

**The Report**  
**Of**  
**Transplant of Human Organs**  
**Act Review Committee**

(as per the Delhi High Court Judgement dated 06.09.2004 in W.P.  
no.813/2004 to review the provisions of the Transplantation of Human  
Organs Act, 1994 and the Transplantation of Human Organs  
Rules, 1995)



**Directorate General of Health Services**  
**Ministry of Health & Family Welfare**

**Govt. of India**

**25<sup>th</sup> May 2005**

# THE REPORT OF THE TRANSPLANTATION OF HUMAN ORGANS ACT REVIEW COMMITTEE

## **PART I - BACKGROUND NOTE**

A Committee, hereinafter referred to as the THOA Review Committee, was constituted in terms of the judgement dated September 6, 2004 passed by Hon'ble Mr. Justice Man Mohan Sarin of High Court of Delhi in WP(C) 813/2004 titled Balbir Singh Vs. The Authorisation Committee and Others (Balbir Singh case) with direction to review the efficacy, relevance and impact of the legal provisions contained in the Transplantation of Human Organs Act, 1994 (TOHO Act) and the Transplantation of Human Organs Rules, 1994 (TOHO Rules).

The Review Committee commenced its working under the chairpersonship of Additional Secretary (Health) to the Government of India and set out to objectively and critically appraise and analyse the practical functionality of the provisions of the TOHO Act and the TOHO Rules, as defined by the Hon'ble High Court of Delhi in the Balbir Singh case.

The terms of reference are as follows: -

1. *Based on the data available on the transplantation of organs and the working of the Authorisation Committees, the Committee to examine and make its recommendations on the composition of Authorisation Committees and changes, if any, required to ensure timely permissions.*
2. *Whether the jurisdiction of the Authorisation Committees should be enlarged by bringing within its ambit the process of certifying a "near relative" or the task be assigned to another Designated authority?*
3. *Review the provisions of the Rules based on the experience of transplantation of organs as carried out and the difficulties arising due to the bottlenecks faced in the said process. The Committee to examine in particular provisions of Section 9 and requirement of carrying out the tests prescribed in Rule 4, certification in Form-3 to review the definition of "near relative" and make its recommendations in the light of the observations made.*
4. *Examine and specify the organs for transplantation of which the tests prescribed in Rule 4(1)(c) to establish the factum of being "near relative" need not be carried out when other evidence is available.*
5. *Examine the feasibility of establishing and setting up Organ Procurement Organizations with data bank to facilitate the*

*dissemination of information on availability of organs for transplantation. To encourage organ donation especially from cadavers, cases of brain stem death and other deceased persons, who had authorized removal of organs upon demise.*

6. *Examine the feasibility of creation of a fund, the corpus to be provided partly come from the Union of India and partly by levying a fixed charge on the total bill of the hospital for transplantation and/or public donations, for providing to a donor social incentives, medical aid and facility of transplantation of organ in future, should the same be required.*
7. *Examine and recommend ways and means to give social incentives, including but not limited, to help and aid and preferred health care, recognition and honour to a donor in the community.*
8. *Examine the causes that lead to exploitation of poor and unaware persons in the process of organ donation and suggest methods to reduce, control and ultimately eradicate such mal-practices. Recommend programmes for dissemination of correct information of ethical, legal and devising procedure concerning organ donation so that a conducive atmosphere is generated and disinformation and misgivings are dispelled.*
9. *Any other matter relevant to the subject.*

The factors that gave rise to a thinking process, requiring re-appraisal of the existing provisions in TOHO Act and Rules, and which in turn contributed to and culminated in determination of the terms of reference for the Review Committee, by the Hon'ble Court of Delhi, may be summarized as under: -

- (i) The determination of the fact as to whether the proposed 'donor' is the "near relative" within the meaning of section 2(i) of TOHO Act, may not necessarily require the 'donor' to undergo the prescribed medical tests in all cases and in the process consume crucial time, if relationship is otherwise ascertainable through other credible evidence.
- (ii) If the factum of relationship is ascertainable from credible documents indicating the same and medical tests are not required to prove the same, then, in such cases, the requirement of a medical practitioner certifying the same may be superfluous and cosmetic.
- (iii) The "Authorisation Committee" as defined under Section 2(c) of the TOHO Act may also be constituted for examining the cases of "near

relatives" as well, so that the appropriate decisions are taken well in time before it is too late for the patient.

- (iv) The existing legal provisions particularly Section 9 of the TOHO 9 and Rule 4 of the TOHO Rules need to be harmonized with the emergent needs of the critical patients requiring immediate transplantations, without compromising the objective of TOHO Act & Rules which are aimed inter-alia to prevent unscrupulous and commercial practices in the matters relating to 'donation' of the human organs for the purposes of transplantation.
- (v) The present formats of the Forms appear to be unsatisfactory and the particulars required to be filled therein may not have nexus with the objectives, which the TOHO Act and the TOHO Rules profess to achieve.

Accordingly, a high-power committee comprising of the following members was constituted by the Hon'ble High Court of Delhi: -

- (i) Secretary, Ministry of Health or his nominee being an officer not less than the rank of Additional Secretary, Ministry of Health, as the Convener.
- (ii) Director General of Health Services or the Addl. Director General of Health Services as the Member Secretary.
- (iii) The Head of Department of Surgery, AIIMS;
- (iv) Dr. Harsha Jauhari, Renal Surgeon, Sir Ganga Ram Hospital;
- (v) Secretary of the Indian Medical Association (IMA); and
- (vi) Mr. Sanjay Jain, Advocate, High Court of Delhi.

In terms of the above, Dr. S.Y. Quraishi presided over the Review Committee as its Convener, having been nominated by the Secretary (in the first meeting Smt. P. Jyoti Rao, Additional Secretary Health had presided); Prof. V.K. Arora, Additional Director General of Health Services is participating as Member-Secretary having been nominated by Director General, DGHS and Dr. S.N. Mehta is participating as Member being Head of Department, Department of Surgery, AIIMS. Dr. Vinay Agarwal participated as Member being Secretary of the Indian Medical Association (IMA).

The Committee was required to submit its report by January 5, 2005. Initially the time was extended by the Hon'ble High Court of Delhi upto 30.04.2005 and thereafter up to 26<sup>th</sup> May 2005. The Committee also availed the benefit of the

following persons in the course of its deliberations, who were requested to participate in deliberation process as special invitees:-

1. Dr. (Mrs.) Anita Roy, DCP, Delhi Police
2. Shri B.P. Sharma, Joint Secretary, MOHFW
3. Dr. R.L. Icchpujani, DDG(P), DteGHS
4. Dr. S. N. Mishra, Hony. Jt. Secretary, IMA
5. Shri Dev Mehra, General Manager, IMA
6. Dr. Sudhir Gupta, CMO(NCD)

In order to collect and collate data regarding transplantation activities from some states and NCT of Delhi; a format was developed and data collected from various institutions registered in Delhi and some state Govts. The photocopy sets of replies received from various institutions containing about 624 pages have been circulated to all members before the second meeting. The meetings have taken place as follows:-

#### **Chronological events of the THOA review committee**

- |     |  |            |
|-----|--|------------|
| 1.  | Court order for constituting committee           | 06-09-2004 |
| 2.  | Review Committee approved by Secy (H)            | 23-11-2004 |
| 3.  | First meeting of Thoa review committee           | 07.12.2004 |
| 4.  | Data requested from Delhi Instt. & 4 states      | 08.12.2004 |
| 5.  | 2 <sup>nd</sup> meeting scheduled & postponed    | 22.12.2004 |
| 6.  | 2 <sup>nd</sup> meeting scheduled & postponed    | 29.12.2004 |
| 7.  | 2 <sup>nd</sup> meeting of Thoa review committee | 01.02.2005 |
| 8.  | 3 <sup>rd</sup> meeting of Thoa review committee | 14.03.2005 |
| 9.  | 4 <sup>th</sup> meeting of Thoa review committee | 31.03.2005 |
| 10. | 5 <sup>th</sup> meeting of Thoa review committee | 21.04.2005 |
| 11. | 6 <sup>th</sup> meeting of Thoa review committee | 18.05.2005 |

12. 7<sup>th</sup> meeting of Thoa review committee 25.05.2005

Other issues which were also discussed include:-

1. Letter from Prof. Madan Mohan for cornea/eye transplantation
2. Letter from Delhi Nephrological Society
3. Offences under THOA Act to be made cognizable (as per HFM meeting 05.03.2004)
4. Extract of Rajya Sabha debate dated 13.12.2004 containing matter of public importance raised in house by Shri B. J. Panda
5. Dr. Harsha Jauhari, Member submitted a written note on the subject to appreciate the background and scope of organ transplantation activities.
6. Dr. S.N. Mehta, Head of Surgery AIIMS submitted his views in form of note.
7. Dr. Anita Roy, DCP, Delhi Police submitted a note regarding legal matters pertaining to organ transplantation.

After several rounds of preliminary discussions, the Review Committee decided to constitute two sub-committees to effectively carry out the terms of reference contained in Balbir Singh case.

## **SUB-COMMITTEE-I**

### **Composition**

- Dr. S.N. Mehta, Head of Department, Surgery AIIMS, New Delhi; Chairman Sub-Committee-I
- Dr. N.K. Mehra, Head of Department, Transplant Immunology & Immunogenetics, AIIMS, New Delhi;
- Dr. I.C. Verma, Immunogenetics Department, Sir Ganga Ram Hospital, New Delhi.

### **Work Assigned to Sub-Committee-I**

To recommend the modalities concerning tests (especially HLA, DNA tests etc.) for establishing the factum of "near relative" and compatibility between the 'donor' and the patient; to consider the availability, costs, needs and procedure relating to such tests.

## **SUB-COMMITTEE-II**

- Dr. S.N. Mehta, Head of Department, Surgery, AIIMS, New Delhi;-  
Chairman Sub-Committee-II
- Dr. Harsha Jauhari, Renal Surgeon, Sir Ganga Ram Hospital;
- Shri Sanjay Jain, Advocate, High Court of Delhi.

### **Work Assigned to Sub-Committee-II**

The sub-committee was requested to examine and give its suggestions the following questions:-

- a) Whether the present working of Authorisation Committee is satisfactory or requires any further improvements in terms of its composition pattern, data base, scope and extent of authority and transparency?
- b) Whether the present working of the Authorisation Committee is conducive to the expeditious disposal of the cases referred to them for grant of approval to the donors to donate human organs?
- c) Whether the scope and extension of Authorisation Committee needs to be enlarged to include in its ambit the cases of near relatives as well?
- d) What steps/remedial measures can be taken to expedite the timely permissions and harmonize the functioning of the Authorisation Committee with the objectives of its existence/ construction?
- e) Whether any of the existing provisions of the Act of 1994 or Rules of 1995 or the Statutory Forms need to be modified/ amended/deleted, if so, in what manner?

Besides above, Dr. V.K. Arora, Additional Director General, DGHS, was requested to examine the data received by the Review Committee from various hospitals concerning transplantation activities and functioning of "Authorisation Committee".

Several meetings of the Review Committee were held from time to time (as detailed earlier). The Committee took note of the entire judgement in Balbir Singh case; discussed various diverse issues emerging from and connected with the terms of reference and considered the relevance of the existing legal provisions in the backdrop of the ground realities and also reflected upon the merits and demerits of the existing laws in addressing the problems that confront the society in general and donors, recipients and surgeons in particular. The Committee also took note of the fact that TOHO Act is a special enactment to deal with the transplantation cases and therefore some changes in the Act and the Rules would be required to establish harmony between the objectives of the enactment and the rationale of the restrictions imposed therein.

Pursuant to the above discussions with the committee members and the special invitees particularly, Dr. (Mrs.) Anita Roy, IPS and after perusal of the report of the sub-committee-I, the Sub-Committee-II, submitted its report, addressing all points of terms of reference as set out in Balbir Singh case. The Sub-Committee-II further suggested amendments in the Act, Rules and Forms. The recommendations of the report are based on sub committee II report and are as under:-

## **PART II - RECOMMENDATIONS**

1. The committee is of the view that the responsibility of certifying a donor as 'near relative' ought not to be placed on the transplant surgeon or any medical practitioner conducting the medical tests to assess the factum of 'near relative'. The present practise puts an unnecessary and avoidable pressure on the concerned medical practitioner and he becomes vulnerable to accusations if something goes wrong. Therefore, there is a definite need to develop a mechanism where all proposed donors including 'near relatives' should be scrutinised by a committee (the authorization committee), particularly, keeping in view, the larger objective of ruling out commercial considerations.
2. The committee is therefore of the view that the jurisdiction of the Authorization Committees should be enlarged by bringing within its ambit the process of certifying a 'near relative' as well. No fruitful purpose will be served by creating another designated authority for the said purpose. Experience of the medical practitioners and police has indicated that there have been several instances where the donors are sought to be projected as near-relatives in order to avoid scrutiny by the Authorization Committees. By way of illustration, we may visualize a case where a particular proposed donor, who initially represents himself as a near relative, on a scrutiny of evidence, turns out to be a non-near-relative, whose affection or attachment with the recipient cannot otherwise be



doubted. If there are two different committees then he is likely to be referred to the other Authorisation Committee. In such cases, there may be an inherent prejudice against him for initially misrepresenting himself as a near-relative and in this process a genuine case of donation of an organ for transplant may be delayed or jettisoned. Therefore, in order to maintain consistency, to save valuable time, to achieve functional efficiency and avoid duality of authority, it is desirable that scrutiny of all types of donors, both those of relatives and non-relatives should be carried out by the same authority i.e. Authorisation Committee. This will also help in eliminating the frivolous attempts laced with commercial incentives to project a non-relative as near-relative which often occurs, as indicated above, to avoid scrutiny of authorisation committee.

3. The next question that emerges is as to what should be the process of certifying the eligibility of the donor within the parameters of the legal provisions of THOA Act and THOA Rules. However, this question is interlinked with the question of the composition of the Authorisation Committees and the guidelines to govern the working of the Authorisation Committees. Once the composition and the working guidelines of the Authorization Committees are determined, the procedural aspects can easily be identified and recommended. In order to recommend a desirable composition of the Authorisation Committee and formulate effective guidelines for the functioning of the Authorisation Committees, it will be imperative for the Committee to look into the existing legal provisions of the THOA Act and THOA Rules and include in its recommendations, the desirable modifications as well, keeping in view the observations made in the Balbir Singh case and the experiences of the medical practitioners and the law enforcing agencies.

#### 4. **AUTHORISATION COMMITTEES**

The committee has observed that in Metropolitan Cities, for different hospitals, providing facilities of transplantation surgery, there are distinct and independent Authorisation Committees. In the considered view of the committee, this practice of hospital based Authorisation Committees is workable and practical in Metropolitan Cities and large capital cities of states where within the city, large distances need to be traveled and it may not be possible for the medical practitioners and other members of the committee to leave hospital and go to another place for attending the meeting. The increasing vehicular traffic in such cities restricts the mobility. But, in non-metropolitan cities and smaller capital cities of states, a single Authorisation Committee for the entire district or a Division comprising of several Districts, depending upon the factors like size of

population; number of transplantation centers available within the territory and other administrative exigencies, would serve the purpose.

**A. COMPOSITION OF HOSPITAL BASED AUTHORISATION COMMITTEES :( to be proposed by institution and notified by Govt.)**

- The senior most person officiating as Medical Director/Medical Superintendent of the Hospital.
- DM/ADM/SDM of the District which include the officers holding equivalent post in hierarchy irrespective of nomenclature of the designation. (To be nominated by concerned State/UT Govt.)
- Two senior medical practitioners from the same hospital who are not part of the transplant team.
- Two members being persons of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in UGC approved University or are self-employed professionals of repute such as lawyers, chartered accountants, writers, journalists and doctors (of Indian Medical Association) etc.
- One Medical Practitioner working in a Government hospital to be nominated by the Central/State Government.

**B. COMPOSITION OF STATE/ DISTRICT LEVEL AUTHORISATION COMMITTEES (to be constituted by concerned State/UT Govt.)**

- A Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District.
- DM/ADM/SDM of the District which include the officers holding equivalent post in hierarchy irrespective of nomenclature of the designation.
- Two senior medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team.

- Two senior citizens, non-medical background (one lady) of high reputation and integrity to be chosen from the pool of such citizens residing in the same district, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in UGC approved University or are self-employed professionals of repute such as lawyers, chartered accountants, writers, journalists and doctors (of Indian Medical Association) etc.
- One Medical Practitioner working in a Government hospital to be nominated by the concerned State/UT Government.

(Note: Effort should be made to have most of the members' ex-officio so that the need to change the composition of committee is less frequent.)

#### **C. QUORUM**

Quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the Administrative head of the hospital (for hospital based committees) or alternatively the person officiating a Chief Medical Officer of the District (for District or Division based Authorisation Committees) DM/SDM/ADM (as the case may be), one Medical Practitioner working in a Government hospital nominated by the concerned State/UT Government, and one member from the non-medical background. The members present in the meeting should be at liberty to opt/nominate any one amongst them to preside as Chairperson.

#### **D. FREQUENCY OF MEETINGS OF THE COMMITTEE**

The frequency of meeting of authorisation committee should depend upon the work load with provisions for emergency meetings, if required. The frequency should be such that under normal circumstance, the Authorisation Committee is able to give its decision at the earliest and not later than two weeks of receiving an application completed in all respects and supported by all required documents.

#### **E. NOTICE OF MEETINGS TO THE MEMBERS**

For the ordinary meetings, the Chairperson of the meeting shall fix a mutually agreed convenient date for each meeting and change in such date, if any, should ordinarily be communicated by the Chairperson to all the members with advance notice of minimum two days.

For emergent meetings, advance notice of two days from the office of Chairperson should be considered as adequate. However, if quorum is incomplete due to non-availability of an indispensable member, attempt should be made to hold the adjourned meeting within three days from the date for which such emergent meeting was originally fixed.

#### **F. JURISDICTION**

The territorial jurisdiction of both types of the authorisation committees should extend to the territorial limits of the entire district or division as the case may be. Its function at jurisdiction should extend to consider and process all such cases:-

- i) where transplantation activity is proposed to be carried out at a hospital/centre located within its jurisdictional territory;
- ii) where, though the transplantation centre is not located within its territorial jurisdiction the donor or the recipient or both ordinarily reside within its jurisdiction and its receives a request from another "Authorisation Committee" to scrutinize, process, consider, determine and report such aspects/facts/issues as may be specified in such request.

#### **G. GUIDELINES FOR WORKING OF THE AUTHORISATION COMMITTEE**

- 1) Secretariat of the Committee shall circulate copies of all joint applications received from the proposed donors and recipients 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 of state/UT Govt., 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.

- 2) In the course, of determining eligibility of the 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:-

- i) Results of tissue typing and other basic tests.
  - ii) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;
  - iii) 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.
  - iv) 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 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:-**

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

- i) 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.
- ii) that the following is specifically assessed by the Authorisation Committee :-
  - a) an explanation of the link between them and the circumstances which led to the offer being made;

- b) Reasons why the donor wishes to donate?
      - c) Documentary evidence of the link e.g. proof that they have lived together etc.
      - d) Old photographs showing the donor and the recipient together.
    - iii) that there is no middleman/tout involved;
    - iv) 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.
    - v) that the donor is not a drug addict or a known person with criminal record;
    - vi) 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.
  - 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 can examine the cases of Indian donors consenting to donate organs to a foreign national, including a foreign national of Indian origin, with greater caution. This should be done rarely in deserving cases only.
- 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 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.

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.

**H. VENUE OF THE MEETINGS & PROVISION TO MEET EXPENSES**

State/UT Government, as the case may be, should ensure that a suitable venue is provided to the State/District Authorisation Committees with requisite infrastructure and appropriate facilities, conducive to the efficient functioning of the State/District Authorisation Committee. The Authorisation Committee will levy an application processing fee not exceeding Rs. 2500 per application, from which the expenses of conducting the meetings, circulating the papers and providing honorarium to the members and payment of salaries/remuneration to the secretarial staff are met. The honorarium amount may be disclosed to the members of the Committee in advance before their acceptance is sought for becoming the member of the Authorisation Committee.

- I. The recommendation to include DM/ADM/SDM or equivalent Govt. officer in the Authorisation Committee is aimed to expedite the decision making process. It is a matter of common knowledge that the bigger irritants/impediments in the expeditious disposal relate the verification of facts, without which any decision, this way or that way, cannot judiciously be taken. To achieve the objective of expedience, the larger objective of eradicating commerce cannot be sacrificed. Need is to create an optimum balance between the two objective, both being equally important. Therefore, to examine the factors such as affection, attachment and special reasons and to rule out the commercial consideration, it is inevitable and absolutely imperative that the committee members proceed on the correct premise of the facts, documents, and surrounding circumstances, are able to assess the financial status of the donor and recipient which obviously cannot be done with some investigation. Therefore, the need for inclusion of the DM/ADM/SDM of equivalent Govt. officer is appropriate.

5. The above analysis, addresses the first two Points of Reference as set out by Hon'ble High Court of Delhi in Balbir Singh case.

6. With regard to the third point of reference, i.e. to review the provisions of the THOA Act and THOA Rules, the committee deems it appropriate to recommend a modification in sub-sections (1) & (3) of section 9 of the THOA Act so as to make it mandatory that all cases whether those of near relatives or non-relatives be routed through and authorisation committee. Therefore as a consequence, to enlarge the scope of Authorisation Committee and to bind the Authorisation Committee to act in accordance with certain pre-determined guidelines, the Sub-Committee-II recommends that appropriate provisions be made for it in the THOA Rules particularly by amending Rules 3, 4(1), 6 and 9 of THOA Rules and the text of the Forms provided under the said Rule. Additionally, a new rule for guidelines to govern functioning of the Authorisation Committee is inserted.

7. The Committee, has prepared a note on the proposed modifications and additions, in the Act/Rules and Forms as contained in Annexure-A (amendments in Act and Rules) and Annexure-B (amendments and additions in Forms) to this Report, recommending that the Central Government amends THOA Act and THOA Rules to incorporate the same. The Committee has reviewed Rule No.9 of THOA Rules extensively and has noticed that several requirements which have been mentioned as mandatory are not actually required in all kinds of transplantation. Not only this, some of the requirements are superficial and not essential. Therefore, retention of the list of requirements, as stipulated in Rule 9, may lead to refusal of registration of a transplantation center, which is otherwise well equipped to be functional in the relevant field of transplantation. In order to remove arbitrariness on the part of decision-making authorities while considering application of a hospital/transplantation center for registration, it is suggested that items presently enlisted as requirements may be reviewed and accordingly the Committee has suggested an amended list of requirements, which find mention in Annexure-A to the Report.

## **MEDICAL TESTS**

8. The Sub-Committee-I was asked to recommend the modalities concerning tests (especially HLA, DNA tests etc) for establishing the "near relatives" and compatibility of the donor and recipient.

9. Based on the report of Sub-Committee-I, the recommendations of the Committee are as follows :

- (1) If a medical practitioner, in a given case is required to ascertain the factum of 'near relative' through medical evidence, he should ensure the following :-

- (a) that the donor has given his authorization in the appropriate Form;
  - (b) that the donor is in proper state of health and is fit to donate the organ, and thereafter he shall sign a certificate specified in the appropriate Form;
  - (c) that the Authorisation Committee has certified the relationship.
- (2) Where 'near relatives' as defined in Section 2(i) of THOA Act, which include spouse, son, daughter, father, mother, brother and sister, are required to be tested in accordance with Rule 4 of THOA Rules, the following procedure may be followed :-.

## Recommended procedure for medical tests for establishing genetic relationship between the recipient and "near relatives" are as follows:-

- (i) The tests for HLA, HLA-B alleles to be performed by the serological and/or PCR based DNA methods.
- (ii) Test for HLA-DR beta genes to be performed using the PCR based DNA methods.
- (iii) Where the above two tests does 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.
- (iv) Where the tests referred to 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.

- (v) The Head of the testing laboratory should state in writing whether or not he/she is satisfied that the claimed genetic relationship between the donor and the recipient is established
- (3) The requisition for HLA test should be sent by the treating physician on the laboratory Proforma along with the photographs of the recipient and the potential donor duly attested by the requisitioning physician. A copy of the certificate signed by the donor that he/she is a 'near relative' of the patient should be enclosed.
- (4) In case recipient is a spouse of the donor, record the statement of the recipient and the donor to the effect that they are so related and shall sign a certificate in the appropriate Form.
- (5) The testing laboratory to be approved by the Director Health Services of state/UT as 'competent' both to specify and to interpret the results of the genetic tests.

**10. Comment on the Availability of the tests**

The HLA tests for defining genetic identity mentioned in sub-rule i) and ii) of Rule 4 are available in most centers involved in the organ transplant program. Commercial kits are available from several companies and a certified competent laboratory and the testers should have no difficulties in proper conduct of the tests and interpretation of results.

Tests mentioned in sub-rule iv) of Rule 4 which will be required only rarely are available in a few specified centers/institutions. In case of urgency on medical ground where one cannot wait for the results of tests mentioned in sub-rule iv) the case may be recommended for consideration by the Authorization Committee with request to take a decision on the basis of the available material without insisting on a test mentioned in sub-rule iv) which is not immediately available or time-consuming.

**11. Comment on the cost of the tests**

In a Government hospital like the AIIMS, a doctor-recipient pair testing for HLA-A, B by serology and HLA-DR by PCR based DNA based methods costs Rs.7,000/-. On the other hand, the private hospitals like the Sir Ganga Ram Hospital charges Rs.12,000/- as a package. The cost varies further in other laboratories or hospitals.

**12. Comment on the reliability of the tests.**

Using serological techniques, it is possible to define 17 alleles in HLA-A locus and 31 in HLA-B locus. Similarly, the PCR-based methods can define 18 alleles at the HLA-DR locus. This number is sufficient to define genetic identity between the donor and the recipient. It is important, however that the testing should be done by only those laboratories which are infrastructurally equipped and that are approved and 'certified' by the Directorate of Health Services of State/UTs and are thus competent. Similarly, it is necessary to certify the testers.

13. Similarly the DNA finger printing tests mentioned in sub-rule iv) are highly reliable.
14. Comment on any differences in tests required to establish 'near relative' status for different organ transplants namely kidney, liver, heart.

Defining 'near relative' status by doing genetic test for organ transplants has dual purpose – one is scientific (medical) and the other ethical.

15. Genetic tests to establish the factum of relationship between the donor and the recipient are essential prior to kidney transplantation because they address both the issues, namely medical (better HLA matching translates into improved graft survival) as well as ethical (curbs commercial dealings in the transplantation of organs as required in the Act and Rules).
16. Although for liver transplants, HLA tests are not essential (although there is some debate that they may be desirable) for medical reasons, they are required for ethical reasons in situation involving live donor for liver transplantation. It may not always be possible for the medical practitioner or the "authorization committee" to ascertain the identity of the proposed donor who claims to be a 'near relative' for a transplantation of an organ like 'liver' and therefore medical tests would be advisable in all cases of 'near relative'.
17. As for Heart transplants, the organ is always from the cadaver donor. The tests to prove genetic relationship are, therefore, not required.
18. Paragraphs 8 to 16 above, thus addresses the fourth reference point as set out in Balbir Singh case.

## **ORGAN PROCUREMENT PROGRAM**

19. The Committee deliberated upon the feasibility of establishment and setting up organ procurement organizations with Data Bank to encourage organ donations; to achieve objectives of THOA Act and THOA Rules and to facilitate the implementation of schemes for the purposes of

dissemination of information on the availability of organs for transplantation. In examining this aspect, the Committee also deliberated upon the steps which may spread the awareness with regard to the organ donations, especially from cases of brainstem death. As integral part of the above discussion, the Committee also examined the feasibility of creation of a Fund to generate awareness, educate public and encourage organ donation through various methods including but not limited to provisions for social security.

20. The committee took note of the fact that at present there exists an organization by the name of Organ Retrieval and Banking Organisation (ORBO) at All India Institute of Medical Sciences (AIIMS). It is a national level facility set up by the Government of India to facilitate transplant program in the country with a view to encourage organ donations, fair and equitable distribution of organs available in the organ bank and optimum utilization of human organs. It is accordingly recommended that the infrastructure, scope and ambit of ORBO activities should be enlarged and the Central Government should create 5 Regional Centres/Units of ORBO to cover Northern, Southern, Eastern, Western and Central Regions of the country. All persons desirous of availing cadaver organs through ORBO must get themselves registered for priority by paying such reasonable registration fees as may be fixed by the Central Government or ORBO. Such Regional Units may in turn have one State Unit covering each State following within the jurisdiction of the Regional Unit. The policy decision and the functioning guidelines of all Regional Units and State Units should be governed by the Central Agency of ORBO in order to keep uniformity of procedures, guidelines, infrastructure and functional norms in all Units in relation to human organ transplant.
21. All Units of ORBO should have provision for preserving all types of preservable human organs so as to keep them transplantable within the period of their shelf-life. The storage/preservations units should be built, equipmentalised and installed as per the contemporary international standards and on adequate mechanism and infrastructure should be made available to each such unit, to facilitate storage/ preservation of donated human organs, which may be received from different sources and under different programs. Technically qualified staff must be employed to regulate the storage/ preservation program function and persons of adequate seniority and high integrity should be employed to control and supervise such activities keeping in view the sensitivity and significance of this entire exercise and also to monitor effective check to prevent any commercial factors creeping into.

22. The Committee is of the considered view that it is extremely important to educate and sensitise public; generate general awareness and remove doubts and misgivings by undertaking nationwide massive publicity campaign using all types of mass-media to promote cadaver organ donation. To be specific, the Committee makes the following recommendations:-

## **I. CADAVER DONORS**

- A. (1) **A national organ transplant program with special emphasis to promote cadaver donations, is recommended.** The program should focus on the following:-
- a) Develop a focussed information, education and Communication (IEC) strategy to create awareness about organ transplantation and cadaver donations.
  - b) Involve Religious leaders and NGOs to sensitize the community about cadaver donations.
  - c) School curriculum may include certain information about organ donation to bring awareness amongst youth.
  - d) Get short films made to be frequently shown in electronic visual media highlighting the desirability and virtuosity of the cadaver donations. Some larger duration, inspiring and enlightening documentary films should also be got made to achieve above objective.
- (2) Every hospital should make it mandatory for the ICU/Treating Medical staff request relatives of brain dead patients for organ donation. A record of all brain dead patients and that the next of kin who are approached should be kept.
- (3) More Hospitals with adequate ICU facilities and availability of specialists to diagnose brain death be recognised as cadaver donor organ harvesting centers.

- (4) Retrieval of organs from non heart beating patients should be permissible after consent of the next of kin is taken. This may serve as a valuable source of organs.
- (5) Adequate facilities/Professional Fee to doctors who certify brain death.
- (6) The Hospitals/centers in transplantation activity be advised to have a post of a Co-coordinator in the ICU (who may be a doctor or a senior nursing staff member) independent of the Transplant Team, who is trained in the communication skills and who can liaison between the treating physician and the relatives of the potential brain-death donor and the ORBO. Such coordinator should possess skills to communicate with the relatives and friends of the patient with a view to explain to them the merits of cadaver organ donation and who possesses adequate knowledge to remove their doubts and answer their queries with regard to the procedure involved in transplantation activity.
- (7) It should be mandatory to report all brain dead potential donors to a central agency (like ORBO).
- (8) Organs should be considered a national resource and established guidelines & mechanism be used to allot cadaver organs equitably & fairly and ordinarily on the basis of priority of registration.

B. Incentives for the family of Cadaver Organ Donor

- (1) Preferred status in organ transplantation waiting list if the next of kin of the brain dead donor requires organ transplantation in future.
- (2) Appreciation letter/award by the State/local Government. Certificate of appreciation by State/local Government with an identity card endorsing his eligibility to obtain and avail various benefits recommended here. The card may prominently display a motivating slogan such as "Thank you for saving a life".
- (3) Life long cost incentives such as discounts and partially free treatment in certain specified types of ailments, to be offered by the concerned hospital at their discretion, which



can be availed in other branches if any as well of the concerned hospital.

- (4) Comprehensive health care scheme for the spouse or one child or the parents of the deceased to be evolved by the Central Government/ State Government as the case may be.
- (5) 0% concession in 2<sup>nd</sup> Class by Indian Railways for the spouse or one child or parents of the cadaver donor.

## II. LIVE DONORS

**A: Promote Swap Operations:** Swap operations that is to say that two different willing but incompatible 'near relative' donors (vis-à-vis their intended related recipient) are permitted to donate their organs in exchange without any commercial interest and only due to the reason that despite willingness, their organ was not found medically compatible for their intended recipients. This would greatly help patients who have 'near relatives' willing to donate but incompatible for their recipient. Swap operations may be considered by authorization committee on case to case basis and as per the existing THOA Act and rules.

### **B: Benefits for Live Donors**

- (1) Comprehensive health care scheme may be evolved by the Government.
- (2) Life long free renal/liver checkup, follow-up and care in hospital, (including its other branches, if any), where organ donation has taken place.
- (3) To secure the donor against mortality risk due to organ donation related reasons, a customized Life Insurance policy of Rs. 2 Lakhs for 3 years with one time premium to be paid by Recipient.
- (4) Certificate of appreciation to all live donors by State/local Government with an identity card endorsing his eligibility to obtain and avail various benefits recommended here. The card should prominently display a slogan such as "Thank you for saving a life".
- (5) Compensation for any expenses / loss of income incurred as specified in Section 2 (k) of the THOA Act.

- (6) 50% concession in 2<sup>nd</sup> Class by Indian Railways.

Those donors who do not wish to avail of any or all of above incentives may waive their entitlement in writing before the Authorisation Committee.

23. In order to create public awareness and educate common-man about organ transplant and organ donation, intensive use of print and electronic media should be undertaken under the supervision of ORBO. Additionally the altruistic virtues of organ donation must also be highlighted in the promotion campaigns with provision for registration with ORBO for altruistic cadaver donations.

#### **FUND TO PROMOTE CADAVER ORGAN DONATIONS**

24. The resources for such activity should be contributed from the Government Fund for which a separate budget should be allocated. Individual, corporate and WHO donations/contributions to this fund must also be encouraged through publicity campaigns and requests. A surcharge of 2 to 4% of the total hospital bill may also be considered to be levied on the recipients, who have taxable income of Rs. 5 lacs per annum and above to augment the corpus of such funds.
25. To make the fund stable and growing, steps to be taken to intensify and popularize the information and education campaign of the above nature. Public personalities and celebrities must be approached to come forward and lend their contribution in raising money for this fund, the utilization of which must be entrusted with ORBO.
26. The above part of the Report address the issues raised in points No.5 to 8 of the Terms of Reference as set out by the Hon'ble High Court of Delhi in Balbir Singh's case.

#### **OTHER RECOMMENDATIONS**

27. It is the need of hour that a separate public health program for creating awareness and generating encouragement for organ donations should be launched through mass-media.
28. The Committee is also of the view that the best way to regulate the activity of human organ transplantation is to ensure that the same is required in the least number of cases. Towards this objective, significant results can be achieved if preventing chronic renal failures is taken up as an important objective of National non communicable disease program

and strategies. It will lead to decrease in the cases requiring kidney transplantation.

29. The Committee is also of the view which is in conformity of the general policy of the Government of India that alleviation of poverty and ignorance and dissemination of education is key to control commercialization of human organs. Poverty and ignorance are the root cause of trade in human organs and, therefore, in the long run, this evil can be cured and controlled only by improving the general living conditions of the common man of the country.
30. Religious leaders should also be approached and requested for their help in disseminating their help in cadaver organ donation, keeping in view that at times these issues are related to religious restrictions and prohibitions by a large number of ill-informed individuals, who avoid or oppose human organ donation on religious grounds or other general or superstitious misgivings/ misbeliefs.
31. While applying the penal provisions to curb commercial dealings and other unfair or unethical practices in the activity of human organ transplantation, it must not be lost sight of that all the three parties, the donor, the recipient and the medical practitioner are delicately placed. The recipient is struggling for his survival. The donor has rendered himself vulnerable to physical complications by contributing to a socio-human cause. The medical practitioner has, by use of his super specialty skills made it possible for the recipient to extend/improve his life and for the donor to enjoy the bliss of his human virtue i.e. of a giver/provider. Transparency in the system while approving the donors for transplantations need be ensured so that dignity of all concerned is upheld at all times.
32. It is therefore strongly recommended that the Central/State Government must ensure that the penal provisions of THOA Act must be enforced strictly in accordance with the scheme of this special Act. Additionally Central Government may also take up the exercise of framing rules to regulate the procedure for taking cognizance of offence and conducting investigation as per sections 13 and 22 of THOA Act under the rule making powers conferred under Section 24 (o) of the THOA Act. Experience shows that in most of the cases where complaints are made, alleging commercial dealing in organ donation, police investigations cannot lead to any conclusive proof of commercial transaction. At best, the police may be able to gather evidence with regard to impersonation, false documentation or wrong affidavits. But evidence of the allegation that money has exchanged hands is extremely difficult to be collected.

The factors like impersonation, forgery or swearing false affidavits are already covered as punishable offences under the Indian Penal Code. Section 19 of THOA Act, except for defining the nature of activities requiring prosecution has no other substantial role to play. Accordingly, it is recommended that the Central Government may review Section 19 of THOA Act. It is also suggested that the THOA Act and rules may be amended to introduce an element of presumption in cases where there has been impersonation and falsification of documents to establish relationship between donor and recipient when none exists. This can at least make law justiciable (effective).

33. The Committee also takes note of the recent judgement of the Hon'ble Supreme Court of India, where the "authorisation committee" of Punjab was directed to examine the donor and the recipient, while the transplantation was to be carried out at Chennai. While an endeavour has been made to recommend the enhanced jurisdiction of the authorisation committees as envisaged in the judgement of Hon'ble Supreme Court of India, yet it is felt that several aspects peculiar to the attending ground realities were not brought to the notice of the Hon'ble Apex Court. For instance what happens if the donor and the recipient hail from different states; what happens if one of them or both hails/hail from a state/states where there is/are no "authorisation committee" and lastly it is not clear as to whether the "authorisation committee" of the state where transplantation is taking place, shall retain some jurisdiction or will be completely without jurisdiction and if latter is the case then how will the medical evidence if required to be assessed, will be assessed by the domicile "authorisation committee" without resulting in delays and without compromising the other laudable objectives of the THOA Act.
34. It is therefore recommended that the Central Government must approach the Hon'ble Supreme Court to seek appropriate clarifications.

The Report of the THOA review committee is submitted accordingly. The document referred to, in the report are enclosed as annexures as per the list of annexures.

**(Shri Sanjay Jain)**

**(Dr. Harsha Johri)**

**Advocate, Delhi High Court**

**Renal Transplant Surgeon,**

**Member**

**Sir Ganga Ram Hospital-**

**Member**

**(Dr. Vinay Agarwal)**  
**Mehta) Hony. Secy., IMA-Member**  
**AIIMS-Member**

**(Prof. S. N.**  
**Head, Surgery,**

**(Prof. V. K. Arora)**

**Addl. DG, Member Secretary**

**(Dr. S. Y. Quraishi)**

**Addl Secy. & DG (NACO)**

**Chairman/Convenor**

## 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><b>3. Authority for Removal of Human Organ.-</b> 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><b>3. Authority for Removal of Human Organ.-</b> 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><b>4. Duties of the Medical Practitioner.-</b> (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</p>	<p><b>4. Duties of the Medical Practitioner.-</b></p> <p>(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</i> Form 1(A) or 1(B) or 1(C).</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</p>

in Form 2.

(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 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

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 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*

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

*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*



recipient  
further tests to  
establish DNA  
polymorphism  
s 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.

*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

	<p>submitted an application in Form 10 jointly with the recipient, the 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><b>6A. <u>GUIDELINES FOR WORKING OF THE AUTHORISATION COMMITTEE</u></b></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</i></p>

*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.*

*2. In the course of determining eligibility of the 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*

	<p><i>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</i></p> <p><i>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.</i></p> <p><i>iii) All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.</i></p> <p><i>6) The Authorisation Committee should employ a Secretariat comprising of adequate number of 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>
<b>9. Conditions for grant of</b>	<b>9. Conditions for grant of Certificate of</b>

**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:-

## **General Requirement**

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.

## **Various Departments**

1. Microbiology

**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:-*

## **General Manpower Requirement Specialised Services and Facilities**

1. *24 hours availability of medical and surgical, (senior and junior) staff.*
2. *24 hours availability of nursing staff, (general and speciality trained).*
3. *24 hours availability of Intensive Care Units with adequate equipments, staff and support system, including specialists in anaesthesiology, intensive care, physiotherapy.*
4. *24 hours availability of laboratory with multiple discipline testing facilities including but not limited to*

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

*Microbiology, Bio-Chemistry, Pathology and Hematology and Radiology departments with trained staff.*

5. *24 hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipments.*

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 .*

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*

**Non-**

# transplantation Programme Team

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff
5. Eye Donation Counsellor/Grief Counsellor.

## Basic Equipment

1. Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.
2. Slit Lamp
3. Special Microscope
4. Operating Microscope

## Additional Equipment Required for Transplantation Programme

1. Cell Saver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both

*available to the transplantation centre.*

### Equipments

*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.*

## Experts

### (A) *Kidney Transplantation*

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.

### (B) *Transplantation of liver and other abdominal organs*

M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with

pneumatic and electric operated.

3. Mobile C-arm, image intensifier for routine biopsies in the sterile operating room.
4. Eact/Alert System for early detection of any infection.
5. Radioimmunoassay for measuring Cyclosporin levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.
7. Autoclave (mandatory)
8. U.V. Lamp }  
Desirable.
9. Laminor Flow }

## Experts

### (A) Kidney Transplantation

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

a reasonable experience of performing liver transplantation as an active member of team.

### (C) *Cardiac, Pulmonary, Cardio-Pulmonary Transplantation*

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.

### (D) *Cornea Transplantation*

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>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><b>9. Restrictions on removal and transplantation of human organs</b></p> <p>—</p>	<p><b>9. Restrictions on removal and transplantation of human organs</b></p> <p>—</p>

(1) Save as otherwise provided in subsection (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 recipient.

(1) Save as otherwise provided in subsection (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 recipient ***and such relationship has been certified by the authorisation committee.***



## CHART SHOWING STATUS OF FORMS

<b>FORM-1</b>	:	Deleted
<b>1</b>		Substituted by Form 1A, 1B and 1C
<b>FORM-2</b>	:	Amended
<b>FORM-3</b>	:	Modified
<b>FORM-4</b>	:	Deleted
<b>FORM-5</b>	:	No Change
<b>FORM-6</b>	:	No Change
<b>FORM-7</b>	:	Deleted as it is identical to Form 6
<b>FORM-8</b>	:	No Change
<b>FORM-9</b>	:	No Change
<b>FORM-10</b>	:	Amended
<b>FORM-11</b>	:	No Change
<b>FORM-12</b>	:	No Change
<b>FORM-13</b>	:	No Change

## ANNEXURE-B TO THE SUB-COMMITTEE-II REPORT

### (AMENDED VERSION OF FORMS)

- I.** : Forms 1(A), 1(B) and 1(C) substituting Form 1
- II.** : Form 2 is amended version of the existing Form 2
- III.** : Form 10 is amended version of the existing Form 10
- IV.** : Form 1 is recommended to be deleted in view of new forms i.e. Forms 1(A), 1(B) and 1(C)
- V.** : Form 4 is recommended to be deleted as they would not be required any further in view of the proposed enlarged scope of the authorisation committees
- VI.** : Form 7 is recommended to be deleted as it is superfluous being repetition of Form 6.

**FORM 1(A)**

*(To be completed by the prospective related donor)*

*(See Rule 3)*

My full name is .....

To be affixed and  
attested by Notary  
Public after it is  
affixed.

and this is my photograph

Photograph of the Donor  
(Attested by Notary Public)

My permanent home address is

.....  
.....  
..... Tel:  
.....

My present home address is

.....  
.....  
..... Tel:.....

Date of birth .....(day/month/year)

\* Ration/Consumer Card number and Date of issue & place:.....

(Photocopy attached)

and/or

\* Voter's I-Card number, date of issue, Assembly constituency.....

(Photocopy attached)

and/or

\* Passport number and country of issue.....

(Photocopy attached)

and/or

\* Driving Licence number, Date of issue, licensing authority.....

(Photocopy attached)

and/or

\* PAN.....

and/or

\* Other proof of identity and address .....

I hereby authorize removal for therapeutic purposes/consent to donate my .....

(state which organ) to my relative ..... (specify son/daughter/father/mother/ brother/sister), whose name is ..... and who was born on .....(day/month/year) and whose particulars are as follows:

To be affixed and attested by Notary Public after it is affixed.

Photograph of the Recipient  
(Attested by Notary Public)

\* Ration/Consumer Card number and Date of issue & place:.....

(Photocopy attached)

and/ or

\* Voter's I-Card number, date of issue, Assembly constituency.....

(Photocopy attached)

and/or

\* Passport number and country of issue.....

(Photocopy attached)

and/ or

\* Driving Licence number, Date of issue, licensing authority.....

(photocopy attached)

and/or

\* PAN.....

and/or

\* Other proof of identity and address .....

**I solemnly affirm and declare that:**

Sections 2, 9 and 19 of The Transplantation of Human Organs Act 1994 have been explained to me and I confirm that:

1. I understand the nature of criminal offences referred to in the Sections.

2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
  
3. I am giving the consent and authorisation to remove my .....(organ) of my own free will without any undue pressure, inducement, influence or allurement.
  
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my .....(organ). That explanation was given by .....(name of registered medical practitioner).
  
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
  
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
  
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....  
 .....

Signature of the prospective donor

Date

Note: To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

\* √ wherever applicable.

**FORM 1(B)**

*(To be completed by the prospective spousal donor)*

*(see Rule 3)*

My full name is .....

and this is my photograph

To be affixed and  
attested by Notary  
Public after it is  
affixed.

Photograph of the Donor

(Attested by Notary Public)

My permanent home address is

..... Tel:  
.....  
.....  
.....

My present home address is ..... Tel :.....

.....

Date of birth .....(day/month/year)

I authorize to remove for therapeutic purposes/consent to donate my  
.....



(state which organ) to my husband/wife..... whose full name is .....and who was born on .....(day/month/year) and whose particulars are

To be affixed and attested by Notary Public after it is affixed.

Photograph of the Recipient

(Attested by Notary Public)

\* Ration/Consumer Card number and Date of issue & place:.....

(photocopy attached)

and/or

\* Voter's I-Card number, date of issue, Assembly constituency.....

(photocopy attached)

and/or

\* Passport number and country of issue.....

(photocopy attached)

and/or

\* Driving Licence number, Date of issue, licensing authority.....

(photocopy attached)

and/or

\*

PAN.....

and/or

\*

Other proof of identity and address

.....

I submit the following as evidence of being married to each other:-

- (a) a certified copy of a marriage certificate

or

- (b) an affidavit of a 'near relative' confirming the status of marriage to be sworn before Class-I Magistrate/Notary Public.
- (c) family photographs
- (d) Letter from member of Gram Panchayat/Tehsildar/Block Development Officer/MLA/MP certifying factum and status of marriage.
- (e) Other credible evidence

**I solemnly affirm and declare that:**

Sections 2, 9 and 19 of The Transplantation of Human Organs Act 1994 have been explained to me and I confirm that

1. I understand the nature of criminal offences referred to in the Sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my .....(organ) of my own free will without any undue pressure, inducement, influence or allurement.

4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my .....(organ). That explanation was given by .....(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....  
 .....

Signature of the prospective donor

Date

Note : To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

\* √ wherever applicable.

**FORM 1(C)**

*(To be completed by the prospective un-related donor)*

*(See Rule 3)*

My full name is .....

and this is my photograph

To be affixed and  
attested by Notary  
Public after it is  
affixed.

Photograph of the Donor

(Attested by Notary Public)

My permanent home address is

..... Tel: .....  
.....

My present home address is ..... Tel:.....

.....

Date of birth .....(day/month/year)

\* Ration/Consumer Card number and Date of issue & place:.....

(photocopy attached)

and/or

\* Voter's I-Card number, date of issue, Assembly constituency.....

(photocopy attached)

and/or

\* Passport number and country of issue.....

(photocopy attached)

and/or

\* Driving Licence number, Date of issue, licensing authority.....

(photocopy attached)

and/or

\* PAN.....

and/or

\* Other proof of identity and address .....

I hereby authorize to remove for therapeutic purposes/consent to donate my .....

To be affixed and attested by Notary Public after it is affixed.

(state which organ) to a person whose full name is  
..... and who was born on  
.....(day/month/year) and whose particulars are.

Photograph of the Recipient

(Attested by Notary Public)

\* Ration/Consumer Card number and Date of issue & place:.....

(photocopy attached)

and/or

\* Voter's I-Card number, date of issue, Assembly constituency.....

(photocopy attached)

and/or

\* Passport number and country of issue.....

(photocopy attached)

and/or

\* Driving Licence number, Date of issue, licensing authority.....

(photocopy attached)

and/or

\* PAN.....

and/or

\* Other proof of identity and address .....

**I solemnly affirm and declare that:**

Sections 2, 9 and 19 of The Transplantation of Human Organs Act 1994 have been explained to me and I confirm that

1. I understand the nature of criminal offences referred to in the Sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.

3. I am giving the consent and authorisation to remove my .....(organ) of my own free will without any undue pressure, inducement, influence or allurements.
  
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my .....(organ). That explanation was given by .....(name of registered medical practitioner).
  
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
  
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
  
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....  
 .....

Signature of the prospective donor

Date

Note : To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

\* √ wherever applicable.



**FORM 2**

[See rule 4(1) (b)]

*(To be completed by the concerned Medical Practitioner)*

I, Dr.....possessing qualification of  
..... registered as medical practitioner at serial no.  
.....by the .....Medical  
Council, certify that I have examined Shri/Smt./Km.  
.....S/o, D/o, W/o Shri .....aged  
..... who has given informed consent about donation of the organ,  
namely..... to Shri/Smt./Km.....who is  
a 'near relative' of the donor/other than near relative of the donor, who had been  
approved by the Authorization Committee and that the said donor is in proper state of  
health and is medically fit to be subjected to the procedure of organ removal.

Place: .....  
.....

Signature of Doctor

Date: .....

To be affixed and  
attested by the doctor  
concerned after  
affixation

To be affixed and  
attested by the doctor  
concerned after  
affixation

Photograph of the Donor  
recipient

(Attested by doctor)  
doctor)

Photograph of the

(Attested by the

FORM 3

[See Rule 4 (1) ( c )]

I, Dr./Mr./Mrs. .... working as  
..... at ..... and  
possessing qualification of ..... certify that Shri/Smt./Km.  
..... s/o ,d/o,w/o Shri  
..... aged ..... the donor and  
Sh./Smt..... s/o, d/o, w/o Shri  
..... aged ..... the proposed recipient of the organ to be  
donated by the said donor are related to each other as  
brother/sister/mother/father/son/daughter as per their statement and the fact of this  
relationship has been established / not established by the results of the tests for  
Antigenic Products of the Human Major Histocompatibility Complex. The results of the  
tests are attached.

Signature

(To be signed by the Head of the Laboratory)

Seal

Place .....

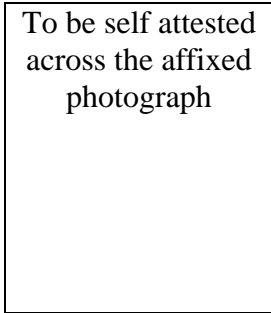
Date .....

**FORM 10**

**APPLICATION FOR APPROVAL FOR TRANSPLANTATION (LIVE DONOR)**

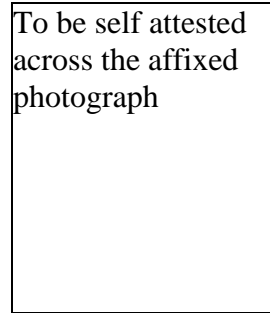
*(To be completed by the proposed recipient and the proposed donor)*

**[See Rule 4 (1) (c)(d)(e)]**



Photograph of the Donor

(Self-attested)



Photograph of the recipient

(Self-attested)

Whereas I .....S/O, D/O, W/O, .....  
aged ..... residing at  
..... have been advised by my doctor  
..... that I am suffering from  
..... and may be benefited by transplantation of  
.....into my body.

And whereas I ..... S/O, D/O,  
W/O,..... aged ..... residing at  
..... by the following reason(s):-

a) by virtue of being a near relative i.e. \_\_\_\_\_

b) by reason of affection/attachment/other special reason as explained below :-

.....  
.....  
.....

I would therefore like to donate my .....to.....  
....

we.....and .....  
.....

(Donor)

(Recipient)

hereby apply to Authorization Committee for permission for such transplantation to be carried out.

We solemnly affirm that the above decision has been taken without any undue pressure, inducement, influence or allurements and that all possible consequences and options of organ transplantation have been explained to us.

Instructions for the applicants:-

1. Form 10 must be submitted along with the completed Form 1(A), or Form 1(B) or Form 1(C) as may be applicable.
2. The applicable Form i.e. Form 1(A) or Form 1(B) or Form 1(C) as the case may be, should be accompanied with all documents mentioned in the applicable form and all relevant queries set out in the applicable form must be adequately answered.
3. Completed Form 3 to be submitted along with the laboratory report.
4. The doctor's advice recommending transplantation must be enclosed with the application.
5. In addition to above, in case the proposed transplant is between unrelated persons, appropriate evidence of vocation and income of the donor as well as the recipient for the last three years must be enclosed with this application. It is clarified that the evidence of income does not necessarily mean the proof of income tax returns, keeping in view that the applicant(s) in a given case may not be filing income tax returns.
6. The application shall be accepted for consideration by the Authorisation Committee only if it is complete in all respects and any omission of the documents or the information required in the forms mentioned above, shall render the application incomplete.

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date :

Date :

Place :

Place :