



भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II — खण्ड 1

PART II — Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं० 22] नई दिल्ली, बुधवार, सितम्बर 28, 2011/ अश्विन 6, 1933 (शक)
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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 28th September, 2011/Asvina 6, 1933 (Saka)

The following Act of Parliament received the assent of the President on the 27th September, 2011, and is hereby published for general information:—

THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) ACT, 2011

(No. 16 OF 2011)

[27th September, 2011.]

An Act to amend the Transplantation of Human Organs Act, 1994.

WHEREAS it is expedient to amend the said law enacted by Parliament relating to regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs;

AND WHEREAS Parliament has no power to make or amend laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

AND WHEREAS in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and West Bengal to the effect that the aforesaid Act should be amended by Parliament;

BE it enacted by Parliament in the Sixty-second Year of the Republic of India as follows:—

1. (1) This Act may be called the Transplantation of Human Organs (Amendment) Act, 2011.

Short title,
application
and
commencement.

(2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and West Bengal and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.

(3) It shall come into force in the States of Goa, Himachal Pradesh and West Bengal and in all the Union territories on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, mean the date on which this Act comes into force in such State or Union territory.

Amendment
of long title.

2. In the Transplantation of Human Organs Act, 1994 (hereinafter referred to as the principal Act), in the long title, for the words "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs", the words "human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues" shall be substituted.

42 of 1994.

Amendment
of section 1.

3. In section 1 of the principal Act, in sub-section (1), for the words "Human Organs", the words "Human Organs and Tissues" shall be substituted.

Substitution
of references
to certain
expressions
by certain
other
expressions.

4. Throughout the principal Act [except clause (h) of section 2, sub-section (5) of section 9, sub-section (1) of section 18 and section 19], unless otherwise expressly provided, for the words "human organ" and "human organs", wherever they occur, the words "human organ or tissue or both" and "human organs or tissues or both" shall respectively be substituted with such consequential amendments as the rules of grammar may require.

Amendment
of section 2.

5. In section 2 of the principal Act,—

(a) after clause (h), the following clauses shall be inserted, namely:—

'(ha) "Human Organ Retrieval Centre" means a hospital,—

(i) which has adequate facilities for treating seriously ill patients who can be potential donors of organs in the event of death; and

(ii) which is registered under sub-section (1) of section 14 for retrieval of human organs;

(hb) "minor" means a person who has not completed the age of eighteen years;';

(b) for clause (i), the following clause shall be substituted, namely:—

'(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter;';

(c) in clause (o), the word "and" shall be omitted;

(d) after clause (o), the following clauses shall be inserted, namely:—

'(oa) "tissue" means a group of cells, except blood, performing a particular function in the human body;

(ob) "Tissue Bank" means a facility registered under section 14A for carrying out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues, but does not include a Blood Bank;';

(e) after clause (p), the following clause shall be inserted, namely:—

'(q) "transplant co-ordinator" means a person appointed by the hospital for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of section 3.'.

6. In section 3 of the principal Act,—

Amendment
of section 3.

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

“(1A) For the purpose of removal, storage or transplantation of such human organs or tissues or both, as may be prescribed, it shall be the duty of the registered medical practitioner working in a hospital, in consultation with transplant co-ordinator, if such transplant co-ordinator is available,—

(i) to ascertain from the person admitted to the Intensive Care Unit or from his near relative that such person had authorised at any time before his death the removal of any human organ or tissue or both of his body under sub-section (2), then the hospital shall proceed to obtain the documentation for such authorisation in such manner as may be prescribed;

(ii) where no such authority as referred to in sub-section (2) was made by such person, to make aware in such manner as may be prescribed to that person or near relative for option to authorise or decline for donation of human organs or tissues or both;

(iii) to require the hospital to inform in writing to the Human Organ Retrieval Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified in clauses (i) and (ii) in such manner as may be prescribed.

(1B) The duties mentioned under clauses (i) to (iii) of sub-section (1A) from such date, as may be prescribed, shall also apply in the case of registered medical practitioner working in an Intensive Care Unit in a hospital which is not registered under this Act for the purpose of removal, storage or transplantation of human organs or tissues or both.”;

(b) in sub-section (4), the following proviso shall be inserted, namely:—

“Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.”;

(c) in sub-section (6), in clause (iii),—

(i) the word “and” shall be omitted; and

(ii) the following proviso shall be inserted, namely:—

“Provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient and to such conditions as may be prescribed.”.

7. In section 9 of the principal Act,—

Amendment
of section 9.

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

“(1A) Where the donor or the recipient being near relative is a foreign national, prior approval of the Authorisation Committee shall be required before removing or transplanting human organ or tissue or both:

Provided that the Authorisation Committee shall not approve such removal or transplantation if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.

(1B) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplantation except in the manner as may be prescribed.

(1C) No human organs or tissues or both shall be removed from the body of a mentally challenged person before his death for the purpose of transplantation.

Explanation.— For the purpose of this sub-section,—

(i) the expression “mentally challenged person” includes a person with mental illness or mental retardation, as the case may be;

(ii) the expression “mental illness” includes dementia, schizophrenia and such other mental condition that makes a person intellectually disabled;

(iii) the expression “mental retardation” shall have the same meaning as assigned to it in clause (r) of section 2 of the Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995.’; 1 of 1996.

(b) after sub-section (3), the following sub-section shall be inserted, namely:—

“(3A) Notwithstanding anything contained in sub-section (3), where—

(a) any donor has agreed to make a donation of his human organ or tissue or both before his death to a recipient, who is his near relative, but such donor is not compatible biologically as a donor for the recipient; and

(b) the second donor has agreed to make a donation of his human organ or tissue or both before his death to such recipient, who is his near relative, but such donor is not compatible biologically as a donor for such recipient; then

(c) the first donor who is compatible biologically as a donor for the second recipient and the second donor is compatible biologically as a donor of a human organ or tissue or both for the first recipient and both donors and both recipients in the aforesaid group of donor and recipient have entered into a single agreement to donate and receive such human organ or tissue or both according to such biological compatibility in the group,

the removal and transplantation of the human organ or tissue or both, as per the agreement referred to above, shall not be done without prior approval of the Authorisation Committee.”;

(c) for sub-section (4), the following sub-section shall be substituted, namely:—

“(4) (a) The composition of the Authorisation Committees shall be such as may be prescribed by the Central Government from time to time.

(b) The State Government and the Union territories shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Governments and the Union territories on such terms and conditions as may be specified in the notification for the purposes of this section.”.

8. In section 10 of the principal Act, in sub-section (1),—

(a) in clause (b), the word “and” occurring at the end shall be omitted;

(b) in clause (c), the word “and” shall be inserted at the end;

(c) after clause (c), the following clause shall be inserted, namely:—

“(d) no Tissue Bank, unless registered under this Act, shall carry out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues.”.

9. In section 13 of the principal Act, in sub-section (3),—

(a) for clause (iii), the following clause shall be substituted, namely:—

“(iii) to enforce such standards, as may be prescribed,—

(A) for hospitals engaged in the removal, storage or transplantation of any human organ;

Amendment
of section 10.

Amendment
of section 13.

(B) for Tissue Banks engaged in recovery, screening, testing, processing, storage and distribution of tissues;”;

(b) after clause (iv), the following clause shall be inserted, namely:—

“(iva) to inspect Tissue Banks periodically;”.

10. After section 13 of the principal Act, the following sections shall be inserted, namely:—

Insertion of new sections 13A, 13B, 13C and 13D.

“13A. (1) The Central Government and the State Governments, as the case may be, by notification, shall constitute an Advisory Committee for a period of two years to aid and advise the Appropriate Authority to discharge its functions.

Advisory Committees to advise Appropriate Authority.

(2) The Advisory Committee shall consist of—

(a) one administrative expert not below the rank of Secretary to the State Government, to be nominated as Chairperson of the Advisory Committee;

(b) two medical experts having such qualifications as may be prescribed;

(c) one officer not below the rank of a Joint Director to represent the Ministry or Department of Health and Family Welfare, to be designated as Member-Secretary;

(d) two eminent social workers of high social standing and integrity, one of whom shall be from amongst representatives of women’s organisation;

(e) one legal expert who has held the position of an Additional District Judge or equivalent;

(f) one person to represent non-governmental organisations or associations which are working in the field of organ or tissue donations or human rights;

(g) one specialist in the field of human organ transplantation, provided he is not a member of the transplantation team.

(3) The terms and conditions for appointment to the Advisory Committee shall be such as may be prescribed by the Central Government.

13B. The Appropriate Authority shall for the purposes of this Act have all the powers of a civil court trying a suit under the Code of Civil Procedure, 1908 and, in particular, in respect of the following matters, namely:—

Powers of Appropriate Authority.

(a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;

(b) discovery and production of any document or material object;

(c) issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement or transplantation of human organs or tissues or both; and

(d) any other matter which may be prescribed.

13C. The Central Government may, by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed.

National Human Organs and Tissues Removal and Storage Network.

National
registry.

13D. The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues.”.

Amendment
of section 14.

11. In section 14 of the principal Act,—

(a) in sub-section (1), for the words “No hospital”, the words “No hospital (including Human Organ Retrieval Centre)” shall be substituted;

(b) after sub-section (3), the following sub-section shall be inserted, namely:—

“(4) No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant co-ordinator having such qualifications and experience as may be prescribed.”.

Insertion of
new section
14A.
Registration of
Tissue Bank.

12. After section 14 of the principal Act, the following section shall be inserted, namely:—

“14A. (1) No Tissue Bank shall, after the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, commence any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues unless it is duly registered under this Act:

Provided that any facility engaged, either partly or exclusively, in any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues immediately before the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, shall apply for registration as Tissue Bank within sixty days from the date of such commencement:

Provided further that such facility shall cease to engage in any such activity on the expiry of three months from the date of commencement of the Transplantation of Human Organs (Amendment) Act, 2011, unless such Tissue Bank has applied for registration and is so registered, or till such application is disposed of, whichever is earlier.

(2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) No Tissue Bank shall be registered under this Act unless the Appropriate authority is satisfied that such Tissue Bank is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.”.

Amendment of
section 15.

13. In section 15 of the principal Act, in sub-section (1), for the words “grant to the hospital”, the words “grant to the hospital or to the Tissue Bank, as the case may be,” shall be inserted.

Amendment of
section 16.

14. In section 16 of the principal Act, for the word “hospital”, wherever it occurs, the words “hospital or Tissue Bank, as the case may be,” shall be substituted.

Amendment of
section 17.

15. In section 17 of the principal Act, after the words, brackets and figure “under sub-section (6) of section 9, or any hospital”, the words “or Tissue Bank, as the case may be,” shall be inserted.

Amendment of
section 18.

16. In section 18 of the principal Act,—

(a) in sub-section (1), for the words “five years and with fine which may extend to ten thousand rupees”, the words “ten years and with fine which may extend to twenty lakh rupees” shall be substituted;

(b) in sub-section (2), for the words "two years", the words "three years" shall be substituted.

(c) after sub-section (2), the following sub-section shall be inserted, namely:—

"(3) Any person who renders his services to or at any hospital and who conducts, or associates with or helps in any manner in the removal of human tissues without authority, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees."

17. In section 19 of the principal Act,—

Amendment
of section 19.

(a) after clause (f), the following clause shall be inserted, namely:—

"(g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs, as a near relative or by reason of affection or attachment towards the recipient.";

(b) for the words "two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees", the words "five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees" shall be substituted;

(c) the proviso shall be omitted.

18. After section 19 of the principal Act, the following section shall be inserted, namely:—

Insertion of
new section
19A.

"19A. Whoever—

Punishment
for illegal
dealings in
human tissues.

(a) makes or receives any payment for the supply of, or for an offer to supply, any human tissue; or

(b) seeks to find person willing to supply for payment and human tissue; or

(c) offers to supply any human tissue for payment; or

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue; or

(e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(f) publishes or distributes or causes to be published or distributed any advertisement—

(i) inviting persons to supply for payment of any human tissue; or

(ii) offering to supply any human tissue for payment; or

(iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d); or

(g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human tissues as a near relative or by reason of affection or attachment towards the recipient,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and shall be liable to fine which shall not be less than five lakh rupees but which may extend to twenty-five lakh rupees."

Amendment
of section 20.

19. In section 20 of the principal Act, for the words “three years or with fine which may extend to five thousand rupees”, the words “five years or with fine which may extend to twenty lakh rupees” shall be substituted.

Amendment
of section 24.

20. In section 24 of the principal Act, in sub-section (2),—

(a) after clause (a), the following clauses shall be inserted, namely:—

“(aa) the human organs or tissues or both in respect of which duty is cast on registered medical practitioner, the manner of obtaining documentation for authorisation under clause (i) of sub-section (1A) of section 3;

(ab) the manner of making the donor or his relative aware under clause (ii) of sub-section (1A) of section 3;

(ac) the manner of informing the Human Organ Retrieval Centre under clause (iii) of sub-section (1A) of section 3;

(ad) the date from which duties mentioned in sub-section (1A) are applicable to registered medical practitioner working in a unregistered hospital under sub-section (1B) of section 3;

(ae) the qualifications and experience of a technician under the proviso to sub-section (4) of section 3;”;

(b) after clause (b), the following clause shall be inserted, namely:—

“(ba) the conditions for nomination of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts under the proviso to clause (iii) of sub-section (6) of section 3;”;

(c) after clause (e), the following clauses shall be inserted, namely:—

“(ea) the manner of removal of human organs or tissues or both from the body of a minor before his death for transplantation under sub-section (1B) of section 9;

(eb) the composition of the Authorisation Committees under sub-section (4) of section 9;”;

(d) after clause (i), the following clauses shall be inserted, namely:—

“(ia) the qualifications of medical experts and the terms and conditions for appointment to Advisory Committee under sub-sections (2) and (3) of section 13A;

(ib) the power of the Appropriate Authority in any other matter under clause (d) of section 13B;

(ic) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be performed by them under section 13C;

(id) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;”;

(e) after clause (k), the following clauses shall be inserted, namely:—

“(ka) the qualifications and experience of a transplant co-ordinator under sub-section (4) of section 14;

(kb) the form and the manner in which an application for registration shall be made, and the fee which shall be accompanied, under sub-section (2) of section 14A;

(kc) the specialised services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a Tissue Bank, under sub-section (3) of section 14A;”;

(f) in clause (l), for the word “hospital”, the words “hospital or Tissue Bank” shall be substituted.

V. K. BHASIN,
Secy. to the Govt. of India.



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असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

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स्वास्थ्य और परिवार कल्याण मंत्रालय

अधिसूचना

नई दिल्ली, 27 मार्च, 2014

सा.का.नि.218(अ).— केन्द्रीय सरकार, मानव अंग प्रतिरोपण अधिनियम, 1994 (1994 का 42) की धारा 24 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और मानव अंग प्रतिरोपण नियम, 1995 को उन बातों के सिवाय अधिकांत करते हुए जिन्हें ऐसे अधिक्रमण से पूर्व किया गया है या करने का लोप किया गया है, निम्नलिखित नियम बनाती है, अर्थात् :-

1. **संक्षिप्त नाम और प्रारंभ** - (1) इन नियमों का संक्षिप्त नाम मानव अंग और उत्तक प्रतिरोपण नियम, 2014 है ।
(2) ये राजपत्र में प्रकाशन की तारीख को प्रवृत्त होंगे ।
2. **परिभाषाएं** - इन नियमों में जब तक कि संदर्भ से अन्यथा अपेक्षित न हो.-
(क) “अधिनियम” से मानव अंग प्रतिरोपण अधिनियम, 1994 अभिप्रेत है ;
(ख) “शव/शवों”, “अंग/अंगों” और “उत्तक/उत्तकों” से क्रमशः मानव शव, मानव अंग और मानव उत्तक अभिप्रेत हैं ;
(ग) “सक्षम प्राधिकारी” से प्रतिरोपण करने वाली संस्था या अस्पताल का प्रधान या इस प्रयोजन के लिए संस्था या अस्पताल के प्रधान द्वारा गठित की गई समिति अभिप्रेत है ;
(घ) “प्ररूप” से इन नियमों से उपाबद्ध प्ररूप अभिप्रेत हैं ;
(ङ) “राष्ट्रीय परीक्षण और अंश शोधन प्रयोगशाला प्रत्यायन बोर्ड (एनएबीएल)” से सरकार, विनियामकों और उद्योग को प्रयोगशालाओं की तकनीकी सक्षमता को औपचारिक रूप से मान्यता प्रदान करने के लिए तृतीय पक्षकार निर्धारण के माध्यम से प्रयोगशाला प्रत्यायन की कोई स्कीम प्रदान करने के उद्देश्य से भारत सरकार के विज्ञान और प्रौद्योगिकी विभाग के तत्वाधान में स्थापित की गई स्वायत्त निकाय अभिप्रेत है और प्रत्यायन सेवाएं, अंतरराष्ट्रीय मानकीकरण संगठन (आईएसओ) मानकों के अनुसार चिकित्सीय प्रयोगशालाओं के परीक्षण और अंश शोधन के लिए प्रदान की जाती है ;
(च) “तकनीकी जो कार्निआ निकाल सकता है” से निम्नलिखित किसी अर्हता और अनुभव वाला तकनीकी अभिप्रेत है जो (नेत्र गोलक को निकालना या कार्निआ को काटना) कार्निआ काट सकता है, अर्थात् :-
i. ऐसा नेत्र विज्ञानी जिसके पास नेत्र विज्ञान में डाक्टर ऑफ मेडिसिन (एम.डी.) या मास्टर ऑफ सर्जरी (एम.एस.) या नेत्र विज्ञान में डिप्लोमा (डी.ओ.) हो ; और
ii. आयुर्विज्ञान की सभी मान्यताप्राप्त प्रणालियों से रजिस्ट्रीकृत डाक्टर, आयुर्विज्ञान की सभी मान्यताप्राप्त प्रणालियों से मान्यताप्राप्त अर्हता रखने वाली नर्स, पराचिकित्सा नेत्र विज्ञान सहायक, नेत्र विज्ञान सहायक, दृष्टिमितिज्ञ, अपवर्तन विज्ञानी, पराचिकित्सा कर्मकार या चिकित्सा तकनीकी अभिप्रेत है परंतु यह तब जब कि व्यक्ति रजिस्ट्रीकृत, प्राधिकृत और

क्रियागत नेत्र बैंक या सरकारी आयुर्विज्ञान महाविद्यालय से दान किए गए कार्निया या आंख को निकालने के लिए सम्यक् रूप से प्रशिक्षित हों और प्रशिक्षण प्रमाणपत्र में यह उल्लेख होना चाहिए कि उसने स्वतंत्र रूप से आंख को निकालने या शव से कार्निया को अलग करने के लिए अपेक्षित कौशल अर्जित कर लिया है ;

(छ) उन शब्दों और पदों का, जो इन नियमों में प्रयुक्त हैं पर परिभाषित नहीं है किंतु अधिनियम में परिभाषित है, क्रमशः वही अर्थ होगा जो अधिनियम में उनका है ।

3. मानव अंग और उत्तक निकालने के लिए प्राधिकार - अधिनियम की धारा 3 के उपबंधों के अधीन कोई जीवित व्यक्ति ऐसी रीति में और ऐसी शर्तों पर जो प्ररूप 1, 2 और 3 में विनिर्दिष्ट की जाएं, चिकित्सा प्रयोजनों के लिए विद्यमान चिकित्सा प्रचलनों के अनुसार उसके जीवनकाल के दौरान उसके शरीर से कोई अंग या उत्तक निकालने के लिए प्राधिकृत कर सकता है/ सकती है ।

4. मस्तिष्क स्तंभ मृत्यु प्रमाणीकरण के लिए विशेषज्ञों का पैनल - मस्तिष्क स्तंभ मृत्यु के प्रमाणीकरण के प्रयोजन के लिए समुचित प्राधिकारी चिकित्सा विशेषज्ञों के बोर्ड के दक्ष कार्यकरण को सुनिश्चित करने के लिए अधिनियम के उपबंधों के अनुसरण में विशेषज्ञों का एक पैनल रखेगा और यह पूर्णतः सक्रियात्मक रहता है ।

5. रजिस्ट्रीकृत चिकित्सा व्यवसायी के कर्तव्य - गहन परिचर्या एकक सुविधा रखने वाले अस्पताल का रजिस्ट्रीकृत चिकित्सा व्यवसायी प्रतिरोपण समन्वयक, यदि उपलब्ध है, के परामर्श से गहन परिचर्या एकक में व्यक्ति की मस्तिष्क स्तंभ मृत्यु के प्रमाणीकरण के पश्चात् उसके वयस्क निकट नातेदार या यदि निकट नातेदार उपलब्ध नहीं है, तो रक्त या विवाह से संबंधित किसी अन्य व्यक्ति से और अदावी शव की दशा में शव का विधिपूर्ण कब्जा रखने वाले व्यक्ति से निम्नलिखित बातें अभिनिश्चित करेगा, अर्थात् :-

(क) क्या व्यक्ति ने अपनी मृत्यु के पूर्व दो या अधिक साक्षियों की उपस्थिति में (जिनमें कम से कम एक व्यक्ति ऐसे व्यक्ति का निकट नातेदार हों) प्ररूप 7 में यथाविनिर्दिष्ट या दस्तावेजों जैसे चालक अनुज्ञप्ति इत्यादि जिनमें इन नियमों की अधिसूचना के पश्चात् दान के उपबंध को सम्मिलित किया जा सके, अपने अंग या उत्तक, जिसके अंतर्गत आंख भी है, चिकित्सा प्रयोजनों के लिए उसकी मृत्यु के पश्चात् निकालने के लिए असंदिग्ध रूप से प्राधिकृत किया है और क्या यह विश्वास करने का कोई कारण नहीं है कि व्यक्ति ने पूर्वोक्त प्राधिकार को पश्चात्वर्ती प्रतिसंहत किया है ;

(ख) जहां उक्त प्राधिकार व्यक्ति द्वारा उसकी मृत्यु के पश्चात् उसके अंगों या उत्तकों का दान करने के लिए नहीं दिया गया है तब रजिस्ट्रीकृत चिकित्सा व्यवसायी प्रतिरोपण समन्वयक, यदि उपलब्ध है, के परामर्श के पश्चात् निकट नातेदार या शव के विधिपूर्ण कब्जा वाले व्यक्ति को इस विकल्प की जानकारी देगा कि वह ऐसे मानव अंग या उत्तक या दोनों (जिनका प्रयोग चिकित्सा प्रयोजनों के लिए किया जा सकता है) जिसके अंतर्गत मृत व्यक्ति की आंख या कार्निया भी है, का दान करने के लिए प्राधिकृत या इंकार कर सकता है और इस आशय की घोषणा या प्राधिकार को निकट नातेदार या शव के विधिपूर्ण कब्जा वाले व्यक्ति से प्ररूप 8 के अनुसार सहमति की प्राप्ति को अभिलिखित करने के लिए अभिनिश्चित किया जाएगा और अदावी शव की दशा में अधिनियम की धारा 5 की उपधारा (1) के अनुसार प्राधिकृत पदधारी द्वारा प्ररूप 9 में प्राधिकार दिया जाएगा ;

(ग) निकट नातेदार या शव के विधिपूर्ण कब्जा वाले व्यक्ति द्वारा मृत व्यक्ति के मानव अंग या उत्तक निकालने के लिए प्राधिकृत करने और उनके दान के लिए सहमति देने के पश्चात् रजिस्ट्रीकृत चिकित्सा व्यवसायी, प्रतिरोपण समन्वयक के माध्यम से अंगों या उत्तकों के रिट्रीवल, भंडारण या परिवहन के लिए उपलब्ध दस्तावेज्य संसूचना की रीति से प्राधिकृत समन्वय संगठन के माध्यम से रजिस्ट्रीकृत मानव अंग रिट्रीवल केन्द्र को सूचित करेगा ।

(2) पूर्व उल्लिखित कर्तव्य इन नियमों की अधिसूचना की तारीख से इस अधिनियम के अधीन रजिस्ट्रीकृत नहीं किए गए किसी अस्पताल की गहन परिचर्या एकक में कार्यरत रजिस्ट्रीकृत चिकित्सा व्यवसायी को भी लागू होंगे ।

(3) रजिस्ट्रीकृत चिकित्सा व्यवसायी किसी जीवित दाता से कोई मानव अंग या उत्तक निकालने से पूर्व अपना निम्नलिखित के बारे में समाधान करेगा -

(क) कि दाता को सभी संभव अनुषंगी प्रभावों, खतरों, उपद्रवों को स्पष्ट कर दिया गया है और यह कि दाता ने, निकट नातेदार दाता के लिए समुचित प्ररूप 1 में या पति-पत्नी दाता के लिए प्ररूप 2 में और निकट नातेदार से भिन्न दाता के लिए प्ररूप 3 में अपना प्राधिकार दे दिया है ;

(ख) कि दाता का शारीरिक और मानसिक मूल्यांकन कर लिया गया है, वह स्वास्थ्य की समुचित अवस्था में है और यह प्रमाणित कर दिया गया है कि वह मानसिक बाधाग्रस्त नहीं है और यह कि वह अंग या उत्तक दान करने के योग्य है ; परंतु दाता की मानसिक बाधाग्रस्त प्राप्ति की बाबत संदेह की दशा में रजिस्ट्रीकृत चिकित्सा व्यवसायी दाता की परीक्षा किसी मनोचिकित्सक से करा सकेगा और रजिस्ट्रीकृत चिकित्सा व्यवसायी इस प्रयोजन के लिए प्ररूप 4 में यथाविहित प्रमाणपत्र पर हस्ताक्षर करेगा ;

(ग) कि दाता प्ररूप 5 में यथा प्रमाणित प्राप्तिकर्ता का निकट नातेदार है और यह कि उसने प्राप्तिकर्ता के साथ संयुक्त रूप से प्ररूप 11 में आवेदन प्रस्तुत कर दिया है और यह कि प्रस्तावित दान का नियम 2(ग) में यथा परिभाषित और प्ररूप 19 में विनिर्दिष्ट सक्षम प्राधिकारी द्वारा अनुमोदन कर दिया गया है और यह कि निकट नातेदारी के तथ्य को अवधारित करने के लिए यथाविहित आवश्यक दस्तावेजों और यथा अपेक्षित चिकित्सा जांचों की रजिस्ट्रीकृत चिकित्सा व्यवसायी और सक्षम प्राधिकारी के समाधानप्रद रूप में परीक्षा कर ली गई है ;

(घ) कि दाता, प्राप्तिकर्ता का पति/ पत्नी होने की दशा में प्ररूप 2 में के प्रमाणपत्र पर हस्ताक्षर करके दाता ने इस प्रभाव का कथन कर दिया है कि वे इस प्रकार नातेदार है और प्राप्तिकर्ता के साथ संयुक्त रूप से प्ररूप 11 में आवेदन प्रस्तुत कर दिया है और यह कि प्रस्तावित दान का नियम 7 के उपनियम (2) के उपबंधों के अधीन सक्षम प्राधिकारी द्वारा अनुमोदन कर दिया गया है ;

(ङ) उस दाता की दशा में, जो निकट नातेदार से भिन्न है उसने प्ररूप 3 पर हस्ताक्षर कर दिए हैं और प्राप्तिकर्ता के साथ संयुक्त रूप से प्ररूप 11 में आवेदन प्रस्तुत कर दिया है, प्राधिकार समिति से उक्त दान के लिए अनुज्ञा अभिप्राप्त कर ली गई है ;

- (च) कि यदि कोई दाता या प्राप्तिकर्ता विदेशी राष्ट्रीय है तो प्राधिकार समिति से उक्त दान के लिए अनुज्ञा अभिप्राप्त कर ली गई है ;
- (छ) अवयस्क द्वारा जीवित रहते अंग या उतक दान की अनुज्ञा पूर्ण न्यायोचित्य सहित ब्यौरे लेखबद्ध किए जाने वाले अपवादित चिकित्सा आधारों और समुचित प्राधिकारी और संबंधित राज्य सरकार के पूर्व अनुमोदन के सिवाय नहीं दी जाएगी ।
- (4) रजिस्ट्रीकृत चिकित्सा व्यवसायी मृतक दाता की मृत्यु के पश्चात् उसके शव से कोई भी अंग या उतक निकालने के पूर्व प्रतिरोपण समन्वयक से परामर्श करके निम्नलिखित के बारे में अपना समाधान करेगा, अर्थात् :-
- (क) कि गहन परिचर्या एकक में भर्ती किसी व्यक्ति के निकट नातेदार या उसके शव के विधिपूर्ण कब्जा वाले व्यक्ति से किसी व्यक्ति की मस्तिष्क स्तंभ मृत्यु के प्रमाणीकरण के पश्चात् ही यह जांच करने में सावधानी बरती गई है कि दाता ने दो या अधिक साक्षियों की उपस्थिति में (जिनमें कम से कम एक व्यक्ति ऐसे व्यक्ति का निकट नातेदार है) प्ररूप 7 में यथाविनिर्दिष्ट या दस्तावेजों जैसे चालक अनुज्ञापति इत्यादि (जिनमें इन नियमों की अधिसूचना के पश्चात् दान के उपबंध को सम्मिलित किया जा सके), अपने अंग या उतक, चिकित्सा प्रयोजनों के लिए उसकी मृत्यु के पश्चात् निकालने के लिए असंदिग्ध रूप से प्राधिकृत किया है और यह अभिनिश्चित कर लिया गया है कि व्यक्ति ने पूर्वोक्त प्राधिकार को पश्चात्वर्ती प्रतिसंहत नहीं किया है और मृतक दाता द्वारा दिए गए प्राधिकार के होते हुए भी निकट नातेदार या शव के विधिपूर्ण कब्जा वाले व्यक्ति की सहमति भी अपेक्षित होगी ; परंतु यदि मृतक व्यक्ति जिसने पूर्व में प्राधिकार दे दिया था किंतु उसे तत्पश्चात् प्रतिसंहत कर लिया था और यदि व्यक्ति ने लिखित में दे दिया है कि उसकी मृत्यु के पश्चात् उसके अंग नहीं निकाले जाने चाहिए तो उसका कोई अंग या उतक नहीं निकाला जाएगा चाहे निकट नातेदार या शव के विधिपूर्ण कब्जा वाले व्यक्ति द्वारा सहमति दे दी गई हो ;
- (ख) कि मृतक व्यक्ति के निकट नातेदार या मृतक दाता के शव के विधिपूर्ण कब्जा वाले व्यक्ति ने प्ररूप 8 में यथाविनिर्दिष्ट घोषणा पर हस्ताक्षर कर दिए हैं ;
- (ग) कि शक्य दाता की मस्तिष्क स्तंभ मृत्यु की दशा में प्ररूप 10 में यथाविनिर्दिष्ट प्रमाणपत्र पर अधिनियम की धारा 3 की उपधारा (6) में निर्दिष्ट चिकित्सा विशेषज्ञ बोर्ड के सभी सदस्यों ने हस्ताक्षर कर दिए हैं ; परंतु जहां तंत्रिका विज्ञानी या तंत्रिका शल्य चिकित्सक उपलब्ध नहीं हैं वहां कोई एनेस्थेतिस्ट या इंटेसिविस्ट, जो समुचित प्राधिकारी द्वारा सम्यक् रूप से पैनल वाले अस्पताल के प्रधान द्वारा नामनिर्दिष्ट प्रतिरोपण दल का भाग नहीं है, उक्त बोर्ड के सदस्य के रूप में मस्तिष्क स्तंभ मृत्यु को प्रमाणित कर सकेगा ;
- (घ) कि 18 वर्ष से कम आयु के व्यक्ति की मस्तिष्क स्तंभ मृत्यु की दशा में अधिनियम की धारा 3 की उपधारा (6) में निर्दिष्ट चिकित्सा विशेषज्ञ बोर्ड के सभी सदस्यों ने प्ररूप 10 में विनिर्दिष्ट प्रमाणपत्र पर हस्ताक्षर कर दिए हैं और प्ररूप 8 में यथाविनिर्दिष्ट प्राधिकार पर ऐसे व्यक्ति के माता या पिता ने या माता-पिता द्वारा प्राधिकृत किसी निकट नातेदार ने हस्ताक्षर कर दिए हैं ।
- (6) **चिकित्सा विधिक मामलों में अंग या उतक दान की प्रक्रिया.**- (1) अंग या उतक निकालने के लिए प्राधिकार अभिप्राप्त करने के पश्चात्, किसी मस्तिष्क स्तंभ मृत दाता से अंग दान करने की सहमति के पश्चात् भी अस्पताल का रजिस्ट्रीकृत चिकित्सा व्यवसायी क्षेत्र के भारसाधक अधिकारी या पुलिस अधीक्षक या उप महानिरीक्षक से या तो प्रत्यक्षतः या अस्पताल में स्थित पुलिस चौकी के माध्यम से दाता से अंग या उतक के उचित समय के भीतर निकालने को सुकर बनाने का अनुरोध करेगा और साथ ही साथ ऐसे अनुरोध की एक प्रति क्षेत्र के पदाभिहित शव परीक्षा डाक्टर के पास भी भेज देनी चाहिए ।
- (2) यह सुनिश्चित किया जाएगा कि अंग के रिट्रीवल से मृत्यु के कारण के अवधारण में कोई खतरा नहीं हो ।
- (3) निकाले जाने वाले अंग या उतक की बाबत निकालने वाले डॉक्टर द्वारा रिट्रीवल के समय चिकित्सा रिपोर्ट तैयार की जाएगी और उसे शव परीक्षा करने वाले रजिस्ट्रीकृत चिकित्सा व्यवसायी द्वारा शव परीक्षा टिप्पणियों में अभिलेख पर रखा जाएगा ।
- (4) जहां संभव हो, शव परीक्षा के लिए पदाभिहित रजिस्ट्रीकृत चिकित्सा व्यवसायी से अंग या उतक के रिट्रीवल के समय कार्यालय समय के पूर्व या पश्चात् भी उपस्थित रहने का अनुरोध करने का प्रयास किया जाना चाहिए ।
- (5) उस दशा में जब कोई निजी रिट्रीवल अस्पताल में शव परीक्षा नहीं की जाती है तो शव को अंग या उतक रिट्रीवल के पश्चात् चिकित्सा अभिलेख सहित पदाभिहित शव परीक्षा केन्द्र को परिवहन करने का प्रबंध किया जाएगा और शव परीक्षा केन्द्र ऐसे मामलों की शव परीक्षा कार्यालय समय के पूर्व या पश्चात् भी पूर्विकता के आधार पर करेगा जिससे शव को कम से कम असुविधा के साथ नातेदारों को सौंपा जा सके ।
7. **प्राधिकार समिति.**- (1) वह चिकित्सा व्यवसायी जो प्रतिरोपण संक्रिया करने के लिए अंग प्रतिरोपण का भाग होगा, अधिनियम की धारा 9 की उपधारा (4) के खंड (क) और खंड (ख) के उपबंधों के अधीन गठित प्राधिकार समिति का सदस्य नहीं होगा ।
- (2) जब प्रस्तावित दाता या प्राप्तिकर्ता या दोनों भारतीय राष्ट्रीय या नागरिक नहीं हैं चाहे वे निकट नातेदार हो या अन्यथा हों, प्राधिकार समिति ऐसी सभी अनुरोधों पर विचार करेगी और यदि प्राप्तिकर्ता कोई विदेशी राष्ट्रीय है और दाता कोई भारतीय राष्ट्रीय है तो प्रतिरोपण की तब तक अनुज्ञा नहीं दी जाएगी जब तक वे निकट नातेदार नहीं हो ।
- (3) जब प्रस्तावित दाता और प्राप्तिकर्ता निकट नातेदार नहीं हैं तो प्राधिकार समिति,-
- (i) यह मूल्यांकन करेगी कि प्राप्तिकर्ता और दाता के बीच कोई वाणिज्यिक संव्यवहार नहीं है और यह कि दाता को कोई संदाय नहीं किया गया है या दाता या किसी अन्य व्यक्ति को संदाय करने का वचन नहीं दिया गया है ;
- (ii) उनके बीच में संबंध और वे परिस्थितियां जिनके कारण प्रस्ताव किया गया है, का स्पष्टीकरण तैयार करेगी ;
- (iii) उन कारणों की परीक्षा करेगी कि दाता की दान करने की इच्छा क्यों है ;
- (iv) संबंध के दस्तावेजी साक्ष्य जैसे यह सबूत कि वे साथ-साथ रहते हैं, आदि की परीक्षा करेगी ;
- (v) दाता और प्राप्तिकर्ता को एक साथ दर्शित करते हुए पुराने फोटो चित्रों की परीक्षा करेगी ;
- (vi) यह मूल्यांकन करेगी कि कोई बिचौलिया या दलाल अंतर्वलित नहीं है ;

- (vii) दाता और प्राप्तिकर्ता की वित्तीय प्रास्थिति की यह मांग करते हुए मूल्यांकन करेगी कि वे गत तीन वित्तीय वर्षों के लिए अपने व्यवसाय और आय का समुचित साक्ष्य दें और उन दोनों की प्रास्थिति के बीच किसी घोर असमानता का मूल्यांकन वाणिज्यिक व्यवहार के निवारण के उद्देश्यों की पृष्ठभूमि में किया जाना चाहिए ;
- (viii) यह सुनिश्चित करेगी कि दाता कोई दुर्व्यसनी नहीं है ;
- (ix) यह सुनिश्चित करेगी कि निकट नातेदार या यदि निकट नातेदार उपलब्ध नहीं है तो प्रस्तावित असंबंधित दाता के रक्त या विवाह द्वारा दाता से संबंधित किसी वयस्क व्यक्ति का उसके अंग या उतक का दान करने के आशय के बारे में जागरूकता, दाता और प्राप्तिकर्ता के बीच संपर्क और दान के कारणों की अधिप्रमाणिकता के बारे में साक्षात्कार किया गया है और ऐसे संबंधी के विरोधी विचारों या असहमति या आक्षेपों को भी अभिलिखित किया जाएगा और उनको ध्यान में रखा जाएगा ।
- (4) अधिनियम की धारा 9 की उपधारा (3क) के अधीन निर्दिष्ट विनियम दान के मामलों का अनुमोदन उस अस्पताल या जिला या राज्य की प्राधिकार समिति द्वारा किया जाएगा जिसमें प्रतिरोपण किया जाना प्रस्तावित है और अंग का दान केवल विनियम प्राप्तिकर्ता के निकट नातेदारों से ही अनुज्ञेय होगा ।
- (5) जब प्राप्तिकर्ता एक सप्ताह के भीतर जीवन रक्षक अंग प्रतिरोपण की आवश्यकता के लिए नाजुक स्थिति में है तो दाता या प्राप्तिकर्ता, प्राधिकारी समिति द्वारा त्वरित मूल्यांकन के लिए अस्पताल प्रभारी से संपर्क कर सकेंगे ।
- 8. अंगों और उतकों का निकाला जाना और परिरक्षण.-** अंगों या उतकों का निकाला जाना किसी रजिस्ट्रीकृत रिट्रीवल या प्रतिरोपण अस्पताल या केन्द्र में अनुज्ञेय होगा और ऐसे निकाले गए अंगों या उतकों का परिरक्षण, प्रतिरोपण के प्रयोजन हेतु जीवन क्षमता सुनिश्चित करने के क्रम में वर्तमान और स्वीकृत वैज्ञानिक रीतियों के अनुसार रजिस्ट्रीकृत रिट्रीवल या प्रतिरोपण केन्द्र या उतक बैंक में सुनिश्चित किया जाएगा ।
- 9. शव या अंगों या उतकों के रिट्रीवल या परिवहन या परिरक्षण के अनुरक्षण की लागत.-** शव (मस्तिष्क स्तंभ मृत घोषित व्यक्ति), अंगों या उतकों का रिट्रीवल, उनके परिवहन और परिरक्षण की लागत दाता कुटुंब द्वारा वहन नहीं की जाएगी और यह प्राप्तिकर्ता या संस्था या सरकार या गैर सरकारी संगठन या सोसाइटी द्वारा क्रमिक राज्य सरकार या संघ राज्य क्षेत्र प्रशासन द्वारा विनिश्चित रूप में वहन की जा सकेगी ।
- 10. जीवित दाता प्रतिरोपण के लिए आवेदन. -** (1) दाता और प्राप्तिकर्ता संयुक्त रूप से प्ररूप 11 में यथा विनिर्दिष्ट सक्षम प्राधिकारी या प्राधिकार समिति के समक्ष किसी मानव अंग के निकाले जाने और प्रतिरोपण के लिए अनुमोदन प्रदान करने का आवेदन करेंगे और प्रतिरोपण के अनुमोदन के लिए कागज पत्र प्रतिरोपण संस्था के रजिस्ट्रीकृत चिकित्सा व्यवसायी और प्रशासनिक खंड द्वारा प्रक्रियागत किए जाएंगे ।
- (2) सक्षम प्राधिकारी या प्राधिकार समिति ऐसे आवेदन पर नियम 18 के अनुसार विनिश्चय करेगी ।
- (3) यदि कोई राज्य प्ररूप 11 का विलय प्ररूप 1, प्ररूप 2 या प्ररूप 3 के साथ करना चाहते हैं तो वे ऐसा कर सकेंगे परंतु यह तब जब कि सिफारिश किए गए प्ररूपों के अंतर्वस्तु विलय किए गए प्ररूप में समाविष्ट हैं और संबंधित राज्य सरकार ने उसका अनुमोदन कर दिया है ।
- 11. प्राधिकार समिति की संरचना.-** (1) एक राज्य स्तरीय प्राधिकार समिति होगी ।
- (2) जिलों या संस्थाओं या अस्पतालों में अतिरिक्त प्राधिकार समितियों की स्थापना नीचे दिए गए मानकों के अनुसार की जा सकेगी जिन्हें संबंधित राज्य सरकार या संघ राज्य क्षेत्र प्रशासन द्वारा समय-समय पर अधिसूचना द्वारा पुनरीक्षित किया जा सकेगा ।
- (3) संस्था के प्रतिरोपण दल का कोई सदस्य अपनी प्राधिकार समिति का सदस्य नहीं होना चाहिए ।
- (4) यदि क्रमिक प्रतिरोपण केन्द्रों पर एक वर्ष में प्रतिरोपणों की संख्या पच्चीस या अधिक है तो प्राधिकार समिति अस्पताल आधारित होनी चाहिए और यदि किसी संस्था या अस्पताल में अंग प्रतिरोपणों की संख्या एक वर्ष में पच्चीस से कम है तब राज्य या जिला स्तरीय प्राधिकार समिति अनुमोदन प्रदान करेगी ।
- 12. अस्पताल आधारित प्राधिकार समिति की संरचना.-** राज्य की दशा में राज्य सरकार द्वारा और संघ राज्यक्षेत्र की दशा में संघ राज्यक्षेत्र प्रशासन द्वारा यथा अधिसूचित अस्पताल आधारित प्राधिकार समिति में निम्नलिखित होंगे,-
- (क) संस्था या अस्पताल का चिकित्सा निदेशक या चिकित्सा अधीक्षक या प्रधान या प्रधान के स्थानापन्न रूप में कार्य करने वाला कोई ज्येष्ठ चिकित्सक व्यक्ति - अध्यक्ष ;
- (ख) उसी अस्पताल के दो ज्येष्ठ चिकित्सा व्यवसायी जो प्रतिरोपण दल के भाग नहीं हैं - सदस्य ;
- (ग) उच्च सत्यनिष्ठा, सामाजिक प्रतिष्ठा और विश्वसनीयता वाले दो व्यक्ति (अधिमानतः एक महिला) जिन्होंने उच्च पंक्ति के सरकारी पदों जैसे-उच्चतर न्यायपालिका, पुलिस सेवा के ज्येष्ठ काडर में सेवा की हो या जिसने विश्वविद्यालय अनुदान आयोग द्वारा अनुमोदित विश्वविद्यालय में उपाचार्य या आचार्य के रूप में सेवा की हो या स्वनियोजित ख्यातिप्राप्त वृत्तिक जैसे अधिवक्ता, चार्टर्ड एकाउंटेंट, भारतीय चिकित्सा संगम के डॉक्टर, ख्याति प्राप्त गैर सरकारी संगठन या विख्यात सामाजिक कार्यकर्ता हों - सदस्य ;
- (घ) राज्य सरकार या संघ राज्यक्षेत्र प्रशासन का सचिव (स्वास्थ्य) या नामनिर्देशिती और निदेशक स्वास्थ्य सेवाएं या नामनिर्देशिती - सदस्य ।
- 13. राज्य या जिला स्तरीय प्राधिकार समितियों की संरचना.-** राज्य की दशा में राज्य सरकार द्वारा और संघ राज्यक्षेत्र की दशा में संघ राज्यक्षेत्र प्रशासन द्वारा यथा अधिसूचित राज्य या जिला स्तरीय प्राधिकार समिति में निम्नलिखित होंगे,-
- (क) जिले के मुख्य या प्रमुख अस्पताल में मुख्य चिकित्सा अधिकारी के स्थानापन्न रूप में कार्य करने वाला कोई चिकित्सा व्यवसायी या कोई अन्य समतुल्य पद - अध्यक्ष ;

- (ख) ऐसे चिकित्सा व्यवसायियों के पूल से चुने जाने वाले दो ज्येष्ठ चिकित्सा व्यवसायी जो संबंधित जिले में निवास करते हैं और जो प्रतिरोपण दल के भाग नहीं हैं - सदस्य ;
- (ग) उच्च सत्यनिष्ठा, सामाजिक प्रतिष्ठा और विश्वसनीयता वाले दो व्यक्ति (अधिमानतः एक महिला) जिन्होंने उच्च पंक्ति के सरकारी पदों जैसे उच्चतर न्यायपालिका पुलिस सेवा के ज्येष्ठ काडर में सेवा की या जिसने विश्वविद्यालय अनुदान आयोग द्वारा अनुमोदित विश्वविद्यालय में उपाचार्य या आचार्य के रूप में सेवा की हो या स्वनियोजित ख्यातिप्राप्त वृत्तिक जैसे अधिवक्ता, चाटर्ड एकाउंटेंट, भारतीय चिकित्सा संगम के डॉक्टर, ख्याति प्राप्त गैर सरकारी संगठन या विख्यात सामाजिक कार्यकर्ता - सदस्य ;
- (घ) राज्य सरकार या संघ राज्यक्षेत्र प्रशासन का सचिव (स्वास्थ्य) या नामनिर्देशिती और निदेशक स्वास्थ्य सेवाएं या नामनिर्देशिती-सदस्य ; परंतु संबंधित राज्य सरकार द्वारा अधिकतम सदस्यों के पदेन सदस्य होने का प्रयास किया जाएगा जिससे समिति की संरचना में परिवर्तन की आवश्यकता की बारंबारता कम हो ।
- 14. आवासीय प्रास्थिति आदि का सत्यापन.** - जब जीवित दाता असंबंधित है और यदि दाता और प्राप्तिकर्ता ऐसे राज्य या संघ राज्यक्षेत्र से भिन्न किसी राज्य या संघ राज्यक्षेत्र से संबंधित है जहां पर प्रतिरोपण किया जाना प्रस्तावित है वहां तहसीलदार या किसी अन्य प्राधिकृत अधिकारी द्वारा इस प्रयोजन के लिए दाता या प्राप्तिकर्ता के अधिवास वाले राज्य या संघ राज्यक्षेत्र के समुचित प्राधिकारी को एक प्रति प्रेषांकित करके उनकी सूचना के लिए आवासीय प्रास्थिति का सत्यापन प्ररूप 20 के अनुसार किया जाना अपेक्षित होगा और अंग दुर्व्यापार का कोई संदेह होने की दशा में अधिवास वाले राज्य या संघ राज्यक्षेत्र का समुचित प्राधिकारी या तहसीलदार या कोई अन्य प्राधिकृत अधिकारी अधिनियम की अनुज्ञा के अनुसार पुलिस विभाग को अन्वेषण करने और कार्रवाई करने के लिए सूचित करेगा ।
- 15. प्राधिकार समिति की गणपूर्ति.**- प्राधिकार समिति की गणपूर्ति न्यूनतम चार होगी और गणपूर्ति अध्यक्ष के भाग लेने, सचिव (स्वास्थ्य) या नामनिर्देशिती और स्वास्थ्य सेवा निदेशक या नामनिर्देशिती की उपस्थिति के बिना पूर्ण नहीं होगी ।
- 16. प्राधिकार समिति के अनुमोदन का रूप विधान.**- प्राधिकार समिति के अनुमोदन का रूप विधान किसी राज्य की सभी संस्थाओं में एक समान होना चाहिए और क्रमिक राज्य सरकार द्वारा रूप विधान प्ररूप 18 के अनुसार अधिसूचित किया जा सकेगा ।
- 17. प्राधिकारी समिति द्वारा आवेदनों की संवीक्षा.**- (1) प्राधिकार समिति सचिवालय, प्रस्तावित दाताओं और प्राप्तिकर्ताओं से प्राप्त सभी आवेदनों की प्रतियां सभी उपाबंधों सहित, जो आवेदनों के साथ फाइल किए गए हों, समिति के सभी सदस्यों को परिचालित करेगा । (2) बैठक के समय प्राधिकार समिति अपनी विनिश्चय प्रक्रिया के अनुक्रम में सभी सुसंगत अंतर्वस्तुओं और दस्तावेजों को ध्यानपूर्वक देखेगी और किसी दस्तावेज या सूचना के अपर्याप्त या संदेहास्पद पाए जाने की दशा में आवेदक से स्पष्टीकरण मांगा जाना चाहिए और यदि यह आवश्यक समझा जाता है कि किसी तथ्य या सूचना की सत्यता या शुद्धता की पुष्टि के क्रम में उसे सत्यापित किया जाना अपेक्षित है तो उसे राज्य सरकार या संघ राज्यक्षेत्र प्रशासन के संबंधित अधिकारी के माध्यम से अभिनिश्चित किया जाएगा ।
- 18. निकट नातेदारों के मामलों में प्रक्रिया.**- (1) जहां अंगों का प्रस्तावित प्रतिरोपण आनुवांशिक रूप से संबंधित निकट नातेदारों अर्थात् दादी, दादा, अठारह वर्ष से अधिक आयु के माता, पिता, भाई, बहिन, पुत्र, पुत्री, पौत्र और पौत्री के बीच है (उस दशा में जब दाता या प्राप्तिकर्ता विदेशी है) तो नियम 2(ग) में यथा परिभाषित सक्षम प्राधिकारी या प्राधिकार समिति निम्नलिखित मूल्यांकन करेगी -
- (i) तहसीलदार या उपखंड मजिस्ट्रेट या महानगर मजिस्ट्रेट या पंचायत के सरपंच से संबंध का दस्तावेजी साक्ष्य अर्थात् सुसंगत जन्म प्रमाणपत्र, विवाह प्रमाणपत्र, अन्य संबंधित प्रमाणपत्र या इसी प्रकार का अन्य पहचान प्रमाणपत्र जैसे निर्वाचन फोटो पहचानपत्र या आधार कार्ड ; और
- (ii) प्रस्तावित दाता की पहचान और निवास का दस्तावेजी साक्ष्य, राशनकार्ड या मतदाता पहचानपत्र या पासपोर्ट या चालक अनुज्ञप्ति या पेन कार्ड या बैंक खाता और प्रस्तावित दाता और प्रस्तावित प्राप्तिकर्ता के साथ दूसरे निकट नातेदार को चित्रित करने वाला कुटुंब फोटो चित्र या इसी प्रकार का अन्य पहचान प्रमाणपत्र जैसे आधार कार्ड [भारतीय अनन्य पहचान प्राधिकरण (यूआईएआई) द्वारा जारी] ।
- (2) यदि सक्षम प्राधिकारी की राय में पूर्वोक्त साक्ष्य के मूल्यांकन के पश्चात् संबंध निश्चायक रूप से स्थापित नहीं हुआ है तो यह अपने विवेकानुसार से और चिकित्सा परीक्षण अर्थात् डेओक्सीरिबोन्यूक्लिक एसिड (डीएनए) प्रोफाइलिंग का निदेश दे सकेगा ।
- (3) उप नियम (2) में निर्दिष्ट परीक्षण, परीक्षण और अंश शोधन प्रयोगशालाओं के लिए राष्ट्रीय प्रत्यायन बोर्ड से प्रत्यायित किसी प्रयोगशाला से कराया जाएगा और प्रमाणपत्र प्ररूप 5 में दिया जाएगा ।
- (4) यदि दस्तावेजी साक्ष्य और उप नियम (1) और उप नियम (2) में निर्दिष्ट परीक्षण से क्रमशः दाता और प्राप्तिकर्ता के बीच आनुवांशिक संबंध स्थापित नहीं होता है तो वहीं प्रक्रिया अधिमानतः दोनों या कम से कम एक के माता पिता पर अपनाई जाएगी और यदि माता पिता उपलब्ध नहीं हैं तो वहीं प्रक्रिया दाता और प्राप्तिकर्ता के ऐसे संबंधियों पर अपनाई जाएगी जो उपलब्ध हैं और परीक्षण किए जाने के लिए रजामंद हैं जिसके असफल होने पर दाता और प्राप्तिकर्ता के बीच आनुवांशिक संबंध का स्थापित नहीं होना समझा जाएगा ।
- (5) जहां प्रस्तावित प्रतिरोपण किसी विवाहित दंपती के बीच है वहां सक्षम प्राधिकारी या प्राधिकार समिति (उस दशा में जब दाता या प्राप्तिकर्ता विदेशी हैं) विवाह के तथ्य और अवधि का मूल्यांकन करना चाहिए और यह सुनिश्चित करना चाहिए कि दस्तावेज जैसे विवाह प्रमाणपत्र, विवाह फोटो चित्र, आदि के साथ संतानों की संख्या और आयु की सूचना और संपूर्ण कुटुंब को चित्रित करने वाला कुटुंब फोटोचित्र, माता पिता की विशिष्टियों सहित संतान का जन्म प्रमाणपत्र अभिलेख पर रखे गए हैं और प्ररूप 6 में प्रमाणपत्र जारी करना चाहिए (पति या पत्नी के दाता होने के लिए)।
- (6) निवास या अधिवास के सबूत से संबंधित कोई दस्तावेज और जनकता की विशिष्टियां यह सुनिश्चित करने के लिए आवेदक के फोटो पहचान से मेल खानी चाहिए कि दस्तावेज उसी व्यक्ति से संबंधित है जो प्रस्तावित दाता है और इस प्रभाव कि किसी अपर्याप्त या

संदेहास्पद सूचना की दशा में, यथास्थिति, सक्षम प्राधिकारी या प्राधिकार समिति अपने विवेकानुसार ऐसी अन्य सूचना या साक्ष्य की मांग कर सकेगा जो मामले के विशिष्ट तथ्यों में समीचीन और वांछनीय हो ।

(7) वह चिकित्सा व्यवसायी, जो प्रतिरोपण शल्य क्रिया करने के लिए अंग प्रतिरोपण दल का भाग होगा, प्रतिरोपण अस्पताल का सक्षम प्राधिकारी नहीं होगा ।

(8) सक्षम प्राधिकारी, अपना विनिश्चय किए जाने के लिए, यदि अपेक्षित हो, तो प्राधिकार समिति की सहायता मांग सकेगा ।

19. **निकट नातेदारों से भिन्न प्रतिरोपण के मामलों में प्रक्रिया-** जहां प्रस्तावित प्रतिरोपण निकट नातेदारों से भिन्न व्यक्तियों के बीच है और उन सभी मामलों में जहां दाता या प्राप्तिकर्ता विदेशी राष्ट्रीय है (उनके निकट नातेदार या अन्यथा होने पर विचार किए बिना) अस्पताल की प्राधिकार समिति द्वारा या यदि अस्पताल आधारित प्राधिकार समिति का गठन नहीं किया गया है तो जिला या राज्य स्तरीय प्राधिकार समिति द्वारा अनुमोदन प्रदान किया जाएगा ।

20. **विदेशियों के मामलों में प्रक्रिया-** जब प्रस्तावित दाता विदेशी है :

(क) उद्भव के देश के किसी ज्येष्ठ राजदूतावास पदधारी को प्ररूप 21 के अनुसार दाता और प्राप्तिकर्ता के बीच संबंध को प्रमाणित करना पड़ता है और यदि किसी देश का राजदूतावास भारत में नहीं है तो उस देश की सरकार द्वारा उसी रूप विधान में संबंध का प्रमाणपत्र जारी किया जाएगा ;

(ख) प्राधिकार समिति, किसी विदेशी राष्ट्रीय (जो कोई निकट नातेदार है) को अंगदान करने की सहमति देने वाले सभी भारतीय दाताओं के मामलों की परीक्षा अधिक सावधानी से करेगी, जिसके अंतर्गत भारतीय मूल के विदेशी राष्ट्रीय भी है और ऐसे मामलों पर अलग-अलग मामले के आधार पर विरलता से ही विचार किया जाना चाहिए ;

परंतु निकट नातेदार से भिन्न किसी विदेशी को दान करने के इच्छुक भारतीय जीवित दाताओं पर विचार नहीं किया जाएगा ।

21. **दान करने के लिए आवेदक की पात्रता-** दान करने के लिए आवेदक की पात्रता के अवधारण के क्रम में प्राधिकार समिति द्वारा आवेदक का व्यक्तिगत रूप से साक्षात्कार किया जाना चाहिए जिसकी वीडियोग्राफी होगी और साक्षात्कार के कार्यवृत्त को अभिलिखित किया जाएगा ।

22. **महिला दाता की दशा में पूर्वावधानियां-** उस दशा में जहां दाता कोई महिला है, अधिक पूर्वावधानियां बरती जानी चाहिए और उसकी पहचान और उसकी स्वतंत्र सहमति की पुष्टि प्राप्तिकर्ता से भिन्न किसी व्यक्ति द्वारा करनी चाहिए ।

23. **प्राधिकार समिति का विनिश्चय-** (1) प्राधिकार समिति को (जो केवल जीवित अंग या उतक दाता को लागू है) विहित प्ररूप 8 में प्रस्तावित जीवित दाता के आवेदन को नामंजूर या अनुमोदित करने के कारणों का लिखित में कथन करना चाहिए और ऐसे सभी अनुमोदन निम्नलिखित शर्तों के अध्यक्ष होने चाहिए, अर्थात् :-

(i) अनुमोदित प्रस्तावित दाता के ऐसे सभी चिकित्सा परीक्षण किए जाएंगे जो प्रश्नगत अंग का दान करने के लिए उसकी जैव क्षमता और अनुरूपता को अवधारित करने के लिए सुसंगत अवस्थाओं में अपेक्षित हों ;

(ii) यह जानने के लिए दाता का शारीरिक और मानसिक मूल्यांकन कर लिया गया है कि क्या वह स्वास्थ्य की समुचित अवस्था में है और प्ररूप 4 में रजिस्ट्रीकृत चिकित्सा व्यवसायी द्वारा यह प्रमाणित कर दिया गया है कि वह मानसिक बाधाग्रस्त नहीं है और अंग या उतक दान करने के योग्य है ;

परंतु दाता के मानसिक बाधाग्रस्त प्रास्थिति का संदेह होने की दशा में रजिस्ट्रीकृत चिकित्सा व्यवसायी या प्राधिकार समिति दाता की परीक्षा मनोचिकित्सक द्वारा करा सकेंगे ;

(iii) प्रतिरोपण की प्रक्रिया में अंतर्वलित सभी सुसंगत व्यक्तियों द्वारा सभी विहित प्ररूप भर दिए गए हैं ;

(iv) सभी साक्षात्कारों की वीडियो रिकार्डिंग की जानी है ।

(2) प्राधिकार समिति ऐसे सभी मामलों में जहां रोगी का प्रतिरोपण तत्काल आधार पर किया जाना अपेक्षित है, विनिश्चय प्रक्रिया को तेज करेगी और अपने विवेक का प्रयोग न्यायिक और व्यवहारिक रूप से करेगी ।

(3) प्रत्येक प्राधिकृत प्रतिरोपण केन्द्र के पास अपनी स्वयं की वेबसाइट होनी चाहिए और प्राधिकार समिति से प्रतिरोपण की अनुज्ञा या नामंजूरी प्रदान करने के लिए बैठक आयोजित करने के चौबीस घंटे के भीतर अंतिम विनिश्चय किया जाना अपेक्षित है ।

(4) प्राधिकरण समिति के विनिश्चय को प्राप्तिकर्ता और दाता की पहचान को गुप्त रखते हुए, तुरंत अस्पताल या संस्था के सूचना पट्ट पर प्रदर्शित किया जाना चाहिए और इसे अस्पताल या संस्था की वेबसाइट पर भी विनिश्चय करने के चौबीस घंटे के भीतर उपदर्शित किया जाना चाहिए ।

24. **अस्पताल या उतक बैंक का रजिस्ट्रीकरण-** (1) प्ररूप 12 या प्ररूप 13 या प्ररूप 14 में इनमें से जो भी लागू हों में यथा विनिर्दिष्ट रूप में रजिस्ट्रीकरण के लिए आवेदन समुचित प्राधिकारी को किया जाएगा और आवेदन के साथ समुचित प्राधिकारी को संदेय बैंक ड्राफ्ट के माध्यम से नीचे विनिर्दिष्ट फीस संलग्न होगी, जिसका यदि आवश्यक हो तो यथास्थिति केन्द्रीय सरकार या राज्य सरकार द्वारा पुनरीक्षण किया जा सकेगा:-

(i) अंग या उतक या कार्निया प्रत्यारोपण केन्द्र: दस हजार रुपए;

(ii) उतक या नेत्र बैंक : दस हजार रुपए;

(iii) गैर प्रत्यारोपण रिट्रिवल केन्द्र: शून्य

(2) समुचित प्राधिकारी जांच करने के पश्चात् और स्वयं का यह समाधान करने के पश्चात् कि आवेदक ने सभी अपेक्षाओं को पूरा कर लिया

है, प्ररूप 16 में विनिर्दिष्ट रजिस्ट्रीकरण प्रमाण पत्र प्रदान करेगा और यह उसके जारी होने की तारीख से पांच वर्ष की अवधि के लिए वैध होगा और इसका नवीकरण किया जा सकेगा।

(3) इस नियम के उपबंधों के अधीन किसी अस्पताल का रजिस्ट्रीकरण करने से पूर्व अस्पताल के लिए प्रत्यारोपण समन्वयक की नियुक्ति करना आज्ञापक होगा।

25. अस्पताल या ऊतक बैंक के रजिस्ट्रीकरण का नवीकरण- (1) प्रमाण पत्र के लिए आवेदन समुचित प्राधिकारी को रजिस्ट्रीकरण के मूल प्रमाण पत्र के समाप्त होने की तारीख से कम से कम तीन मास पूर्व किया जाएगा और इसके साथ बैंक ड्राफ्ट के माध्यम से समुचित प्राधिकारी को संदेय फीस संलग्न होगी जिसका यदि आवश्यक हो तो यथास्थिति केन्द्रीय सरकार या राज्य सरकार द्वारा पुनरीक्षण किया जा सकेगा:-

(i) अंग या ऊतक या कार्निया प्रत्यारोपण केन्द्र: पांच हजार रुपए;

(ii) ऊतक या नेत्र बैंक: पांच हजार रुपए;

(iii) गैर प्रत्यारोपण रिट्रिवल केन्द्र: शून्य

(2) प्ररूप 17 में यथा विनिर्दिष्ट रजिस्ट्रीकरण के नवीकरण के लिए प्रमाण पत्र पांच वर्ष की अवधि के लिए वैध होगा।

(3) यदि किसी जांच जिसके अंतर्गत अस्पताल या ऊतक बैंक का निरीक्षण भी है और उसके पूर्व कार्यकरण की संवीक्षा करने के पश्चात् तथा आवेदक को अवसर दिए जाने के पश्चात्, समुचित प्राधिकारी का यह समाधान हो जाता है कि आवेदक ने नियम 24 के उपनियम (2) के अधीन रजिस्ट्रीकरण का प्रमाण पत्र प्रदान किए जाने के पश्चात् अधिनियम और इन नियमों की अपेक्षाओं का तथा उन शर्तों का जिनके अधीन रजिस्ट्रीकरण प्रमाण पत्र प्रदान किया गया था का अनुपालन नहीं किया है, कारणों को लेखबद्ध करते हुए वह रजिस्ट्रीकरण के प्रमाण पत्र का नवीकरण करने से इनकार कर सकेगा।

26. अंग या ऊतक प्रत्यारोपण केन्द्रों को रजिस्ट्रीकरण प्रमाण पत्र प्रदान किए जाने की शर्तें और मानक—(1) किसी अस्पताल को अंग प्रत्यारोपण के लिए रजिस्ट्रीकरण प्रमाण पत्र प्रदान नहीं किया जाएगा सिवाय तब जब वह निम्नलिखित शर्तों और मानकों को पूरा करता हो, अर्थात्:-

अ. साधारण जनशक्ति की अपेक्षा और विशेषीकृत सेवाएं और प्रसुविधाएं:

(क) चिकित्सा और शल्य चिकित्सा (ज्येष्ठ और कनिष्ठ) कर्मचारिवृंद की चौबीस घंटे उपलब्धता ;

(ख) परिचर्या कर्मचारिवृंद (साधारण और विशेष रूप से प्रशिक्षित) की चौबीस घंटे उपलब्धता ;

(ग) पर्याप्त उपस्कर, कर्मचारिवृंद और सहायक प्रणाली जिसके अंतर्गत संवेदनाहरण और गहन देखरेख भी है के साथ गहन देखरेख एककों की चौबीस घंटे उपलब्धता ;

(घ) बहु विषयक परीक्षण सुविधाओं जिसके अंतर्गत प्रशिक्षित कर्मचारिवृंद के साथ सूक्ष्म जीव विज्ञान, जीव रसायन विज्ञान, विकृति विज्ञान, रुधिर विज्ञान और विकिरण विभाग भी हैं परंतु इन तक ही सीमित नहीं के साथ रुधिर बैंक (स्वयं का या पहुंचनीय), की चौबीस घंटे उपलब्धता ;

(ङ.) योजना और अपातकालीन प्रक्रियाओं के लिए पर्याप्त कर्मचारिवृंद के साथ आपरेशन थियेटर प्रसुविधाएं (ओ.टी. प्रसुविधाएं), सहायता प्रणाली और उपस्कर की चौबीस घंटे उपलब्धता ;

(च) पावर बैंक अप जिसके अंतर्गत बहु लाइन वाले टेलीफोन, लोक टेलीफोन प्रणालियां, कंप्यूटर और पेपर फोटो इमेजिंग मशीन भी है किंतु केवल उन तक ही सीमित नहीं के साथ संचार प्रणाली की चौबीस घंटे उपलब्धता ;

(छ) सुसंगत और सहबद्ध विशेषज्ञ(सुसंगत प्रत्यारोपण के लिए अपेक्षित विशेषज्ञों से भिन्न) किंतु उन तक ही सीमित नहीं और अपेक्षा पर निर्भर करते हुए, आंतरिक आयुर्विज्ञान, डायबेटोलॉजी, जठर तंत्र विज्ञान, वृक्क रचना विज्ञान, तंत्रिका विज्ञान, बालरोग विज्ञान, स्त्री रोग विज्ञान, प्रतिरक्षा विज्ञान और हृदय रोग विज्ञान आदि में विशेषज्ञ प्रत्यारोपण केन्द्र में उपलब्ध होंगे ;

(ज) प्रत्यारोपण अस्पताल में संबंधित अंग या ऊतक प्रत्यारोपण के लिए एक चिकित्सा विशेषज्ञ उपलब्ध होगा ; और

(झ) मानव ल्यूकोसाइट एंटीजन(एचएलए) सुमेलन प्रसुविधाएं(स्वयं की या आउटसोर्स की गई) उपलब्ध होंगी।

आ. उपस्कर:

प्रत्यारोपित किए जा रहे अंगों या ऊतकों की संभावित चालू और भावी वैज्ञानिक अपेक्षाओं के अनुसार उपस्कर और प्रत्यारोपण केन्द्र अनुपंगियों, हिस्से-पुर्जों की उपलब्धता और सभी सुसंगत उपस्करों से संबंधित बेक-अप, अनुरक्षण, सेवा सहायता प्रणालियों का भी सुनिश्चय करेगा।

इ. विशेषज्ञ और उनकी अर्हताएं:

(क) गुर्दा प्रत्यारोपण:

शल्य चिकित्सा (साधारण) निष्णात या समतुल्य अर्हता के साथ शल्य चिकित्सा निष्णात के पश्चात् भारत में या विदेश में किसी मान्यता प्राप्त प्रत्यारोपण केन्द्र में तीन वर्ष का प्रशिक्षण और दल के एक सक्रिय सदस्य के रूप में पर्याप्त संख्या में गुर्दा प्रत्यारोपण में भाग लिया हो ।

(ख) फेफड़े और पेट के अन्य अंगों का प्रत्यारोपण:

शल्य चिकित्सा (साधारण) निष्णात या समतुल्य अर्हता के साथ शल्य चिकित्सा निष्णात के पश्चात् विशेषज्ञता में तीन वर्ष का अनुभव और दल के एक सक्रिय सदस्य के रूप में पर्याप्त संख्या में गुर्दा प्रत्यारोपण में भाग लिया हो ।

(ग) हृदय, फुफुस-संबंधी, हृदय - फुफुस-संबंधी प्रत्यारोपण :

वक्षीय शल्य विज्ञान और वाहिका शल्य चिकित्सा मेजिस्टर चिरुरगुई, या भारत या विदेश में समतुल्य अर्हता के साथ दल के एक सक्रिय सदस्य के रूप में तीन वर्ष का अनुभव और प्रतिवर्ष पर्याप्त संख्या में हृदय शल्य चिकित्सा के साथ साथ वाहिका बाईपास शल्य चिकित्सा और हृदय वाल्व शल्य चिकित्सा के साथ भली प्रकार परचित ।

(घ) नैदानिक प्रतिष्ठापन(रजिस्ट्रीकरण और विनियमन) अधिनियम, 2010 (2010 का 23) के अधीन रजिस्ट्रीकृत अस्पताल उस अधिनियम के अधीन यथा विहित न्यूनतम मानकों का जनशक्ति, उपस्कर आदि के संबंध में पालन करेंगे;

(ड.) रजिस्ट्रीकृत किया गया अस्पताल प्रतिकूल घटनाओं की रिपोर्ट सहित दस्तावेज और अभिलेखों का अनुरक्षण करेगा।

(2) किसी अस्पताल को अधिनियम के अधीन उतकों के प्रत्यारोपण के लिए रजिस्ट्रीकरण प्रमाण पत्र प्रदान नहीं किया जाएगा सिवाय तब जब वह निम्नलिखित शर्तों और मानकों को पूरा करता हो, अर्थात् :-

(क) कोर्निया प्रत्यारोपण :

नेत्र विज्ञान में एम.डी. या एम.एस. या डिप्लोमा (डी.ओ.) या एम.डी. या एम.एस. या डी.ओ. अर्हता पश्च तीन मास का किसी मान्यता प्राप्त अस्पताल या संस्था में कोर्निया प्रत्यारोपण आपरेशनों को प्रशिक्षण;

(ख) हृदय वाल्व, त्वचा, हड्डी आदि अन्य ऊतक:

स्नातकोत्तर डिग्री(एम.डी. या एम.एस.) या संबंधित विशेषज्ञता में समतुल्य अर्हता के साथ किसी मान्यता प्राप्त अस्पताल में संबंधित ऊतक प्रत्यारोपण आपरेशन और हृदय वाल्व प्रत्यारोपण करने का पश्च एम.डी. या एम.एस. तीन मास का प्रशिक्षण और विशेषज्ञता की अर्हता और अनुभव, हृदय संवाहिका तथा वक्ष शल्य चिकित्सा(सी.टी.वी.एस.) में एम.सीएच. डिग्री या पश्च एम.सीएच. किसी मान्यता प्राप्त अस्पताल में हृदय वाल्व प्रत्यारोपण करने का तीन मास का प्रशिक्षण;

(ग) नैदानिक प्रतिष्ठापन(रजिस्ट्रीकरण और विनियमन) अधिनियम, 2010 (2010 का 23) के अधीन रजिस्ट्रीकृत अस्पताल उस अधिनियम के अधीन यथा विहित न्यूनतम मानकों का जनशक्ति, उपस्कर आदि के संबंध में पालन करेगा;

(घ) रजिस्ट्रीकृत किया गया अस्पताल प्रतिकूल घटनाओं की रिपोर्ट सहित दस्तावेज और अभिलेखों का अनुरक्षण करेगा।

27. अंग ल केन्द्रों के लिए रजिस्ट्रीकरण प्रमाण पत्र प्रदान करने की शर्तें और मानक:

(1) ल केन्द्र को केवल मृतक दानकर्ताओं से अंग निकालने के प्रयोजन के लिए ही रजिस्ट्रीकृत किया जाएगा और अंग ल केन्द्र अस्पताल होंगे जिनमें मस्तिष्क स्तंभ मृत व्यक्तियों का निदान करने और अनुरक्षण करने तथा उनके अस्थायी भंडारण के लिए प्रसुविधाओं सहित अंगों और ऊतकों को निकालने और उनके परिवहन के लिए यथा अपेक्षित जनशक्ति, अवसंरचना और उपस्कर होंगे ।

(2) प्रत्यारोपण केन्द्रों के रूप में रजिस्ट्रीकृत सभी अस्पताल स्वतः ल केन्द्रों के रूप में अर्हित होंगे ।

(3) ल केन्द्र का नजदीकी सरकारी अस्पतालों के साथ जो शव परीक्षण के लिए अभिहित हैं चिकित्सा-विधिक मामलों में ल के लिए संपर्क होना चाहिए ।

(4) मृतक व्यक्ति से शल्य क्रिया द्वारा ऊतकों को रखने और ऊतकों की शल्य क्रिया द्वारा अपशिष्टकरण ताकि जो अपेक्षित न हों उन्हें खारिज किया जा सके करने के लिए अस्पताल का रजिस्ट्रीकरण ।

28. ऊतक बैंकों को रजिस्ट्रीकरण प्रमाण पत्र प्रदान करने के लिए शर्तें और मानक:

(क) प्रसुविधा और परिसर:

(1) प्रसुविधाएं उन मानकों और दिशा-निर्देशों के अनुरूप होनी चाहिए जो इस प्रयोजन के लिए अधिकथित किए गए हैं तथा राज्य और संघ राज्य क्षेत्र की पृथक रजिस्ट्रकरण फीस और प्रक्रिया हो सकेगी ताकि वह अपनी ऊतक बैंक की गतिविधियों का ध्यान रख सके ।

(2) संबंधित राज्य या संघ राज्य क्षेत्र प्राधिकारी ऊतक विनिर्दिष्ट मानकों और संबंधित विषयों पर सलाह देने के लिए एक विशेषज्ञ समिति का गठन कर सकेंगे ।

(3) ऊतक बैंक के पास उसके परिसर और प्रसुविधाओं के अनुरक्षण के लिए लिखित दिशा-निर्देश और मानक प्रचालन प्रक्रिया अनिवार्य रूप से होनी चाहिए जिसके अंतर्गत निम्नलिखित शामिल हैं-

(क) नियंत्रित पहुंच ;

(ख) सफाई और अनुरक्षण प्रणालियां;

(ग) अपशिष्ट निपटान;

(घ) कर्मचारिवृंद का स्वास्थ्य और सुरक्षा;

(ड.) जोखिम निर्धारण प्रोटोकॉल; और

(च) प्रोटोकॉल का अनुसरण ।

(4) क्रय किए जा रहे, प्रसंस्कृत, भंडार और वितरित किए जा रहे ऊतकों से विनिर्दिष्ट वैज्ञानिक अपेक्षाओं के अनुसार उपस्कर और ऊतक बैंक सभी उपस्करों की अनुषंगियों, अतिरिक्त हिस्से-पुर्जों और बेक-अप, अनुरक्षण तथा सेवा सहायता का सुनिश्चय करना चाहिए ।

(5) जहां अपेक्षित हो कण गणना और जीवाणु कालोनी गणना अनुपालन का सुरक्षा के लिए सुनिश्चय किया जाएगा ।

(6) रसायनों या पर्यावरणीय संदूषण और संक्रमण के किसी ज्ञात स्रोत से संपर्क से बचने के लिए भंडारण क्षेत्र को पदाभिहित किया जाएगा।

(7) भंडारण प्रसुविधा पृथक होगी और सुभिन्न ऊतकों को करंटाइन में रखा जाएगा, छोड़ा जाएगा और अस्वीकार किया जाएगा ।

(ख) दाता की छानबीन:

(8) दाता की पूर्ण छानबीन अनिवार्य रूप से की जाएगी जिसके अंतर्गत चिकित्सा या सामाजिक पृष्ठ भूमि और चिकित्सा अवस्था या रोग प्रक्रियाओं के लिए सीरोलॉजिकल मूल्यांकन भी है ताकि प्रत्यारोपण के लिए उपयुक्त न पाए गए ऊतकों के दान को उपदर्शित किया जा सके और नेत्रों के कोर्निया की रिपोर्ट को दो नेत्र विज्ञानियों की समिति द्वारा उनके वैकल्पिक उपयोग को प्रमाणित किया जाएगा ।

(ख) प्रयोगशाला जांच:

(9) रक्त और ऊतक नमूनों की सुसंगत प्रयोगशाला जांच के लिए प्रसुविधा उपलब्ध होगी और रक्त और ऊतक के नमूनों की जांच दाता के छानबीन पर आरंभ होगी और ल और प्रसंस्करण के दौरान जारी रहेगी ।

(घ) खरीद और अन्य प्रक्रियाएं:

(10) ऊतक की खरीद रजिस्ट्रीकृत सुरक्षा देख रेख पेशेवरों या तकनीशियनों जो आवश्यक अनुभव या विशेष प्रशिक्षण प्राप्त हैं द्वारा की जाएगी ;

(11) खरीद के लिए सहमति अभिप्राप्त की जाएगी ।

(12) खरीद अभिलेखों का अनुरक्षण किया जाएगा ।

(13) निम्नलिखित के लिए मानक प्रचालन प्रक्रिया का अनुसरण किया जाएगा, अर्थात् :-

(क) ल और प्रत्यारोपण के लिए खरीद;

(ख) प्रसंस्करण और जीवाणु विहित करना;

(ग) पैकेजिंग, लेबलीकरण और भंडारण ;

(घ) वितरण या आबंटन;

(ड.) प्रत्यारोपण; और

(च) गंभीर प्रतिकूल प्रतिक्रियाओं की रिपोर्ट ।

ड. दस्तावेज और अभिलेख:

(14) दाता से ऊतक और ऊतक से दाता तक ऊतक का पता लगाने में समर्थ होने के लिए प्राप्त और वितरित ऊतकों और अभिलेख उन तारीखों को भी प्रदर्शित करेंगे तथा ऊतकों को हटाने या प्रसंस्करण या वितरण में विनिर्दिष्ट कदम उठाने वाले कर्मचारिवृंद की पहचान के लॉग का अनुरक्षण किया जाएगा ।

च. डाटा का संरक्षण और गोपनीयता :

(15) प्रत्येक दाता के लिए एक विशिष्ट दाता पहचान संख्या का उपयोग किया जाएगा और दाता के अभिलेखों तक पहुंच निर्विधित होगी ।

छ. क्वालिटी प्रबंधन :

(16) क्वालिटी प्रबंधन प्रणाली क्वालिटी नियंत्रण प्रक्रियाओं को परिभाषित करेगी जिसके अंतर्गत निम्नलिखित शामिल हैं, अर्थात् :-

(क) पर्यावरण की मानीटरी;

(ख) उपस्कर अनुरक्षण और मानीटरी;

(ग) प्रक्रियाधीन नियंत्रणों की मानीटरी;

(घ) आंतरिक ऑडिट जिसके अंतर्गत अभिकर्मक और आपूर्ति मानीटरी शामिल हैं;

(ड.) संदर्भ मानकों, स्थानीय विनियमों, क्वालिटी मेन्यूअलों या दस्तावेजी मानक प्रचालन प्रक्रियाओं का अनुपालन ; और

(च) कार्य वातावरण की मानीटरी ।

ज. प्राप्तिकर्ता की सूचना:

(17). सभी प्राप्तिकर्ताओं का ध्यान रखा जाएगा और प्रतिकूल घटनाओं की दशा में तुरंत और समुचित सुधारकारी तथा निवारक कार्रवाई की जाएगी ।

29. प्रत्यारोपण समन्वयक की अर्हता, भूमिका आदि- (1) प्रत्यारोपण समन्वयक रजिस्ट्रीकृत अस्पताल का एक कर्मचारी होगा जिसके पास निम्नलिखित अर्हताएं होंगी जैसे कि:

(क) आयुर्विज्ञान की किसी मान्यता प्राप्त प्रणाली का स्नातक ; या

(ख) परिचारक ; या

(ग) किसी भी विषय में स्नातक डिग्री और सामाजिक कार्य या मनोचिकित्सा या समाजशास्त्र या सामाजिक विज्ञान या लोक स्वास्थ्य में निष्णात डिग्री को अधिमानतः

(2) संबंधित संगठन या संस्था प्रारंभिक प्रशिक्षण के उपरांत आवधिक अंतरालों पर पुनः प्रशिक्षण सुनिश्चित करेंगे और प्रत्यारोपण समन्वयक मृतक व्यक्ति के कुटुंब के सदस्य या नजदीकी नातेदारों को मानव अंग या ऊतक जिसके अंतर्गत नेत्र या कोर्निया भी हैं का दान करने के लिए परामर्श देगा और दान और प्रत्यारोपण की प्रक्रिया का समन्वय करेगा ।

(3) नेत्र बैंक के लिए किसी अस्पताल में रजिस्ट्रीकृत प्रत्यारोपण समन्वयक या परामर्शी के पास उपनियम (1) में विनिर्दिष्ट अर्हता भी होगी ।

30. समुचित प्राधिकारी को सहायता और परामर्श देने के लिए केन्द्रीय या राज्य सरकार की सलाहकार समिति-(1) यथस्थिति केन्द्रीय सरकार और राज्य सरकार अधिसूचना द्वारा राज्य सरकार के सचिव की पंक्ति से अन्यून प्रशासनिक विशेषज्ञ की अध्यक्षता में दो वर्ष की अवधि के लिए समुचित प्राधिकारी को सहायता और परामर्श देने के लिए एक सलाहकार समिति का गठन करेगी और अधिनियम की धारा 13क की उपधारा (2) के खंड (ख) में निर्दिष्ट दो आयुर्विज्ञान विशेषज्ञों के पास आयुर्विज्ञान स्नातकोत्तर डिग्री और अंग या ऊतक प्रत्यारोपण के क्षेत्र में पांच वर्ष का अनुभव होगा ।

(2) सलाहकार समिति की नियुक्ति के निबंधन और शर्तें नीचे दिए अनुसार होंगे:

(क) समिति के अध्यक्ष और सदस्य की नियुक्ति दो वर्ष की अवधि के लिए की जाएगी ;

(ख) समिति के अध्यक्ष और सदस्य समिति की बैठकों में भाग लेने के लिए भारत सरकार के संयुक्त सचिव के स्तर के अधिकारी के समान हवाई यात्रा भाडे के और अन्य भत्तों के हकदार होंगे ;

(ग) केन्द्रीय सरकार या राज्य सरकार या संघ राज्यक्षेत्र प्रशासन को भ्रष्टाचार के आरोपों या किन्हीं अन्य आरोपों के मामलों में उसे सुने जाने का युक्तियुक्त अवसर प्रदान करने के पश्चात् बदलने या पद से हटाने की पूरी शक्ति होगी ।

(घ) अध्यक्ष और सदस्य वैयक्तिक कारणों से भी पद से त्यागपत्र दे सकेंगे ।

(ड.) नियुक्ति के समय अध्यक्ष या किसी सदस्य के विरुद्ध भ्रष्टाचार या दांडिक मामला नहीं होगा ;

(च) अध्यक्ष या कोई सदस्य पद पर नहीं रहेंगे यदि उनके विरुद्ध भ्रष्टाचार या दांडिक मामले में उन्हें सुने जाने का युक्तियुक्त अवसर प्रदान करने के पश्चात् आरोप विरचित किए जाते हैं ।

31. राष्ट्रीय या प्रादेशिक या राज्य मानव अंग या ऊतक हटाना तथा भंडारण नेटवर्कों की स्थापना की रीति और उनके कृत्य - (1) केन्द्र में अधिसूचना द्वारा जैसाकि केन्द्रीय सरकार विनिर्दिष्ट करे एक सर्वोच्च राष्ट्रीय नेटवर्किंग संगठन होगा ।

(2) जहां बड़ी संख्या में अंगों या ऊतकों का प्रत्यारोपण किया जाता है वहां प्रादेशिक और राष्ट्रीय स्तर के नेटवर्किंग संगठन होंगे जैसाकि केन्द्रीय सरकार अधिसूचना द्वारा विनिर्दिष्ट करे ।

(3) राज्य एककों को अस्पतालों अंग या ऊतक मैच करने वाली प्रयोगशालाओं और ऊतक बैंकों के साथ उनके क्षेत्र के भीतर जोड़ा जाएगा और प्रादेशिक और राष्ट्रीय नेटवर्किंग संगठनों से भी जोड़ा जाएगा ।

(4) अंग आवंटन और हिस्सेदारी के मुख्य तौर पर सिद्धांत नीचे दिए अनुसार होंगे,-

(क) प्रत्यारोपण केन्द्र की वेबसाइट को राज्य या प्रादेशिक-सह-राज्य या राष्ट्रीय नेटवर्कों से अंग उपाप्त करने, बांटने और प्रत्यारोपण के लिए एक ऑन-लाइन प्रणाली के माध्यम से जोड़ा जाएगा ।

(ख) रोगी या प्राप्तिकर्ता किसी प्रत्यारोपण केन्द्र के माध्यम से रजिस्ट्रीकृत होंगे किंतु केवल राज्य या प्रादेशिक एक केन्द्र में (यदि राज्य में कोई केन्द्र नहीं है) और उसके व्यौरों को नेटवर्किंग संगठनों को आन-लाइन उपलब्ध कराया जाएगा जो रजिस्ट्रीकरण संख्या आवंटित करेंगे जो रोगी के अस्पताल बदलने पर भी वही रहेगी;

(ग) बांटे जाने वाले अंग के आबंटन का विनिश्चय राज्य नेटवर्किंग संगठन और दिल्ली के मामले में राष्ट्रीय नेटवर्किंग संगठन द्वारा किया जाएगा ;

(घ) सभी प्राप्तिकर्ताओं को मृतक दानकर्ताओं से अंगों के लिए अनुरोध के लिए सूचीबद्ध किया जाएगा यद्यपि निम्नलिखित क्रम में पूर्विकता दी जाएगी, अर्थात् :-

(i) वे जिनके पास नजदीकी नातेदारों में कोई समुचित जीवित दानकर्ता नहीं है ;

(ii) वह जिनके पास नजदीकी नातेदारों में कोई जीवित दानकर्ता है किंतु दानकर्ता ने दान करने से लिखित में इनकार कर दिया है ; और

(iii) वे जिनके पास समुचित जीवित दानकर्ता उपलब्ध है किंतु उसने लिखित में इनकार भी नहीं किया है ;

(ङ) अंगों के आबंटन का क्रम निम्नलिखित क्रम में होगा:- राज्य सूची- प्रादेशिक सूची-राष्ट्रीय सूची-भारतीय मूल का व्यक्ति-विदेशी ;

(च) नियम 32 के अधीन यथा वर्णित राष्ट्रीय रजिस्ट्री की आन-लाइन नेटवर्किंग प्रणाली और ढांचा तथा प्ररूपों का विकास सर्वोच्च नेटवर्किंग संगठनों द्वारा किया जाएगा जिसका अनुसरण राज्य सरकारों या संघ राज्यक्षेत्र प्रशासनों द्वारा किया जाएगा और आबंटन मानदंड राज्य विनिर्दिष्ट हो सकेंगे जिनको अंतिम रूप और अवधारण राज्य सरकार द्वारा राज्य स्तर पर नेटवर्किंग संगठनों, जहां ऐसे संगठन विद्यमान हैं के परामर्श से किया जाएगा:

परंतु अंग बांटना और राज्यों की नेटवर्किंग नीति या अस्पतालों की प्रास्थिति सशस्त्र बल चिकित्सा सेवा (एएफएमएस) पर बाध्यकर नहीं होगी और सशस्त्र बल अंग या ऊतक आबंटन और बांटने के लिए स्वयं की नीति बनाने के लिए स्वतंत्र होंगे तथा महानिदेशक, सशस्त्र बल चिकित्सा सेवा का सशस्त्र बल चिकित्सा सेवा अस्पतालों के बीच स्वयं की नेटवर्किंग होगी जिसे उनके राज्य क्षेत्राधिकार के भीतर अस्पतालों से अंग स्वीकार करने की अनुज्ञा होगी ।

(5) नेटवर्किंग संगठन अंगों और ऊतकों के, भंडारण, परिवहन, मैचिंग, आबंटन और प्रत्यारोपण का समन्वय करेंगे और ऐसे कार्यकलापों के लिए और ऊतकों के लिए जहां तक संभव हो मानकों और मानक प्रचालन प्रक्रियाओं का विकास करेंगे ।

(6) नेटवर्किंग संगठन नए प्रत्यारोपण और ल केन्द्रों तथा ऊतक बैंकों की स्थापना के लिए और विद्यमान को सुदृढ़ करने के लिए संबंधित राज्य सरकारों के साथ समन्वय करेंगे ।

(7) राज्य या प्रादेशिक संगठनों द्वारा गठित किया जाने वाला आवश्यकता के अनुसार राज्य या जिला या संस्था में अभिहित अंग या ऊतक ल दल होंगे ।

(8) ऊतकों के ल के लिए राज्य सरकार या संघ राज्य प्रशासन द्वारा जहां अपेक्षित हो ल दल बनाए जाएंगे ।

(9) नेटवर्किंग को ई-समर्थ बनाया जाएगा और यह समर्पित वेबसाइट के माध्यम से पहुंचनीय होगी ।

(10) संदर्भ या आबंटन मानदंड का नेटवर्किंग संगठनों द्वारा विकास किया जाएगा और उसे यथास्थिति केन्द्रीय या राज्य सरकार के साथ परामर्श से नियमित रूप से अद्यतन किया जाएगा ।

(11) नेटवर्किंग संगठन मृतकों के अंग और ऊतक के दान के संवर्द्धन के लिए सूचना शिक्षा और संपर्क (आईसी) ऐसी गतिविधियों को हाथ में लेंगे ।

(12) नेटवर्किंग संगठन अंग या ऊतक दान और प्रत्यारोपण रजिस्ट्री का संबंधित स्तर पर अनुरक्षण करेंगे और अद्यतन करेंगे ।

32. मानव अंग और ऊतक के दानकर्ताओं और प्राप्तिकर्ताओं के संबंध में राष्ट्रीय रजिस्ट्री में सम्मिलित की जाने वाली सूचना-

अंग प्रत्यारोपण रजिस्ट्री:

(1) अंग प्रत्यारोपण रजिस्ट्री में रोगी, दाता अस्पतालों प्राप्तिकर्ता और दाता के फॉलोअप ब्यौरे, प्रत्यारोपण प्रतिक्षा सूची आदि के विषय में भौगोलिक डाटा शामिल होंगे और डाटा को सभी ल और प्रत्यारोपण केन्द्रों से संगृहीत किया जाएगा ।

(2) डाटा संग्रहण आवृत्ति आदि सलाहकार समिति द्वारा विनिश्चित मानदंडों के अनुसार होगी जो कि अधिमानतः वेब आधारित इंटरफेस के माध्यम से या पेपर प्रस्तुत करके किया जाएगा और सूचना को विशिष्ट अंग वार रखा जाएगा और एक समेकित प्ररूप में रखा जाएगा ।

(3) अस्पताल या संस्था अपनी वेबसाइट को कुल प्रत्यारोपणों की संख्या के संबंध में नियमित रूप से अद्यतन करेगी और वही डाटा इकट्ठा करने, विश्लेषण और उपयोग के लिए संबंधित राज्य सरकारों और केन्द्रीय सरकार के प्राधिकृत व्यक्तियों के उपयोग के लिए पहुंचनीय होगा ।

(4) वार्षिक रिपोर्टें प्रकाशित की जाएंगी और उन्हें योगदान करने वाले एककों तथा अन्य पणधारियों के साथ बांटा जाएगा तथा मुख्य घटनाओं (नए रोगियों, मृत्यु तथा प्रत्यारोपणों) को उनके किसी अस्पताल में घटित होने के तुरंत पश्चात अधिसूचित किया जाएगा तथा इसकी सूचना संबंधित नेटवर्क को कम से कम मासिक रूप में भेजी जाएगी ।

अंग दान रजिस्ट्री:

(5) अंगदान रजिस्ट्री में दानकर्ता (जीवित और मृतक दोनों), अस्पताल ऊंचाई और वजन, वृत्ति, मृतक दानकर्ता की दशा में मृत्यु का प्रारंभिक कारण, सहबद्ध चिकित्सीय बीमारी, सुसंगत प्रयोगशाला जांच, दानकर्ता अनुरक्षण ब्यौरे, चालन अनुज्ञप्ति या दान का प्रतिज्ञान करने का अन्य दस्तावेज, जिसके द्वारा दान का अनुरोध किया गया है, प्रत्यारोपण समन्वयक, किए गए अंग या ऊतक दान किए गए अंग या ऊतक का परिणाम, प्राप्तिकर्ता के ब्यौरे आदि शामिल होंगे ।

ऊतक रजिस्ट्री :

(6) ऊतक रजिस्ट्री में दानकर्ता के संबंध में भौगोलिक जानकारी, ऊतक ल या दान का स्थान अस्पताल ऊंचाई और वजन, वृत्ति, मृतक दानकर्ता की दशा में मृत्यु का प्रारंभिक कारण मस्तिष्क स्तंभ मृतक दानकर्ता की दशा में दानकर्ता अनुरक्षण के ब्योरे, सहबद्ध चिकित्सीय बीमारी, सुसंगत प्रयोगशाला जांच, दानकर्ता अनुरक्षण ब्योरे, चालन अनुज्ञप्ति या दान का प्रतिज्ञान करने का अन्य दस्तावेज, परामर्शियों की पहचान, ऊतक प्राप्तकर्ता के भौगोलिक डाटा, प्रत्यारोपण करने वाला अस्पताल, प्रत्यारोपण प्रतीक्षा सूची और गंभीर रोगियों की पूर्विकता, यदि यह विद्यमान हैं, तो प्रत्यारोपण के लिए उपदर्शन, प्रत्यारोपित ऊतकों आदि का परिणाम ।

(7) राष्ट्रीय रजिस्ट्री के संबंध में वार्षिक रिपोर्टें प्रकाशित की जाएंगी और उन्हें योगदान करने वाले एककों तथा अन्य पणधारियों के साथ बांटा जाएगा ।

मृत्यु के बाद अंग या ऊतक दान करने का प्रतिज्ञान:

(8) ऐसे रोगी जिन्होंने अपने जीवनकाल के दौरान अपने अंगों या ऊतकों को उनकी मृत्यु के पश्चात् दान करने का प्ररूप 7 में प्रतिज्ञान किया है, वह इसे पेपर या इलेक्ट्रानिक रीति में संबंधित नेटवर्किंग संगठन को या संस्था को भेजेंगे जहां प्रतिज्ञान किया गया है, वह इसे संबंधित नेटवर्किंग संगठन को अग्रेषित करेंगे और प्रतिज्ञान करने वाले के पास संसूचना द्वारा प्रतिज्ञान को वापस लेने का विकल्प होगा ।

(9) रजिस्ट्री को समर्पित वेबसाइट के माध्यम से आनलाइन एक्सेस किया जा सकेगा तथा यह वैश्विक रूप से अनुरक्षित रजिस्ट्रियों के अनुरूप होगी इसके अतिरिक्त इसमें राष्ट्रीय, प्रादेशिक और राज्य स्तरीय विशिष्टियां होंगी ।

(10) राष्ट्रीय या प्रादेशिक रजिस्ट्री को उसके समान राज्य स्तर की रजिस्ट्रियों के अनुसार बनाया जाएगा ।

(11) डाटा बेस में लोगों की पहचान को पब्लिक डोमेन में नहीं रखा जाएगा और सभी संग्रहित सूचना की सुरक्षा करने के लिए उपाय किए जाएंगे ।

(12) शामिल की जाने वाली सूचना को लागू वैश्विक पद्धतियों के अनुरूप अद्यतन किया जाएगा ।

33. अपील-(1) धारा 9 की उपधारा (6) के अधीन प्राधिकरण समिति के किसी आदेश से या अधिनियम की धारा 16 की उपधारा (2) के अधीन समुचित प्राधिकारी के किसी आदेश से व्यथित कोई व्यक्ति आदेश की प्राप्ति की तारीख से तीस के भीतर संघ राज्यक्षेत्रों के संबंध में केन्द्रीय सरकार को और राज्यों की दशा में संबंधित राज्य सरकार को अपील कर सकेगा।

(2) प्रत्येक अपील लिखित में होगी और उसके उस आदेश जिसके विरुद्ध अपील की जा रही है की प्रति संलग्न होगी ।

प्ररूप 1**दाता के निकट नातेदार के रूप में जीवित से अंग या ऊतक दान के लिए**

(उसके द्वारा पूरा किया जाए)

(नियम 3 और 5(3)(क) देखें)

मेरा पूरा नाम (संभावित दाता)

और मेरा फोटो यह है ।

दाता का फोटो
(चिपकाने के पश्चात् नोटेरी
पब्लिक द्वारा फोटो को
काटते हुए अनुप्रमाणित
होनी चाहिए)

यहां पर चिपकाएं ।

मेरे घर का स्थायी पता

.....दूरभाष सं०..... है ।

मेरे घर का वर्तमान पता

.....दूरभाष सं०..... है ।

जन्म की तारीख.....(दिन/मास/वर्ष)

मैं निम्नलिखित दस्तावेजों की प्रतियां संलग्न करता हूं : (अपना निकट नाता उपदर्शित करने के लिए निम्नलिखित संबंधित दस्तावेजों में से कम से कम दो की अनुप्रमाणित प्रतियां लगाएं) :

- राशन/उपभोक्ता कार्ड सं० और जारी करने की तारीख और स्थान.....

- और / या
- मतदाता पहचान पत्र संख्या, जारी करने की तारीख, विधान सभा क्षेत्र.....
और / या
 - पासपोर्ट संख्या और जारी करने का देश
और / या
 - चालन अनुज्ञप्ति संख्या, जारी करने की तारीख, अनुज्ञापन प्राधिकारी.....
और / या
 - स्थायी लेखा सं० (पैन).....
और / या
 - आधार सं०.....
और / या
 - निकट नाते को दर्शाते हुए पहचान और पते का अन्य सबूत
.....

मैं चिकित्सीय प्रयोजन के लिए अपना अंग.....(अंग/उत्तक का नाम) अपने नातेदार.....(पुत्र/पुत्री/पिता/माता/भाई/बहन/दादा/दादी/पोता/पोती विनिर्दिष्ट करें) के लिए जिसका नाम.....है जिसका जन्म(दिन/मास/वर्ष) को हुआ था तथा उसकी विशिष्टियां निम्न प्रकार हैं, निकाले जाने हेतु प्राधिकृत करता हूँ और सहमति देता हूँ :

प्राप्त करने वाले का फोटो
(चिपकाने के पश्चात् नोटेरी
पब्लिक द्वारा फोटो का काटते
हुए अनुप्रमाणित होनी चाहिए)

यहां पर चिपकाएं ।

प्राप्त करने वाले के निम्नलिखित दस्तावेजों की प्रतियां संलग्न हैं: (अपना निकट नाता उपदर्शित करने के लिए संबंधित दस्तावेजों में से कम से कम दो की अनुप्रमाणित प्रतियां लगाएं) :

- राशन/उपभोक्ता कार्ड सं० और जारी करने की तारीख और स्थान.....
और / या
- मतदाता पहचान पत्र संख्या, जारी करने की तारीख, विधान सभा क्षेत्र.....
और / या
- पासपोर्ट संख्या और जारी करने का देश
और / या
- चालन अनुज्ञप्ति संख्या, जारी करने की तारीख, अनुज्ञापन प्राधिकारी.....
और / या
- स्थायी लेखा सं० (पैन).....
और / या
- आधार सं० (भारतीय विशिष्ट पहचान प्राधिकरण द्वारा जारी)
.....
और / या
- निकट नाते को दर्शाते हुए पहचान और पते का अन्य सबूत
.....

मैं सत्यानिष्ठा से प्रतिज्ञा करता हूँ/करती हूँ और घोषणा करता/करती हूँ कि :

मानव अंग प्रतिरोपण अधिनियम, 1994 की धारा 2, धारा 9 और धारा 19 मुझको बता दी गई हैं और मैं पुष्टि करता/करती हूँ कि :

1. मैं धाराओं में निर्दिष्ट दंडिक अपराधों की प्रकृति को समझता हूँ/समझती हूँ ।

2. मुझको अधिनियम की धाराओं में यथानिर्दिष्ट धन या धन का मूल्य का संदाय नहीं किया गया है या मुझको या किसी अन्य व्यक्ति को नहीं किया जाएगा ।
3. बिना किसी असम्यक दबाव उत्प्रेरण या प्रभाव या प्रलोभन के अपनी स्वतंत्र इच्छा से अपने.....(अंग/ऊतक का नाम) को निकाले जाने के लिए सहमति और प्राधिकार दे रहा हूँ ।
4. मुझको मेरे.....(अंग/ऊतक का नाम) के निकाले जाने में निहित चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए निहित खतरों को पूर्णतः स्पष्ट कर दिया गया है । यह कि स्पष्टीकरण.....(रजिस्ट्रीकृत चिकित्सीय व्यवसायी का नाम) द्वारा दिया गया है ।
5. मैं चिकित्सा व्यवसायी द्वारा यथास्पष्ट उस चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए होने वाले खतरों को समझता/समझती हूँ ।
6. मैं समझता हूँ कि मैं शल्य क्रिया होने से पूर्व किसी समय भी अंग को निकाले जाने की अपनी सहमति को वापस ले सकता / सकती हूँ ।
7. मैं कथन करता हूँ/करती हूँ कि प्ररूप में मेरे द्वारा भरी गई विशिष्टियां मेरे ज्ञान में सत्य और सही हैं और कुछ भी मेरे द्वारा छिपाया नहीं गया है ।

.....
तारीख

संभावित दाता के हस्ताक्षर
(पूरा नाम)

टिप्पण : उस पब्लिक नोटेरी के जो उस समय अनुप्रमाणित कर रहा है, समक्ष शपथ लेगा और सुनिश्चित करेगा कि नोटेरी रजिस्टर पर शपथपत्र/शपथपत्रों पर हस्ताक्षर कर शपथ ले रहा व्यक्ति वही है ।

प्ररूप 2

जीवित पति-पत्नी दाता द्वारा अंग या ऊतक दान के लिए

(पति पत्नी दाता द्वारा पूरा किया जाए)

(नियम 3, 5(3)(क) और 5(3)(ख) देखें)

मेरा पूरा नाम (संभावित दाता)

.....
और मेरा फोटो यह है ।

दाता का फोटो
(चिपकाने के पश्चात् नोटेरी पब्लिक
द्वारा फोटो को काटते हुए अनुप्रमाणित
होनी चाहिए)

यहां पर चिपकाएं ।

मेरे घर का स्थायी पता

.....
.....दूरभाष सं०.....है ।

पत्र व्यवहार के लिए मेरे घर का वर्तमान पता

.....
.....दूरभाष सं०.....है ।

जन्म की तारीख.....(दिन/मास/वर्ष)

मैं चिकित्सीय प्रयोजन के लिए अपना अंग.....(अंग का नाम) अपने
पति/पत्नी.....के लिए जिसका नाम.....है जिसका जन्म

.....(दिन/मास/वर्ष) को हुआ था तथा उसकी विशिष्टियां निम्न प्रकार हैं, निकाले जाने हेतु प्राधिकृत करता हूं और सहमति देता हूं :

प्राप्त करने वाले का फोटो
(चिपकाने के पश्चात् नोटेरी
पब्लिक द्वारा फोटो का काटते
हुए अनुप्रमाणित होनी चाहिए)

यहां पर चिपकाएं ।

मैं निम्नलिखित दस्तावेजों की प्रतियां संलग्न करता हूं : (अपना निकट नाता उपदर्शित करने के लिए निम्नलिखित संबंधित दस्तावेजों में से कम से कम दो की अनुप्रमाणित प्रतियां लगाएं) :

- राशन/उपभोक्ता कार्ड सं० और जारी करने की तारीख और स्थान.....

और / या

- मतदाता पहचान पत्र संख्या, जारी करने की तारीख, विधान सभा क्षेत्र.....

और / या

- पासपोर्ट संख्या और जारी करने का देश

और / या

- चालन अनुज्ञप्ति संख्या, जारी करने की तारीख, अनुज्ञापन प्राधिकारी.....

और / या

- स्थायी लेखा सं० (पैन).....

और / या

- आधार सं० (भारतीय विशिष्ट पहचान प्राधिकरण द्वारा जारी)

और / या

- पति पत्नी के संबंध को स्थापित करते हुए पहचान और पते का अन्य सबूत

मैं प्राप्तिकर्ता से विवाहित होने के साक्ष्य के रूप में निम्नलिखित प्रस्तुत करता हूं-

- (क) विवाह प्रमाणपत्र की सत्यापित प्रति

या

- (ख) प्रथम श्रेणी मजिस्ट्रेट / नोटेरी पब्लिक के समक्ष शपथ किया हुआ विवाह की प्रास्थिति की पुष्टि करने वाला 'निकट नातेदार' का एक शपथ पत्र

- (ग) कुटुम्ब फोटोग्राफ

- (घ) विवाह की वास्तविकता और प्रास्थिति को प्रमाणित करने वाला ग्राम पंचायत सदस्य/तहसीलदार/खंड विकास अधिकारी/विधान सभा सदस्य/संसद् सदस्य का पत्र ।

या

- (ङ) अन्य विश्वसनीय साक्ष्य

मैं सत्यानिष्ठा से प्रतिज्ञा करता /करती हूं और घोषणा करता/करती हूं कि मानव अंग प्रतिरोपण अधिनियम, 1994 (1994 का 42) की धारा 2, धारा 9 और धारा 19 मुझको बता दी गई हैं और मैं पुष्टि करता हूं कि :

1. मैं धाराओं में निर्दिष्ट दांडिक अपराधों की प्रकृति को समझता हूं/समझती हूं ।

2. मुझको अधिनियम की धाराओं में यथानिर्दिष्ट धन या धन का मूल्य का संदाय नहीं किया गया है या मुझको या किसी अन्य व्यक्ति को नहीं किया जाएगा ।
3. बिना किसी असम्यक दबाव उत्प्रेरण या प्रभाव या प्रलोभन के अपनी स्वतंत्र इच्छा से अपने.....(अंग) को निकाले जाने के लिए सहमति और प्राधिकार दे रहा हूँ ।
4. मुझको मेरे.....(अंग) के निकाले जाने में निहित चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए निहित खतरों को पूर्णतः स्पष्ट कर दिया गया है । यह कि स्पष्टीकरण.....(रजिस्ट्रीकृत चिकित्सीय व्यवसायी का नाम) द्वारा दिया गया है ।
5. मैं चिकित्सा व्यवसायी द्वारा यथास्पष्ट उस चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए होने वाले खतरों को समझता हूँ ।
6. मैं समझता हूँ कि मैं शल्य क्रिया होने से पूर्व किसी समय भी अंग को निकाले जाने की अपनी सहमति को वापस ले सकता हूँ/ले सकती हूँ ।
7. मैं कथन करता हूँ/करती हूँ कि प्ररूप में मेरे द्वारा भरी गई विशिष्टियां मेरे ज्ञान में सत्य और सही हैं और कुछ भी मेरे द्वारा छिपाया नहीं गया है ।

.....
संभावित दाता के हस्ताक्षर (पूरा नाम)

.....
तारीख

टिप्पण : पब्लिक नोटेरी जो उस समय अनुप्रमाणित कर रहा है, के समक्ष शपथ लेगा और सुनिश्चित करेगा कि नोटेरी रजिस्टर पर शपथपत्र/शपथपत्रों पर हस्ताक्षर कर शपथ ले रहा व्यक्ति वही है ।

प्ररूप 3

निकट जीवित नातेदार से अन्य द्वारा अंग या ऊक्तक दान के लिए
(उसके द्वारा पूरा किया जाए)
(नियम 3, 5(3)(क) और 5(3)(ड) देखें)

मेरा पूरा नाम

.....
और मेरा फोटो यह है ।

दाता का फोटो
(चिपकाने के पश्चात् नोटेरी पब्लिक
द्वारा फोटो को काटते हुए अनुप्रमाणित
होनी चाहिए)

यहां पर चिपकाएं ।

मेरे घर का स्थायी पता

.....
.....दूरभाष सं०.....है ।

पत्र व्यवहार के लिए मेरे घर का वर्तमान पता

.....
.....दूरभाष सं०.....है ।

जन्म की तारीख.....(दिन/मास/वर्ष)

मैं निम्नलिखित दस्तावेजों की प्रतियां संलग्न करता हूँ : (अपना निकट नाता उपदर्शित करने के लिए निम्नलिखित संबंधित दस्तावेजों में से कम से कम दो की अनुप्रमाणित प्रतियां लगाएं) :

- राशन/उपभोक्ता कार्ड सं० और जारी करने की तारीख और स्थान.....
और / या
- मतदाता पहचान पत्र संख्या, जारी करने की तारीख, विधान सभा क्षेत्र.....
और / या
- पासपोर्ट संख्या और जारी करने का देश
और / या
- चालन अनुज्ञप्ति संख्या, जारी करने की तारीख, अनुज्ञापन प्राधिकारी.....
और / या
- स्थायी लेखा सं० (पैन).....
और / या
- आधार सं०
.....
और / या
- पहचान और पते का अन्य सबूत
.....
और / या

दाता के पिछले तीन वर्ष की आय और व्यवसाय का विवरण (दस्तावेजी साक्ष्य संलग्न)

.....

.....

मैं चिकित्सीय प्रयोजन के लिए अपना अंग.....(अंग/ऊतक का नाम)
व्यक्ति..... के लिए जिसका नाम..... है जिसका जन्म(दिन/मास/वर्ष) को हुआ
था तथा उसकी विशिष्टियां निम्न प्रकार हैं, निकाले जाने हेतु प्राधिकृत करता हूँ और सहमति देता हूँ :

प्राप्त करने वाले का फोटो
(चिपकाने के पश्चात् नोटेरी
पब्लिक द्वारा फोटो का काटते
हुए अनुप्रमाणित होनी चाहिए)

यहां पर चिपकाएं ।

(प्राप्त करने वाले की पहचान साबित करने के लिए कम से कम दो संबंधित दस्तावेजों की अनुप्रमाणित प्रतियां लगाएं) :

- राशन/उपभोक्ता कार्ड सं० और जारी करने की तारीख और स्थान.....
(फोटोकापी संलग्न)
और / या
- मतदाता पहचान पत्र संख्या, जारी करने की तारीख, विधान सभा क्षेत्र.....
(फोटोकापी संलग्न)
और / या
- पासपोर्ट संख्या और जारी करने का देश
(फोटोकापी संलग्न)
और / या
- चालन अनुज्ञप्ति संख्या, जारी करने की तारीख, अनुज्ञापन प्राधिकारी.....
(फोटोकापी संलग्न)

और / या

• स्थायी लेखा सं० (पैन).....

और / या

• आधार सं०

.....

और / या

• पहचान और पते का अन्य सबूत

.....

मैं सत्यानिष्ठा से प्रतिज्ञा करता /करती हूँ और घोषणा करता/करती हूँ कि मानव अंग प्रतिरोपण अधिनियम, 1994 (1994 का 42) की धारा 2, धारा 9 और धारा 19 मुझको बता दी गई हैं और मैं पुष्टि करता हूँ कि :

1. मैं धाराओं में निर्दिष्ट दांडिक अपराधों की प्रकृति को समझता हूँ/समझती हूँ ।
2. मुझको अधिनियम की धाराओं में यथानिर्दिष्ट धन या धन का मूल्य का संदाय नहीं किया गया है या मुझको या किसी अन्य व्यक्ति को नहीं किया जाएगा ।
3. बिना किसी असम्यक दबाव उत्प्रेरण या प्रभाव या प्रलोभन के अपनी स्वतंत्र इच्छा से अपने.....(अंग/उत्तक का नाम) को निकाले जाने के लिए सहमति और प्राधिकार दे रहा हूँ ।
4. मुझको मेरे.....(अंग/उत्तक का नाम) के निकाले जाने में निहित चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए निहित खतरों को पूर्णतः स्पष्ट कर दिया गया है । यह कि स्पष्टीकरण.....(रजिस्ट्रीकृत चिकित्सीय व्यवसायी का नाम) द्वारा दिया गया है ।
5. मैं चिकित्सा व्यवसायी द्वारा यथास्पष्ट उस चिकित्सीय प्रक्रिया की प्रकृति और मेरे लिए होने वाले खतरों को समझता हूँ ।
6. मैं समझता हूँ कि मैं शल्य क्रिया होने से पूर्व किसी समय भी अंग को निकाले जाने की अपनी सहमति को वापस ले सकता हूँ/ले सकती हूँ ।
7. मैं कथन करता हूँ/करती हूँ कि प्ररूप में मेरे द्वारा भरी गई विशिष्टियां मेरे ज्ञान में सत्य और सही हैं और कुछ भी मेरे द्वारा छिपाया नहीं गया है ।

.....
संभावित दाता के हस्ताक्षर (पूरा नाम)

.....
तारीख

टिप्पण : पब्लिक नोटेरी जो उस समय अनुप्रमाणित कर रहा है, के समक्ष शपथ लेगा और सुनिश्चित करेगा कि नोटेरी रजिस्टर पर शपथपत्र/शपथपत्रों पर हस्ताक्षर कर शपथ ले रहा व्यक्ति वही है ।

प्ररूप 4

जीवित दाता के चिकित्सीय योग्यता के प्रमाणीकरण के लिए
(रजिस्ट्रीकृत चिकित्सा व्यवसायी द्वारा दिया जाए)
[नियम 5(3)(ख) का परन्तुक देखें]

मैं, डाक्टर.....अर्हता प्राप्त.....चिकित्सा परिषद् द्वारा क्रम संख्यांक.....पर चिकित्सा व्यवसायी के रूप में रजिस्ट्रीकृत, यह प्रमाणित करता हूँ कि मैंने श्री/श्रीमती/कुमारी.....का/की पुत्र/पुत्री/पत्नी.....आयु का/की है जिसने अंग (अंग का नाम) अर्थात्के श्री/श्रीमति/कुमारी.....को जो दाता का निकट नातेदार/दाता के निकट नातेदार से भिन्न है और जो प्राधिकरण समिति/रजिस्ट्रीकृत चिकित्सा व्यवसायी अर्थात् प्रतिरोपण केन्द्र का भारसाधक (यथास्थिति) द्वारा अनुमोदित है तथा उक्त दाता के स्वास्थ्य की दशा ठीक है और अंग निकाले जाने की प्रक्रिया के अधीन होने के लिए चिकित्सक दृष्टया योग्य है ।

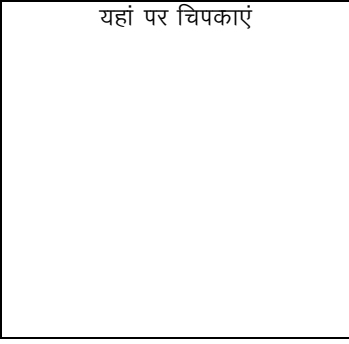
स्थान.....

चिकित्सक के हस्ताक्षर

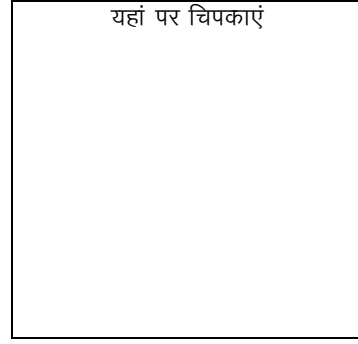
तारीख.....

मुहर

यहां पर चिपकाएं



यहां पर चिपकाएं



दाता का फोटो
(चिकित्सक द्वारा अनुप्रमाणित)

प्राप्त कर्ता का फोटो
(चिकित्सक द्वारा अनुप्रमाणित)

हस्ताक्षर और मुहर भागतः फोटोग्राफ और दस्तावेज पर फोटोग्राफ में चेहरे का विकृत किए बिना लगे होने चाहिए ।

*दाता के मानसिक रूप से आक्षेपित होने की स्थिति में संदेह की दशा में, रजिस्ट्रीकृत चिकित्सक दाता का निरीक्षण मनोचिकित्सक द्वारा करा सकेगा ।

प्ररूप 5

प्राप्त करने वाले के साथ जीवित दाता की आनुवांशिक नातेदारी के प्रमाणीकरण के लिए
(नातेदारी को प्रमाणित करने वाले विकृति प्रयोगशाला के प्रधान द्वारा भरा जाए)

[नियम 5(3)(ग) और 18(3) देखें]

मैं डाक्टर/श्री/श्रीमति..... के रूप में..... कार्यरत पर कार्यरत हूँ और.....अर्हता प्राप्त हूँ प्रमाणित करता हूँ कि श्री/श्रीमति/कुमारी.....जो श्री/श्रीमति का/की पुत्र/पुत्री/पत्नी.....आयु का/की.....दाता और श्री/श्रीमति.....जो श्री/श्रीमती की/का पुत्र/पुत्री/पत्नी.....आयु का/की है उक्त दाता द्वारा संदान किए गए अंग का संभावित प्राप्तकर्ता, उनके अपने कथन के अनुसार आपस में भाई/बहन/माता/पिता/पुत्र/पुत्री, दादी, दादा, पोता और पोती रूप में संबंधित हैं । इस नातेदारी का तथ्य मानव प्रमुख उन्नत संयोज्य तक कॉम्पलैक्स के प्रतिजनी उत्पादों के लिए जांच के परिणाम से स्थापित हो गया है/ नहीं हुआ है । परीक्षणों के परिणाम संलग्न हैं ।

हस्ताक्षर
(प्रयोगशाला के प्रधान द्वारा हस्ताक्षर किए जाएं)
मुहर

स्थान.....

तारीख.....

प्ररूप 6

पति पत्नी जीवित दाता के लिए

(सक्षम प्राधिकारी और अस्पताल या विदेशी की दशा में जिला या राज्य की प्राधिकारी समिति द्वारा भरा जाए)

[नियम 18(2) देखें]

मैं, डाक्टर/श्री/श्रीमती.....अर्हता प्राप्त.....चिकित्सा परिषद् द्वारा क्रम संख्यांक.....पर चिकित्सा व्यवसायी के रूप में रजिस्ट्रीकृत, यह प्रमाणित करता हूँ कि :-

श्री.....पुत्र.....आयु.....का निवासी और श्रीमती.....पुत्री/पत्नी.....आयु.....की निवासी.....उनके दिए गए कथन के अनुसार आपस में पति

पत्नी हैं तथा उक्त श्री/श्रीमती.....के शरीर से अंग निकाले जाने से पूर्व निम्नलिखित साक्ष्यों द्वारा उनके कथन की पुष्टि कर ली गई है (केवल उन मामलों में जहां आवश्यक समझें) ।

या

उपरोक्त उल्लिखित श्री/श्रीमती की नैदानिक स्थिति की दशा में, जो इस प्रकार है कि उसका कथन रिकार्ड करना व्यवहार्य नहीं है, तो दस्तावेजी साक्ष्यों पर ही भरोसा किया जाएगा (यहां दस्तावेजी साक्ष्यों का उल्लेख करें).....

- क. विवाह की तारीख उपदर्शित करते हुए विवाह का प्रमाणपत्र
 ख. विवाह के फोटोचित्र
 ग. तारीख जब अस्पताल द्वारा प्रत्यारोपण का परामर्श दिया गया (विवाह की अवधि से तुलना की जाए)
 घ. बच्चों की संख्या और आयु तथा उनके जन्म प्रमाणपत्र
 ङ. कोई अन्य दस्तावेज

सक्षम प्राधिकारी*/विदेशी होने की दशा में प्राधिकारी समिति के मुहर सहित हस्ताक्षर

स्थान.....

तारीख.....

*निदेशक या चिकित्सीय अधीक्षक या अस्पताल प्रभारी या मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के नियमों के अधीन यथा परिभाषित उद्देश्य के लिए गठित अस्पताल की अंतरीय समिति ।

प्ररूप 7

अंग या ऊतक गिरवी रखने के लिए

(18 वर्ष या उससे ऊपर के व्यक्ति द्वारा भरा जाए)

[नियम 5(4)(क) देखें]

अंग (अंगों) और ऊतक (ऊतकों) दाता प्ररूप

(तीन प्रतियों में भरा जाए)

रजिस्ट्रीकृत संख्यांक (अंगदाता रजिस्ट्री द्वारा प्रदान किया जाए).....

मैं.....पुत्र/पुत्री/पत्नी.....आयु.....और जन्म की तारीख.....का निवासी नीचे उल्लिखित व्यक्तियों की उपस्थिति में, चिकित्सीय विशेषज्ञों की बोर्ड द्वारा मस्तिष्क स्तंभ को मृत घोषित किए जाने के पश्चात् अपने शरीर से निम्नलिखित अंग (अंगों) और या ऊतक(ऊतकों) को निकाले जाने हेतु सुस्पष्ट रूप से प्राधिकृत करता हूँ और चिकित्सीय प्रयोजन के लिए उनका दान करने की सहमति देता हूँ ।

(निम्नलिखित ऊतकों को मस्तिष्क स्तंभ मृत्यु के साथ हृदयिक मृत्यु के पश्चात् भी दान किया जा सकता है)

हृदय	कोर्निया/आंख की पुतलियां
फेफड़े	त्वचा
गुर्दे	हड्डियां
यकृत	हृदय पम्प
अग्नाशय	रक्त वाहिनियां
कोई अन्य अंग(कृपया विनिर्दिष्ट करें)	कोई अन्य ऊतक (कृपया विनिर्दिष्ट करें).....
सभी अंग	सभी ऊतक

मेरा रक्त समूह (यदि ज्ञात हो).....है ।

गिरवी रखने वाले के हस्ताक्षर.....

पत्र व्यवहार का पता.....
दूरभाष सं०.....
ईमेल पता.....
तारीख.....

(टिप्पण : गिरवी के आनलाइन रजिस्ट्रीकृत किए जाने की दशा में, जहां गिरवी रखा गया है, वहां गिरवी को प्रति गिरवी रखने वाले के द्वारा तथा एक प्रति संस्था द्वारा रखी जाएगी और गिरवी रखने वाले व्यक्ति के द्वारा तथा दो गवाहों द्वारा हस्ताक्षरित एक हार्ड प्रति नोडल संगठन को भेजी जाएगी ।)

(गवाह 1 के हस्ताक्षर)

1. श्रीमती/कु०.....पुत्र/पुत्री/पत्नी.....आयु.....
निवासी.....दूरभाष नं०.....ईमेल पता.....

(गवाह 2 के हस्ताक्षर)

1. श्रीमती/कु०.....पुत्र/पुत्री/पत्नी.....आयु.....
निवासी.....दूरभाष नं०.....ईमेल पता.....के रूप में दाता के निकट रिश्तेदार हैं ।

तारीख.....
स्थान.....

टिप्पण : (i) अंगदान एक पारिवारिक निर्णय है । इसलिए यह महत्वपूर्ण है कि आप अपने निर्णय के बारे में परिवार के सदस्यों और अपने प्रियों से चर्चा करें जिससे उनके लिए आपकी इच्छाओं का पूरा करना ज्यादा आसान होगा ।

(ii) गिरवी प्ररूप/गिरवी कार्ड की एक प्रति अपने-अपने नेटवर्किंग संस्थान के पास होना चाहिए, एक प्रति उस संस्था द्वारा, जहां गिरवी रखा गया है, रखी जानी चाहिए और एक प्रति गिरवी रखने वाले को हस्तान्तरित होनी चाहिए ।

(iii) वह व्यक्ति जो गिरवी रख रहा है के पास गिरवी को वापस लेने का विकल्प है ।

प्ररूप 8

घोषणा व सहमति के लिए

स्तिष्क स्तंभ मृत व्यक्ति के नजदीकी रिश्तेदार या विधिपूर्ण कब्जा लेने वाले द्वारा भरा जाए)

[नियम 5(1)(ख), 5(4) (ख) और 5(4) (घ)]

घोषणा और सहमति प्ररूप

मैं.....सुपुत्र/सुपुत्री/

पत्नी.....आयु.....निवासी.....निम्नलिखित व्यक्तियों की उपस्थिति में, इसके द्वारा घोषणा करता हूं ।

1. मुझे सूचित किया गया है कि मेरे नातेदार (नातेदार लिखें)सुपुत्र/सुपुत्री/पत्नी.....आयु.....

को मस्तिष्क स्तंभ मृतमृत घोषित किया जा चुका है

2. मेरे श्रेष्ठ ज्ञान के अनुसार (जो लागू न हो, काट दें) :

(क)(मृतक का नाम) ने अपनी मृत्यु के पश्चात् थैराप्यूटिक प्रयोजन के लिए अपने अंग(अंग/उत्तक/ दोनो को निकालने के लिए पूर्व प्राधिकृत किया/नहीं किया है ।

(ख)(मृतक का नाम) ने उपलिखित क्रमांक 2(क) के अनुसार प्राधिकार का प्रतिसंहरण नहीं किया है ।

(ग) यह विश्वास किया जाता है कि उक्त मृतक व्यक्ति के किसी भी नजदीकी रिश्तेदार को उसके किसी भी अंग/उत्तक का थैराप्यूटिक प्रयोजन के लिए उपयोग करने में कोई आपत्ति नहीं है ।

3 मुझे ये सूचित किया गया है कि ऐसे प्राधिकार की अनुपस्थिति में, मुझे थैराप्यूटिक प्रयोजन के लिए

मृतक का नाम) के अंग/उतक/दोनो के सहित आंख स्वच्छमंडल/आंख थैराप्यूटिक प्रयोजन के लिए उपयुक्त नहीं पाई गई, तो उन्हें शिक्षा/अनुसंधान के लिए उपयोग में लाया जा सकता है।

4. मैं इसके द्वारा अपने अंग/अंगो और उतक /उतकों जैसे कि (कोई अंग और उतक/गुरदा/जिगर /हृदय/फेंफड़े/आंत स्वच्छमंडल चर्म हड्डी हृदय वाल्व अन्य कोई, कृपया लिखेको थैराप्यूटिक प्रयोजन हेतु निकालने के लिए प्राधिकृत करता नहीं करता हूं। मैं सीरम विज्ञान परीक्षण के लिए रक्त का नमूना लेने की अनुमति देता हूं और अंगों और उतकों के सुरक्षित प्रतिरोपण के लिए दाता की सही जांच की सुविधा को ली अपनी सामाजिक व्यवहारिकता और चिकित्सीय इतिहास को बांटने का इच्छुक हूं।
तारीखनजदीकी रिश्तेदार के हस्ताक्षर / मृत शरीर का विधिपूर्ण कब्जे में लेने वाला व्यक्ति और पत्राचार के लिए पता।

स्थान टेलिफोन नं0.....ई मेल

*नाबालिग की दशा में घोषणा, नाबालिग के माता पिता में से किसी एक द्वारा हस्ताक्षर की जाएगी या माता पिता द्वारा प्राधिकृत कोई नजदीकी रिश्तेदार। यदि नजदीकी रिश्तेदार या व्यक्ति जिसके विधिपूर्ण कब्जे में शरीर है, इस प्ररूप पर हस्ताक्षर करने से मना कर देता है, तो रजिस्टर्ड चिकित्सा व्यवसायीकर्ता द्वारा उसे लिखित रूप में रिकार्ड किया जाएगा।

(गवाह 1 के हस्ताक्षर)

1. श्री/श्रीमति/कुमारी.....सुपुत्र /सुपुत्री /पत्नी.....आयु
निवासी.....टेलिफोन नं0.....ईमेल.....

(गवाह 2 के हस्ताक्षर)

2. 1. श्री/श्रीमति /कुमारी.....सुपुत्र/सुपुत्री/पत्नी.....आयु
निवासी.....टेलिफोन नं0.....ईमेल.....

प्ररूप 9

कारावास या अस्पताल में लावारिस शरीर के लिए

(लावारिस शरीर का कब्जा लेने वाले व्यक्ति द्वारा पूरा किया जाए)

[नियम 5(1)(ख) देखें]

मैं....., सुपुत्र/सुपुत्री /पत्नी.....आयु.....
निवासी.....के पास श्री/श्रीमति/कुमारी.....
सुपुत्र /सुपुत्री /पत्नीआयु.....निवासी.....

.....के मृत शरीर का कब्जा है और जैसा कि जानकारी है कोई भी व्यक्ति मृत्यु के 48 घंटे बाद भी मृतक के शरीर पर दावे के लिए आगे नहीं या और ऐसा विश्वास करने का कोई कारण नहीं है कि कोई व्यक्ति शरीर पर दावा करने आएगा, मैं, इसके द्वारा थैराप्यूटिक प्रयोजन के लिए उसके शरीर के अंग/अंगो और उतक/उतकों जो किहैं, को निकालने के लिए प्राधिकार देता हूं।

हस्ताक्षर, नाम, पद और मृत शरीर का विधिपूर्ण कब्जा लेने वाले व्यक्ति की मोहर।

तारीख.....स्थान.....

पत्राचार के लिए पता.....

दूरभाष नं०.....ईमेल.....

(गवाह 1 के हस्ताक्षर)

1. श्री/श्रीमति/कुमारी.....सुपुत्र/सुपुत्री/पत्नी.....आयु
निवासी.....टेलिफोन नं०.....ईमेल.....

(गवाह 2 के हस्ताक्षर)

2. 1. श्री/श्रीमति/कुमारी.....सुपुत्र/सुपुत्री /पत्नी.....आयु
निवासी.....टेलिफोन नं०.....ईमेल.....

प्ररूप 10

ब्रेन स्टेम मृत्यु का प्रमाण पत्र

(मृत्यु को प्रमाणित करते हुए, चिकित्सा विशेषज्ञों द्वारा भरा जाए)

[नियम 5(4) और 5(4) (घ) देखें]

हम, चिकित्सा विशेषज्ञ बोर्ड के निम्नलिखित सदस्य, वासधानीपूर्वक वैयक्तिक परीक्षा के पश्चात् यह प्रमाणित करते हैं कि श्री/श्रीमति/कुमारी.....जो लगभग आयु का/की.....का/की पुत्र/पुत्री/पत्नी.....का/की निवासी है, मस्तिष्क-स्तंभ के सभी कार्य स्थायी और अपरिवर्तनीय रूप से समाप्त हो जाने के कारण मृत हो गया/ गई है हमारे द्वारा कए गए परीक्षण और उनके निष्कर्ष इससे उपाबद्ध मस्तिष्क स्तंभ मृत्यु प्रमाणपत्र में अभिलिखित है ।

तारीख.....

हस्ताक्षर

1. आर.एम.पी. उस अस्पताल का भारसाधक जिसमें मस्तिष्क स्तंभ मृत्यु हुए हैं	2.समुचित प्राधिकारी द्वारा अनुमोदित नामों के पैनल में से नामित आर.एम.पी.
3. समुचित प्राधिकारी द्वारा अनुमोदित नामों के पानल में से नामित तंत्रिका विज्ञानी तंत्रिका शल्य चिकित्सक	4. पूर्वोक्त मृत व्यक्ति का उपचार करने वाला आर.एम.पी ।

(जब तंत्रिका विज्ञानी/तंत्रिका शल्य चिकित्सक उपलब्ध नहीं हो तो चिकित्सालय द्वारा भेजे गए नामों के पैनल से और समुचित प्राधिकारी द्वारा अनुमोदित चिकित्सा प्रशासक भारसाधक द्वारा नामनिर्दिष्ट कोई शल्य चिकित्सक या चिकित्सक और निश्चेतना विशेषज्ञ या गहनता विशेषज्ञ सम्मिलित किया जाएगा)

मस्तिष्क स्तंभ मृत्यु प्रमाण-पत्र

(अ) रोगी के ब्यौरे :

1. रोगी का नाम पुत्र /पुत्री/पत्नी	श्री/श्रीमति श्री/श्रीमति लिंगआयु
2. घर का पता

3. अस्पताल संख्यांक
4. अगले निकट संबंधी या रोगी के लिए उत्तरदायी व्यक्ति का नाम और पता (यदि कोई नहीं है तो विनिर्दिष्ट किया जाना चाहिए)
5. क्या रोगी या अगला निकट संबंधी किसी प्रतिरोपण के लिए सहमत है ?
6. क्या यह पुलिस मामला है	हां नहीं

(आ) पूर्व-दशाएं									
<p>1. निदान :</p> <p>दुर्घटना बीमारी होने की तारीख और समय</p> <p>आवेदनशील अचेतनावस्था होने की तारीख और समय</p>	<p>क्या रोगी कोई बीमारी या दुर्घटना से पीड़ित था किसी अपरिवर्त्य मस्तिष्क क्षति हुई ? ब्यौरे विनिर्दिष्ट करें :</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>								
<p>2. चिकित्सा-विशेषज्ञ बोर्ड के निष्कर्ष :</p> <p>(i) अचेतनावस्था के निम्नलिखित प्रतिवर्त्य कारण अपवर्जित किए गए हैं :-</p> <p>मत्सत्तार एल्कोहल</p> <p>प्रावसादक औषधियां</p> <p>विश्रामक (तंत्रिकापेशीय अवरोधक कारक)</p> <p>प्राथमिक अतिताप</p> <p>हाइवोलैमिक प्रघात</p> <p>उपापचयी या अंतःताव अव्यवस्था</p> <p>मस्तिष्क स्तंभ कार्यो के न होने के लिए परीक्षण</p>	<table border="1"> <tr> <td colspan="2">पहली चिकित्सा परीक्षा</td> <td colspan="2">दूसरी चिकित्सा परीक्षा</td> </tr> <tr> <td>पहली</td> <td>दूसरी</td> <td>पहली</td> <td>दूसरी</td> </tr> </table>	पहली चिकित्सा परीक्षा		दूसरी चिकित्सा परीक्षा		पहली	दूसरी	पहली	दूसरी
पहली चिकित्सा परीक्षा		दूसरी चिकित्सा परीक्षा							
पहली	दूसरी	पहली	दूसरी						
2. चैतनावस्था									
3. स्वतः श्वसन का समापन									
4. पुतली का आकार									
5. पुतली परावृत्त प्रकाश									
6. पुतिलका शीर्ष नेत्र संचलन									
7. कार्निया परावत (दोनों तरफ)									

8. किसी कपालीय तंत्रिका वितरण में चालक पेशी प्रतिक्रिया चेहरा, अंग या घड़ के उद्दीपन की प्रतिक्रियाएं	
9. गैंग परावृत	
10. खांसी (श्वस प्रणाली)	
11. द्विपाशवीय वर्ग परीक्षण करने पर नेत्र संचलन	
12. यथा-विनिर्दिष्ट अवश्वसन परीक्षण	
13. क्या कोई प्रश्वसन क्रिया दिखाई दी थी	
प्रथम परीक्षण की तारीख और समय
द्वितीय परीक्षण की तारीख और समय

यह प्रमाणित किया जाता है कि रोगी की लगभग छह घंटे के अंतराल के पश्चात् दो बार सावधानीपूर्वक जांच की गई है और ऊपर अभिलिखित निष्कर्षों के आधार पर श्री/ सुश्री.....

की मस्तिष्क स्तंभ मृत घोषित किया जाता है ।

तारीख.....

मस्तिष्क स्तंभ मृत प्रमाणिकता बोर्ड (बीएसडी) से सदस्य के हस्ताक्षर :

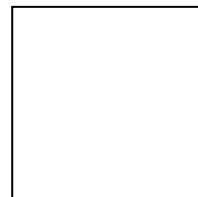
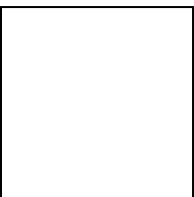
1. चिकित्सा प्रशासन
2. प्राधिकृत विशेषज्ञ
- अस्पताल का भारसाधक
3. तंत्रिका विज्ञानी तंत्रिका शल्य चिकित्सक
4. रोगी का उपचार करने वाला चिकित्सा अधिकारी

टिप्पण :

- I. जहां तंत्रिका विज्ञानी / तंत्रिका शल्य चिकित्सक उपलब्ध नहीं है तो अस्पताल के चिकित्सा प्रशासक भारसाधक द्वारा नियुक्त कोई शल्य चिकित्सक या चिकित्सक और निश्चेतक व इन्टेसिविस्ट मस्तिष्क स्तंभ मृत्यु प्रमाण पत्र जारी करने हेतु चिकित्सा विशेषज्ञ बोर्ड के सदस्य होंगे।
- II बालिगों के पहले और दूसरे परीक्षण के बीच में कम से कम छह घण्टों का अन्तराल होगा । 6 से 12 वर्ष के बच्चों का दशा में 1 से 5 वर्ष की आयु के बच्चों और शिशुओं की दशा में समय का अंतराल बी एस डी विशेषज्ञों के सुझावों पर निर्भर करता है ।
- III संख्या 2 और संख्या 3 की सह चुनाव अस्पताल के प्रशासन भारसाधक द्वारा विशेषज्ञों की तालिका से होगा (अस्पताल द्वारा नियुक्त और समचित प्राधिकारी द्वारा अनुमोदित)

प्ररूप 11

जिवित दाता से प्रतिरोपण के अनुमोदनार्थ आवेदन
(प्रस्तवित प्रापक और प्रस्तावित जिवित दाता द्वारा पूरी किया जाए)
[नियम 593)(घ),5(3)(ड)और 10 देखें]



चूँकि मैं सुपुत्र / सुपुत्री /पत्नी श्री/ श्रीमतिआयु
निवासी.....हूँ मुझे / मेरे चिकित्सक
 ने परामर्श दिया है कि मैं से ग्रसित हूँ और मेरे शरीर मेंके प्रतिरोपण से लाभ दिया जाए ।

और चूँकि मैं सुपुत्र / सुपुत्री /पत्नी श्री/ श्रीमतिआयु.....
 निवासी.....निम्नलिखित कारणवश :-

(क) नजदीकी रिश्तेदार होने से , जैसे किस्पष्ट किया गया है, से

अतः मैं, श्री/ श्रीमतिको पना (अंग का नाम) दान करना चाहूँगा ।

हम.....(दाता) और(प्रापक), इस के द्वारा इस तरह का प्रतिरोपण करने की अनुमति के लिए सक्षम प्राधिकारी प्राधिकरण कमेटी को आवेदन करते हैं । हम यह प्रमाणित करते हैं कि उपरोक्त निर्णय बिना किसी असम्यक दबाव, उत्प्रेरणी, प्रभाव या प्रलोभन से लिया गया है और अंग प्रतिरोपण के सभी संभव दुष्प्रभावों और विकल्पों को हमें स्पष्ट कर दिया गया है ।

आवेदकों के लिए अनुदेश :-

1. जैसा संभव हो, प्ररूप 11 को पूर्ण रूप से भरे गए प्ररूप 1 व प्ररूप 2 व प्ररूप 3 साथ जमा किया जाए ।
2. यथासंभव, उपयुक्त प्ररूप जैसे प्ररूप 1 व प्ररूप 2 व प्ररूप 3 को, उपयुक्त प्ररूप में उल्लेखित सभी दस्तावेजों के साथ लगाए और उपयुक्त प्ररूप में रखे गए प्रश्नों का पर्याप्त उत्तर दिया जाना चाहिए ।
3. प्ररूप 5 को प्रयोगशाला रिपोर्ट के साथ जमा करना चाहिए ।
4. आवेदन के साथ चिकित्सक द्वारा प्रतिरोपण के लिए जारी की गई परामर्श रिपोर्ट भी संलग्न होनी चाहिए ।
5. इसके अतिरिक्त, यदि प्रस्तावित प्रतिरोपण बिना संबंध के व्यक्तियों में हो रहा है तो इस आवेदन के साथ, दाता के साथ साथ प्रापक के पिछले तीन सालों के व्यवसाय और आय के समुचित साक्ष्य संलग्न होने चाहिए । इसे साफ किया गया है कि आय कर विवरणी के सबूत को जरूरी नहीं है कि आय का साक्ष्य माना जाए, इसे देखते हुए जैसे कि किसी मामले में आवेदक आयकर विवरणी दायर नहीं कर रहा हो ।
6. आवेदन, सोच विचार के लिए सक्षम प्राधिकारी/ प्राधिकरण कमेटी केवल तभी स्वीकार करेगी, यदि यह हर तरह से पूर्ण है और किसी दस्तावेज या प्ररूप में उपर उल्लेखित अपेक्षित जानकारी में कोई त्रुटि है तो आवेदन को अधूरा मान कर लौटा दिया जाएगा ।
7. जब दाता रिश्तेदार न हो और जिस राज्य/संघ राज्य क्षेत्र में प्रतिरोपण किया जाता है, जो दाता व प्रापक के संबंधित राज्य/संघ राज्य क्षेत्र से भिन्न है, तब यथास्थिति दाता व प्रापक के मूल अधिवास राज्य के प्रयोजन हेतु तहसीलदार या प्राधिकृत अधिकारी, यथास्थिति प्ररूप 20 के अनुसार दाता/ प्रापक के मूल अधिवास प्रमाण-पत्र का सत्यापन करेगा । राज्य/दाता/ प्रापक के मूल अधिवास प्रमाण पत्र का सत्यापन करेगा । राज्य / जिला/ अस्पताल (यथास्थिति) जहां प्रतिरोपण किया जाना है की प्राधिकरण कमेटी द्वारा प्रतिरोपण के अनुमोदन पर विचार करेगी । इस प्रकार का सत्यापन प्रमाणपत्र नजदीकी रिश्तेदारों के लिए साथ-साथ अंगों की अदला बदली (जो केवल नजदीकी रिश्तेदारों में ही अनुज्ञेय है) में अपेक्षित नहीं है ।

हमने उपलिखित अनुदेशों को पढ़ और समझ लिया है ।

पूर्वक्षित दाता के हस्ताक्षर

पत्राचार के लिए पता

तारीख :

स्थान:

पूर्वक्षित प्रापक के हस्ताक्षर

पत्राचार के लिए पता

तारीख :

स्थान

प्ररूप 12

अस्पताल द्वारा स्वच्छमंडल के अतिरिक्त अंग व उतक का प्रतिरोपण करने हेतु रजिस्ट्रेशन केलि आवेदन
(संस्थान आवेदन प्रधान द्वारा भरा जाए)
(नियम 24(1) देखें)

सेवा में,

अंग प्रतिरोपण समुचित प्राधिकारी

(राज्य या संघ राज्य क्षेत्र)

हम अंग प्रतिरोपण करने केलिए एक संस्था के रुप में मान्यता देने के लिए आवेदन करते हैं । अस्पताल में उपलब्ध सुविधाओं के बारे में
अपेक्षित आंकड़े निम्नलिखित है :-

(अ) अस्पताल :

1. नाम
2. अस्पताल
3. सरकारी/प्राईवेट.....
4. अध्यापन/अद्यापनेत्तर
5. पहुंच-मार्ग :

सड़क :	हां	नहीं
रेल :	हां	नहीं
विमान :	हां	नहीं

6. कुल बिस्तरों की संख्या
7. अस्पताल में शाखाओं की संख्या
8. वार्षिक बजट
9. प्रतिवर्ष आने वाले रोगी
- (अ) शल्य चिकित्सीय दल
1. बिस्तरों की संख्या
2. स्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
3. अस्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
4. प्रतिवर्ष की गई शल्य क्रियाओं की संख्या
5. प्रत्यारोपण के लिए उपलब्ध प्रशिक्षित व्यक्ति (कृपया प्रत्यारोपण के लिए अंग विनिर्दिष्ट करें) :

(इ) चिकित्सा सुविधाएं

1. बिस्तरों की संख्या
2. स्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
3. अस्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
4. प्रतिवर्ष आने वाले रोगियों की संख्या
5. प्रतिरोपण के लिए उपलब्ध प्रशिक्षित व्यक्ति(कृपया प्रतिरोपण के अंग विनिर्दिष्ट करें).....
6. प्रतिवर्ष प्रवेश किए गए अंग प्रतिरोपण अभ्यर्थियों की संख्या

(ई) निश्चेतना विज्ञान :

1. स्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
2. अस्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम सहित संख्या.....
3. किए गए शल्य क्रियाओं के नाम और उनकी संख्या
4. उपलब्ध उपस्कर के नाम और उनकी संख्या.....
5. अस्पताल में शल्य क्रिया-थियेटर्स की कुल संख्या.....
6. आपातकालीन शल्य क्रिया थियेटर्स की कुल संख्या
7. पृथक अंग प्रतिरोपण शल्य क्रिया थियेटर की कुल संख्या

(उ) गहन देख रेख एकक/ हृदय रोग एकक सुविधाएं

1. गहन देख रेख एकक / हृदय रोग एकक सुविधाएं विद्यमानअविद्यमान.....
2. गहन देख रेख एकक में बिस्तरों की संख्या
3. प्रशिक्षित.....नर्स
- तकनीशियन
4. गहन देख रेख एकक में उपस्करों के नाम और उनकी संख्या

(ऊ) अन्य सहायक सुविधाएं

अस्पताल में उपलब्ध सुविधाओं के आंकड़े ।

(ए) प्रयोगशाला सुविधाएं :

1. स्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
2. अस्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
3. विभाग में किए गए अन्वेषणों के नाम ।
4. उपलब्ध उपस्करों के नाम और उनकी संख्या ।

(ऐ) इमेजिंग सेवाएं :

1. स्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
2. अस्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
3. विभाग में किए गए अन्वेषणों के नाम ।
4. उपलब्ध उपस्करों के नाम और उनकी संख्या ।

(ओ) रुधिर विज्ञान सेवाएं :

1. स्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
2. अस्थायी कर्मचारिवृंद की उनके पदनाम सहित संख्या.....
3. विभाग में किए गए अन्वेषणों के नाम ।
4. उपलब्ध उपस्करों के नाम और उनकी संख्या ।

(औ) रक्त बैंक सुविधाएं : हां नहीं.....

(अं) डाइलासिस सुविधाएं हां नहीं.....

(ऐ6) प्रत्यारोपण समन्वयक (कॉर्निया प्रत्यारोपण के मामले में नेत्रदाता परामर्शदाता) :

हां नहीं.....

पदस्थ संख्या :

प्रशिक्षित संख्या :

(अं) अन्य सहायक विशेषज्ञ कार्मिक

1.	वृक्क रचना विज्ञानी	हां/नहीं
2.	तंत्रिका विज्ञानी	हां/नहीं
3.	तंत्रिका शल्य चिकित्सक	हां/नहीं
4.	मूत्र विज्ञानी	हां/नहीं
5.	जी.आई.शल्य चिकित्सक	हां/नहीं
6.	शिशु रोग विशेषज्ञ	हां/नहीं
7.	भौतिक चिकित्सा विज्ञानी	हां/नहीं
8.	सामाजिक कार्यकर्ता	हां/नहीं
9.	प्रतिक्षा विज्ञानी	हां/नहीं
10.	हृदय रोग विज्ञानी	हां/नहीं
11.	अन्य.....	हां/नहीं

उपलिखित सूचना मेरे सर्वोत्तम ज्ञान के अनुसार सत्य है और मुझे प्राधिकृत कार्मिक द्वारा हमारी सुविधा की संवीक्षा में कोई आपत्ति नहीं है ।
1000/-रु० (नए रजिस्ट्रीकरण के लिए) और 5000/-रु० (नवीकरण के लिए) का बैंक ड्राफ्ट/चैक.....के पक्ष में संलग्न है ।

ह०/-
संस्था प्रमुख

प्ररूप 13

**नेत्र/कॉर्निया पुनःप्राप्ति से भिन्न अंग/ऊतक पुनःप्राप्ति के लिए चिकित्सा के रजिस्ट्रीकरण के लिए आवेदन
(संस्था के प्रमुख द्वारा भरा जाए)
(नियम 24(1) देखें)**

टिप्पण : पुनःप्राप्ति चिकित्सालयों का पूर्व परिभाषित मापदंड के आधार पर भी पहचाना जा सकता है और समुचित प्राधिकारी द्वारा पुनःप्राप्ति चिकित्सालय के रूप में रजिस्ट्रीकृत किया जा सकता है ।

सेवा में,

अंग प्रत्यारोपण के लिए समुचित प्राधिकारी.....
(राज्य या संघ राज्यक्षेत्र)

हम अंग/ऊतक प्रत्यारोपण के लिए संस्था के रूप में रजिस्ट्रीकरण के लिए आवेदन करते हैं ।
चिकित्सालय में उपलब्ध सुविधाओं के बारे में अपेक्षित डाटा निम्नानुसार है :

(क) चिकित्सालय :

1. नाम :
2. अवस्थिति :
3. सरकारी/निजी :
4. शैक्षिक/गैर शैक्षिक :
5. पहुंच :

सड़क :	हां	नहीं
रेलमार्ग :	हां	नहीं
वायुमार्ग :	हां	नहीं

6. कुल बिस्तर संख्या :
7. चिकित्सालय में संकायों के नाम :

8. वार्षिक बजट :
9. रोगी आवर्त/वर्ष :

(ख) शल्य चिकित्सा सुविधाएं

1. बिस्तरों की संख्या :
2. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
3. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
4. प्रतिवर्ष की गई शल्य क्रियाओं की संख्या :
5. पुनःप्राप्ति के लिए उपलब्ध प्रशिक्षित व्यक्ति (कृपया पुनःप्राप्ति के लिए अंग और/या उक्तक विनिर्दिष्ट करें)

(ग) चिकित्सा सुविधाएं :

1. बिस्तरों की संख्या :
2. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
3. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
4. रोगी आवर्त प्रतिवर्ष :
5. पुनःप्राप्ति के लिए उपलब्ध प्रशिक्षित व्यक्ति (कृपया पुनःप्राप्ति के लिए अंग और/या उक्तक विनिर्दिष्ट करें)
6. प्रतिवर्ष भर्ती किए गए गंभीर आघात मामलों की संख्या
7. प्रतिवर्ष घोषित मानसिक मृत्युओं की संख्या ।

(घ) संवेदनाहरण विज्ञान :

1. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
2. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
3. प्रतिवर्ष की गई शल्य क्रियाओं की संख्या :
4. उपलब्ध उपस्करों का नाम और सं० :
5. चिकित्सालय में शल्य क्रिया कक्षों की कुल सं० :
6. आपात शल्य क्रिया कक्षों की सं० :
7. पृथक पुनःप्राप्ति शल्य क्रिया कक्षों की सं० :

(ङ) आई.सी.यू./एच.डी.यू. सुविधाएं :

1. आई.सी.यू./एच.डी.यू. सुविधाएं : विद्यमान.....विद्यमान नहीं.....
2. आई.सी.यू. और एच.डी.यू. बिस्तरों की सं०
3. प्रशिक्षित :-
नर्स :
टेक्नीशियन :
4. आई.सी.यू. में उपस्कर का नाम

(च) अन्य सहायक सुविधाएं :

चिकित्सालय में उपलब्ध सुविधाओं के बारे में डाटा :

(च1) प्रयोगशाला सुविधाएं :

1. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
2. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
3. विभाग में किए गए अन्वेषणों के नाम:
4. उपलब्ध उपस्करों का नाम और सं० :

(च2) इमेजिंग सुविधाएं :

1. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
2. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
3. विभाग में किए गए अन्वेषणों के नाम :
4. उपलब्ध उपस्करों का नाम और सं० :

(च3)

1. पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या :
2. पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या :
3. विभाग में किए गए अन्वेषणों के नाम :
4. उपलब्ध उपस्करों का नाम और सं० :

(च4) रक्त बैंक सुविधाएं : (विद्यमान या पहुंच में) हां.....नहीं.....

(च5) प्रत्यायोजन समन्वयक हां.....नहीं.....
पदस्थ संख्या :
प्रशिक्षित संख्या

उपलिखित सूचना मेरे सर्वोत्तम ज्ञान के अनुसार सत्य है और मुझे प्राधिकृत कार्मिक द्वारा हमारी सुविधा की संवीक्षा में कोई आपत्ति नहीं है। मैं यह प्रतिज्ञान करता हूं कि हम, जब भी आवश्यकता हो, अंग/ऊतक की पुनःप्राप्ति के लिए, चिकित्सालय की पुनः प्राप्ति टीम समेत चिकित्सालय की सुविधाएं उपलब्ध करवाएंगे।

ह०/-
संस्था प्रमुख

प्ररूप 14
नेत्र बैंक से भिन्न ऊतक बैंकों के रजिस्ट्रीकरण के लिए आवेदन
(संस्था के प्रमुख द्वारा भरा जाए)
(नियम 24(1))

सेवा में,

अंग प्रत्यारोपण के लिए समुचित प्राधिकारी.....
(राज्य या संघ राज्यक्षेत्र)

हम ऊतक बैंक के रूप में रजिस्ट्रीकृत होने के लिए आवेदन करते हैं, नाम :
ऊतक (अस्थि, हृदय वाल्व, त्वचा, कोर्निया आदि) का नाम जिसके लिए रजिस्ट्रीकरण अपेक्षित है.....

(क) चिकित्सालय :

1. नाम :
2. अवस्थिति :
3. सरकारी/निजी :
4. शैक्षिक/गैर शैक्षिक :
5. पहुंच :

सड़क :	हां	नहीं
रेलमार्ग :	हां	नहीं
वायुमार्ग :	हां	नहीं

5. ऊतक दान के लिए सूचना, शिक्षा और संसूचना
6. ऊतक बैंक का प्रकार : आटो लॉगोन्स/एलोग्राफ/दोनों

ख. दानकर्ता स्क्रीनिंग
ऊतक निकालना और भंडारण

1.	ऊतक निकालने के लिए पर्याप्त प्रशिक्षित और दक्ष कर्मिकों की उपलब्धता (ब्यौरे संलग्न करें)	हां/नहीं
2.	चिकित्सकों/तकनीशियनों के नाम, अर्हता और पते, जो ऊतक निकालेंगे (ब्यौरे संलग्न)	हां/नहीं

3.	उक्तक निकालने के लिए सुविधाएं (ब्यौरे संलग्न)	हां/नहीं
4.	क्या प्राप्तकर्ता प्रतीक्षा सूची का रजिस्टर उपलब्ध है।	हां/नहीं
5.	दूरभाषा व्यवस्था उपलब्ध है (दूरभाष सं०.....)	हां/नहीं
6.	बाहर से उक्तक इकट्ठा करने के लिए एम्बुलेंस/यान की सुविधा या टैक्सी के संदाय के लिए निधियां :	हां/नहीं
7.	उक्तक हटाने के लिए उपकरणों का सैट	हां/नहीं
8.	उक्तक के प्रसंस्करण के लिए सुविधाएं	हां/नहीं
9.	उक्तक के परिरक्षण के लिए प्रशीतक	हां/नहीं
10.	परिवहन के दौरान उक्तक के परिरक्षण के लिए विशेष आधान।	हां/नहीं
11.	उपयुक्त परिरक्षण मीडिया	हां/नहीं
12.	उक्तक के अनुसार कोई अन्य विशिष्ट अपेक्षा	हां/नहीं

ग	उक्तक के परिरक्षण	
	उक्तक के परिरक्षण की व्यवस्था	हां/नहीं

घ	अभिलेख	
1.	अभिलेख रखने के लिए व्यवस्था	हां/नहीं
2.	मामलों, दानकर्ताओं और मामलों के अनुगमन के लिए व्यवस्था।	हां/नहीं

ङ	उपस्कर	
	उक्तक के लिए विशिष्ट उपकरण	हां/नहीं

च	प्रयोगशाला सुविधाएं (यदि जानकारी संपूर्ण है तो कृपया संलग्न करें)	
क.	विभाग में किए गए अन्वेषणों के नाम।	
ख.	निम्नलिखित के परीक्षण के लिए सुविधा	
	i. ह्यूमन इम्यूनोडेफिशिएंसी वायरस प्रकार 1 और 2	हां/नहीं
	ii. हेपेटाइटिस बी वायरस-एचबीसी और एचबीएस	
	iii. हेपेटाइटिस सी वायरस - एचसीवी	
	iv. सिफिलिस - वीडिआरएल	
ग	यदि नहीं, तो आपने कहां इसका लाभ उठाया है ? कृपया संस्थान का नाम और पता वर्णित करें।	हां/नहीं
घ	उक्तक के संवर्धन और संवेदनशीलता के लिए सुविधा।	हां/नहीं

छ	अन्य कार्मिक	
1.	पदनाम के साथ स्थायी कर्मचारिवृंद की संख्या	
2.	पदनाम के साथ अस्थायी कर्मचारिवृंद की संख्या	
3.	प्रशिक्षित व्यक्तियों की सं०	

अन्य कोई जानकारी

उपलिखित सूचना मेरे सर्वोत्तम ज्ञान के अनुसार सत्य है और मुझे प्राधिकृत कार्मिक द्वारा हमारी सुविधा की संवीक्षा में कोई आपत्ति नहीं है। 1000/-रु० (नए रजिस्ट्रीकरण के लिए) और 5000/-रु० (नवीकरण के लिए) का बैंक ड्राफ्ट/चैक.....के पक्ष में संलग्न है।

ह०/-
संस्था प्रमुख

प्ररूप 15

मानव अंग प्रतिरोपण अधिनियम के अधीन नेत्र बैंक, कोर्निया प्रत्यारोपण केन्द्र, नेत्र पुनःप्राप्ति केन्द्र के रजिस्ट्रीकरण के लिए आवेदन (नियम 24(1) देखें)

1. नेत्र बैंकिंग :

अ.	नेत्र/साधारण चिकित्सालय सहबद्ध नेत्र बैंक और संस्था	
	1. नाम	

	2. पता 3. सरकारी/निजी/स्वैच्छिक 4. शैक्षिक/गैर-शैक्षिक 5. नेत्र दान के लिए आईईसी	
आ.	नेत्र गोलक निकालना और भंडारण	
	1. संपूर्ण ग्लोब या कोर्निया निकालने के लिए पर्याप्त प्रशिक्षित और सहकर्मियों की उपलब्धता (ब्यौरा संलग्न करें)	हां/नहीं
	2. पदाभिहीत कर्मचारिवृंद के नाम, अर्हता और पते जो संपूर्ण ग्लोब/कोर्निया निकालेंगे । (ब्यौरा संलग्न करें)	हां/नहीं
	3. अपेक्षा अनुसार निम्नलिखित की उपलब्धता : क. क्या उक्त अनुरोध के लिए रखा गया रजिस्टर कोर्निया प्रत्यारोपण केन्द्र के शल्य चिकित्सक से प्राप्त हुआ ।	हां/नहीं
	ख. उपलब्ध दूरभाष व्यवस्था । (समर्पित दूरभाष संख्या.....)	हां/नहीं
	ग. बाहर से नेत्र गोलक एकत्र करने के लिए परिवहन सुविधा	हां/नहीं
	घ. अपेक्षा अनुसार संपूर्ण ग्लोब/कोर्निया निकालने के लिए उपकरणों का सैट	हां/नहीं
	ङ. परिवहन के दौरान नेत्र गोलक/कोर्निया के परिरक्षण के लिए स्टैंड के साथ विशेष बोटलें ।	हां/नहीं
	च. उपयुक्त परिरक्षण मीडिया	हां/नहीं
	छ. जैव चिकित्सीय अपशिष्ट प्रबंधन	हां/नहीं
	ज. अबाधित विद्युत आपूर्ति	हां/नहीं
इ.	जनशक्ति 1. भारसाधक/निदेशक (नेत्र रोग विशेषज्ञ) 2. नेत्र बैंक टेक्नीशियन-2 3. नेत्रदान परामर्शदाता (ईडीसी)-2 प्रति संलग्न एचसीआरपी (चिकित्सालय कोर्निया पुनःप्राप्ति कोर्निया कार्यक्रम) अस्पताल, जो नेत्र बैंक पर पदस्थ होंगे । 4. (बहुकार्य कर्मचारिवृंद)-2	
ई.	नेत्र बैंकों के लिए स्थान की अपेक्षा (न्यूनतम 400 वर्ग फुट)	हां/नहीं
उ.	अभिलेख	
	1. अभिलेख रखने के लिए व्यवस्था	हां/नहीं
	2. प्रतिज्ञा/दानकर्ताओं के रजिस्ट्रीकरण तथा उपयोगिता रिपोर्ट रखने के लिए व्यवस्था	हां/नहीं
	3. इंटरनेट सुविधा तथा प्रिंटर के साथ कंप्यूटर	हां/नहीं
ऊ.	उपस्कर :	
	1. स्लिट लैंप बायोमाइक्रोस्कोप-1	हां/नहीं
	2. नेत्र बैंक के लिए स्पेकुलर माइक्रोस्कोप-1	
	3. लेमिनर फ्लो (वर्ग 2)-1	
	4. रोगाणुहीन सुविधा (इन-हाउस या आउटसोर्सड)	
	5. नेत्र गोलक/कोर्निया-1 के परिरक्षण के लिए तापमान मानीटरी के साथ प्रशीतक	
ऋ.	प्रयोगशाला सुविधाएं	
	1. एचआईवी, हेपेटाइटिस बी और सी परीक्षण के लिए सुविधा ।	हां/नहीं
	2. यदि नहीं, तो आपने कहाँ इसका लाभ उठाया है ? कृपया संस्थान का नाम और पता वर्णित करें ।	
	3. कोर्निया स्कलेरल रिंग के संवर्धन और संवेदनशीलता के लिए सुविधा ।	हां/नहीं
ए.	रजिस्ट्रीकरण का नवीकरण : पिछले रजिस्ट्रीकरण के 5 वर्ष पश्चात् नवीकरण की अवधि । 5 वर्ष में न्यूनतम 500 कोर्निया एकत्रित किए जाने हैं । नेत्र बैंक मानकों को बनाए रखना (मार्गनिर्देश के अनुसार)	

3

2.	नेत्र पुनःप्राप्ति केन्द्र (ईआरसी)	
अ.	पुनःप्राप्ति केन्द्र - किसी नेत्र बैंक से सहबद्ध कोई केन्द्र 1. नाम 2. पता	

	3. सरकारी/निजी/स्वैच्छिक 4. शैक्षिक/गैर शैक्षिक 5. नेत्र दान के लिए सूचना, शिक्षा और संसूचना गतिविधियां 6. उस नेत्र बैंक की नाम जिससे ईआरसी सहबद्ध है ।	
आ.	नेत्र गोलक निकालना और भंडारण	
	1. जनशक्ति: नेत्र गोलक/कॉर्निया निकालने के लिए पर्याप्त प्रशिक्षित और अर्ह कार्मिक (ब्यौरा संलग्न करें) क. भार साधक/निदेशक-1 ख. तकनिशियन-1 ग. बहुकार्य कर्मचारिवृंद 2. भंडारण मीडियम के साथ परिवहन सुविधा (या आउटसोर्स)	
इ.	कर्मिकों के नाम, अर्हता और पते जो कॉर्निया निकालेंगे/हटाएंगे (ब्यौरे संलग्न करें)	
ई.	निम्नलिखित की उपलब्धता : 1. दूरभाष । (संख्या.....) 2. बाहर से नेत्र गोलक एकत्र करने के लिए परिवहन सुविधा : 3. अपेक्षा अनुसार संपूर्ण ग्लोब/कोर्निया निकालने के लिए उपकरणों का सैट 4. परिवहन के दौरान नेत्र गोलक/कोर्निया के परिरक्षण के लिए स्टैंड के साथ विशेष बोटलें । 5. उपयुक्त परिरक्षण मीडिया 6. जैव चिकित्सीय अपशिष्ट प्रबंधन 7. जैव चिकित्सीय अपशिष्ट प्रबंधन 8. अपेक्षित स्थान : अभिहित क्षेत्र	
उ.	अभिलेख 1. अभिलेख रखने के लिए व्यवस्था	
ऊ.	उपस्कर : 1. रोगाणुहीनता सुविधा 2. नेत्र गोलक/कोर्निया-1 के परिरक्षण के लिए तापमान मानीटरी के साथ प्रशीतक 3. पुनःप्राप्ति केन्द्र नेत्र बैंक से सहबद्ध है और केवल नेत्र बैंक कॉर्निया वितरण के लिए प्राधिकृत है ।	
3.	कॉर्नियल प्रत्यारोपण केन्द्र	
अ	1. प्रत्यारोपण केन्द्र/चिकित्सालय का नाम 2. पता : 3. सरकारी/निजी/स्वैच्छिक 4. शैक्षिक/गैर-शैक्षिक 5. नेत्र दान के लिए आईईसी : हां/नहीं 6. उक्तक उपाप्त करने के लिए रजिस्ट्रीकृत नेत्र बैंक का नाम	
आ	कर्मचारिवृंद ब्यौरे : 1. स्थायी कर्मचारिवृंद सदस्यों की उनके पदनाम के साथ सं० (टिप्पण : नेत्र शल्य चिकित्सक का अनुभव : एमडी/एमएस/डीएनबी/डीओ के पश्चात् तीन मास) 2. पदनाम के साथ अस्थायी कर्मचारिवृंद	
	3. केरेटोप्लास्टी और कॉर्नियल प्रत्यारोपण के लिए प्रशिक्षित व्यक्ति उनके नामों और अर्हताओं के साथ : 2 (संस्थान के वेतन रोल पर एक कॉर्नियल प्रत्यारोपण शल्यचिकित्सक होना चाहिए)	
इ	उपस्कर : स्लिट लैम्प, क्लीनिकल स्पेकुलर, केरेटोप्लास्टी या इंद्राँक्युलर उपकरण	
ई	ओटी सुविधाएं	
उ	सुरक्षित भंडारण सुविधा	
ऊ	अभिलेख रजिस्ट्रीकरण और अनुगमन	
ऋ	कोई अन्य सूचना	

उपलिखित सूचना मेरे सर्वोत्तम ज्ञान के अनुसार सत्य है और मुझे प्राधिकृत कार्मिक द्वारा हमारी सुविधा की संवीक्षा में कोई आपत्ति नहीं है ।
1000/-₹0 (नए रजिस्ट्रीकरण के लिए) और 5000/-₹0 (नवीकरण के लिए) का बैंक ड्राफ्ट/चैक.....के पक्ष में संलग्न है ।

संस्था प्रमुख
(नाम और पदनाम)

प्ररूप 16

**अंग/उक्तक प्रत्यारोपण/पुनःप्राप्ति और/या उक्तक बैंकिंग के लिए रजिस्ट्रीकरण का प्रमाणपत्र
(नियम 24(2) देखें)**

यह प्रमाणित किया जाता है कि.....पर स्थित.....चिकित्सालय/उक्तक बैंक का निरीक्षण कर लिया गया है और मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अधीन निम्नलिखित अंग(गों)/उक्तक(कों) (नामों का वर्णन करें) अंग/उक्तक पुनःप्राप्ति/प्रत्यारोपण/बैंकिंग के लिए रजिस्ट्रीकरण का प्रमाणपत्र अनुदत्त किया जाता है :-

1.
2.
3.
4.

यह रजिस्ट्रीकरण का प्रमाणपत्र जारी करने की तारीख से पांच वर्ष की अवधि के लिए विधिमाम्य है ।

यह अनुज्ञा प्रस्तुत आवेदन पर में दशित वर्तमान सुविधाओं और कर्मचारिवृद के साथ दी जा रही है । कर्मचारिवृद और/या सुविधा में कोई कमी अधोहस्ताक्षरी की जानकारी में लाई जानी चाहिए ।

समुचित प्राधिकारी के हस्ताक्षर.....
मुहर.....

स्थान.....
तारीख.....

प्ररूप 17

**रजिस्ट्रीकरण का नवीनीकरण प्रमाणपत्र
(लेटर हैड पर समुचित प्राधिकारी द्वारा प्रदान किया जाए)
[नियम 25(2) देखें]**

यह मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अधीन अंग (अंगों)/उक्तक(उक्तकों) के रिट्रीवल/प्रत्यारोपण करने/बैंक में रखने के लिए रजिस्ट्रीकरण के प्रमाणपत्र के नवीकरण के लिए.....(अस्पताल/उक्तक बैंक का नाम) से प्राप्त आवेदन पत्र, तारीख.....के संदर्भ में है ।

समुचित प्राधिकारी, पूर्वोक्त अस्पताल/उक्तक बैंक की सुविधाओं और मानकों पर विचार करने के उपरांत, उक्त अस्पताल/उक्तक बैंक के रजिस्ट्रीकरण प्रमाणपत्र पांच वर्ष की अवधि के लिए नवीकृत करता है ।

यह नवीकरण वर्तमान आवेदन प्ररूप में दर्शित विद्यमान सुविधाओं और कर्मचारिवृद के अनुसार प्रदान किया जा रहा है । कर्मचारिवृद और/या सुविधा में कोई भी कमी अधोहस्ताक्षरी के ध्यान में लाई जानी चाहिए ।

स्थान.....
तारीख.....

समुचित प्राधिकारी के हस्ताक्षर.....
मुद्रा.....

प्ररूप 18

जहां प्रत्यारोपण किया जाना है वहां अस्पताल की प्राधिकार समिति (यदि अस्पताल प्राधिकार समिति उपलब्ध नहीं है तो जिला/राज्य की प्राधिकार समिति) द्वारा प्रमाणपत्र

(लेटरहेड पर जारी किया जाए)
[नियम 16 और नियम 23 देखिए]

प्रमाणित किया जाता है कि दाता और प्रापक, जिसके ब्यारे और फोटो उनके पहचान और सत्यापन दस्तावेजों के साथ नीचे दिए गए हैं, द्वारा.....को प्रस्तुत मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अधीन निकट नातेदार/ स्वैप दान मामलों/ सभी विदेशी

व्यक्तियों से भिन्न जीवित दाता से.....(अंग/उतक का नाम) के प्रत्यारोपण के लिए प्ररूप 10 में आवेदन के अनुसार, मामले पर तारीख..... को आयोजित बैठक में प्राधिकार समिति द्वारा लागू किए गए अनुसार दाता और प्रापक (यदि चिकित्सीय रूप से साक्षात्कार लिए जाने के लिए योग्य हैं) के वैयक्तिक साक्षात्कार के पश्चात् विचार किया गया था ।

प्रापक के ब्यौरे

दाता के ब्यौरे

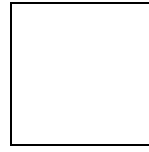
नाम.....
आयु.....
लिंग.....
पिता/ पति का नाम.....
.....
पता.....
.....
अस्पताल रजि. सं.....

नाम.....
आयु.....
लिंग.....
पिता/ पति का नाम.....
.....
पता.....
.....
अस्पताल रजि. सं.....

प्रापक के साथ दाता का संबंध.....



प्रापक



दाता

(प्रापक और दाता की फोटो हस्ताक्षरित होनी चाहिए और उसे चिपकाने के पश्चात् फोटो आरपार स्टांपित होनी चाहिए)

समिति के सदस्यों की सर्वोत्तम जानकारी के अनुसार स्नेह और अनुराग के कारण दान करने की अनुज्ञा प्रदान की जाती है और प्रापक तथा दाता के बीच कोई वित्तीय संव्यवहार नहीं है और दाता पर कोई दबाव या जबर्दस्ती नहीं है ।

निम्नलिखित दस्तावेजों.....
..... के प्रस्तुत किए जाने तक अनुज्ञा रोक दी गई है ।

निम्नलिखित कारणों.....
.....से अनुज्ञा प्रदान नहीं की गई है ।

(सदस्य)
नाम और पदनाम

(सदस्य)
नाम और पदनाम

(सदस्य)
नाम और पदनाम

(सदस्य)
नाम और पदनाम

(सदस्य)
स्वास्थ्य सचिव या
नामनिर्देशिती

(सदस्य)
स्वास्थ्य सेवानिदेशक या
नामनिर्देशिती
नाम और पदनाम

(स्टांप सहित अध्यक्ष के हस्ताक्षर)
नाम और पदनाम

तारीख और स्थान.....

*स्वैप प्रत्यारोपण की दशा में ब्यौरे उपाबद्ध किए जाएं ।

प्ररूप 19

पति या पत्नी से भिन्न भारतीय निकट नातेदार के मामलों के संबंध में [नियम 2(ग) में यथा परिभाषित] (पति या पत्नी दाता की दशा में प्ररूप 6 लागू होगा)

(नियम 5(3) (ग) देखिए)

(सक्षम प्राधिकारी के विनिश्चय के लिए रुपनिधान)

प्रमाणित किया जाता है कि दाता और प्रापक, जिसके ब्यौरे और फोटो उनके पहचान और सत्यापन दस्तावेजों के साथ नीचे दिए गए हैं, द्वारा.....को प्रस्तुत मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अधीन जीवित दाता जो प्रापक का निकट नातेदार है, से.....(अंग/उत्तक का नाम) के प्रत्यारोपण के लिए प्ररूप 11 में आवेदन के अनुसार, मामले पर तारीख..... को आयोजित बैठक में सक्षम प्राधिकारी द्वारा दाता और प्रापक (यदि चिकित्सीय रूप से साक्षात्कार लिए जाने के लिए योग्य है) के वैयक्तिक साक्षात्कार के पश्चात् विचार किया गया था ।

प्रापक के ब्यौरे

दाता के ब्यौरे

नाम.....
 आयु.....
 लिंग.....
 पिता/ पति का नाम.....

 पता.....

 अस्पताल रजि. सं.....

नाम.....
 आयु.....
 लिंग.....
 पिता/ पति का नाम.....

 पता.....

 अस्पताल रजि. सं.....



प्रापक



दाता

(प्रापक और दाता की फोटो हस्ताक्षरित होनी चाहिए और चिपकाने के पश्चात् फोटो आरपार स्टांपित होनी चाहिए)

समिति के सदस्यों की सर्वोत्तम जानकारी के अनुसार, उनके निकट नातेदार होने के कारण दान करने की अनुज्ञा प्रदान की जाती है और प्रापक तथा दाता के बीच कोई वित्तीय संव्यवहार नहीं है और दाता पर कोई दबाव या जबर्दस्ती नहीं है ।

निम्नलिखित दस्तावेजों
 के प्रस्तुत किए जाने तक अनुज्ञा रोक दी गई है ।

निम्नलिखित कारणों.....
 से अनुज्ञा प्रदान नहीं की गई है ।

प्ररूप 20

प्राप्तिकर्ता या दाता की अधिवास प्रास्थिति के संबंध में सत्यापन प्रमाण-पत्र

[प्रयोजन के लिए तहसीलदार या किसी अन्य प्राधिकृत अधिकारी द्वारा जारी किया जाएगा (केवल दाता निकट संबंधी के अतिरिक्त या प्राप्तिकर्ता के लिए आवश्यक जो उस राज्य से संबंध नहीं रखते जहां शल्य क्रिया के लिए चिन्हित प्रत्यारोपण अस्पताल अवस्थित है)]

[नियम 14 देखें]

भाग 1 (आवेदक दाता या प्राप्तिकर्ता द्वारा तीन अलग प्रतियों में भरा जाए)

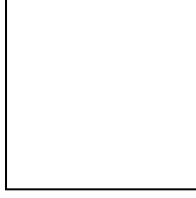
मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42), के अधीन, जीवित दाता (निकट संबंधी के अतिरिक्त) द्वारा.....(अंग/उत्तक का नाम) के दान के लिए अधिवास प्रास्थिति के सत्यापन के लिए, आवेदक दाता या प्राप्तिकर्ता द्वारा.....तारीख को, निम्नलिखित ब्यौरे और फोटो सहित, उसका या उसकी पहचान और सत्यापन के लिए अधिवास प्रास्थिति के साथ प्रस्तुत आवेदन के संदर्भ में आवेदक प्राप्तिकर्ता या दाता के ब्यौरे

नाम.....
 आयु.....
 लिंग.....
 पिता या पति का नाम.....

 पता :

.....

 अस्पताल की रजि० सं०.....



(आवेदक का नवीनतम फोटो चिपकाकर उस पर वो हस्ताक्षर करेगा)

मेरे दाता या प्राप्तिकर्ता के ब्यौरे निम्नलिखित है और मैंने उसके स्वहस्ताक्षरित नवीनतम फोटो संलग्न किया है :

नाम.....
 आयु.....
 लिंग.....
 पिता या पति का नाम.....

.....

पता :

.....

 अस्पताल की रजि० सं०.....

आवेदक के हस्ताक्षर

संलग्न : आवेदक के लिए दाता या प्राप्तिकर्ता के स्वहस्ताक्षरित प्रति (संलग्न की जाए)

भाग 2 (प्रमाण-पत्र जारीकर्ता प्राधिकारी द्वारा भरा जाए):

उपरोक्त निवेदन का परीक्षण कर लिया गया है और यह प्रमाणित किया जाता है कि आवेदक दाता या प्राप्तिकर्ता की ऊपर वर्णित अधिवास प्रास्थिति को निम्नलिखित सत्यापित किया जाता है :

नाम.....का/की पुत्र या पुत्री या पत्नी..... गांव या वार्ड.....तहसील या तालुक.....जिला.....

राज्य या केन्द्र शासित राज्य के निवासी है

और सही या गलत पाया

.....

तारीखस्थान.....

संदर्भ सं०.....

प्राधिकृत हस्ताक्षरी

नाम और पदनाम
 कार्यालय की मुहर

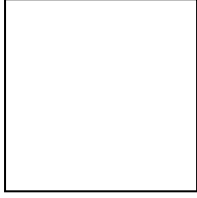
2. प्राधिकृत हस्ताक्षरी या सत्यापन प्रमाणपत्र आवेदक या उसके प्रतिनिधि को सौंप देगा, जिसे वह (यथास्थिति) अस्पताल या जिला या राज्य जहां प्रत्यारोपण होने वाला है, वहां की प्राधिकर्ता कमिटी के अध्यक्ष के सामने प्रस्तुत करेगा ।
3. प्राधिकृत हस्ताक्षरी इस सत्यापन प्रमाणपत्र की एक प्रति अपने अभिलेख के लिए रखेगा और एक प्रति राज्य सरकार के स्वास्थ्य एवं परिवार कल्याण सचिव (ध्यान दे अंग प्रत्यारोपण के लिए समुचित प्राधिकारी को सूचना के लिए भेजे)
4. अंग व्यापार की किसी शंका के मामले में, ऊपर वर्णित प्राधिकृत हस्ताक्षरी या राज्य के समुचित प्राधिकारी, मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अनुसार जांच और आवश्यक कार्यवाही के लिए पुलिस को सूचित करेगा ।

विदेशी व्यक्तियों की दशा में दाता और प्रापक के बीच संबंध का प्रमाणपत्र
(संबद्ध दूतावास द्वारा जारी किया जाए)

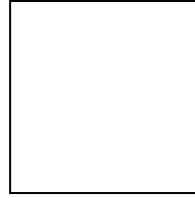
[नियम 20(क)]

भारत में.....(देश का नाम) के दूतावास को मानव अंग प्रत्यारोपण अधिनियम, 1994 (1994 का 42) के अधीन चिकित्सीय प्रयोजनों के लिए प्रापक.....(प्रापक का नाम) को जीवित दाता.....
(दाता का नाम) से.....(अंग या उत्तक के नाम) के दान की सुविधा के लिए.....(मूल के देश के सरकारी विभाग का नाम) द्वारा सिफारिश की गई(तारीख) को.....(अंग दाता और प्रापक का नाम) से आवेदन प्राप्त हुआ है दाता और प्रापक के ब्यौरे तथा फोटो नीचे दी गई हैं ।

प्रापक के ब्यौरे	दाता के ब्यौरे
नाम.....	नाम.....
आयु.....	आयु.....
लिंग	लिंग
पिता या पति का नाम.....	पिता या पति का नाम.....
.....
पता	पता
.....
.....



प्रापक



दाता

(फोटो चिपकाने के पश्चात् प्रापक और दानदाता के फोटो हस्ताक्षरित एवं आरपार स्टांपित होना चाहिए)

1. यह प्रमाणित किया जाता है कि दाता और प्रापक बीचका संबंध है ।
2. निम्नलिखित संलग्न पहचान और सत्यापन दस्तावेजों की अधिप्रमाणिकता प्रमाणित की जाती है ।
क.....
ख.....

मेरी सर्वोत्तम जानकारी के अनुसार, अनापत्ति प्रमाणपत्र प्रदान किया जाता है, दाता प्रापक के प्रति स्नेह और अनुराग या मोह के कारण दान कर रहा है और प्रापक तथा दाता के बीच कोई वित्तीय संव्यवहार नहीं है और दाता पर कोई दबाव या जबरदस्ती नहीं है ।

(ज्येष्ठ दूतावास पदाधिकारी के हस्ताक्षर)

तारीख :

नाम :

स्थान :

पदनाम.....

[फा. सं. एस-12011/28/2012-एमजी/एमएस]

अरुण के.पण्डा, संयुक्त सचिव

**MINISTRY OF HEALTH AND FAMILY WELFARE
NOTIFICATION**

New Delhi, the 27th March, 2014.

G.S.R. 218 (E).— In exercise of the powers conferred by section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994) and in supersession of the Transplantation of Human Organs Rules, 1995, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely:-

1. **Short title and commencement** — (1) These rules may be called the Transplantation of Human Organs and Tissues Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. **Definitions:** - In these rules unless the context otherwise requires,—

(a) “Act” means the Transplantation of Human Organs Act, 1994;

(b) “cadaver(s)”, “organ(s)” and “tissue(s)” means human cadaver(s), human organ(s) and human tissue(s), respectively;

- (c) “competent authority” means the Head of the institution or hospital carrying out transplantation or committee constituted by the head of the institution or hospital for the purpose;
- (d) “Form” means a Form annexed to these rules;
- (e) National Accreditation Board for Testing and Calibration Laboratories (NABL) means the autonomous body established under the aegis of Department of Science and Technology, Government of India with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognising the technical competence of laboratories and the accreditation services are provided for testing and calibration of medical laboratories in accordance with International Organisation for Standardisation (ISO) Standards;
- (f) “the technician who can enucleate cornea” means the technician with any of the following qualifications and experience who can harvest corneas (enucleate eyeballs or excise corneas), namely:-
 - (i) Ophthalmologists possessing a Doctor of Medicine (M.D) or Master of Surgery (M.S) in Ophthalmology or Diploma in Ophthalmology (D.O.); and
 - (ii) registered Doctors from all recognised systems of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Refractionists, Paramedical Worker or Medical Technician with recognised qualification from all recognised systems of medicine, provided the person is duly trained to enucleate a donated cornea or eye from registered, authorised and functional eye Bank or Government medical college and, the training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye or removal of cornea from a cadaver;
- (g) words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings, respectively, assigned to them in the Act.

3. **Authority for removal of human organs or tissues.**—Subject to the provisions of Section 3 of the Act, a living person may authorise the removal of any organ or tissue of his or her body during his or her lifetime as per prevalent medical practices, for therapeutic purposes in the manner and on such conditions as specified in Form 1, 2 and 3.

4. **Panel of experts for brain-stem death certification.**—For the purpose of certifying the brain-stem death, the Appropriate Authority shall maintain a panel of experts, in accordance with the provisions of the Act, to ensure efficient functioning of the Board of Medical Experts and it remains fully operational.

5. **Duties of the registered medical practitioner.**— (1) The registered medical practitioner of the hospital having Intensive Care Unit facility, in consultation with transplant coordinator, if available, shall ascertain, after certification of brain stem death of the person in Intensive Care Unit, from his or her adult near relative or, if near relative is not available, then, any other person related by blood or marriage, and in case of unclaimed body, from the person in lawful possession of the body the following, namely:-

- (a) whether the person had, in the presence of two or more witnesses (at least one of who is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license, etc. wherein the provision for donation may be incorporated after notification of these rules, the removal of his or her organ(s) or tissue(s) including eye, after his or her death, for therapeutic purposes and there is no reason to believe that the person had subsequently revoked the aforesaid authorisation;
 - (b) where the said authorisation was not made by the person to donate his or her organ(s) or tissue(s) after his or her death, then the registered medical practitioner in consultation with the transplant coordinator, if available, shall make the near relative or person in lawful possession of the body, aware of the option to authorise or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye or cornea of the deceased person and a declaration or authorisation to this effect shall be ascertained from the near relative or person in lawful possession of the body as per Form 8 to record the status of consent, and in case of an unclaimed body, authorisation shall be made in Form 9 by the authorised official as per sub-section (1) of section 5 of the Act;
 - (c) after the near relative or person in lawful possession of the body authorises removal and gives consent for donation of human organ(s) or tissue(s) of the deceased person, the registered medical practitioner through the transplant coordinator shall inform the authorised registered Human Organ Retrieval Centre through authorised coordinating organisation by available documentable mode of communication, for removal, storage or transportation of organ(s) or tissue(s).
- (2) The above mentioned duties shall also apply to the registered medical practitioner working in an Intensive Care Unit in a hospital not registered under this Act, from the date of notification of these rules.
- (3) The registered medical practitioner shall, before removing any human organ or tissue from a living donor, shall satisfy himself –
- (a) that the donor has been explained of all possible side effects, hazards and complications and that the donor has given his or her authorisation in appropriate Form 1 for near relative donor or Form 2 for spousal donor or Form 3 for donor other than near relative;

- (b) that the physical and mental evaluation of the donor has been done, he or she is in proper state of health and it has been certified that he or she is not mentally challenged and that he or she is fit to donate the organ or tissue:

Provided that in case of doubt regarding mentally challenged status of the donor the registered medical practitioner may get the donor examined by a psychiatrist and the registered medical practitioner shall sign the certificate as prescribed in Form 4 for this purpose;

- (c) that the donor is a near relative of the recipient, as certified in Form 5, and that he or she has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority as defined at rule 2(c) and specified in Form 19 and that the necessary documents as prescribed and medical tests, as required, to determine the factum of near relationship, have been examined to the satisfaction of the registered medical practitioner and the competent authority;
- (d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2 and has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority under the provisions of sub-rule (2) of rule 7;
- (e) that in case of a donor who is other than a near relative and has signed Form 3 and submitted an application in Form 11 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained;
- (f) that if a donor or recipient is a foreign national, the approval of the Authorisation Committee for the said donation has been obtained;
- (g) living organ or tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the State Government concerned.
- (4) A registered medical practitioner, before removing any organ or tissue from the body of a person after his or her death (deceased donor), in consultation with transplant coordinator, shall satisfy himself the following, namely:-
- (a) that caution has been taken to make inquiry, from near relative or person in lawful possession of the body of a person admitted in Intensive Care Unit, only after certification of Brain Stem death of the person that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license etc. (wherein the provision for donation may be incorporated after notification of these rules), the removal of his or her organ(s) or tissue(s) after his or her death, for therapeutic purposes and it has been ascertained that the donor has not subsequently revoked the aforesaid authorisation, and the consent of near relative or person in lawful possession of the body shall also be required notwithstanding the authorisation been made by deceased donor:
- Provided that if the deceased person who had earlier given authorisation but had revoked it subsequently and if the person had given in writing that his organ should not be removed after his death, then, no organ or tissue will be removed even if consent is given by the near relative or person in lawful possession of the body;
- (b) that the near relative of the deceased person or the person lawfully in possession of the body of the deceased donor has signed the declaration as specified in Form 8.
- (c) that in the case of brain-stem death of the potential donor, a certificate as specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act:
- Provided that where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empanelled by Appropriate Authority may certify the brain stem death as a member of the said Board;
- (d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 8 has been signed by either of the parents of such person or any near relative authorised by the parent.

6. Procedure for donation of organ or tissue in medicolegal cases.— (1) After the authority for removal of organs or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.

- (2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardised.
- (3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in postmortem notes by the registered medical practitioner doing postmortem.

- (4) Wherever it is possible, attempt should be made to request the designated postmortem registered medical practitioner, even beyond office timing, to be present at the time of organ or tissue retrieval.
- (5) In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated postmortem centre and the post mortem centre shall undertake the postmortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

7 Authorisation Committee.—(1) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

- (2) When the proposed donor or recipient or both are not Indian nationals or citizens whether near relatives or otherwise, the Authorisation Committee shall consider all such requests and the transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.
- (3) When the proposed donor and the recipient are not near relatives, the Authorisation Committee shall,
 - (i) evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person;
 - (ii) prepare an explanation of the link between them and the circumstances which led to the offer being made;
 - (iii) examine the reasons why the donor wishes to donate;
 - (iv) examine the documentary evidence of the link, e.g. proof that they have lived together, etc.;
 - (v) examine old photographs showing the donor and the recipient together;
 - (vi) evaluate that there is no middleman or tout involved;
 - (vii) evaluate that financial status of the donor and the recipient by asking them to give appropriate evidence of their vocation and income for the previous three financial years and any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;
 - (viii) ensure that the donor is not a drug addict;
 - (ix) ensure that the near relative or if near relative is not available, any adult person related to donor by blood or marriage of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ or tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong views or disagreement or objection of such kin shall also be recorded and taken note of.
- (4) Cases of swap donation referred to under subsection (3A) of section 9 of the Act shall be approved by Authorisation Committee of hospital or district or State in which transplantation is proposed to be done and the donation of organs shall be permissible only from near relatives of the swap recipients.
- (5) When the recipient is in a critical condition in need of life saving organ transplantation within a week, the donor or recipient may approach hospital in-charge to expedite evaluation by the Authorisation Committee.

8. Removal and preservation of organs or tissues.—The removal of the organ(s) or tissue(s) shall be permissible in any registered retrieval or transplant hospital or centre and preservation of such removed organ(s) or tissue(s) shall be ensured in registered retrieval or transplant centre or tissue bank according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

9. Cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues.—The cost for maintenance of the cadaver (brain-stem dead declared person), retrieval of organs or tissues, their transportation and preservation, shall not be borne by the donor family and may be borne by the recipient or institution or Government or non-Government organisation or society as decided by the respective State Government or Union territory Administration.

10. Application for living donor transplantation.—(1) The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the competent authority or Authorisation Committee as specified in Form 11 and the papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation.

(2) The competent authority or Authorisation Committee shall take a decision on such application in accordance with the rule 18.

(3) If some State wants to merge Form 11 with Form 1, Form 2 or Form 3, they may do so, provided the content of the recommended Forms are covered in the merged Form and the same is approved by the State Government concerned.

11. Composition of Authorisation Committees.—(1) There shall be one State level Authorisation Committee.

(2) Additional Authorisation Committees in the districts or Institutions or hospitals may be set up as per norms given below, which may be revised from time to time by the concerned State Government or Union territory Administration by notification.

(3) No member from transplant team of the institution should be a member of the respective Authorisation Committee.

(4) Authorisation Committee should be hospital based if the number of transplants is twenty five or more in a year at the respective transplantation centres, and if the number of organ transplants in an institution or hospital are less than twenty-five in a year, then the State or District level Authorisation Committee would grant approval(s).

12. **Composition of hospital based Authorisation Committees.**— The hospital based Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

- (a) the Medical Director or Medical Superintendent or Head of the institution or hospital or a senior medical person officiating as Head - Chairperson;
- (b) two senior medical practitioners from the same hospital who are not part of the transplant team – Member;
- (c) two persons (preferably one woman) 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 University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;
- (d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration - Member.

13. **Composition of State or District Level Authorisation Committees.**— The State or District Level Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

- (a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main or major Government hospital of the District – Chairperson;
- (b) two senior registered 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– Member;
- (c) two persons (preferably one woman) 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 University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;
- (d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration–Member :

Provided that effort shall be made by the State Government concerned to have most of the members' ex-officio so that the need to change the composition of Committee is less frequent.

14. **Verification of residential status, etc.**—When the living donor is unrelated and if donor or recipient belongs to a State or Union territory, other than the State or Union territory where the transplantation is proposed to be undertaken, verification of residential status by Tehsildar or any other authorised officer for the purpose with a copy marked to the Appropriate Authority of the State or Union territory of domicile of donor or recipient for their information shall be required, as per Form 20 and in case of any doubt of organ trafficking, the Appropriate Authority of the State or Union territory of domicile or the Tehsildar or any other authorised officer shall inform police department for investigation and action as per the provisions of the Act.

15. **Quorum of Authorisation Committee.**— The quorum of the Authorisation Committee should be minimum four and the quorum shall not be complete without the participation of the Chairman, the presence of Secretary (Health) or nominee and Director of Health Services or nominee.

16. **Format of approval of Authorisation Committee.**— The format of the Authorisation Committee approval should be uniform in all the institutions in a State and the format may be notified by the respective State Government as per Form 18.

17. **Scrutiny of applications by Authorisation Committee.**— (1) Secretariat of the Authorisation Committee shall circulate copies of all applications received from the proposed donors and recipients to all members of the Committee along with all annexures, which may have been filed along with the applications.

(2) 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 concerned officer(s) of the State Government or Union territory Administration.

18. **Procedure in case of near relatives.**— (1) Where the proposed transplant of organs is between near relatives related genetically, namely, grandmother, grandfather, mother, father, brother, sister, son, daughter, grandson and granddaughter, above the age of eighteen years, the competent authority as defined at rule 2(c) or Authorisation Committee (in case donor or recipient is a foreigner) shall evaluate;

- (i) documentary evidence of relationship e.g. relevant birth certificates, marriage certificate, other relationship certificate from Tehsildar or Sub-divisional magistrate or Metropolitan Magistrate or

Sarpanch of the Panchayat, or similar other identity certificates like Electors Photo Identity Card or AADHAAR card; and

- (ii) documentary evidence of identity and residence of the proposed donor, ration card or voters identity card or passport or driving license or PAN card or bank account and family photograph depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR Card (issued by **Unique Identification Authority of India**).

- (2) If in the opinion of the competent authority, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical test, namely, Deoxyribonucleic Acid (DNA) Profiling.
- (3) The test referred to in sub-rule (2) shall be got done from a laboratory accredited with National Accreditation Board for Testing and Calibration Laboratories and certificate shall be given in Form 5.
- (4) If the documentary evidences and test referred to in sub-rules (1) and (2), respectively do not establish a genetic relationship between the donor and the recipient, the same procedure be adopted on preferably both or at least one parent, and if parents are not available, the same procedure be adopted on such relatives of donor and recipient as are available and are willing to be tested, failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.
- (5) Where the proposed transplant is between a married couple the competent authority or Authorisation Committee (in case donor or recipient is a foreigner) must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and a family photograph depicting the entire family, birth certificate of children containing the particulars of parents and issue a certificate in Form 6 (for spousal donor).
- (6) Any document with regard to the proof of residence or 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 Competent Authority or Authorisation Committee as the case may be, may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.
- (7) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a competent authority of the transplant hospital.
- (8) The competent authority may seek the assistance of the Authorisation Committee in its decision making, if required.

19. **Procedure in case of transplant other than near relatives.—**

Where the proposed transplant is between other than near relatives and all cases where the donor or recipient is foreign national (irrespective of them being near relative or otherwise), the approval will be granted by the Authorisation Committee of the hospital or if hospital based Authorisation Committee is not constituted, then by the District or State level Authorisation Committee.

20. **Procedure in case of foreigners.—**

When the proposed donor or the recipient are foreigners;

- (a) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 21 and in case a country does not have an Embassy in India, the certificate of relationship, in the same format, shall be issued by the Government of that country;
- (b) the Authorisation Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution and such cases should be considered rarely on case to case basis:
Provided that the Indian living donors wanting to donate to a foreigner other than near relative shall not be considered.

21. **Eligibility of applicant to donate.—** In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee which shall be videographed and minutes of the interview shall be recorded.

22. **Precautions in case of woman donor.—**

In case where the donor is a woman, greater precautions ought to be taken and her identity and independent consent should be confirmed by a person other than the recipient.

23. **Decision of Authorisation Committee.—** (1) The Authorisation Committee (which is applicable only for living organ or tissue donor) should state in writing its reason for rejecting or approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions, namely:-

- (i) the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his or her biological capacity and compatibility to donate the organ in question;
- (ii) the physical and mental evaluation of the donor has been done to know whether he or she is in proper state of health and it has been certified by the registered medical practitioner in Form 4 that he or she is not mentally challenged and is fit to donate the organ or tissue:

Provided that in case of doubt for mentally challenged status of the donor the registered medical practitioner or Authorisation Committee may get the donor examined by psychiatrist;

- (iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation;
- (iv) all interviews to be video recorded.
- (2) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on urgent basis.
- (3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant.
- (4) The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden.

24. Registration of hospital or tissue bank.— (1) An application for registration shall be made to the Appropriate Authority as specified in Form 12 or Form 13 or Form 14 or Form 15, as applicable and the application shall be accompanied by fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be:-

- (i) for Organ or Tissue or Cornea Transplant Centre: Rupees ten thousand;
- (ii) for Tissue or Eye Bank: Rupees ten thousand;
- (iii) for Non-Transplant Retrieval Centre: Nil.
- (2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 16 and it shall be valid for a period of five years from the date of its issue and shall be renewable.
- (3) Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to appoint a transplant coordinator.

25. Renewal of registration of hospital or tissue bank.— (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority at least three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be,-

- (i) for Organ or Tissue or Cornea Transplant Centre: Rupees five thousand;
- (ii) for Tissue or Eye Bank: Rupees five thousand;
- (iii) for Non-Transplant Retrieval Centre: Nil.
- (2) A renewal certificate of registration shall be as specified in Form 17 and shall be valid for a period of five years.
- (3) If, after an inquiry including inspection of the hospital or tissue bank and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of rule 24 has not complied with the requirements of the Act and these rules and the conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

26. Conditions and standards for grant of certificate of registration for organ or tissue transplantation centres.— (1) No hospital shall be granted a certificate of registration for organ transplantation unless it fulfills the following conditions and standards, namely:-

A. General manpower requirement specialised services and facilities:

- (a) Twenty-four hours availability of medical and surgical, (senior and junior) staff;
- (b) twenty-four hours availability of nursing staff (general and specialty trained);
- (c) twenty-four hours availability of Intensive Care Units with adequate equipment staff and support system, including specialists in anesthesiology and intensive care;
- (d) twenty-four hours availability of blood bank (in house or access) , laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology,-Hematology and Radiology departments with trained staff;
- (e) twenty-four hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipment;
- (f) twenty-four 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;
- (g) experts (other than the experts required for the relevant transplantation) of relevant and associated specialties including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, pediatrics, gynecology, immunology and cardiology, etc., shall be available in the transplantation centre;

- (h) one medical expert for respective organ or tissue transplant shall be available in the transplantation hospital; and
- (i) Human Leukocyte Antigen (HLA) matching facilities (in house or outsourced) shall be available.

B. Equipments:

Equipments as per current and expected scientific requirements specific to organ (s) or tissue (s) being transplanted and the transplant centre should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support system in relation to all relevant equipments.

C. Experts and their qualifications:

- (a) Kidney Transplantation:
M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised transplant 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 three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant center;
- (c) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:
M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three 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) the hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010 (23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;
- (e) the hospital registered shall have to maintain documentation and records including reporting of adverse events.
- (2) No hospital shall be granted a certificate of registration for tissue transplantation under the Act unless it fulfills the following conditions and standards, namely:-
 - (a) Cornea Transplantation:
M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or M.S or DO training in Corneal transplant operations in a recognised hospital or institution;
 - (b) Other tissues such as heart valves, skin, bone, etc.:
Post graduate degree (MD or MS) or equivalent qualification in the respective specialty with three months post M.D. or M.S training in a recognised hospital carrying out respective tissue transplant operations and for heart valve transplantation, and the qualification and experience of expert shall be MCh degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation;
 - (c) the Hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010(23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;
 - (d) the Hospital registered shall have to maintain documentation and records including reporting of adverse events.

27. Conditions and standards for grant of certificate of registration for organ retrieval centres.—

- (1) The retrieval center shall be registered only for the purpose of retrieval of organ from deceased donors and the organ retrieval centre shall be a hospital having Intensive Care Unit (ICU) facilities along with manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including the facility for their temporary storage.
- (2) All hospitals registered as transplant centres shall automatically qualify as retrieval centres.
- (3) The retrieval centre should have linkages with nearby Government hospital designated for post-mortem, for retrieval in medico-legal cases.
- (4) Registration of hospital for surgical tissue harvesting from deceased person and for surgical tissue residues, that are routinely discarded, shall not be required.

28. Conditions and standards for grant of certificate of registration for tissue banks.—

A. Facility and premises:

- (1) Facilities must conform to the standards and guidelines laid down for the purpose and the States and Union territories may have separate registration fee and procedure to keep track of their tissue bank activities.
- (2) The respective State or Union territory Appropriate Authority may constitute an expert committee for advising on the matter related to tissue specific standards and related issues.
- (3) The tissue bank must have written guidelines and standard operating procedures for maintenance of its premises and facilities which include-
 - (a) controlled access;
 - (b) cleaning and maintenance systems;
 - (c) waste disposal;

- (d) health and safety of staff;
- (e) risk assessment protocol; and
- (f) follow up protocol.

- (4) Equipments as per scientific requirements specific to tissue (s) being procured, processed, stored and distributed and the tissue bank should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support for all equipments.
- (5) Air particle count and microbial colony count compliance shall be ensured for safety where necessary.
- (6) Storage area shall be designated to avoid contact with chemicals or atmospheric contamination and any known source of infection.
- (7) Storage facility shall be separate and distinguish tissues, held in quarantine, released and rejected.

B. Donor screening:

- (8) Complete screening of donor must be conducted including medical or social history and serological evaluation for medical conditions or disease processes that would contraindicate the donation of tissues and the report of corneas or eyes not found suitable for transplantation and their alternate use shall be certified by a committee of two Ophthalmologists.

C. Laboratory tests:

- (9) Facility for relevant Laboratory tests for blood and tissue samples shall be available and testing of blood and tissue samples shall begin at Donor Screening and continue during retrieval and throughout processing.

D. Procurement and other procedures:

- (10) Procurement of tissue must be carried out by registered health care professionals or technicians having necessary experience or special training.
- (11) Consent for the procurement shall be obtained.
- (12) Procurement records shall be maintained.
- (13) Standard operating procedure for following shall be followed, namely :-
 - (a) procurement or Retrieval and transplantation;
 - (b) processing and sterilisation;
 - (c) packaging, labeling and storage;
 - (d) distribution or allocation;
 - (e) transportation; and
 - (f) reporting of serious adverse reactions.

E. Documentation and Records:

- (14) A log of tissue received and distributed shall be maintained to enable traceability from the donor to the tissue and the tissue to the donor and the records shall also indicate the dates and the identities of the staff performing specific steps in the removal or processing or distribution of the tissues.

F. Data Protection and Confidentiality:

- (15) A unique donor identification number shall be used for each donor, and access to donor records shall be restricted.

G. Quality Management:

- (16) The Quality Management System shall define quality control procedures that include the following, namely:-
 - (a) environmental monitoring;
 - (b) equipment maintenance and monitoring;
 - (c) in-process controls monitoring;
 - (d) internal audits including reagent and supply monitoring;
 - (e) compliance with reference standards, local regulations, quality manuals or documented standard operating procedures; and
 - (f) monitoring work environment.

H. Recipient Information:

- (17) All tissue recipients shall be followed up and prompt and appropriate corrective and preventive actions taken in case of adverse events.

29. Qualification, role, etc., of transplant coordinator.— (1) The transplant coordinator shall be an employee of the registered hospital having qualification such as:

- (a) graduate of any recognised system of medicine; or
- (b) Nurse; or
- (c) Bachelor's degree in any subject and preferably Master's degree in Social work or Psychiatry or Sociology or Social Science or Public Health

- (2) The concerned organisation or institute shall ensure initial induction training followed by retraining at periodic interval and the transplant coordinator shall counsel and encourage the family members or near relatives of the

deceased person to donate the human organ or tissue including eye or cornea and coordinate the process of donation and transplantation.

- (3) The transplant coordinator or counselor in a hospital registered for eye banking shall also have qualification specified in sub-rule (1).

30. Advisory committee of the Central or State Government to aid and advise appropriate authority.— (1) The Central Government and the State Government, as the case may be, shall constitute by notification an Advisory Committee under Chairpersonship of administrative expert not below the rank of Secretary to the State Government for a period of two years to aid and advise the Appropriate Authority and the two medical experts referred to in clause(b) of sub-section(2) of section 13A of the Act shall possess a postgraduate medical degree and at least five years' experience in the field of organ or tissue transplantation.

(2) The terms and conditions for appointment to the Advisory Committee are as under:

- (a) the Chairperson and members of the Committee shall be appointed for a period of two years;
- (b) the Chairperson and members of the Committee shall be entitled to the air fare and other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India;
- (c) the Central Government or State Government or Union territory Administration shall have full powers to replace or remove the Chairperson and the members in cases of charges of corruption or any other charges after giving a reasonable opportunity of being heard;
- (d) the Chairperson and members can also resign from the Committee for personal reasons;
- (e) there shall not be a corruption or criminal case pending against Chairperson and members at the time of appointment;
- (f) the Chairperson or any of the members shall cease to function if charges have been framed against him or her in a corruption or criminal case after having been given a reasonable opportunity of being heard.

31. Manner of establishing National or Regional or State Human Organs and Tissues Removal and Storage Networks and their functions.— (1) There shall be an apex national networking organisation at the centre, as the Central Government may by notification specify.

- (2) There shall also be regional and State level networking organisations where large number of transplantation of organ(s) or tissue (s) are performed as the Central Government may by notification specify.
- (3) The State units would be linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to regional and national networking organisations.
- (4) The broad principles of organ allocation and sharing shall be as under,—
 - (a) The website of the transplantation center shall be linked to State or Regional cum State or National networks through an online system for organ procurement, sharing and transplantation.
 - (b) patient or recipient may get registered through any transplant centre, but only one centre of a State or region (if there is no centre in the State) and his or her details shall be made available online to the networking organisations, who shall allocate the registration number, which shall remain same even if patient changes hospital;
 - (c) the allocation of the organ to be shared, is to be decided by the State networking organization and by the National networking organization in case of Delhi;
 - (d) all recipients are to be listed for requests of organs from deceased donors, however priority is to be given in following order, namely:-
 - (i) those who do not have any suitable living donor among near relatives;
 - (ii) those who have a suitable living donor available among near relatives but the donor has refused in writing to donate; and
 - (iii) those who have a suitable living donor available and who has also not refused to donate in writing;
 - (e) sequence of allocation of organs shall be in following order: State list----Regional List-----National List---- Person of Indian Origin ----Foreigner;
 - (f) the online system of networking and framework and formats of national registry as mentioned under rule 32 shall be developed by the apex networking organisation which shall be followed by the States Governments or Union territory Administrations and the allocation criteria may be State specific which shall be finalised and determined by the State Government, in consultation with the State level networking organisation, wherever such organisation exists:
 Provided that the organ sharing and networking policy of States or locations of hospitals shall not be binding on the Armed Forces Medical Services (AFMS) and the armed forces shall be free to have their own policy of organ or tissue allocation and sharing, and the Director General Armed Forces Medical Services shall have its own networking between the Armed Forces Medical Services hospitals, who shall be permitted to accept organs when available from hospitals with in their State jurisdiction.

- (5) The networking organisations shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.
- (6) The networking organisations shall coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.
- (7) There shall be designated organ and tissue retrieval teams in State or District or institution as per requirement, to be constituted by the State or Regional networking organisation.
- (8) For tissue retrieval, the retrieval teams shall be formed by the State Government or Union territory Administration where ever required.
- (9) Networking shall be e-enabled and accessible through dedicated website.
- (10) Reference or allocation criteria would be developed and updated regularly by networking organisations in consultation with the Central or State Government, as the case may be.
- (11) The networking organisation(s) shall undertake Information Education and Communication (IEC) Activities for promotion of deceased organ and tissue donation.
- (12) The networking organisation(s) shall maintain and update organ or tissue Donation and Transplant Registry at respective level.

32. Information to be included in National Registry regarding donors and recipients of human organ and tissue.— The national registry shall be based on the following, namely:-

Organ Transplant Registry:

- (1) The Organ Transplant Registry shall include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list, etc., and the data shall be collected from all retrieval and transplant centers.
- (2) Data collection frequency, etc., will be as per the norms decided by the Advisory Committee which may preferably be through a web-based interface or paper submission and the information shall be maintained both specific organ wise and also in a consolidated format.
- (3) The hospital or Institution shall update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable detail of each transplantation and the same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government.
- (4) Yearly reports shall be published and also shared with the contributing units and other stakeholders and key events (new patients, deaths and transplants) shall be notified as soon as they occur in the hospital and this information shall be sent to the respective networking organisation, at least monthly.

Organ Donation Registry:

- (5) The Organ Donation Registry shall include demographic information on donor (both living and deceased), hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

Tissue Registry:

- (6) The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.
- (7) Yearly reports in respect of National Registry shall be published and also shared with the contributing units and other stakeholders

Pledge for organ or tissue donation after death:

- (8) Those persons, who, during their lifetime have pledged to donate their organ(s) or tissue(s) after their death, shall in Form 7 deposit it in paper or electronic mode to the respective networking organisation(s) or institution where the pledge is made, who shall forward the same with the respective networking organisation and the pledger has the option to withdraw the pledge through intimation.
- (9) The Registry will be accessible on-line through dedicated website and shall be in conformation to globally maintained registry (ies), besides having national, regional and State level specificities.
- (10) National or regional registry shall be compiled based on similar registries at State level.
- (11) The identity of the people in the database shall not be put in public domain and measures shall be taken to ensure security of all collected information.
- (12) The information to be included shall be updated as per prevalent global practices from time to time.

33. Appeal.— (1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9 or by an order of the Appropriate Authority under sub-section (2) of section 15 or sub-section (2) of section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government in case of the Union territories and respective State Government in case of States.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

FORM 1

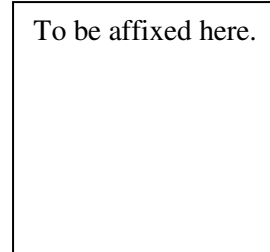
For organ or tissue donation from identified living near related donor

(to be completed by him or her)

(See rules 3 and 5(3)(a))

My full name (proposed donor) is

and this is my photograph



Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

My permanent home address is

.....

.....Tel:

My present address for correspondence is

.....

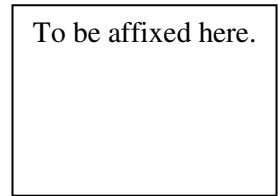
..... Tel:.....

Date of birth(day/month/year)

I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place:.....
and/or
- Voter's I-Card number, date of issue, Assembly constituency.....
and/or
- Passport number and country of issue.....
and/or
- Driving License number, Date of issue, licensing authority.....
and/or
- Permanent Account Number (PAN).....
and/or
- AADHAAR No.
and/or
- Any other valid proof of identity and address reflecting near relationship
.....

I authorise removal for therapeutic purposes and consent to donate my
(Name of organ/tissue) to my relative (Specify son/daughter/father/mother/ brother/sister/grand-
father/grand-mother/grand-son/grand-daughter), whose particulars are as follows and name is
..... and who was born on
.....(day/month/year) :



Photograph of the Recipient
(Attested by Notary Public
across the photo after affixing)

The copies of following documents of recipient are enclosed (attach attested photocopy of at least two relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place:.....
and/ or

- Voter's I-Card number, date of issue, Assembly constituency.....
and/or
- Passport number and country of issue.....
and/ or
- Driving License number, Date of issue, licensing authority.....
and/or
- Permanent Account Number (PAN)
and/or
- AADHAAR No (Issued by Unique Identification Authority of India).
and/or
- Any other valid proof of identity and address reflecting near relationship
.....

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 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 (name of organ/tissue) 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 (name of organ)/tissue). 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 the best of my knowledge and belief and nothing material has been concealed by me.

.....

.....

Date

Signature of the prospective donor
(Full Name)

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.

FORM 2

For organ or tissue donation by living spousal donor

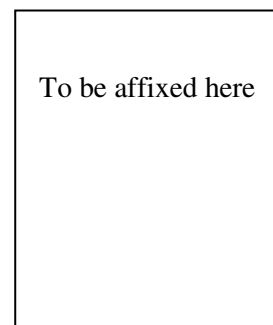
*(To be completed by him/her)
(See rules 3, 5(3)(a) and 5(3)(d))*

My full name (proposed donor) is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

To be affixed here

My permanent home address is



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

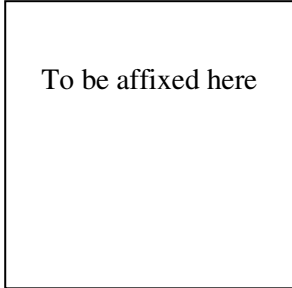
My present address for correspondence is

..... Tel:

Date of birth(day/month/year)

I authorize removal for therapeutic purposes and consent to donate my (Name of organ) to my husband/wife..... whose particulars are as follows and full name is and who was born on (Day/month/year):

Photograph of the Recipient
(Attested by Notary Public
across the photo after affixing)



I enclose copies of the following documents **(attach attested photocopy of at least two of following relevant documents to indicate the spousal relationship):**

- Ration/Consumer Card number and Date of issue and place:.....
and/or
- Voter’s Identity-Card number, date of issue, Assembly constituency.....
and/or
- Passport number and country of issue.....
and/or
- Driving License number, Date of issue, licensing authority.....
and/or
- Permanent Account Number (PAN)
.....
and/or
- AADHAAR No. (issued by Unique Identification Authority of India)
.....
and/or
- Any other proof of identity and address establishing spousal relationship
.....

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

- (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 Head of Gram Panchayat / Tehsildar / Block Development Officer/Member of Legislative Assembly/Member of Legislative Council (MLC)/Member of Parliament with seal certifying factum and status of marriage.

OR

- (e) Other credible evidence

I solemnly affirm and declare that sections 2, 9 and 19 of the Transplantation of Human Organs Act, 1994 (42 of 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 authorisation to remove my (organ) and consent to donate the same ,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 to the best of my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor
(Full Name)

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

FORM 3

For organ or tissue donation by other than near relative living donor

(To be completed by him/her)
(See rules 3, 5(3)(a) and 5(3)(e))

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

To be affixed here

My permanent home address is Tel:

My present address for correspondence is Tel:.....

Date of birth (day/month/year)

I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to prove your identity):

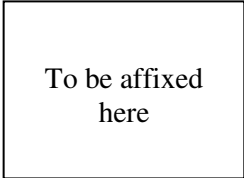
- Ration/Consumer Card number and Date of issue and place:.....
(Photocopy attached)
and/or
- Voter's I-Card number, date of issue, Assembly constituency.....
(Photocopy attached)
and/or
- Passport number and country of issue.....
(Photocopy attached)
and/or
- Driving Licence number, Date of issue, licensing authority.....
(Photocopy attached)
and/or
- PAN.....

- AADHAAR No..... and/or
- Other proof of identity and address and/or

Details of last three years income and vocation of donor (enclose documentary evidence)

I authorize removal for therapeutic purposes and consent to donate my (Name of organ/tissue) to a person whose full name is and who was born on (day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public across the
Photo after affixing)



(attach attested photocopy of at least two relevant documents to prove identity of recipient)

- Ration/Consumer Card number and Date of issue and 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
- AADHAAR No. 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 (42 of 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 (name of organ/tissue) 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 (name of organ/tissue). 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 the 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 the best of my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor
(Full Name)

.....
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.

FORM 4

For certification of medical fitness of living donor

(To be given by the Registered Medical Practitioner)

[See proviso to rule 5(3)(b)]

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 for donation of his/her (Name of the organ) to Shri/Smt./Km who is a 'near relative' of the donor/other than near relative of the donor and has been approved by the competent authority or Authorisation Committee (as the case may be) and it is certified that the said donor is in proper state of health, not mentally challenged * and is medically fit to be subjected to the procedure of organ or tissue removal.

Place:

.....

Signature of Doctor

Date:

Seal

To be affixed
(pasted) here

To be affixed
(pasted) here

Photograph of the Donor
(Attested by doctor)

Photograph of the recipient
(Attested by the doctor)

The signatures and seal should partially appear on photograph and document without disfiguring the face in photograph

* In case of doubt for mentally challenged status of the donor, the Registered Medical Practitioner may get the donor examined by psychiatrist.

FORM 5

For certification of genetic relationship of living donor with recipient

(To be filled by the head of Pathology Laboratory certifying relationship)

[See rules 5(3)(c) and 18(3)]

I, Dr./Mr./Mr/Miss. working as at and possessing qualification of certify that Shri/ Smt./ Km. S/o, D/o, W/o Shri/ Smt. aged the donor and Shri/ Smt. S/o, D/o, W/o Shri/Smt..... aged the prospective recipient of the organ to be donated by the said donor are related to each other as brother/sister/mother/father/son/daughter, grandmother, grandfather, grandson and granddaughter as per their statement. The fact of this relationship has been established / not established by the results of the tests for DNA profiling. The results of the tests are attached.

Signature
(To be signed by the Head of the Laboratory)

Seal

Place

Date

FORM 6

For spousal living donor

(to be filled by competent authority and Authorisation Committee, of the hospital or district or state in case of foreigners)*

[See rule 18(2)]

I, Dr./Mr./Mrs/Miss. possessing qualification of
registered as medical practitioner at serial No. by the
..... Medical Council, certify that:-

Mr.....S/o.....aged.....resi
dent ofand Mrs.....D/o,
W/o.....aged.....resident of
..... are related to each other as spouse according to the statement given
by them and their statement has been confirmed by means of following evidence before effecting the organ removal from
the body of the said Shri/Smt/..... (Applicable only in the cases where considered
necessary).

OR

In case the Clinical condition of Shri/Smt..... mentioned above is such that recording of
his/her statement is not practicable, reliance will be placed on the documentary evidence(s). (mention documentary
evidence(s) here).....

- a.Marriage certificate indicate date of marriage
- b.Marriage photographs
- c.Date when transplantation was advised by the hospital (to be compared with duration of marriage):
- d.Number and age of children and their birth certificates
- e.Any other document

Signature of *competent authority*/Authorisation committee in case of foreigners along with Seal/Stamp*

Place

Date

*Director or Medical Superintendent or In Charge of the hospital or the internal committee of the hospital formed for the
purpose.as defined under the rules of Transplantation of Human Organ Act, 1994(42 of 1994).

FORM 7

For organ or tissue pledging

(To be filled by individual of age 18 year or above)

[See rule 5(4)(a)]

ORGAN(S) AND TISSUE(S) DONOR FORM

(To be filled in triplicate)

Registration Number (To be allotted by Organ Donor Registry).....

I.....S/o,D/o,W/o.....aged.....
.....and date of birthresident of
.....in the presence of persons mentioned below hereby unequivocally
authorise the removal of following organ(s) and/or tissue(s), from my body after being declared brain stem dead by the
board of medical experts and consent to donate the same for therapeutic purposes.

Please tick as applicable

(Following tissues can also be donated after

			brain stem death as well as cardiac death)
Heart	<input type="checkbox"/>	Corneas/Eye Balls	<input type="checkbox"/>
Lungs	<input type="checkbox"/>	Skin	<input type="checkbox"/>
Kidneys	<input type="checkbox"/>	Bones	<input type="checkbox"/>
Liver	<input type="checkbox"/>	Heart Valves	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>	Blood Vessels	<input type="checkbox"/>
Any Other Organ (Pl. specify) _____		Any other Tissue (Pl. specify) _____	
All Organs	<input type="checkbox"/>	All Tissues	<input type="checkbox"/>

My blood group is (if known).....

Signature of Pledger.....

Address for correspondence.....

Telephone No.....

Email :

Dated:

(Note: In case of online registration of pledge, one copy of the pledge will be retained by pledger, one by the institution where pledge is made and a hard copy signed by pledger and two witnesses shall be sent to the nodal networking organisation.)

(Signature of Witness 1)

1. Shri/Smt./Km.....S/o,D/o,W/o.....
 aged.....resident of..... Telephone
 No.....Email:.....

(Signature of Witness 2)

2. Shri/Smt./Km.....S/o,D/o,W/o.....
 aged.....resident of Telephone
 No.....Email:..... is a near relative to the donor as

Dated.....

Place

Note: (i) Organ donation is a family decision. Therefore, it is important that you discuss your decision with family members and loved ones so that it will be easier for them to follow through with your wishes.

(ii) One copy of the pledge form/pledge card to be with respective networking organisation, one copy to be retained by institution where the pledge is made and one copy to be handed over to the pledger.

(iii) The person making the pledge has the option to withdraw the pledge.

FORM 8

For Declaration cum consent

(To be filled by near relative or lawful possessor of brain-stem dead person)

[See rules 5(1)(b), 5(4)(b) and 5(4)(d)]

DECLARATION AND CONSENT FORM

I.....S/o,D/o,W/o.....

aged.....resident ofin the presence of persons mentioned below, hereby declare that:

1. I have been informed that my relative (specify relation)

S/o,D/o,W/o.....aged.....has been declared brain-stem dead / dead.

2. To the best of my knowledge (Strike off whichever is not applicable):

- a. He/She. (Name of the deceased)..... had / had not, authorised before his/her death, the removal of(Name of organ/tissue/both) of his/her body after his/her death for therapeutic purpose. The documentary proof of such authorisation is enclosed/not available
- b. He/She. (Name of the deceased)..... had not revoked the authority as at No. 2 (a) above (If applicable) .
- c. There are reasons to believe that no near relative of the said deceased person has objection to any of his/her organs/tissue being used for therapeutic purposes.
3. I have been informed that in the absence of such authorisation, I have the option to either authorise or decline donation of organ/tissue/both including eye/cornea of(Name of the deceased) for therapeutic purposes. I also understand that if corneas/eyes are not found suitable for therapeutic purpose, then may be used for education/research.
4. I hereby authorise / do not authorize removal of his/her body organ(s) and/or tissue(s), namely (*Any organ and tissue/ Kidney /Liver /Heart /Lungs /Intestine /Cornea /Skin /Bone /Heart Valves /Any other; please specify*) for therapeutic purposes. I also give permission for drawing of a blood sample for serology testing and am willing to share social/behavioural and medical history to facilitate proper screening of the donor for safe transplantation of the organs/ tissues.

Date..... Signature of near relative /person in lawful possession of the dead body, and address for correspondence*.

Place Telephone No.....Email:

* in case of the minor the declaration shall be signed by one of the parent of the minor or any near relative authorised by the parent. In case the near relative or person in lawful possession of the body refuses to sign this form, the same shall be recorded in writing by the Registered Medical Practitioner on this Form.

(Signature of Witness 1)

1.Shri/Smt./Km.....S/o,D/o,W/o.....

aged.....resident of..... Telephone

No.....Email:

(Signature of Witness 2)

2.Shri/Smt./Km.....S/o,D/o,W/o.....

aged.....resident of Telephone

No.....Email:.....

FORM 9

For unclaimed body in a hospital or prison

(To be completed by person in lawful possession of the unclaimed body)

[see rule 5(1)(b)]

I.....S/o,D/o,W/o.....

aged.....resident ofhaving lawful possession of the dead body of Shri/Smt./Km.....

S/o,D/o,W/o..... aged.....resident of

.....and having known that no person has come forward to claim the body of the deceased after 48 hours of death and there being no reason to believe that any person is likely to come to claim the body I hereby, authorise removal of his/her body organ(s) and/or tissue(s), namely.....for therapeutic purposes.

Signature, Name, designation and Stamp of person in lawful possession of the dead body.

Dated.....Place.....

Address for correspondence.....

Telephone No.....Email

(Signature of Witness 1)

1. Shri/Smt./Km.....S/o,D/o,W/o.....
aged.....resident of..... Telephone
No.....Email

(Signature of Witness 2)

2. Shri/Smt./Km.....S/o,D/o,W/o.....
aged.....resident of Telephone No.....Email
.....

FORM 10

For certification of brain stem death

(To be filled by the board of medical experts certifying brain-stem death)

[See rules 5(4)(c) and 5(4)(d)]

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Km.....

aged aboutson of /wife of / daughter of Resident of
.....

is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated..... Signature.....

1. R.M.P.- Incharge of the Hospital 2. R.M.P. nominated from the panel of
In which brain-stem death has occurred. Names sent by the hospitals and
approved by the Appropriate Authority.

3. Neurologist/Neuro-Surgeon 4. R.M.P. treating the aforesaid deceased person

(where Neurologist/Neurosurgeon is not available, any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge from the panel of names sent by the hospital and approved by the Appropriate Authority shall be included)

BRAIN-STEM DEATH CERTIFICATE

(A) PATIENT DETAILS.....

1. Name of the patient: Mr./Ms.....

S.O./D.O./W.O. Mr./Ms.....

Sex.....Age.....

2. Home Address:

.....

.....

3. Hospital Patient Registration Number (CR No.):

4. Name and Address of next of kin or person.....

responsible for the patient

(if none exists, this must be specified)

.....

.....

5. Has the patient or next of kin agreed

to any donation of organ and/or tissue?

6. Is this a Medico-legal Case? Yes.....No.....

(B) PRE-CONDITIONS:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage?
Specify details.....

.....

.....
 Date and time of accident/onset of illness.....
 Date and onset of non-reversible coma.....

2. Findings of Board of Medical Experts:

First Medical Examination Second Medical Examination

- (1) The following reversible causes of coma have been excluded:
 Intoxication (Alcohol)
 Depressant Drugs
 Relaxants (Neuromuscular blocking agents)
 Primary Hypothermia
 Hypovolaemic shock
 Metabolic or endocrine disorders
 Tests for absence of brain-stem functions
- (2) Coma
- (3) Cessation of spontaneous breathing
- (4) Pupillary size
- (5) Pupillary light reflexes
- (6) Doll's head eye movements
- (7) Corneal reflexes (Both sizes)
- (8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.
- (9) Gag reflex
- (10) Cough (Tracheal)
- (11) Eye movements on caloric testing bilaterally.
- (12) Apnoea tests as specified.
- (13) Were any respiratory movements seen?

.....
 Date and time of first testing:

Date and time of second testing:

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above,

Mr./Ms.....is declared brain-stem dead.

Date:

Signatures of members of Brain Stem Death (BSD) Certifying Board as under:

- | | |
|---|--|
| 1. Medical Administrator Incharge of the hospital | 2. Authorised specialist. |
| 3. Neurologist/Neuro-Surgeon | 4. Medical Officer treating the Patient. |

Note.

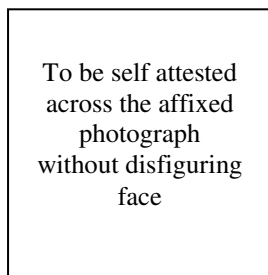
- I. Where Neurologist/Neurosurgeon is not available, then any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge of the hospital shall be the member of the board of medical experts for brain-stem death certification.
- II. The minimum time interval between the first and second testing will be six hours in adults. In case of children 6 to 12 years of age, 1 to 5 years of age and infants, the time interval shall increase depending on the opinion of the above BSD experts.
- III. No.2 and No.3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts (Nominated by the hospital and approved by the Appropriate Authority).

FORM 11

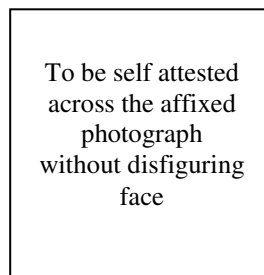
APPLICATION FOR APPROVAL OF TRANSPLANTATION FROM LIVING DONOR

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

[See rules 5(3)(d), 5(3)(e) and 10]



Photograph of the Donor



Photograph of the recipient

Whereas I S/o, D/o, W/o, Shri/Smt.
 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, Shri/Smt.
 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 (name of the organ) to Shri/Smt.

We and
 (Donor) (Recipient)

hereby apply to competent authority / Authorisation 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 11 must be submitted along with the completed Form 1 or Form 2 or Form 3 as may be applicable.
2. The applicable Form i.e. Form 1 or Form 2 or Form 3 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 5 must 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 competent authority / 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.
7. When the donor is unrelated and the donor and/or recipient belong to a State/Union Territory other than the State/Union Territory, where the transplant is intended to take place, then the Tehsildar or the officer authorised for the purpose of the domicile state of the donor or recipient as the case may be, would provide the verification certificate of domicile of donor/recipient as the case may be as per Form 20. The approval for transplantation would be considered by the authorisation committee of the State/District/hospital (as the case may be) where the transplantation is intended to be done. Such verification Certificate will not be required for near relatives including cases involving swapping of organs (permissible between near relatives only).

We have read and understood the above instructions.

Signature of the Prospective Donor

Address for correspondence:

Date :

Place :

Signature of Prospective Recipient

Address for correspondence:

Date :

Place :

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN OR TISSUE TRANSPLANTATION OTHER THAN CORNEA

(To be filled by head of the institution)

(See rule 24(1))

To

The Appropriate Authority for organ transplantation.....

(State or Union territory)

We hereby apply to be registered as an institution to carry out organ/tissue transplantation.

Name(s) of organ (s) or tissue (s) for which registration is required.....

The required data about the facilities available in the hospital are as follows:-

(A) HOSPITAL:

1. Name:
2. Location:
3. Government/Private:
4. Teaching/Non-teaching:
5. Approached by:

Road:	Yes	No
Rail:	Yes	No
Air:	Yes	No

6. Total bed strength:
7. Name of the disciplines in the hospital:
8. Annual budget:
9. Patient turn-over/year:

(B) SURGICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff with their designation:
4. No. of operations done per year:
5. Trained persons available for transplantation (Please specify Organ for transplantation):

(C) MEDICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff members with their designation:
4. Patient turnover per year:
5. Trained persons available for transplantation (Please specify Organ for transplantation):
6. No. of potential transplant candidates admitted per year:

(D) ANAESTHESIOLOGY:

1. No. of permanent staff members with their designations:
2. No. of temporary staff members with their designations:
3. Name and No. of operations performed:
4. Name and No. of equipments available:
5. Total No. of operation theatres in the hospital:
6. No. of emergency operation-theatres:
7. No. of separate transplant operation theatre:

(E) I.C.U./H.D.U. FACILITIES:

1. I.C.U./H.D.U. facilities: Present..... Not present.....
2. No. of I.C.U. and H.D.U. beds:
3. Trained:-

Nurses:

Technicians:

4. Name of equipment in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

(F1) LABORATORY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F2) IMAGING FACILITIES :

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F3) HAEMATOLOGY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F4) BLOOD BANK FACILITIES (Inhouse or access): Yes No.....

(F5) DIALYSIS FACILITIES : Yes No.....

F 6. Transplant coordinators (Eye Donation Counselors, in case of Cornea Transplantaion):

Yes No

Number Posted :

Number Trained

(F 7) OTHER SUPPORTIVE EXPERT PERSONNEL:

1. Nephrologist Yes/No
2. Neurologist Yes/No
3. Neuro-Surgeon Yes/No
4. Urologist Yes/No
5. G.I. Surgeon Yes/No
6. Paediatrician Yes/No
7. Physiotherapist Yes/No
8. Social Worker Yes/No
9. Immunologists Yes/No
10. Cardiologist Yes/No
11. Respiratory physician Yes /No
12. Others..... Yes / No

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/cheque of Rs. 10000/ (for new registration) and Rs. 5000 (for renewal) in favour of _____ is enclosed.

Sd/-

HEAD OF THE INSTITUTION

FORM 13**APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/TISSUE RETRIEVAL OTHER THAN EYE/CORNEA RETRIEVAL****(To be filled by head of the institution)****(See rule 24(1))**

Note: Retrieval Hospitals may also be identified based on pre-defined criteria and registered as retrieval hospital by the appropriate authority.

To

The Appropriate Authority for organ transplantation.....

(State or Union territory)

We hereby apply to be registered as an institution to carry out organ/tissue retrieval.

The required data about the facilities available in the hospital are as follows:-

(A) HOSPITAL:

1. Name:
2. Location:
3. Government/Private:
4. Teaching/Non-teaching:

5. Approached by:
- | | | |
|-------|-----|----|
| Road: | Yes | No |
| Rail: | Yes | No |
| Air: | Yes | No |
6. Total bed strength:
7. Name of the disciplines in the hospital:
8. Annual budget:
9. Patient turn-over/year:
- (B) SURGICAL FACILITIES:
- No. of beds:
 - No. of permanent staff members with their designation:
 - No. of temporary staff with their designation:
 - No. of operations done per year:
 - Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):
- (C) MEDICAL FACILITIES:
- No. of beds:
 - No. of permanent staff members with their designation:
 - No. of temporary staff members with their designation:
 - Patient turnover per year:
 - Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):
 - No. of critical trauma cases admitted per year.
 - No. of brain stem death declared per year.
- (D) ANAESTHESIOLOGY:
- No. of permanent staff members with their designations:
 - No. of temporary staff members with their designations:
 - Name and No. of operations performed:
 - Name and No. of equipments available:
 - Total No. of operation theatres in the hospital:
 - No. of emergency operation-theatres:
 - No. of separate retrieval operation theatre:
- (E) I.C.U./H.D.U. FACILITIES:
- I.C.U./H.D.U. facilities: Present..... Not present.....
 - No. of I.C.U. and H.D.U. beds:
 - Trained:-
 - Nurses:
 - Technicians:
 - Name of equipment in I.C.U.
- (F) OTHER SUPPORTIVE FACILITIES:
- Data about facilities available in the hospital:
- (F1) LABORATORY FACILITIES:
- No. of permanent staff with their-designations:
 - No. of temporary staff with their designations:
 - Names of the investigations carried out in the Deptt.:
 - Name and number of equipments available:
- (F2) IMAGING FACILITIES:
- No. of permanent staff with their-designations:
 - No. of temporary staff with their designations:
 - Names of the investigations carried out in the Deptt.:
 - Name and number of equipments available:
- (F3) HAEMATOLOGY FACILITIES:
- No. of permanent staff with their-designations:
 - No. of temporary staff with their designations:
 - Names of the investigations carried out in the Deptt.:
 - Name and number of equipments available:
- (F4) BLOOD BANK FACILITIES: (in house or access) Yes No.....
- (F 5) Transplant coordinators: Yes No
- Number Posted:
- Number Trained

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. I hereby give an undertaking that we shall make the facilities of the hospital including the retrieval team of the hospital available for retrieval of the organ/tissue as and when needed.

Sd/-
HEAD OF THE INSTITUTION

FORM 14
APPLICATION FOR REGISTRATION OF TISSUE BANKS OTHER THAN EYE BANKS
(To be filled by head of the institution)
(See rule 24(1))

To

The Appropriate Authority for organ transplantation.....
(State or Union Territory)

We hereby apply to be registered as Tissue bank , Name :

Name(s) of tissue (s)(Bone, heart valves, skin, cornea etc) for which Registration is required.....

The required data about the facilities available in the institution are as follows:-

A. General Information :

1. Name

2. Address

3. Government/Private/NGO

4. Teaching /Non- teaching

5. Approached by:

Rail: Yes No

Road: Yes No

Air: Yes No

5.Information Education and Communication (IEC) for Tissue Donation

6.Type of tissue bank: Auto Logons /Allograph/Both

B. DONOR SCREENING

REMOVAL OF TISSUE AND STORAGE:

1.Availability of adequate trained and qualified Personnel for removal Tissue (annex detail). Yes/No

2. Names, qualification and address of the doctors/technician who will be doing removal of tissue. (annex details) Yes/No

3.Facilities for removal of Tissues Yes/No

4.Whether register of recipient waiting list available. Yes/No

5. Telephone arrangement available. (Telephone Number.....) Yes/No

6. Availability of ambulance/ vehicle or funds to Pay taxi for collecting tissue from outside: Yes/No

7. Sets of instruments for removal of tissue Yes/No

8. Facilities for processing of tissue Yes/No

9. Refrigerator for preservation of tissue Yes/No

10. Special containers for preservation of tissue during transit. Yes/No

11. Suitable preservation media Yes/No

12. Any other specific requirement as per tissue Yes/No

C.PRESERVATIONS OF TISSUE

Arrangement of preservation of Tissue Yes/No

D.RECORDS

1. Arrangement for maintaining the records Yes/No

2. Arrangement for registration of cases, donors and follow up of cases. Yes/ No

E.EQUIPMENT:

Instruments specific for the tissue Yes/No

F.LABORATORY FACILITIES(If the information is exhaustive please annex it)

- a. Names of the investigations carried out in the department.
- b. Facility for testing for :
- i. Human Immunodeficiency Virus Type I and II Yes/No
 - ii. Hepatitis B Virus – HBc and HBs
 - iii. Hepatitis C Virus – HCV
 - iv. Syphilis – VDRL
- c. If no where do you avail it ? Please mention name and address of institute.
- d. Facility for culture and sensitivity of tissue Yes/No

G.OTHER PERSONNEL

1. No. of permanent staff member with their designation.
2. No. of temporary staff with their designation
3. No. of trained persons

ANY OTHER INFORMATION

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Daft/cheque of Rs. 10000/ (for new registration) and Rs. 5000 (for renewal) in favour of _____ is enclosed.

Sd/
HEAD OF THE INSTITUTION

FORM 15**APPLICATION FOR REGISTRATION OF EYE BANK, CORNEAL TRANSPLANTATION CENTRE, EYE RETRIEVAL CENTRE UNDER TRANSPLANTATION OF HUMAN ORGANS ACT**

[See rule 24(1)]

I. EYE BANKING:

A.	EYE BANK and institution affiliated Ophthalmic / General Hospital	
	1. Name 2. Address 3. Government/Private/Voluntary 4. Teaching /Non- teaching 5. IEC for Eye Donation	
B.	REMOVAL OF EYE BALLS AND STORAGE:	
	1. Availability of adequate trained and qualified personnel for removal of whole globe or corneal (annex detail)	Yes/No
	2. Names, qualification and address of the designated staff who will be doing removal of whole globe / cornea retrieval. (annex details)	Yes/No
	3. Availability of following as per requirement:	Yes/No
	a. Whether register maintained for tissue request received from surgeon of corneal transplant centre.	
	b. Telephone arrangement available. (Dedicated Telephone Number.....)	Yes/No
	c. Transport facility for collecting Eyeballs from outside:	Yes/No
	d. Sets of instruments for removal of whole globe / cornea as per requirement	Yes/No

	e. Special bottles with stands for preservation of Eye balls/ cornea during transit.	Yes/No
	f. Suitable preservation media	Yes/No
	g. Biomedical Waste Management.	Yes/No
	h. Uninterrupted Power supply.	Yes/No
C	Manpower 1. Incharge / Director (Ophthalmologist) -1 2. Eye Bank Technician- 2 3. Eye Donation Counselors (EDC)-2 per attached HCRP (Hospital Cornea Retrieval Cornea Programme) Hospital, who will be posted at eye Bank. 4. Multi task Staff(MTS) -2	
D.	Space requirement for eye Banks (400sqft minimum)	Yes/No
E.	RECORDS	
	1. Arrangement for maintaining the records	Yes/ No
	2. Arrangement for registration of pledges,/ donors and maintenance of utilization report	Yes/ No
	3. Computer with internet facility and Printer	Yes/ No
F.	EQUIPMENT:	
	1. Slit Lamp Biomicroscope-1 2. Specular Microscope for Eye Bank-1 3. Laminar flow(Class II)-1 4. Sterilization facility (In-house or outsourced) 5. Refrigerator with temperature monitoring for preservation of eye balls/Cornea-1	Yes/No
G	LABORATORY FACILITIES	
	1. Facility for HIV, Hepatitis B and C testing.	Yes/No
	2. If no where do you avail it? Please mention Name and address of institute.	
	3. Facility for culture and sensitivity of Corneoscleral ring.	Yes/No
H	RENEWAL OF REGISTRATION: Period of renewal 5years after last registration. Minimum of 500 corneas to be collected in 5 years. Maintenance of eye bank standards(as per Guidelines)	
II. EYE RETRIEVAL CENTRE (ERC):		
A.	RETRIEVAL CENTRE– A Centre affiliated to an Eye Bank 1. Name 2. Address 3. Government/Private/Voluntary 4. Teaching /Non- teaching 5. Information, Education and Communication Activities for Eye Donation 6. Name of Eye Bank to which ERC is affiliated.	
B	REMOVAL OF EYE BALLS AND STORAGE: 1. Manpower : Adequate trained and qualified personnel for removal of eye balls/cornea (annex detail): a. Incharge / Director) -1 b. Technician -1 c. MTS (Multi task Staff) -1 2. Transport facility(or outsource) with storage medium	
C	Names, qualification and address of the personnel who will be doing enucleation/ removal of cornea. (annex details)	
D	AVAILABILITY OF FOLLOWING: 1. Telephone. (Number.....) 2. Ambulance/ vehicle or funds to pay taxi for collecting eyeballs from outside: 3. Sets of instruments for removal of Eye Balls/cornea 4. Special bottles with stands for preservation of 5. Eye balls/ cornea during transit: 6. Suitable preservation media 7. Waste Disposal (Biomedical waste Management)	

	8. Space requirement: Designated area	
E	RECORDS 1. Arrangement for maintaining the records	
F	EQUIPMENT: 1. Sterilization facility 2. Refrigerator temperature control 24 hrs for preservation of Eye balls/Cornea.(power back up) - 1 3. The retrieval centre is affiliated with an Eye bank and Eye Bank is only authorised to distribute corneas.	
III. CORNEAL TRANSPLANTATION CENTRE		
A	1. Name of the Transplant Centre /hospital: 2. Address: 3. Government/Private/Voluntary: 4. Teaching /Non- teaching: 5. IEC for Eye Donation: Yes/No 6. Name of the registered Eye Bank for procuring tissue:	
B	Staff details: 1. No. of permanent staff member with their designation. (Note : Eye Surgeon's Experience : 3 month post MD/MS/DNB/DO)	
	2. No. of temporary staff with their designation	
	3. Trained persons for Keratoplasty and Corneal Transplantation with their names and qualifications: 2 (one Corneal Transplant surgeon should be on the pay roll of the Institute)	
C	Equipment : Slit lamp, Clinical Specular, Keratoplasty or intraocular instruments	
D	OT facilities	
E	Safe Storage facility	
F	Records Registration and follow up	
G	Any other information	

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank draft/cheque of Rs. 10000- for new registration and Rs 5000/ for renewal of registration drawn in favour of _____ is enclosed.

Head of the Institute
(Name and designation)

FORM 16
**CERTIFICATE OF REGISTRATION FOR PERFORMING ORGAN/TISSUE
TRANSPLANTATION/RETRIEVAL AND/OR TISSUE BANKING**

(See rule 24(2))

This is to certify that Hospital/Tissue Bank located at..... has been inspected and certificate of registration is granted for performing the organ/tissue retrieval/transplantation/banking of the following organ(s)/tissue(s) (mention the names) under the Transplantation of Human Organs Act, 1994 (42 of 1994):-

1.
2.
3.
4.

This certificate of registration is valid for a period of five years from the date of issue.

This permission is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place.....

Signature of Appropriate Authority.....

Seal:

Date.....

FORM 17

Certificate of Renewal of Registration

(To be given by the appropriated authority on the letter head)

[See rule 25(2)]

This is with reference to the application dated..... from..... (Name of the hospital/tissue bank) for renewal of certificate of registration for performing organ(s)/tissue(s) retrieval/transplantation/banking under the Transplantation of Human Organs Act, 1994 (42 of 1994).

After having considered the facilities and standards of the above-said hospital/tissue bank, the Appropriate Authority hereby renews the certificate of registration of the said hospital/tissue bank for a period of five years.

This renewal is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place..... Signature of Appropriate Authority.....
Date.....Seal.....

FORM 18

Certificate by the Authorisation Committee of Hospital (If Hospital Authorisation committee is not available then the Authorisation Committee of the district/State) where the transplantation has to take place

(To be issued on the letter head)

[See rules 16 and 23]

This is to certify that as per application in form-10 for transplantation of _____(Name of Organ/tissue) from living donor, other than near relative/ swap donation cases/ all foreigner under the Transplantation of Human Organs Act,1994 (42 of 1994) submitted on..... by the donor and recipient, whose details and photographs are given below, along with their identifications and verification documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) and their relatives as applicable by the Authorisation Committee in the meeting held on ...dated.....

Details of Recipient

Details of Donor

Name.....

Name:.....

Age.....

Age

Sex

Sex

Father / Husband Name

Father / Husband name.....

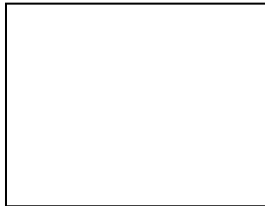
Address:

Address:

Hospital Reg. No

Hospital Reg. No.....

Relation of donor with Recipient



Recipient

Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

Permission is granted, as to the best of knowledge of the members of the committee, donation is out of love and affection and there is no financial transaction between recipient and donor and there is no pressure on / coercion of the donor.

Permission is withheld pending submission of the following documents.....

Permission is not granted for the following reasons.....

(Member)

(Member)

(Member)

(Member)

Name and Designation

Name and Designation

Name and Designation

Name and Designation

(Member)

(Member)

(Sign of Chairman with stamp)

Health Secretary

DHS or Nominee

Name and Designation

Or Nominee

Name and Designation

Date and place.....

* In case of SWAP transplants, details are to be annexed

FORM 19

Certificate by competent authority [as defined at rule 2(c)] For Indian near relative, other than spouse, cases (In case of spousal donor, Form 6 will be applicable)

[See rule 5(3)(c)]

(Format for the decision of Competent Authority)

This is to certify that as per application in Form-11 for transplantation of _____(Name of Organ or Tissue) from living donor who is a near relative of the recipient under the Transplantation of Human Organs Act, 1994(42 of 1994), submitted on..... by the donor and recipient, whose details and photographs are given below, along with their identifications and verifications documents, the case was considered after the personal

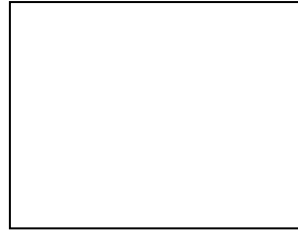
interview of donor and recipient (if medically fit to be interviewed) by the competent authority in the meeting held on

Details of Recipient

Name.....
Age.....
Sex
Father or Husband Name
Address:
.....
.....
Hospital Reg. No
Relation of donor with Recipient

Details of Donor

Name:.....
Age
Sex
Father or Husband name.....
Address:
.....
.....
Hospital Reg. No.....



Recipient

Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

Permission is granted, as to the best of knowledge of the members of the committee, donation is out of their being near relative and there is no financial transaction between recipient and donor and there is no pressure on / coercion of the donor.

Permission is withheld pending submission of following documents.....

Permission is not granted for the following reasons.....

(Signature and stamp of competent authority)

Date and place.....

FORM 20

Verification certificate in respect of domicile status of recipient or donor

[To be issued by tehsildar or any other authorised officer for the purpose (required only for the donor - other than near relative or recipient if they do not belong to the state where transplant hospital identified for operation is located)]

[See rule 14]

Part I (To be filled by applicant donor or recipient separately in triplicate)

In reference to application for verification of domicile status for donation of _____(Name of organ/Tissue) from living donor (other than near relative) or recipient under Transplantation of Human Organ Act, 1994 (42 of 1994), submitted on (date)..... by the applicant donor or recipient, with following details and photograph, along with his or her identification and domicile status for verification

Details of Applicant Recipient or Donor

Name.....
Age.....
Sex
Father or Husband Name
Address:
.....
.....
Hospital Reg. No



(Recent Photo of Applicant must be signed by him or her across the photo after affixing it)

The detail of my donor or recipient are as under and I have enclosed his or her self-signed recent photograph :

Name.....

Age.....
 Sex
 Father or Husband Name

 Address:

 Hospital Reg. No

Signature of Applicant

Enclosure : Self signed copy of the donor or recipient for the applicant (to be enclosed)

Part II (To be filled by the certificate issuing authority):

The above request has been examined and it is certified that the domicile status of the applicant donor or recipient mentioned as above has been verified as under:

Name Son or Daughter or Wife of
 resident of village or wardTehsil or Taluka.....District.....State or
 UT.....
 and found correct or incorrect

.....

DatePlace

Authorised Signatory
 Name and Designation
 Office Stamp

Reference No

- 2.The authorised signatory will hand over this verification certificate to the applicant or his or her representative for submission to the Chairperson of the Authorisation Committee of the hospital or district or state (as the case may be), where transplantation has to take place.
- 3.The authorised signatory shall keep one copy of the above verification certificate for his records and send a copy to the Secretary, Health and Family Welfare of the State Government (Attention Appropriate authority for organ transplant) for information.
- 4.In case of any suspicion of organ trading, the authorised signatory mentioned above or Appropriate Authority of the state may inform police for making enquiry and taking necessary action as per the Transplantation of Human Organs Act, 1994 (42 of 1994).

FORM 21

Certificate of relationship between donor and recipient in case of foreigners

(To be issued by the Embassy concerned)

[See rule 20(a)]

The embassy of _____(Name of Country) in India, is in receipt of an application received from _____(Name of Organ donor and recipient) on _____(Date) recommended by _____(Name of Government Department of country of origin) for facilitation of donation of _____(Name of Organ or Tissue) from living donor _____(Name of donor) to the recipient _____(Name of recipient) for therapeutic purposes under the Transplantation of Human Organ Act, 1994(42 of 1994). The details of donor and recipient and photographs are as given below.

Details of Recipient
 Name.....
 Age.....
 Sex
 Father or Husband Name

 Address:

Details of Donor
 Name:.....
 Age
 Sex
 Father or Husband name.....

 Address:



Recipient

Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

1, This is to certify that relationship between donor and Recipient is.....
2. The authenticity of following enclosed identification and verification documents is certified

- a. _____
- b. _____

'No objection certificate' is granted, as to the best of my knowledge, the donor is donating out of love and affection or affection and attachment towards the recipient, and there is no financial transaction between recipient and donor and there is no pressure on or coercion of the donor.

(Signature of Senior Embassy Official)

Date:
Place:

Name:
Designation.....

[No S.12011/28/2012-MG/MS]
ARUN K. PANDA, Jt. Secy.

11 8 DEC 2009

Bill No. 136 of 2009

THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT)
BILL, 2009

A

BILL

to amend the Transplantation of Human Organs Act, 1994.

WHEREAS it is expedient to amend the said law enacted by Parliament relating to regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs;

5 AND WHEREAS Parliament has no power to make or amend laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

10 AND WHEREAS in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and West Bengal to the effect that the aforesaid Act should be amended by Parliament;

Be it enacted by Parliament in the Sixtieth Year of the Republic of India as follows:—

1. (1) This Act may be called the Transplantation of Human Organs (Amendment) Act, 2009.

15 (2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and West Bengal and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.

Short title,
application
and com-
mencement.

(3) It shall come into force in the States of Goa, Himachal Pradesh and West Bengal and in all the Union territories on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, mean the date on which this Act comes into force in such State or Union territory.

Amendment of long title.

2. In the Transplantation of Human Organs Act, 1994 (hereinafter referred to as the principal Act), in the long title, for the words "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs", the words "human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues" shall be substituted. 42 of 1994. 10

Amendment of section 1.

3. In section 1 of the principal Act, in sub-section (1), for the words "Human Organs", the words "Human Organs and Tissues" shall be substituted.

Substitution of references to certain expressions by certain other expressions.

4. Throughout the principal Act [except clause (h) of section 2], unless otherwise expressly provided, for the words "human organ" and "human organs", wherever they occur, the words "human organ or tissue or both" and "human organs or tissues or both" shall respectively be substituted with such consequential amendments as the rules of grammar may require. 15

Amendment of section 2.

5. In section 2 of the principal Act,—

(a) for clause (i), the following clause shall be substituted, namely:— 20

'(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter;'

(b) in clause (o), the word "and" shall be omitted;

(c) after clause (o), the following clauses shall be inserted, namely:—

'(oa) "tissue" means a group of cells except blood performing a particular function in the human body; 25

'(ob) "transplant coordinator" means a person of the hospital appointed for coordinating all matters relating to removal or transplantation of human organs or tissues or both; and'

Amendment of section 3

6. In section 3 of the principal Act,— 30

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

'(1A) In respect of such human organs or tissues or both, as may be prescribed, it shall be the duty of a registered medical practitioner working in a hospital registered under this Act, for the purpose of removal, storage or transplantation of human organs or tissues or both,— 35

(i) to ascertain from the person admitted to the Intensive Care Unit or from his near relative that such person had authorised at any time before his death the removal of any human organ or tissue or both of his body under sub-section (2), then the hospital shall proceed to obtain the documentation for such authorisation; 40

(ii) where no such authority as referred to in sub-section (2) was made by such person, to make aware to that person or near relative for option to authorise or decline for donation of human organs or tissues or both;

(iii) to require the hospital to inform in writing to the Human Organ Removal Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified in clauses (i) and (ii) in such manner as may be prescribed.

5 (1B) The duties mentioned under clauses (i) to (iii) of sub-section (1A) from such date, as may be prescribed, shall also apply in the case of a registered medical practitioner working in an Intensive Care Unit in a hospital which is not registered under this Act for the purpose of removal, storage or transplantation of human organs or tissues or both.";

10 (b) in sub-section (4), the following proviso shall be inserted, namely:—

"Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.";

(c) in sub-section (6), in clause (iii),—

(i) the word "and" shall be omitted; and

15 (ii) the following proviso shall be inserted, namely:—

"Provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient and to such conditions as may be prescribed;"

20

7. In section 9 of the principal Act,—

Amendment
of section 9.

(a) after sub-section (1), the following sub-sections shall be inserted, namely:—

25 "(1A) Where the donor or the recipient being near relative is a foreign national, prior approval of the Authorisation Committee shall be required before removing or transplanting human organ or tissue or both:

Provided that the Authorisation Committee shall not approve such removal or transplantation if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.

30

(1B) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplantation except in the manner as may be prescribed,";

(b) after sub-section (3), the following sub-section shall be inserted, namely:—

35 "(3A) Notwithstanding anything contained in sub-section (3), where—

(a) any donor has agreed to make a donation of his human organ or tissue or both before his death to a recipient, who is his near relative, but such donor is not compatible biologically as a donor for the recipient; and

40

(b) the second donor has agreed to make a donation of his human organ or tissue or both before his death to such recipient, who is his near relative, but such donor is not compatible biologically as a donor for such recipient; then

(c) the first donor who is compatible biologically as a donor for the second recipient and the second donor is compatible biologically as a donor of a human organ or tissues or both for the first recipient and both donors and both recipients in the aforesaid group of donor and recipient have entered into a single agreement to donate and receive such human organ or tissue or both according to such biological compatibility in the group,

the removal and transplantation of the human organ or tissue or both, as per the agreement referred to above, shall not be done without prior approval of the Authorisation Committee.";

(c) for sub-section (4), the following sub-section shall be substituted, namely:—

"(4)(a) The composition of the Authorisation Committees shall be such as may be prescribed by the Central Government from time to time.

(b) The State Governments and the Union territories shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Governments and the Union territories on such terms and conditions as may be specified in the notification for the purposes of this section."

8. After section 13 of the principal Act, the following sections shall be inserted, namely:—

"13A. (1) The Central Government and the State Governments, as the case may be, by notification, shall constitute an Advisory Committee for a period of two years to aid and advise the Appropriate Authority to discharge its functions.

(2) The Advisory Committee shall consist of—

(a) one administrative expert not below the rank of Secretary to the State Government, to be nominated as Chairperson of the Advisory Committee;

(b) two medical experts having such qualifications as may be prescribed;

(c) one officer not below the rank of a Joint Director to represent the Ministry or Department of Health and Family Welfare, to be designated as Member-Secretary;

(d) two eminent social workers of high social standing and integrity, one of whom shall be from amongst representatives of women's organisation;

(e) one legal expert who has held the position of an Additional District Judge or equivalent.

(3) The terms and conditions for appointment to the Advisory Committee shall be such as may be prescribed by the Central Government.

13B. The Appropriate Authority shall for the purposes of this Act have all the powers of a civil court trying a suit under the Code of Civil Procedure, 1908 and, in particular, in respect of the following matters, namely:—

(a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;

(b) discovery and production of any document or material object;

(c) issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement or transplantation of human organs or tissues or both; and

(d) any other matter which may be prescribed.

Insertion of
new sections
13A, 13B, 13C
and 13D.
Advisory
Committees to
advise
Appropriate
Authority.

Powers of
Appropriate
Authority.

13C. The Central Government may, by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed.

National Human Organs and Tissues Removal and Storage Network.

5 13D. The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues."

National registry.

9. In section 14 of the principal Act, after sub-section (3), the following sub-sections shall be inserted, namely:—

Amendment of section 14.

10 "(4) No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant coordinator having such qualifications and experience as may be prescribed.

15 (5) The non-governmental organisations, registered societies, charitable trusts and such other entities engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ and tissues for therapeutic purposes, shall immediately apply for registration in such manner as may be prescribed."

10. In section 18 of the principal Act,—

Amendment of section 18.

20 (a) in sub-section (1), for the words "five years and with fine which may extend to ten thousand rupees", the words "ten years and with fine which may extend to five lakh rupees" shall be substituted;

(b) in sub-section (2), for the words "two years", the words "three years" shall be substituted.

11. In section 19 of the principal Act,—

Amendment of section 19.

25 (a) after clause (f), the following clause shall be inserted, namely:—

"(g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs or tissues or both, as a near relative or by reason of affection or attachment towards the recipient.";

30 (b) for the words "two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees", the words "five years but which may extend to ten years and shall be liable to fine which shall not be less than five lakh rupees but may extend to twenty lakh rupees" shall be substituted;

(c) the proviso shall be omitted.

35 12. In section 20 of the principal Act, for the words "three years or with fine which may extend to five thousand rupees", the words "five years or with fine which may extend to five lakh rupees" shall be substituted.

Amendment of section 20.

13. In section 24 of the principal Act, in sub-section (2),—

Amendment of section 24.

40 (a) after clause (a), the following clauses shall be inserted, namely:—

45 "(aa) the human organs or tissues or both under sub-section (1A) and the manner of informing to the Human Organ Removal Centre under clause (iii) of sub-section (1A) of section 3 and the date from which duties mentioned in clauses (i) to (ii) of sub-section (1A) are to apply to a registered medical practitioner working in a Intensive Care Unit of a hospital which is not registered under this Act under sub-section (1B) of that section;

(ab) the qualifications and experience of a technician under the proviso to sub-section (4) of section 3;"

(b) after clause (b), the following clause shall be inserted, namely:—

"(ba) the conditions for nomination of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts under the proviso to clause (iii) of sub-section (6) of section 3;" 5

(c) after clause (e), the following clauses shall be inserted, namely:—

"(ea) the manner of removal of human organs or tissues or both from the body of a minor before his death for transplantation under sub-section (1B) of section 9; 10

(eb) the composition of the Authorisation Committees under sub-section (4) of section 9;"

(d) after clause (i), the following clauses shall be inserted, namely:—

"(ia) the qualifications of medical experts and the terms and conditions for appointment to Advisory Committee under sub-sections (2) and (3) of section 13A; 15

(ib) the power of the Appropriate Authority in any other matter under clause (d) of section 13B;

(ic) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be performed by them under section 13C; 20

(id) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;"

(e) after clause (l), the following clauses shall be inserted, namely:—

"(ka) the qualifications and experience of a transplant coordinator under sub-section (4) of section 14; 25

(kb) the manner of registration of the non-governmental organisations, registered societies, charitable trusts and such other entities under sub-section (5) of section 14;"

STATEMENT OF OBJECTS AND REASONS

The Transplantation of Human Organs Act, 1994 came into force on the 4th day of February, 1995 in the States of Goa, Himachal Pradesh and Maharashtra and all the Union territories. Thereafter, it has been adopted by all the States except the States of Jammu and Kashmir and Andhra Pradesh which have enacted their own legislation to regulate transplantation of human organs. The main purpose of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes and to prevent commercial dealings in human organs.

2. It has been observed that despite having put into place a regulatory mechanism for transplantation of human organs, there has been a spate of reports in the print and electronic media about thriving human organ trade in India and the consequential exploitation of economically weaker sections of the society. There has, therefore, been an increasing perception in civil society that the said Act has not been effective in curbing commercial transactions in organ transplant and thwarted genuine cases due to the complicated and long drawn process of organ donation.

3. On the above issue, Hon'ble High Court of Delhi in its judgment dated 6-9-2004 in W.P. No. 813 of 2004 Balbir Singh v.s. Union of India and Others constituted a committee to examine the lacunae in implementation of the said Act. The recommendations of the said Committee were examined along with the recommendations of the Rajiv Gandhi Foundation. The draft guiding principles of the organ transplantation prepared by the World Health Organisation were also taken into consideration and after wide consultation, the administrative Ministry proposes to amend the said Act.

4. The amendments proposed, *inter alia*, are as follows:—

(i) presently the said Act regulates transplantation of the human organs, it has been proposed that the said Act also regulate the transplantation of tissues of the human body. Therefore, it is proposed to amend the long title, short title of the Act and also to insert appropriate definition of "tissues" in the definition clause and consequential amendments in other sections of the Act;

(ii) to expand the definition of "near relative" in order to include the grandfather, grandmother, grandson and granddaughter as near relative;

(iii) amendment of section 3 with a view to make mandatory for the Intensive Care Unit or Treating Medical Staff to request relatives of brain dead patients for organ donation and to provide for the enucleating of corneas by a trained technician. Further to enable a surgeon or a physician and an anaesthetist or intensivist to be included in the medical board in the event of non-availability of a neurosurgeon or neurologist for certification of brain death;

(iv) amendment of section 9 to regulate the transplantation of organs for foreign nationals, to prevent the exploitation of minors, to provide for Swap Donations of organs, to empower the Central Government to prescribe the composition of Authorisation Committees and to empower State Governments and Union territories to set up their own Authorisation Committees;

(v) insertion of a new section 13A to constitute the Advisory Committees to advise the Appropriate Authorities;

(vi) insertion of a new section 13B to empower the Appropriate Authorities to summon persons, seek production of documents, issue search warrants, etc.;

(vii) insertion of new section 13C to establish a National Human Organs and Tissues Removal and Storage Network;

(viii) to provide for the development and maintenance of a national registry of the recipients of human organs transplants;

(ix) amendment of section 14 to appoint a "transplant coordinator" in all hospitals registered for organ retrieval and transplantation; and to provide for the registration of non-governmental organisations working in the field of organ retrieval, banking and transplantation;

(x) amendment of sections 18, 19 and 20 to enhance the penalties provided under the Act; and

(xi) consequential amendment in section 24 in respect of the rule making power of the Central Government.

5. The Bill seeks to achieve the above objectives.

NEW DELHI;

The 17th November, 2009.

GHULAM NABI AZAD

PRESIDENT'S RECOMMENDATION UNDER ARTICLE 117 OF THE CONSTITUTION
OF INDIA

[Copy of letter No. S.12011/13/2007—MS dated the 30th November, 2009 from Shri Ghulam Nabi Azad, Minister of Health and Family Welfare to the Secretary-General, Lok Sabha]

The President, having been informed of the subject matter of the proposed Transplantation of Human Organs (Amendment) Bill, 2009 recommends to the House the consideration of the Bill under article 117(3) of the Constitution.

Ministry of Law, Justice and Company Affairs
(Legislative Department)

New Delhi, the 11th July, 1994

The following Act of Parliament received the assent of the President on the 8th July, 1994 and is hereby published for general information:-

THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994

No.42 OF 1994

[8th July, 1994]

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto.

Whereas it is expedient to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs;

And whereas Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

And whereas in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and Maharashtra to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

Be it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows:

Chapter I
Preliminary

- | | | |
|---|----|--|
| Short title,
application and
commencement | 1. | (1). This Act may be called the Transplantation of Human Organs Act, 1994.
(2). It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and Maharashtra and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.
(3). It shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union Territory, mean the date on which this Act comes into force in such State or Union Territory. |
| Definitions | 2. | In this Act, unless the context otherwise requires:
(a) "advertisement" includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;
(b) "Appropriate Authority" means the Appropriate Authority |

- appointed under section 13;
- (c) "Authorisation Committee" means the committee constituted under clause (a) or clause (b) of sub-section (4) of section 9;
 - (d) "brain-stem death" means the stage at which all functions of the brain stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3;
 - (e) "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;
 - (f) "donor" means any person, not less than eighteen years of age, who voluntarily authorizes the removal of any of his human organs for therapeutic purposes under sub-section (1) or sub-section (2) of section 3;
 - (g) "hospital" includes a nursing home, clinic, medical centre, medical or teaching institution for therapeutic purposes and other like institution;
 - (h) "human organ" means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;
 - (i) "near-relative" means spouse, son, daughter, father, mother, brother or sister;
 - (j) "notification" means a notification published in the Official Gazette;
 - (k) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing –
 - (i) the cost of removing, transporting or preserving the human organ to be supplied; or
 - (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body;
 - (l) "prescribed" means prescribed by rules made under this Act;
 - (m) "recipient" means a person into whom any human organ is, or is proposed to be, transplanted;
 - (n) "registered medical practitioner" means a medical practitioner who possesses any recognized medical qualification as defined in clause (h) of section-2 of the Indian Medical Council Act, 1956, and who is enrolled on a State Medical Register as defined in clause (k) of that section;
 - (o) "therapeutic purposes" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and
 - (p) "transplantation" means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

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Authority for the removal of human organs

- Authority for removal of human organs
3. (1). Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes.
- (2). If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorized at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.
- (3). Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person's human organs being used for therapeutic purposes, authorize the removal of any human organ of the deceased person for its use for therapeutic purposes.
- (4). The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.
- (5). Where any human organ is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body or, where it appears to be a case of brain-stem death, that such death has been certified under sub-section (6).
- (6). Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following namely:
- (i) the registered medical practitioner in charge of the hospital in which brain-stem death has occurred;
 - (ii) an independent registered medical practitioner, being a specialist, to be nominated by the

registered medical practitioner specified in cause (i), from the panel of names approved by the Appropriate authority;

(iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and

(iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

(7). Notwithstanding anything contained in sub-section (3), where brain-stem death of any person, less than eighteen years of age, occurs and is certified under sub-section (6), any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the removal of any human organ from the body of the deceased person.

Removal of human organs not to be authorised in certain cases.

4. (1). No facilities shall be granted under sub-section (2) of section 3 and no authority shall be given under sub-section (3) of that section for the removal of any human organ from the body of a deceased person, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

(2). No authority for the removal of any human organ from the body of a deceased person shall be given by a person to whom such body has been entrusted solely for the purpose of interment, cremation or other disposal.

Authority for removal of human organs in case of unclaimed bodies in hospital or prison.

5. (1). In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(2). No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even through such near relative has not come forward to claim the body of the deceased person within the time specified in such sub-section (1).

Authority for removal of human organs from bodies sent for post-

6. Where the body of a person has been sent for post-mortem examination-

(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause;

mortem
examination for
medico-legal or
pathological
purposes.

OR

(b) for pathological purposes,
the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorize the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

Preservation of 7. After the removal of any human organ from the body of any human organs. person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

Savings 8. (1). Nothing in the foregoing provisions of this Act shall be construed as rendering unlawful any dealing with the body or with any part of the body of a deceased person if such dealing would have been lawful if this Act had not been passed.

45 of 1860 (2). Neither the grant of any facility or authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable under section 297 of the Indian Penal Code.

Restrictions on 9 (1). Save as otherwise provided in sub-section (3), no human removal and transplanted of human organs. 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.

(2). Where any donor authorizes the removal of any of his human organs after his death under sub-section (2) of section 3 of any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.

(3). If any donor authorizes the removal of any of his human organs before his death under sub-section (1) of section 3 for transplanted into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.

(4). (a) The Central Government shall constitute, by notification, one or more Authorisation Committees

consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union Territories for the purposes of this section.

(b) The State Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Government on such terms and conditions as may be specified in the notification for the purposes of this section.

- (5). On an application jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the Authorisation Committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organs.
- (6). If, after the inquiry and after giving an opportunity to the applicants of being heard, the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for approval.

Chapter III Regulation of hospitals

Regulation of hospitals conducting the removal, storage or transplantation of human organs

10. (1). On and from the commencement of this Act:
- (a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplantation of any human organ;
 - (b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and
 - (c) no place including a hospital registered under sub-section (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ except for therapeutic purposes.
- (2). Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purposes, by a registered medical practitioner.

Explanation: For the purposes of this sub-section, "ears" includes ear drums and ear bones.

Prohibition of removal or transplantation of human organs

11. No donor and no person empowered to give authority for the removal of any human organ shall authorise the removal of any human organ for any purpose other than therapeutic purposes.

organs for any purpose other than therapeutic purposes.

Explaining effects, etc., to donor and recipient.

12. No registered medical practitioner shall undertake the removal or transplantation of any human organ unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplantation to the donor and the recipient respectively.

Chapter IV Appropriate Authority

Appropriate Authority

13. (1). The Central Government shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for the purposes of this Act.
(2). The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.
(3). The Appropriate Authority shall perform the following functions, namely:
 - (i) to grant registration under sub-section (1) of section 15 or renew registration under sub-section (3) of that section;
 - (ii) to suspend or cancel registration under sub-section (2) of section 16;
 - (iii) to enforce such standards as may be prescribed, for hospitals engaged in the removal, storage or transplantation of any human organ;
 - (iv) to investigate any complaint of breach of any of the provisions of this Act or any of the rules made thereunder and take appropriate action;
 - (v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and
 - (vi) to undertake such other measures as may be prescribed.

Chapter V Registration of Hospitals

- Registration of hospitals engaged in removal, storage or transplantation of human organs.
14. (1). No hospital shall commence any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes after the commencement of this act unless such hospital is duly registered under this Act. Provided that every hospital engaged, either partly or exclusively in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:
 Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has applied for registration and is so registered or till such application is disposed of, whichever is earlier.
- (2). Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.
- (3). No hospital shall be registered under this Act unless the Appropriate authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.
- Certificate of registration
15. (1). The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the hospital a certificate of registration in such form, for such period and subject to such conditions as may be prescribed.
- (2). If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.
- (3). Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.
- Suspension or cancellation of registration
16. (1). The Appropriate Authority may, suo moto or on complaint, issue a notice to any hospital to show cause why its registration under this Act should not be suspended or cancelled for the reasons mentioned in the notice.
- (2). If, after giving a reasonable opportunity of being heard to the hospital, the Appropriate Authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any criminal action that it may take against such hospital, suspend its registration for such period as

it may think fit or cancel its registration:

Provided that where the Appropriate authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any hospital without issuing any notice.

- Appeals
17. (1). Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under sub-section (6) of section 9, or any hospital aggrieved by an order of the Appropriate Authority rejecting an application for registration under sub-section (2) of section 15 or an order of suspension or cancellation of registration under sub-section (2) of section 16, may, within thirty days from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against such order to:
- (i) the Central Government where the appeal is against the order of the Authorisation Committee constituted under clause (a) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (1) of section 13; or
 - (ii) the State Government, where the appeal is against the order of the Authorisation Committee constituted under clause (b) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (2) of section 13.

Chapter VI Offences and Penalties

- Punishment for removal of human organ without authority.
18. (1). Any person who renders his services to or at any hospital and who, for purposes of transplantation, conducts associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.
- (2). Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.
- Punishment for commercial dealings in human organs
19. Whoever –
- (a) makes or received any payment for the supply of, or for an offer to supply, any human organ;
 - (b) seeks to find person willing to supply for payment any human organ;
 - (c) offers to supply any human organ for payment;
 - (d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;

- (e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or
- (f) publishes or distributes or causes to be published or distributed any advertisement-
 - (a) inviting persons to supply for payment of any human organ;
 - (b) offering to supply any human organ for payment; or
 - (c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees:

Provided that the court may, for any adequate and special reason to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

Punishment for contravention of any other provision of this Act. 20. Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

Offences by companies. 21. (1). Where any offence, punishable under this Act, has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2). Notwithstanding anything contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation: For the purposes of this section:

- (a) “company” means any body corporate and includes a firm or other association of individuals; and
 - (b) “director”, in relation to a firm, means a partner in the firm.
- Cognizance of offence 22. (1). No court shall take cognizance of an offence under this Act except on a complaint made by:
- (a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or
 - (b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of his intention to make a complaint to the court.
- (2). No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.
- (3). Where a complaint has been made under clause (b) of sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

Chapter VII Miscellaneous

- Protection of action taken in good faith. 23. (1). No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.
- (2). No suit or other legal proceeding shall lie against the Central Government or the State Government for any damage caused or likely to be caused for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.
- Power to make rules. 24. (1). The Central Government may, by notification, make rules for carrying out the purposes of this Act.
- (2). In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:
- (a) the manner in which and the conditions subject to which any donor may authorise removal, before his death, of any human organ of his body under sub-section (1) of section 3;
 - (b) the form and the manner in which a brain-stem death is to be certified and the conditions and requirements which are to be satisfied for that purpose under sub-section (6) of section 3;
 - (c) the form and the manner in which any of the parents may give authority, in the case of brain-stem death of a minor, for the removal of any

- human organ under sub-section (7) of section 3;
 - (d) the form in which authority for the removal of any human organ from an unclaimed dead body may be given by the person incharge of the management or control of the hospital or prison, under sub-section (1) of section 5;
 - (e) the steps to be taken for the preservation of the human organ removed from the body of any person, under section 7;
 - (f) the form and the manner in which an application may be jointly made by the donor and the recipient under sub-section (5) of section 9;
 - (g) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under section 12;
 - (h) the standards as are to be enforced by the Appropriate authority for hospitals engaged in the removal, storage or transplantation of any human organ under clause (iii) of sub-section (3) of section 13;
 - (i) the other measures as the Appropriate Authority shall undertake in performing its functions under clause (vi) of sub-section (3) of section 13;
 - (j) the form and the manner in which an application for registration shall be made and the fee which shall be accompanied, under sub-section (2) of section 14;
 - (k) the specialised services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a hospital for registration, under sub-section (3) of section 14;
 - (l) the form in which, the period for which and the conditions subject to which certificate of registration is to be granted to a hospital, under sub-section (1) of section 15;
 - (m) the manner in which and the fee on payment of which certificate of registration is to be renewed under sub-section (3) of section 15;
 - (n) the manner in which an appeal may be preferred under section 17;
 - (o) the manner in which a person is required to give notice to the Appropriate Authority of the alleged offence and of his intention to make a complaint to the court, under clause (b) of sub-section (1) of section 22; and
 - (p) any other matter which is required to be, or may be prescribed.
- (3). Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of

thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

- Repeal and 25. (1). The Ear Drums and Ear Bones (Authority for Use for saving 28 of 1982 and 29 of 1982 Therapeutic Purposes) Act, 1989 and the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 are hereby repealed.
- (2). The repeal shall, however, not affect the previous operation of the Acts so repealed or anything duly done or suffered thereunder.

MINISTRY OF HEALTH AND FAMILY WELFARE

NOTIFICATION

New Delhi, the 4th February, 1995

G.S.R. 51 (E)-In exercise of the powers conferred by sub-section (1) of Section 24 of the Transplantation of Human Organs Act, 1994(42 of 1994), the Central Government here by makes the following rules, namely:-

1. SHORT TITLE AND COMMENCEMENT

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

(2) They shall come into force on the date of their publication in the official Gazette.

2. DEFINITIONS

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

(b) "Form" means a form annexed to these Rules;

(c) "Section" means a section of the Act;

(d) words and expression used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. AUTHORITY FOR REMOVAL OF HUMAN ORGAN

Any donor may 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 1.

4. DUTIES OF THE MEDICAL PRACTITIONER

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

(a) that the donor has given his authorization in Form 1;

(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.

(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 polymorphism;

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

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

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

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

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

(b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 6 or Form 7.

(3) A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brainstem death, satisfy himself-

(a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act;

(b) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of Section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

5. PRESERVATION OF ORGANS

The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

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.

7. REGISTRATION OF HOSPITAL

(1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.

8. RENEWAL OF REGISTRATION

(1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.

(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and Rules made there under and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

9. CONDITIONS FOR GRANT OF CERTIFICATE OF REGISTRATION

No hospital shall be granted a certificate of registration under this Act unless it fulfills 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

VARIOUS DEPARTMENTS

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I. Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology

NON-TRANSPLANTATION PROGRAMME TEAM

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff

BASIC EQUIPMENT

Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.

ADDITIONAL EQUIPMENT REQUIRED FOR TRANSPLANTATION PROGRAMME

1. Cell Saver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both 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 Cyclosporine levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.

EXPERTS

(A) Kidney Transplantation

M.S.(Gen.) surgery or equivalent qualification with three years post M.S. training in a recognized centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B) Transplantation of Liver & Other Abdominal Organs

M.S.(Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation

M. Ch. Cardio-thorasis 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.

10. APPEAL

(1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of Section 9 or by an order of the Appropriate Authority under sub-section (2) of Section 15 and Section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

[F. No. S. 12011/2/94-MS]

O.P. NIGAM, Chief Controller of Accounts

MINISTRY OF HEALTH AND FAMILY WELFARE
NOTIFICATION
New Delhi, the 4th February, 1995

G.S.R. 51 (E)-In exercise of the powers conferred by sub-section (1) of Section 24 of the Transplantation of Human Organs Act, 1994(42 of 1994), the Central Government here by makes the following rules, namely:-

1. SHORT TITLE AND COMMENCEMENT

- (1) These rules may be called the Transplantation of Human Organs Rules, 1995.
- (2) They shall come into force on the date of their publication in the official Gazette.

2. DEFINITIONS

- (a) "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);
- (b) "Form" means a form annexed to these Rules;
- (c) "Section" means a section of the Act;
- (d) words and expression used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. AUTHORITY FOR REMOVAL OF HUMAN ORGAN

Any donor may 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 1.

4. DUTIES OF THE MEDICAL PRACTITIONER

- (1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death satisfy himself-
 - (a) that the donor has given his authorization in Form 1;
 - (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.
 - (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 polymorphism;
 - (iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;
 - (iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphisms using at least five single locus polymorphic probes.
- (d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that that are so related and shall sign a certificate in Form 4.
- (2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself-
- (a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;
 - (b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form6 or Form 7.
- (3) A registered medical practitioner shall, before removing a human organ from the body of a person I the event of his brainstem death, satisfy himself-
- (a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act;
 - (b) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of Section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

5. PRESERVATION OF ORGANS

The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

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.

7. REGISTRATION OF HOSPITAL

- (1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.
- (2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.

8. RENEWAL OF REGISTRATION

- (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.
- (2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.
- (3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and Rules made there under and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

9. CONDITIONS FOR GRANT OF CERTIFICATE OF REGISTRATION

No hospital shall be granted a certificate of registration under this Act unless it fulfills 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

VARIOUS DEPARTMENTS

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I. Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology

NON-TRANSPLANTATION PROGRAMME TEAM

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff

BASIC EQUIPMENT

Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.

ADDITIONAL EQUIPMENT REQUIRED FOR TRANSPLANTATION PROGRAMME

1. Cell Saver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both 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 Cyclosporine levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.

EXPERTS

(A) Kidney Transplantation

M.S.(Gen.) surgery or equivalent qualification with three years post M.S. training in a recognized centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B) Transplantation of Liver & Other Abdominal Organs

M.S.(Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation

M. Ch. Cardio-thorasis 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.

10. APPEAL

- (1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of Section 9 or by an order of the Appropriate Authority under sub-section (2) of Section 15 and Section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.
- (2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

[F. No. S. 12011/2/94-MS]
O.P. NIGAM, Chief Controller of Accounts

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st July, 2008

G.S.R. 571(E).— In exercise of the powers conferred by sub-section (1) of section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following amendments to the Transplantation of Human Organs Rules, 1995, namely:-

1. Short title and Commencement

(1) These rules may be called the Transplantation of Human Organs (Amendment) Rules, 2008.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Transplantation of Human Organs (Amendment) Rules, 2008 (hereinafter referred to as the said rules), - (i) clause (d) shall be renumbered as clause (f), thereof and before clause (f) as so renumbered the following clauses shall be inserted, after clause (c), namely:

(i) after sub-rule (c) of Rule 2, the following shall be inserted:

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

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

3. In the said rules, in rule 3, for the words and figure "Form.1" the words, figures and letters "Forms 1(A), 1(B) and 1(C) shall be substituted:

4. In the said rules, - (i). in rule 4 for sub-rule(1) the following sub-rule shall be substituted, namely:-

"(i) Duties of the Medical Practitioner:

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

- (a) that the donor has given his authorization in appropriate Form 1(A) or 1(B) or 1(C).
- (b) that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.
- (c) that the donor is a near relative of the recipient, as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary documents as prescribed and medical tests, if required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant centre.
- (d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provisions of sub-rule(2) of rule 4A.
- (e) In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.

(ii) In rule 4 in sub-rule(2) for clause (b) the following clause shall be substituted, namely:-

"(b) that then person lawfully in possession of the dead body has signed a certificate as specified in Form 6."

(iii) the existing Form 7 shall be omitted.

5. In the said rules, after rule 4 the following rule shall be inserted, namely:-

"4-A. (1) The medical practitioner who will be part of the organ transplantation Authorisation Committee shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

- (2) Where the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e. Incharge of transplant centre must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and family photograph depicting the entire immediate family, birth certificate of children containing particulars of parents.
- (3) When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committees shall consider all such requests.
- (4) when the proposed donor and the recipient are not 'near relatives', as defined under clause(i) of section 2 of the Act, the Authorisation Committee shall evaluate that,-
 - (i) there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;
 - (ii) the following shall specifically be 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 or 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 known person with criminal record;
 - (vi) that the next of the kin of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection of such kin shall also be recorded and taken note of.

6. In the said rules:-

- (i) For rule 6 the following rules shall be substituted, namely:-

"6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the concerned competent authority or Authorisation Committee as specified in Form 10. The Authorisation Committee shall take a decision on such application in accordance with the guidelines in rule 6-A."

(ii) after rule 6, the following rule shall be inserted, namely:-

"6A. Composition of Authorisation Committees:

1. There shall be one State level Authorisation Committee.

2. Additional authorisation committees may be set up at various levels as per norms given below, namely:-

(i) no member from transplant team of the institution should be a member of the respective Authorisation Committee. All Foreign Nationals (related and unrelated) should go to 'Authorisation Committee' as abundant precaution needs to be taken in such cases;

(ii) Authorisation Committee should be Hospital based in Metro and big cities if the number of transplants exceed 25 in a year at the respective transplantation centres. In smaller towns, there are State or District level Committees if transplants are less than 25 in a year in the respective districts.

(A) Composition of Hospital Based Authorisation Committees: (To be constituted by the State Government and in case of Union territory by the Central Government).

(a) the senior most person officiating as Medical Director or Medical Superintendent of the Hospital;

(b) two senior medical practitioners from the same hospital who are not part of the transplant team;

(c) 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 University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc.; and

(d) Secretary (Health) or nominee and Director Health Services or nominee.

(B) Composition of State or District Level Authorisation Committees: (To be constituted by the State Government and in case of Union territory by the Central Government).

- (a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District.
- (b) 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.
- (c) 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 University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc.; and
- (d) Secretary (Health) or nominee and Director Health Services or nominee.

(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.)

6B. The State level committees shall be formed for the purpose of providing approval or no objection certificate to the respective donor and recipient to establish the legal and residential status as a domicile state. It is mandatory that if donor, recipient and place of transplantation are from different states, then the approval or 'no objection certificate' from the respective domicile State Government should be necessary. The institution where the transplant is to be undertaken in such case the approval of Authorisation Committee is mandatory.

6C. The quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the Chairman. The presence of Secretary (Health) or nominee and Director of Health Services or nominee is mandatory.

6D. The format of the Authorisation Committee approval should be uniform in all the institutions in a State. The format may be notified by respective State Government.

6E. Secretariat of the Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee. 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 concerned officer(s) of the State/ Union territory Government.

6F. The Authorisation Committee shall focus its attention on the following, namely:-

(a) Where the proposed transplant is between persons related genetically, Mother, Father, Brother, Sister, Son or Daughter above the age of 18 years).

the concerned competent authority shall 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 or Voters identity Card or Passport or Driving License or PAN Card or 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 as below:
 - (a) the tests for Human Leukocyte Antigen (HLA), Human Leukocyte Antigen-B alleles to be performed by the serological and/or Polymerase chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - (b) test for Human Leukocyte Antigen-DR beta genes to be performed using the Polymerase chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - (c) the tests referred to in sub-rules (i) and (ii) shall be got done from a laboratory accredited with National Accreditation Board for Laboratories (NABL)."
 - (d) where the tests referred to in (i) to (iii) 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, preferably both parents. 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 failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

- (b) The papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation, while the approval will be granted by the Authorisation Committee.
- (c) Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorisation Committee):

The concerned competent authority or authorisation committee as the case may be 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.

- (d) Where the proposed transplant is between individuals who are not "near relatives". The authorization committee shall 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. In this connection the Authorisation Committee shall take into consideration:-

- (a) an explanation of the link between them and the circumstances which led to the offer being made;
- (b) documentary evidence of the link e.g. proof that they have lived together etc.;
- (c) reasons why the donor wishes to donate; and
- (d) old photographs showing the donor and the recipient together.

- (ii) that there is no middleman/tout involved;
- (iii) 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;
- (iv) that the donor is not a drug addict or a known person with criminal record;
- (v) 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 or disagreement or 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.
 - (ii) Authorisation Committee shall examine the cases of Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution. Such cases should be considered rarely on case to case basis.
- (f) 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 be videographed.
- (g) In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed by a person other than the recipient. Any document with regard to the proof of residence or 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.
- (h) 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 would 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.
 - (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.
 - (iv) all interviews to be video recorded.
- (i) 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.

(j) Every authorised transplantation centre must have its own website. The Authorisation Committee is required to take final decision within 24 hours of holding the meeting for grant of permission or rejection for transplant. The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within 24 hours of taking the decision. Apart from this, the website of the hospital or institution must update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with the details of each transplantation. The same data should be accessible for compilation, analysis and further use by respective State Governments and Central Government.

7. In the said rules, in rule 7, after clause(2) the following clause shall be inserted, namely:-

"7(3) before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant coordinator."

8. In the said rules, for rule 9 the following rule shall be substituted, namely:-

"9. Conditions for grant of Certificate of Registration:

No hospital shall be granted a certificate of registration under this Act unless it fulfils the following requirement of manpower, equipment, specialized services and facilities as laid down below:-

A 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.
- (4) 24 hours availability of laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology and Hematology and Radiology departments with trained staff.
- (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 specialties including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology,

gastroenterology, nephrology, neurology, paediatrics, gynaecology immunology and cardiology etc. should be available to the transplantation centre.

B Equipments:

Equipments as per current and expected scientific requirements specific to organ or 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.

C Experts and their qualifications:-

(A) Kidney Transplantation:

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised 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 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 operations.

[F. No. S-12011/12/2007-MS]

VINEET CHAUDHRY, Jt. Secy.

FORM 1(A)

(Page 1 of 2)

*(To be completed by the prospective related donor)**(See Rule 3)*

My full name is

and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

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

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:

Photograph of the Recipient
(Attested by Notary Public)

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

FORM 1(A) [Page- 2]

- 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 1(B)

(Page 1 of 2)

(To be completed by the prospective spousal donor)

(see Rule 3)

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

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

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 as
follows:

Photograph of the Recipient
(Attested by Notary Public)

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

- 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

FORM 1(B) [Page-2]

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

- (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.

OR

- (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 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 1(C)

(Page 1 of 2)

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

(See Rule 3)

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

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

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

Details of last three years income and vocation of donor

I hereby authorize to remove for therapeutic purposes/consent to donate my (state which organ) to a person whose full name is and who was born on (day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public)

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

FORM 1(C) [Page-2]

- 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 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 (name
 of the organ) 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 Authorisation Committee/ Registered Medical Practitioner i.e. Incharge of
 transplant centre (as the case may be) 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:

Date:

Signature of Doctor
Seal

To be affixed
(pasted) and
attested by the
doctor concerned.

The signatures and
seal should partially
appear on
photograph and
document without
disfiguring the face
in photograph.

Photograph of the Donor
(Attested by doctor)

To be affixed
(pasted) and
attested by the
doctor concerned.

The signatures and
seal should partially
appear on
photograph and
document without
disfiguring the face
in photograph.

Photograph of the recipient
(Attested by the doctor)**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/ Smt. aged the donor
 and Shri/ Smt. S/o, D/o, W/o
 Shri/Smt. 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.

Place

Date

Signature
(To be signed by the Head of the Laboratory

Seal

2945 GI/08-5

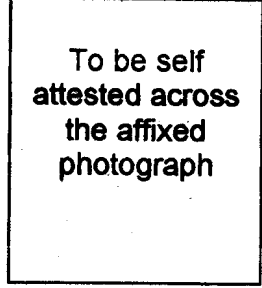
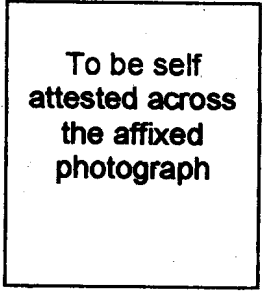
FORM 10

(Page 1 of 2)

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,
Shri/Smt. 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,
Shri/Smt. 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 (name of the organ) to
Shri/Smt.

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.

FORM 10 [Page 2]**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.
7. As per the Supreme Court's judgement dated 31.03.2005, the approval/ No Objection Certificate from the concerned State/ Union Territory Government or Authorisation Committees is mandatory from the domicile State/ Union Territory of donor as well as recipient. It is understood that final approval for transplantation should be granted by the Authorisation Committee/ Registered Medical Practitioner i.e. Incharge of transplant centre (as the case may be) where transplantation should be done.

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date :

Date :

Place :

Place :