. Mobile C-arm, image intensifier for routine biopsies in the sterile operating room.</p> <p>4. Eact/Alert System for early detection of any infection.</p> <p>5. Radioimmunoassay for measuring Cyclosporin levels.</p> <p>6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.</p> <p>7. Autoclave (mandatory)</p> <p>8. U.V. Lamp } Desirable.</p>	<p><i>Transplantation</i></p> <p>M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery.</p> <p>(D) <i>Cornea Transplantation</i></p> <p>M.D./M.S. ophthalmology or equivalent qualification with one year post M.D./M.S training in a recognised hospital carrying out Corneal transplant operation.</p>
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<p>9. Laminor Flow } Experts</p> <p>(A) Kidney Transplantation</p> <p>M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognized center in India or abroad and having attended to adequate number of renal transplantation as an active member of team.</p> <p>(B) Transplantation of liver and other abdominal organs</p> <p>M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with a reasonable experience of performing liver transplantation as an active member of team.</p> <p>(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation</p> <p>M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery.</p>	
<p>Existing Section 9(1) of the Transplantation of Human Organs Act, 1994</p>	<p>Proposed Section 9(1) Transplantation of Human Organs Act, 1994</p>
<p>9. Restrictions on removal and transplantation of human organs –</p> <p>(1) Save as otherwise provided in sub-section (3), no human Organ removed from the body of a donor before his death shall be transplanted into a recipient unless</p>	<p>9. Restrictions on removal and transplantation of human organs –</p> <p>(1) Save as otherwise provided in sub-section (3), no human Organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the</p>

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recipient and such relationship has been certified by the authorisation committee.