

15 -ാം കേരള നിയമസഭ

5 -ാം സമ്മേളനം

നക്ഷത്രചിഹ്നമിട്ട ചോദ്യം നം. 180

06-07-2022 - ൽ മറുപടിയ്ക്ക്

അവയവദാന ശസ്ത്രക്രിയകൾക്ക് പ്രോട്ടോക്കോൾ

ചോദ്യം	ഉത്തരം
<p align="center">ശ്രീ. സജീവ് ജോസഫ്, ശ്രീ പി സി വിഷ്ണുനാഥ്, ശ്രീ. ഐ .സി .ബാലകൃഷ്ണൻ , ശ്രീ. അൻവർ സാദത്ത്</p>	<p align="center">ശ്രീമതി വിനോ ജോർജ്ജ് (ആരോഗ്യ- വനിത-ശിശുവികസന വകുപ്പ് മന്ത്രി)</p>
<p>(എ)</p> <p>സംസ്ഥാനത്ത് അവയവദാന ശസ്ത്രക്രിയകൾ നടത്തുന്നതുമായി ബന്ധപ്പെട്ട് അംഗീകൃത പ്രോട്ടോക്കോൾ നിലവിലുണ്ടോ; എങ്കിൽ ഇതിന്റെ പ്രധാന വ്യവസ്ഥകൾ എന്തൊക്കെയാണെന്ന് വ്യക്തമാക്കുമോ;</p>	<p>(എ)</p> <p>1994 ൽ ഇന്ത്യൻ പാർലമെന്റ് പാസ്സാക്കിയ ട്രാൻസ്പ്ലാന്റേഷൻ ഓഫ് ഹ്യൂമൻ ഓർഗൻസ് ആക്ടിലെ എല്ലാ നിയമങ്ങളും 2014-ൽ നിലവിലുവന്ന ട്രാൻസ്പ്ലാന്റേഷൻ ഓഫ് ഹ്യൂമൻ ഓർഗൻ ആന്റ് ടിഷ്യൂസ് റൂൾസും പാലിച്ചുകൊണ്ടാണ് സംസ്ഥാനത്ത് അവയവദാനവും അവയവം മാറ്റിവെക്കൽ ശസ്ത്രക്രിയയും നടക്കുന്നത്. ടി ആക്ടിന്റെ പരിധിയിൽ നിന്നുകൊണ്ട് സംസ്ഥാന സർക്കാർ സംസ്ഥാനത്ത് അവയവമാറ്റ ശസ്ത്രക്രിയകൾ നടത്തുന്നതിനുള്ള മാർഗ്ഗനിർദ്ദേശങ്ങൾ 19.11.2010 ലെ 14931/എസ്2/2009/ആ.ക.വ പ്രകാരം വിജ്ഞാപനം ചെയ്തിട്ടുണ്ട്. പകർപ്പ് അനുബന്ധം 1 ആയി ചേർത്തിരിക്കുന്നു.</p> <p>മസ്തിഷ്ക മരണാനന്തര അവയവദാനവുമായി ബന്ധപ്പെട്ട് പാലിക്കേണ്ട മാർഗരേഖകൾ 04.02.2012 ലെ സ.ഉ.(കൈ) നം.36/ 2012/ആകവ, സ.ഉ.(കൈ)നം.37/2012/ആകവ, സ.ഉ. (കൈ)നം.38/2012/ആകവ എന്നീ സർക്കാർ ഉത്തരവുകൾ പ്രകാരം പുറപ്പെടുവിച്ചിട്ടുണ്ട്. പകർപ്പുകൾ അനുബന്ധം 2 ആയി ചേർത്തിരിക്കുന്നു.</p> <p>കൂടാതെ മസ്തിഷ്ക മരണ സ്ഥിരീകരണവുമായി ബന്ധപ്പെട്ടു രാജ്യത്തു തന്നെ ആദ്യമായി ഒരു സ്റ്റാൻഡേർഡ് ഓപ്പറേറ്റിംഗ് പ്രൊസീജിയർ 19.01.2020ലെ സ.ഉ(കൈ)നം.07/2020/ആ.ക.വ പ്രകാരം പുറപ്പെടുവിച്ചിട്ടുള്ളത് കേരള സർക്കാർ ആണ്. പകർപ്പ് അനുബന്ധം 3 ആയി ചേർത്തിരിക്കുന്നു. തുടർന്ന് പല സംസ്ഥാനങ്ങളും ഇത് മാതൃകയാക്കുകയും ചെയ്തിട്ടുണ്ട്.</p>

<p>(ബി)</p>	<p>തിരുവനന്തപുരം മെഡിക്കൽ കോളേജിൽ വൃക്ക മാറ്റിവെക്കൽ ശസ്ത്രക്രിയയെ തുടർന്ന് രോഗി മരിച്ച സംഭവത്തിൽ ഏതൊക്കെ വിഭാഗങ്ങൾക്ക് വീഴ്ച സംഭവിച്ചിട്ടുള്ളതായാണ് കണ്ടെത്തിയിട്ടുള്ളതെന്നും ഉത്തരവാദികളായവർക്കെതിരെ എന്തെങ്കിലും ശിക്ഷാ നടപടികൾ സ്വീകരിച്ചിട്ടുണ്ടോയെന്നും വ്യക്തമാക്കുമോ;</p>	<p>(ബി)</p> <p>തിരുവനന്തപുരം മെഡിക്കൽ കോളേജിൽ വൃക്ക മാറ്റിവെക്കൽ ശസ്ത്രക്രിയയെത്തുടർന്ന് രോഗി മരിച്ച സംഭവത്തിൽ യൂറോളജി, നെഫ്രോളജി വിഭാഗം വകുപ്പ് മേധാവികളെ അന്വേഷണ വിധേയമായി സസ്പെൻഡ് ചെയ്തിട്ടുണ്ട്. ഈ കാര്യങ്ങളുമായി ബന്ധപ്പെട്ട് വിശദമായ അന്വേഷണം നടത്തുന്നതിലേയ്ക്കായി ആരോഗ്യ കുടുംബക്ഷേമ വകുപ്പ് അഡീഷണൽ ചീഫ് സെക്രട്ടറിയെ ചുമതലപ്പെടുത്തിയിട്ടുണ്ട്.</p> <p>ഈ കാര്യങ്ങളുടെ വിശദമായ അന്വേഷണം നടന്നു വരികയാണ്.</p>
<p>(സി)</p>	<p>ഇത്തരം സംഭവങ്ങൾ ആവർത്തിക്കാതിരിക്കാൻ എന്തെങ്കിലും തിരുത്തൽ നടപടികൾ സ്വീകരിച്ചിട്ടുണ്ടോ; എങ്കിൽ വിശദാംശം നൽകുമോ?</p>	<p>(സി)</p> <p>നിലവിലുള്ള മാർഗ്ഗ നിർദ്ദേശങ്ങൾ കർശനമായി പാലിക്കുന്നതിന് മെഡിക്കൽ വിദ്യാഭ്യാസ വകുപ്പ് ഡയറക്ടർക്കും കേരള സ്റ്റേറ്റ് ഓർഗൻ ആന്റ് ടിഷ്യൂ ട്രാൻസ്പ്ലാന്റ് ഓർഗനൈസേഷൻ എക്സിക്യൂട്ടീവ് ഡയറക്ടർക്കും കർശന നിർദ്ദേശം നൽകിയിട്ടുണ്ട്.</p>

സെക്ഷൻ ഓഫീസർ



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department - Guidelines for the Brain Death Certification - Orders issued.

HEALTH & FAMILY WELFARE (B) DEPARTMENT

G.O.(Ms)No.7/2020/H&FWD Dated, Thiruvananthapuram, 19/01/2020

- Read:-
1. G.O (Rt) No.3060/2018/H&FWD dated 06.10.2018
 2. Letter dated 16.02.2019 from Dr. Thomas Iype, Professor & Head, Department of Neurology, Government Medical College, Thiruvananthapuram.
 3. Letter No.CA No.10/2019/SPL dated 24.05.2019 from the Special Officer, Directorate of Medical Education.
 4. Letter No.615/2019/KNOS dated 05.11.2019 from Dr. Noble Gracious, Nodal Officer, Kerala Network for Organ Sharing.

ORDER

In order to streamline the procedure for declaration of brain stem death, uniform procedure has to be laid down. The determination of brain stem death should be decided based on a standard clinical practice which is adapted world over as per the present medical and scientific knowledge. It is also imperative to do proper capacity building among medical practitioners and generate awareness among people on brain stem death and its certification procedure.

2. Section 2(1)(b) of The Registration of Births and Deaths Act, 1969 defines "death" as the "permanent disappearance of all evidence of life at any time after live-birth has taken place." There is no specific reference to the cessation of cardiac or respiratory functions in this definition. It is clear from the scheme of the Act that the main purpose of the Act is to maintain and collect information about births and deaths, rather than prescribing how death should be determined. The determination of death is a medical function, which is reflected in the provisions of the Act. The Rules framed under the Act specify the format for the medical certificate of the cause of death (Form No.4 under the Kerala Registration of Births and Deaths Rules, 1999), which lays an emphasis on the kinds of information that are to be documented, rather than prescribing the method that medical practitioners should adopt to reach a determination of death. The form requires information about the immediate cause of death as well as other significant conditions of death.

3. In the section on "Cause of Death", the directions for completing Form

No.7 state that medical practitioners must first enter the immediate cause of death. It is then clarified that: "This does not mean the mode of dying, e.g., heart failure, respiratory failure etc." The use of the term "etc" in this context is of significance. It suggests that there may be other modes of dying apart from heart failure or respiratory failure. One of these modes is brain stem death and therefore, brain-stem death is also considered death under the Registration of Births and Deaths Act, 1969.

4. The WHO, Global Glossary of Terms and Definitions on Donation and Transplantation, 2009, defines brain-stem death as: "Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time."

5. In Indian law on the determination of brain-stem death, it is clear that declaration of brain-stem death means, declaring a person to be dead - both clinically and legally. Allowing the brain-dead to continue on ventilators may lead to potential harms which include mistreatment of the dead, deprivation of dignity, provision of false hope with resultant distrust, prolongation of the grieving process, undermining the professional responsibility of the physician to achieve a timely and accurate diagnosis, and an anticipated societal harm arising from a negotiated and inconsistent standard of death determination.

6. Considering all these aspects, as per the Government Order read above, an Expert Committee was constituted for developing parameters for Brain Death Certification so as to remove the ambiguities in the minds of health care providers as well as the public, thereby making the process of declaration of death transparent. The Committee has submitted its report as per the letter read as 2nd paper above. A Workshop was conducted on 14.05.2019 participating experts in various specialities including national experts to discuss the report submitted by the Expert Committee. Another meeting was also conducted with academic, administrative and legal experts on 16.10.2019. By consolidating the opinion received during the workshop and the meeting, the Nodal Officer, Kerala Network for Organ Sharing, as per the letter read as 4th paper above, has submitted a proposal for issuing guidelines for Brain Stem Death Certification.

7. Government have examined the matter in detail and are pleased to issue the following guidelines for Brain Stem Death Certification with the objective of ensuring appropriate level of care to patients, to perform standard clinical procedure to follow for declaration of death by brain stem death criterion and to ensure dignity of the deceased.

- i. The clinical evidence of an acute central nervous system catastrophe which is compatible with a clinical diagnosis of brain death should be established before subjecting a person to further tests for evaluating brain stem death.
- ii. The medical practitioners should have a conversation with the near relatives/caregiver regarding the medical status and prognosis of the patient in whom brain stem death testing including apnoea test is being considered

for confirmation of brain stem death diagnosis.

- iii. The assessment of brain stem reflexes should be done using a series of tests, which are to be repeated after an interval of six hours by a panel of four doctors, including a doctor empanelled by the Appropriate Authority. One doctor in the panel has to perform the test and it is mandatory that other panel members have to witness and interpret these tests.
- iv. The Apnoea test is the last brain stem reflex test to be performed, and that too, only if all other tests confirm the absence of other brain stem reflexes.
- v. All the prescribed tests are required to be performed twice by the panel of doctors with the minimum interval of 6 hours between the tests "to ensure that there has been no observer error" and persistence of the clinical state can be documented with absolute degree of certainty. It is to be noted that the diagnosis is based only on the clinical examination.
- vi. A neurophysiological or imaging study to prove the absence of electrical activity or blood flow should be carried out if the treating team or panel of doctors who are certifying, are in doubt in the diagnosis of brain stem death.
- vii. After the completion of two consistent examinations by the panel of medical experts, if criteria for brain stem death are met, the committee must declare the patient dead and note the date and time of the declaration in the medical record.
- viii. The time of death is the time the arterial pCO₂ reached the target value in the second apnoea test.
- ix. The family member/caregiver should be provided with brain stem death confirmation report signed by all the four members of the brain stem death certifying team.
- x. All treatment including Cardiorespiratory support must be discontinued once brain stem death is pronounced.

8. The prescription of the tests to be followed in sequence to ascertain the absence of brain-stem functions are elaborately enumerated in the Annexures attached to this order.

(By order of the Governor)

RAJAN NAMDEV KHOBRAGADE
PRINCIPAL SECRETARY

The Advocate General, Ernakulam (with C/L).
The Director of Medical Education, Thiruvananthapuram.
The Director of Health Services, Thiruvananthapuram
The Principals/Superintendents of all Government Medical Colleges
(Through Director of Medical Education)
Dr. Noble Gracious, Nodal Officer, Kerala Network for Organ Sharing, Super

Speciality Block, Government Medical College, Thiruvananthapuram
The Principal Accountant General (Audit), Kerala, Thiruvananthapuram
The Accountant General (A&E), Kerala, Thiruvananthapuram.
The Information & Public Relations Department (Web & New Media)

Stock File/Office Copy

Copy to:- The P.S to Minister (Health, Social Justice and Women & Child
Development)

The P.S to Principal Secretary, Health & Family Welfare Department

Forwarded/By order

Section Officer

ANNEXURE 1

**PROCEDURE TO BE FOLLOWED FOR BRAIN STEM DEATH
CONFIRMATION**

**STEP 1 - PREREQUISITE FOR BRAIN STEM DEATH
CONFIRMATION**

The most important step before subjecting a patient for brain stem death confirmation is to rule out any reversible causes of coma.

1. Establish the irreversible and proximate cause of coma. History, clinical and/or neuroimaging evidence of an acute central nervous system (CNS) catastrophe that is compatible with the clinical diagnosis of brain stem death such as severe traumatic head injury, aneurysmal subarachnoid haemorrhage, severe ischemic stroke, hypoxic-ischemic brain injury etc. should be present. The patient should be in apnoeic coma that is unresponsive on a ventilator, due to a cause which is irremediable. Irremediable means that no treatment nor any therapeutic endeavours may be reasonably expected to change the patient's condition even after an adequate period of observation.
2. Exclusion of reversible cause of coma:- There is no urgency to make a diagnosis of brain stem death and all the confounding factors have to be excluded by sufficient means.

a. Intoxication

Acute intoxication (alcohol and other drugs) is the commonest cause that needs to be excluded. If intoxication is suspected, it is important to keep in mind the approximate plasma half-lives of various coma-producing drugs and that brain concentrations may lag significantly behind blood concentrations. When toxicological facilities are available, the facility may be utilized for screening drug levels of the suspected intoxicant which may interfere with the brain stem death confirmation.

b. Relaxants (Neuromuscular blocking agents)

Drug-induced residual neuromuscular junction blockade can mask brain stem reflexes and produce apnoea. This must be excluded if neuromuscular blocking agents have been used or suspected to have been used. If residual neuromuscular blockade should be tested, it should be done with the peripheral nerve stimulator. (Annexure- 2)

c. Depressant Drugs

The length of time between discontinuation of depressant drugs and undertaking brain-stem testing depends on several factors including total dose, duration of exposure to the drug, the underlying kidney and liver function and

the ability to measure the drug concentrations in blood. Hence it is essential that the recent history of the drugs ingested or administered be carefully reviewed before proceeding with brain stem death confirmation.

d.Primary Hypothermia

Temperatures between 32-34°C are occasionally associated with an impaired level of consciousness but brain-stem reflexes tend to be lost if the temperature falls below 28°C. These deficits are potentially reversible. Hence it is recommended the core temperature should be > 32°C at the time of brain stem death diagnosis.

Core temperature:

Age > 18 years - core temperature >36° C

Age > 1 year to 18 years - core temperature 36° C

e. Hypovolemic shock

Systolic blood pressure must be > 90 mm HG in age >18 years.

f. Endocrine & metabolic disorders:

It is recognised that metabolic and endocrine disturbances (e.g. hypernatremia, diabetes insipidus) are likely accompaniments of death as a result of the cessation of brain-stem function. It is important to emphasise that these may be the effect rather than the cause of cessation of brain stem function and do not preclude the diagnosis of death by neurological testing of brain-stem reflexes. Furthermore it may be detrimental to correct such abnormalities too rapidly and to delay testing of brain-stem reflexes, simply because of the need for strict adherence to attain a predetermined blood electrolyte concentration.

STEP 2—ASSESSMENT OF BRAIN STEM REFLEXES

2.1. Two sets of tests are required to be done, the minimum time interval between the first and second testing will be 6 hours in adults. In the case of children of age more than 30 days to 18 years, minimum interval should be 12 hours.

2.2. It is mandatory that two series of tests are performed for brain stem death diagnosis.

- i. Pupillary size (Both sides to be tested)
- ii. Pupillary light reflexes (The pupils are fixed and do not respond to sharp changes in the intensity of incident light) (Both sides to be tested)
- iii. Dolls head eye movements or Oculo-cephalic reflex ("absence of movements of the eyes in relation to head movement). Both sides have to be tested NB:- These tests cannot be performed in persons with cervical spine injury.
- iv. Corneal-conjunctival reflex (There should be no corneal reflex - care

should be taken to avoid damage to the cornea). Both sides have to be tested separately.

- v. Motor responses to central and peripheral noxious stimuli (No motor response can be elicited to supra orbital or peripheral (nail bed) pressure in brain stem dead patients). Both sides to be tested.
- vi. Cough and Gag reflex (There is no cough reflex response to tracheal stimulation by a suction catheter placed down the trachea to the carina, or gag response to stimulation of the posterior pharynx using a spatula)
- vii. Eye movements on caloric testing (No eye movements are seen during or following the slow injection of at least 30-50 ml of ice-cold water over 30 seconds into each external auditory meatus in turn. Clear access to the tympanic membrane must be established by direct inspection and the head should be at 30° to the horizontal plane unless this positioning is contraindicated by the presence of an unstable spinal injury).

Procedure for the cold caloric test:-

The head end of the bed is elevated to 30 degrees.

30 to 50 ml of ice-cold water is injected slowly over 30 seconds into the ear.

Once the water is injected, both the eyes are held open to observe the ocular movement.

In patients with an intact brain stem, a slow movement of the patients eyes to the side of the ice-water irrigation, followed by a rapid corrective movement of the eyes to the opposite side is noted.

The second ear should be tested after a gap of 5 minutes.

STEP 3- APNOEA TEST

The process for testing the response of respiratory centre of the brain stem to carbon dioxide stimulus (Apnoea Test). This should be the last brain stem function to be tested and should not be performed if any of the preceding tests confirm the presence of brain stem reflex. Correction of hypotension, metabolic acidosis (acceptable pH of 7.2) and pre-oxygenation is mandatory before apnoea testing

3.1. Preparation for apnoea test

- i. The adult patient should have a temperature of more than 36 degree centigrade and adequate circulating fluid volume with Systolic blood pressure of > 90mm of Hg.
- ii. The first apnoea test should be performed only after a minimum of four hours of apnoeic coma associated with the absence of brain stem reflexes. This refers to the clinical examination done and not to Step 2 of the brain stem death tests. In the case of Anoxic/hypoxic brain damage, this period should be extended to 12 hours or more.
- iii. Ventilator manipulation is performed to raise the PaCO₂ => 40 mmHg.

- iv. The patient should be preoxygenated with 100% Oxygen for 15 minutes, while still on the ventilator, before the apnoea test.
- v. A blood gas test should be done to determine the adequacy of the baseline before the test. SP02 should be monitored during Apnoea test
- vi. Place the patient on 100% Oxygen through a tracheal catheter with the tip towards the end of the tube with a continuous 6L/min O2 flow
- vii. The patient is kept off the ventilator for a variable period (usually 5 to 8 minutes) to allow the PaCO₂ to rise > 60mm Hg or > 20mmHg over baseline. During this time, the patient's chest and abdomen is exposed and observed for respiratory movements
- viii. The brain stem certifying expert committee should present during step 1, 2 and 3 for recording the time of death if apnoea test is positive.

Test interpretations:

- a. Positive Test - implying apnoea despite adequate stimulation
The patient remains apnoeic, without respiratory movements.
PaCO₂ is >60mm Hg or >20 mmHg from baseline.
- b. Negative test - Implying apnoea is not present
Respiratory efforts noted at any time during the test
- c. Indeterminate test
PaCO₂ <60 mmHg or, there is less than 20mm Hg increase over baseline.

Indeterminate tests can either be repeated or, another confirmatory test as prescribed in Annexure5 may be utilized.

Apnoea test should be aborted if the patient develops hypotension, desaturation or significant cardiac arrhythmias. (use of CPAP valve to counter desaturation, may be useful here)

These norms will vary for patients less than 12 years and patients with major chest trauma.

d. When to abandon the certification process: Rather than ordering ancillary tests, physicians may decide not to proceed with the declaration of brain stem death if clinical findings are unreliable.

ANNEXURE 2

TESTS TO EXCLUDE NEURO MUSCULAR BLOCKING AGENTS

PERIPHERAL NERVE STIMULATION TEST

Apply train of four stimuli (20 mA, 0.2-millisecond Jules, 500 milliseconds apart on Ulnar Nerve at the wrist and look for movements of adductor pollicis muscle (medial adduction movement of thumb across the palm).

DESCRIPTION

- i. A peripheral nerve is stimulated by an electrical signal
- ii. Twitch = muscle response to the stimulus
- iii. The ulnar nerve is most commonly used; alternatives include posterior tibial, facial and peroneal nerve
- iv. ECG dots (ensure good skin contact and current flow)
- v. Electrodes (black and red)
- vi. Nerve stimulator console

METHOD OF USE

Ulnar nerve:

> ECG dots placed

- i. First dot on the palmar aspect of the wrist 1-2 cm proximal to the wrist
- ii. Second dot in the same line 3 cm proximal to the first dot.

> Electrodes attached

- i. Black (negative) electrode is attached to dot closest to hand (place as close to nerve as possible).
- ii. Red (positive) attached to the proximal dot (must be in line to minimise nerve-muscle artefact and ensure maximal stimulation).

> Stimulator is attached

- i. Voltage is slowly increased starting at 20mA, the voltage should not exceed 60 mA
- ii. Red pulse light indicates voltage conduction.
- iii. Observe twitching of adductor pollicis (medial adduction of the thumb across the palm)

Interpretation:- Presence of twitch indicates that there is no residual muscle paralysis that is producing a falsely absent brain stem reflex.

ANNEXURE 3

CHECKLIST FOR DETERMINATION OF BRAIN DEATH PRE-REQUISITRES (all must be checked)

A. Pre-requisites for brain stem death testing

- i. Coma, irreversible and cause known.
- ii. Neuroimaging explains coma.
- iii. CNS depressant drug effect absent (if indicated toxicology screen; if barbiturates given, serum level <10 mcg/ml).
- iv. No evidence of residual paralytics (electrical stimulation if paralytics used).
- v. Absence of severe acid-base, electrolyte, endocrine abnormality.
- vi. Normothermia or mild hypothermia (core temperature >35°C).
- vii. Systolic blood pressure >90 mm Hg.
- viii. No spontaneous respirations.

B. Assessment of brain stem reflexes

- i. Pupils nonreactive to bright light.
- ii. Comeal reflex absent.
- iii. Oculocephalic reflex absent (tested only if C-spine integrity ensured).
- iv. Oculovestibular reflex absent.
- v. No facial movement to noxious stimuli at supraorbital nerve, temporomandibular joint.
- vi. Gag reflex absent.
- vii. Cough reflex absent to tracheal suctioning.
- viii. Absence of motor response to noxious stimuli in all four limbs (spinally mediated reflexes are permissible).

C. Apnoea testing

- i. Patient is hemodynamically stable.

- ii. Ventilator adjusted to provide normocarbica (PaCO₂ 35-45 mm Hg).
- iii. Patient preoxygenated with 100% FiO₂ for >10 minutes to PaO₂ >200 mm Hg.
- iv. Patient well-oxygenated with a positive end-expiratory pressure (PEEP) of 5 cm of water.
- v. Provide oxygen via a suction catheter to the level of the carina at 6 L/min or attach
- vi. T-piece with continuous positive airway pressure (CPAP) at 10 cm H₂O.
- vii. Disconnect ventilator.
- viii. Spontaneous respirations absent.
- ix. Arterial blood gas drawn at 8-10 minutes, patient reconnected to ventilator.
- x. PCO₂ >60 mm Hg, or 20 mm Hg rise from normal baseline value.

*Sequence to be followed

Step B to be considered if all the requirements of Step A are fulfilled.

Step C should be performed if both A and B are consistent with the diagnosis of brain stem death.

ANNEXURE 5

ANCILLARY TESTS

(To be considered in the following situations)

- I. SPINAL REFLEXES - When brain stem death testing is performed, very infrequently, the patient may move an extremity in response to noxious stimulation (Lazarus Phenomenon). If there is any question about the significance of movements or other responses, any one of the objective confirmatory tests should be performed-CT angiogram, EEG, Transcranial Doppler, cerebral scintigraphy, Nuclear brain scanning, Transcranial Doppler ultrasonography, Cerebral arteriography.
- II. APNOEA TEST- The apnoea test is performed by pre-oxygenating the patient with 100% oxygen and then allowing the patient's PCO₂ to rise to 60 mmHg or greater. Occasionally, the apnoea test will not be tolerated by some patients whose cardiopulmonary status is unstable. In these patients brain death cannot be determined on clinical grounds alone. Therefore any one of the objective confirmatory tests may be performed- CT angiogram, EEG, Transcranial Doppler, cerebral scintigraphy, Nuclear brain scanning, Transcranial Doppler ultrasonography, Cerebral arteriography.



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – Transplantation of Human Organs – Declaration of brain death mandatory in Government and Private Hospitals in the State – Procedure for declaration of brain death -- Orders issued

HEALTH AND FAMILY WELFARE (S) DEPARTMENT

G.O (MS)No.36/2012/H&FWD

Dated, Thiruvananthapuram 04.02.2012

Read:- 1) GO(Rt)No.572/2011/H&FWD dated 14.2.2011
2) Letter No.A1-11317/MCT/2011 dated 20.06.2011 from the Principal, Government Medical College, Thiruvananthapuram

ORDER

1. A large number of patients are suffering from on account of irreversible organ ailments involving heart, liver, pancreas and kidney. Many of them could lead healthy lives if they had the opportunity to have transplant surgery. Considering the ethical issues surrounding the live and deceased organ transplantation, Government felt the need to streamline the procedures for deceased donor organ transplantation (DDOT) in the State.

2. In order to study the feasibility of deceased donor organ procurement and transplantation in the State, a Committee of doctors was constituted as per the Government Order read above. A detailed report in this regard was submitted by the Committee to Government as per the letter read as 2nd paper above.

3. Government have considered the report in detail. Organ transplantation is a life saving procedure and a large number of patients with end stage organ failure are waiting to undergo organ transplantation. Majority of end stage organ failure patients in India die due to the non availability of organs and / or non affordability. The deceased organ donation rate in our country is 0.08 per million populations and the overall potential of organ donation following brain death is extremely high. The Transplantation of Human Organs Act, 1994 (THOA) is an enabling legislation as far as deceased donor transplantation is concerned. There is at present no established procedure or guideline in the State to deal with situations that arise when brain deaths occur in hospitals that are not registered under THOA, 1994, even when the families of brain dead persons wish to give consent to donate the organs of their deceased family member. Considering the fact that the deceased donor organ donations are done with altruistic motive and in a generous and charitable manner as a willing contribution to the society, it is necessary that this organ donation be governed by transparency on all fronts to ensure that the sentiments of the donor's relatives are adequately respected.

4. One of the major impediments in deceased donor transplantation in the State is the lack of clarity in brain death certification and its optional nature. There are also doubts in medical circles on the authority by which doctors may declare "Brain Death", whenever required. The Transplantation of Human Organs Act, 1994 (THOA, 1994) and the Transplantation of Human Organs Rules, 1995 (THO Rules) made there under are the only pieces of legislation available wherein brain death certification procedures have been elaborately laid down, it is hereby decided that the procedures outlined therein will also be adopted as brain death certification procedure in Kerala. This order will also elaborate on the above format to ensure its applicability to the entire State of Kerala. Government therefore hereby order and made it mandatory that whenever the medical condition (clinical and medical criteria have been met for) of a patient has reached a brain death stage, brain death certification is done as stipulated in this order. This will come into force with immediate effect in all Government District Hospitals & General Hospitals and all the 5 Government Medical Colleges and Private hospitals in the State registered as Transplant Centres with the Appropriate Authority for certifying Brain Death as per the THO Act, in the event of a family of brain dead person consenting to organ donation. All Organ Transplantation Centres will register with the Appropriate Authority for this purpose.

5. From 8 of the THO Act and Rules as found in the Annexure-I to this order are prescribed as the brain death certification format to be utilised for any given situation requiring certification that a person is dead on account of permanent and irreversible cessation of all functions of the brain stem. The tests prescribed therein and the findings required shall remain the same.

6. According to Form 8 of the said Act and Rules, when such certification is required, there shall be two medical examinations conducted by a team of doctors after a minimum interval of six hours and the findings made based on the tests prescribed therein. One aspect of the above form requires further classification and this is provided in Annexure II of this Order. Section 3(6) of the THO Act and Rules prescribes a Board of Medical Experts consisting four Doctors, who are authorised to certify brain death and this provision is clarified further.

(A) Doctor No.1 is the 'R.M.P'. in charge of the hospital in which brain-stem death has occurred.' Accordingly, the Registered Medical Practitioner in charge of the hospital in which brain-stem death has occurred shall refer to either the Head of the Institution or RMO.

(B) Doctor No.2 is an independent R.M.P. nominated from the panel of names approved by the Appropriate Authority.' Accordingly, a panel of names shall be sent by the Medical Superintendent/Medical Director of the hospital through the District Medical Officer to the Appropriate Authority namely the CCCT (Core Committee for Cadaver Transplantation) and on approval shall then be utilised as the panel from which a R.M.P. shall be nominated for each brain death certification. Each hospital may decide on the panel of names for this duty.

(C) Doctor No.3 is 'Neurologists/Nuero-Surgeon nominated from the panel of names approved by the Appropriate Authority'. Again, a panel of names shall be sent by the Medical Superintendent/Medical Director of the Hospital through the District Medical Officer to the Appropriate Authority and on approval shall then be utilised as the panel from which one specialist as in the category therein shall be nominated for each brain death certification. Each hospital may determine its own procedure for this duty.

(D) Doctor No.4 is the R.M.P. treating the aforesaid person. (No clearances are required from the Appropriate Authority in this category).

Note: i) Doctor No.2 and 3 should be from outside the Hospital where the Brain stem death patient is taking treatment and to get their services, the hospital concerned, shall make a request to the DMO concerned.

ii) The 1st and 2nd Medical examination as defined in Form-8 of the THO Rules shall be conducted by category 2 and 3 Doctors from the panel approved by the Appropriate Authority.

7. This procedure shall be applicable to all hospitals including private hospitals which wish to certify Brain Death as and when required. Accordingly, the categories that require for the panel to be approved shall be done so on submission to the Appropriate Authority (Core Committee for Cadaver Transplantation).

8. The Director of Medical Education and the Director of Health Services are directed to periodically organise awareness workshops on the provisions of this order.

**(By Order of the Governor)
RAJEEV SADANANDAN
Principal Secretary to Government**

To

The Director Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Medical College, Thiruvananthapuram, Kottayam,
Alappuzha, Thrissur & Kozhikode
All the District Medical Officers (Health) (through DHS)
Stock file/Office Copy

Forwarded by Order

Section Officer

FORM 8

[Refer rule 4(3) (a) and (b) of the THO Rules 1995]

We, the following members of the Board of Medical Experts after careful personal examination, hereby certify that Shri/ Smt. / Km
aged about S / o, W /o, D / o, Shri.....
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.

Date.....

Signature.....

1. R.M.P., In charge of the Hospital in which
brain-stem death has occurred

2. R.M.P., nominated from the
panel of names approved by the
Appropriate Authority

. .

2. Neurologist / Neuro-Surgeon nominated
from the panel of names approved by
the Appropriate Authority

4. R.M.P., treating the aforesaid
deceased person

.

BRAIN-STEM DEATH CERTIFICATE

Patient Details:

1. Name of the Patient: Shri/ Smt. / Km.
S/o. / W/o / D/o : Shri
Sex..... Age.....

2. Home Address:
.....
.....
.....

3. Hospital Number:

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 transplant?
.....
.....

6. Is this a Police Case? Yes..... No.....

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-responsible coma:

2. Findings of Board of Medical Experts:

(i) The following reversible cause of coma have been excluded:-

Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

First Medical Examination Second Medical Examination

1st

2nd

1st

2nd

Primary hypothermia

Hypovolaemic shock

Metabolic of endocrine disorders

Test for absence of brain-stem functions

(ii) Coma

(iii) Cessation of spontaneous breathing

(iv) Pupillary size

(v) Pupillary light reflexes

(vi) Doll's head eye movements

(vii) Corneal reflexes (Both sizes)

(viii) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk

(ix) Gag reflex

(x) Cough (Tracheal)

(xi) Eye movements on coloric testing bilaterally

(xii) Apnoea tests as specified

(xiii) 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,

Shri / Smt / Km..... is declared brain-stem dead.

1. Medical Administrator In charge of the hospital.

2. Authorised Specialist.

3. Neurologist / Neuro-Surgeon.

4. Medical Officer treating the patient.

N.B I. The Minimum time interval between the first testing and second Testing will be six hours.

II. No. 2 and No. 3 will be co-opted by the Administrator in charge of the hospital from the panel of experts approved by the Appropriate Authority.

ANNEXURE – II

Guidelines for Apnoea Test:

Patient should have a temperature of more than 35⁰ centigrade euvolemic and with Systolic pressure \geq 90mm of Hg.

- i. The first Apnoea test should be performed only after 4 hours of Coma associated with absence of brain stem reflexes. In the case of Anoxic brain damage, this period should be extended to 12 hours.
- ii. The physician involved in certifying brain death shall be present during Ventilator removal to attest the presence of Apnoea if found
- iii. Ventilator manipulation is performed to raise the PaCo₂ \geq 40 mmHg
- iv. The patient should be hyper oxygenated with 100% Oxygen for 15 minutes, while still on the Ventilator, prior to the Apnoea test
- v. Either a blood gas or trending of ETCO₂ should be used to determine the adequacy of the baseline prior to the test. SPO₂ should be monitored during Apnoea test.
- vi. Place the patient on 100% Oxygen through a tracheal catheter with the tip towards the end of the tube with a continuous 6L/min O₂ flow.
- vii. The patient is taken off the Ventilator in the presence of a physician certifying brain death. The patient is kept off the Ventilator for a variable period of time (usually 3 to 8 minutes) to allow the PaCo₂ to rise \geq 55 mm Hg or \geq 15mmHg over baseline. During this time, the patient is observed for respiratory movements.
- viii. Test interpretations:
 - a. Positive Test – implying Apnea despite adequate stimulation
 - i. Patient remain Apneic, without respiratory movements
 - ii. PaCo₂ is \geq 55mm Hg or \geq 15mmHg from baseline
 - b. Negative test – Implying Apnea is not present
 - i. Respiratory efforts noted at any time during the test
 - c. Indeterminate test
 - i. PaCo₂ < 55mmHg or there is less than 15mm Hg increase over baseline
 - d. Indeterminate tests can either be repeated or another confirmatory test utilised.
- ix. Apnoea test should be aborted if the patient develops hypotension, or significant cardiac arrhythmias.
- x. These norms will vary for patients less than 12 years and patients with major chest trauma.



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – Transplantation of Human Organs – Cadaver Organ Transplantation Programme – Procedure to be adopted by the Government and Private Hospitals approved for Organ Transplantation – Guidelines Issued –

HEALTH AND FAMILY WELFARE (S) DEPARTMENT

G O (MS)No.37/2012/H&FWD

Dated, Thiruvananthapuram 04 02 2012

Read - 1) G O (MS)No 36/2012/H&FWD dated 04 02 2012

ORDER

Being aware that a large number of patients who are suffering on account of various organ ailments ranging from heart, liver, kidney etc have to wait long periods due to paucity in organs donated by living donors, Government as per the Government Order read above have issued orders for implementing Cadaver Organ Transplantation in the State Government is also aware that the success of Organ Transplant especially Cadaver Organ Transplantation depends on efficacious donor management and meticulous co-ordination with Organ Retrieving Centres and Organ Transplant Centres Government have considered the suggestions and opinions from stakeholders and Non Governmental Organisations working for the cause of organ donation and opinions brought forward by the medical professional related to this field and the combined opinions of the Director of Medical Education and Director of Health Services and they felt the need for an established procedure and guidelines for the effective co-ordination and implementation of the programme Accordingly the following orders are issued

2) When the family of the brain dead patient is willing to donate his/her organ(s) to benefit others, the following procedures shall be strictly adhered to -

(i) The procedures in declaring brain death shall be adhered to as laid out in the Government Order read above

(ii) Form 6 as laid out in the Transplantation of Human Organs Rules, 1995 shall duly be signed by the person(s) responsible for the brain dead patient and in the case of children below the age of eighteen years, the appropriate form namely Form 9 of the Transplantation of Human Organs Rules, 1995 requires to be signed by the persons concerned before organ retrieval

(iii) Organ(s) retrieval shall not be carried out on a brain dead patient merely due to an earlier declaration by the said patient in Form 5 of the Transplantation of Human Organs Rules 1995. While such a declaration shall presuppose the previous intentions of the brain dead patient to donate his/her organ(s), consent in form 6 of the Transplantation of Human Organs Rules, 1995, is necessary to continue with the process of organ retrieval

(iv) Each hospital should have its own waiting list for each organ, which will include the date of registration The criteria as well as the prioritized waitlist, continually updated should be made available online to the Convenor, Cadaver Transplant programme Kerala Some hospitals may prefer date of registration Exceptions to the already notified criteria must be substantiated with reasons to the Convenor, Cadaver Transplant programme

Kerala when a request is made otherwise The decision of the Convenor, Cadaver Transplant Programme, Kerala is final

(v) Any individual needing organ transplant through cadaver organ donation can be registered through only one hospital at a given time She or he is free to change the registration to any other transplant hospital, but the original date of registration will continue to apply for purposes of prioritization or organ allocation

3) Following the above criteria for allocation, the organ(s) of the brain dead patient shall be shared in the following order, based on the respective prioritization list

(i) If there is a patient who is to be a multi organ recipient and a matching organ donor is available, then the multi organ recipient takes precedence over all others on the regular waiting list. The Convenor, Cadaver Transplant program, Kerala will take the appropriate decision regarding allocation criteria when such a situation arises

(ii) Considering the peculiar nature of certain liver ailments, a provision is made which is as follows

4) Potential liver recipients in hospitals are to be listed in one of the two categories namely 'Urgent' or 'Standard'

(a) Urgent Those on the urgent list are those who have

(i) Hepatic Artery Thrombosis following a liver transplant

(ii) Primary Non function of a graft

(iii) Fulminant hepatic failure

These conditions do not require a waiting time on the list

(b) Standard This list refers to all patients who need a liver transplant but do not fulfill criteria for urgent listing Patients on the standard list have to be registered for more than 24 hours to be listed in this category

The Liver is to be allotted to participating hospitals in turn

Note Patients on the urgent list supersede the standard list and the hospital misses its regular turn on the rota

(iii) Similarly, potential heart recipients in hospitals are to be listed in one of the two categories namely 'Urgent' or 'Standard'

(a) Urgent

(i) Patients with Left Ventricular Assist Device (LVAD)

(ii) Followed by patients with Intraaortic Balloon Pump(IABP)

(b) Standard Sick, but stable patients waiting at home for a heart transplant

A Heart is to be allotted to participating hospitals in turn

(iv) Likewise for lungs, prioritization would be made according to the urgency of transplant and allotted to participating hospitals in turn

(v) For kidneys no out of turn allocation would be permitted and the sharing criteria in the following para shall be followed

5) Sharing of Organs for waitlisted recipients, retrieved from cadaver donors in Government Institutions will be as follows

(i) First priority to the list of the Government Hospital where the deceased donor is located, for liver, heart and one kidney The other kidney would be allocated to the general pool in the priority sequence as listed below

(ii) Second priority to the combined Government Hospitals list

(iii) Third priority to the combined Private Hospitals list

(iv) Fourth priority to Government Hospitals outside the State, (in order to maximize organ utilization)-provided earlier information and such a request has been registered with the Advisory committee / Convenor, Cadaver Transplant Program, Kerala

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(v) Fifth priority to Private Hospitals outside the State (in order to maximize organ utilization) provided earlier information and such a request has been registered with the Advisory committee / Convenor, Cadaver Transplant Program, Kerala

6) Sharing of Organs for waitlisted recipients retrieved from cadaver donors in Private Hospitals, which are transplant centres.

(i) First priority to the list within the Private Hospital where the deceased donor is located, for liver, heart and one kidney. The other kidney would be allocated to the general pool in the priority sequence as listed below

(ii) Second priority to the combined list of Government and Private Hospitals

(iii) Third priority to Government / private hospitals outside the State, (in order to maximize organ utilization) provided earlier information and such a request has been registered with the Advisory committee/Convenor, Cadaver Transplant Program, Kerala

(iv) Finally, if the organ(s) remains unutilized by the above criteria, it may be offered to a foreign national registered in Government or private hospital within and then outside the state, provided earlier information and such a request has been registered with the Advisory committee /Convenor, Cadaver Transplant Program, Kerala

7) Whenever a deceased donor becomes available in a hospital, the concerned hospital shall contact the Transplant Co-ordinator, Government Medical College Thiruvananthapuram, who will then make allocations based on the above. Non Governmental Organisations promoting organ transplantation may assist the Transplant Co-ordinator, Government Medical College, Thiruvananthapuram to facilitate this arrangement and ensure that most number of cadaver organs donated are utilized to benefit organ failure patients

8) Considering that a number of practical issues are involved such as

(i) establishing formats and procedures for recipient listing, organ allocation and transfer

(ii) co-ordination between hospitals where donor / recipient are located

(iii) working towards a coordinating body that would be institutionalized and fine-tuning identification criteria to determine the beneficiaries-

(iv) Proposing policy initiatives from time to time

(v) Need for watching the working of the cadaver organ transplantation program, the Government have decided to form an Advisory committee at the State Level called CTAC that would address the above issues and ensure stability in functioning of the cadaver organ transplant program

9) The Advisory committee shall consist of

(i) Principal Secretary, Health & Family Welfare Department -- Chairman

(ii) Law Secretary or his nominee -- Member

(iii) One Senior Police Officer of DIG rank nominated by the Director General of Police, Kerala -- Member

(iv) Director of Medical Education -- Member

(v) Director of Health Services -- Member

(vi) Principal, Government Medical College, Thiruvananthapuram -- Member

(vii) Professor & Head of Department, Forensic Medicine, Government Medical College, Thiruvananthapuram -- Convenor

(viii) An NGO to be nominated by the Government -- Member

- 12
- (ix) One transplant team member from three different private hospitals that currently have largest cadaver donation experience – Member
- 10) Besides the CTAC another Committee at the State Level named 'Core Committee for Cadaver Transplantation (CCCT)' will be formed for co-ordination with Non Transplant Organ Retrieval Centres and Organ Transplant Centres engaged in Cadaver Transplant Programme. The composition of the Core Committee for Cadaver Transplantation will be as follows
- (i) The Director of Medical Education – Chairman
 - (ii) The Director of Health Services – Co-Chairman
 - (iii) Principal, Government Medical College, Thiruvananthapuram – Member
 - (iv) Prof & HoD, Forensic Medicine & Transplant Co-ordinator, Kerala – Convenor
 - (v) Core Committee for Cadaver Transplantation can co-opt another member who is a multi organ transplant expert to assist and advice subject, however to the condition that such a person shall not have any affiliation to any Pvt Hospital registered as a Organ Transplantation Committee
- 11) The Core Committee for Cadaver Transplantation shall in turn nominate four sub-committees to assist in its functioning for
- (i) Liver
 - (ii) Heart
 - (iii) Kidney
 - (iv) other organs- to determine the severity of illness for listing a patient for transplant
- 12) The Core Committee for Cadaver Transplantation shall discharge the following functions and responsibilities
- (i) The Core Committee for Cadaver Transplantation is the legal entity authorised with statutory powers under the Transplantation of Human Organs Rules 1995. It shall act as the Appropriate Authority under the Transplantation of Human Organs Act, 1994
 - (ii) Registration of hospitals as Non Transplant Organ Retrieval Centres or Organ Transplant Centres
 - (iii) Supervision and regulation of the functioning of Non Transplant Organ Retrieval Centres and Organ Transplant Centres, including exercising the powers to suspend the registration in the event of any deviation or misconduct
 - (iv) Allocation of the organs available from cadavers to the registered patients (recipients) strictly following the priority laid down ibid
 - (v) Empanelment of specialists, especially in the specialities of Neurosurgery, Neurology and Physicians/Surgeons whose services can be availed by Non Transplant Organ Retrieval Centres or Organ Transplant Centres to be part of the Medical Board for the purpose of declaring brain death
 - (vi) Conduct of programmes to raise awareness in general public (Se 30.D) such as mass media communication, conduct of annual events, establishing a system of online and postal pledging of organs by willing individuals in a central registry through a Web based portal, and issuing donor cards
 - (vii) Any other functions and responsibilities for the effective implementation of Cadaver Transplant Programme
- 13) The CCCT will meet as and when required or at least once in every month and will furnish necessary recommendations to the Cadaver Transplant Advisory Committee upon receipt and evaluation of feed back from the Organ Transplant Centres and Non Transplant Organ Retrieval Centers (NTORC), on the modifications if any as they deem necessary in the implementation of the programme. The Cadaver Transplant Advisory Committee (CTAC) will meet periodically at least once in every 3 months and will review

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the performance of Core Committee for Cadaver Transplantation, Organ Transplant Centres and Non Transplant Organ Retrieval Centre and will make appropriate recommendations to Government for modifications in the implementation of the scheme

(By Order of the Governor)

RAJEEV SADANANDAN
Principal Secretary to Government

To

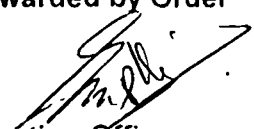
The Director Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Medical College, Thiruvananthapuram, Kottayam, Alappuzha,
Thrissur & Kozhikode

All the District Medical Officers
Stock file/Office Copy

Copy to

The Private Secretary to Chief Minister
The Private Secretary to Minister (Health & Family Welfare Department)
The Private Secretary to Leader of Opposition
The Personal Assistant to Principal Secretary, Health & Family Welfare Dept

Forwarded by Order


Section Officer



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – Non Transplant Organ Retrieval Centers (NTORC) – Criteria for non-transplant centres to retrieve organs from brain dead persons – Detailed instructions – Orders Issued

HEALTH AND FAMILY WELFARE (S) DEPARTMENT

G.O (MS)No.38/2012/H&FWD

Dated, Thiruvananthapuram, 04.02.2012

- Read:- 1) GO(Ms)No.36/2012/H&FWD dated 04.02.2012
2) GO(Ms)No.37/2012/H&FWD dated 04.02.2012

ORDER

1. The success of organ transplantation as a life saving procedure in end stage organ diseases has lead to its wide spread application. Being aware of the life saving potential of organ transplantation and considering the paucity of living donor organs cadaver organ transplant programme following brain death has been implemented in the State as per the Government Order read as 1st paper above. The procedures to be followed by the Government and private hospitals that are registered under the Transplantation of Human Organs Act, 1994 as transplant centres when dealing with cadaver organ transplant has been detailed in the Government Order read second above.

2. But, at present, no established procedure or guideline to deal with situations that arise when brain deaths occur in hospitals in the state that are not registered under The Transplantation of Human Organs Act,1994 (THO Act) even when the families of the brain dead persons wish or consent to donate the organs of their deceased family member. It is therefore imperative to permit organs to be retrieved when there is a willingness to donate organs at those centers which have the facilities to maintain brain dead deceased donors, so that more lives of organ failure patients can be saved. Considering the fact that a large number of brain deaths occur in non-transplant hospitals the Appropriate Authority shall take the initiative to register those hospitals that fulfill the following conditions as "Non Transplant Organ Retrieval Centers".

3. The following orders are issued in the matter:

(i) The Appropriate Authority shall register on application by the hospitals, concerned all hospitals in the State that have a minimum of 50 beds along with Operation Theatre and Intensive Care Unit as Non Transplant Organ Retrieval Centers (NTORCs). These hospitals are permitted to certify brain death as per the procedures stipulated in the Government Order as 1st paper above and thereafter organ retrieval for therapeutic purposes, but are not permitted to perform actual transplantation of human organs.

(ii) The procedures stipulated in the Government Order second read above to be followed by the participating Government hospitals and all private hospitals registered with the Appropriate Authority, for certifying brain death as per the Transplantation of Human Organs Act, in those hospitals, will apply for brain death certification in Non Transplant Organ Retrieval Centers as well, in the event of a family of brain dead person consenting to organ donation. Non Transplant Organ Retrieval Centers can utilize the services of any medical professional authorized in the Government order 1st read above, for certification by Doctors No.2 and 3 as specified in the said Government Order.

(iii) Any Non Transplant Organ Retrieval Center can take assistance and support from any hospital registered with the Appropriate Authority as a transplant center for maintaining the brain dead person in stable condition until organ retrieval is carried out.

(iv) Whenever a brain death occurs in an Non Transplant Organ Retrieval Center and the deceased person's family consents to organ donation, the Non Transplant Organ Retrieval Center should contact the Transplant Coordinator, at Government Medical College Hospital, Thiruvananthapuram is for organ allocation as per norms.

(v) The organs shall be allocated following the prioritization norms as established for organs located in the Government hospitals if the concerned Non Transplant Organ Retrieval Center is a Government hospital and the prioritization norms as established for organs located in private hospitals if the concerned Non Transplant Organ Retrieval Center is a private hospital detailed in the Government Order 2nd read above.

4. All other procedures for cadaveric organ donation and organ retrieval as specified in the Transplantation of Human Organs Act and Rules and other relevant Government Orders would apply to Non Transplant Organ Retrieval Centers as well.

(By Order of the Governor)
RAJEEV SADANANDAN
Principal Secretary to Government

To

The Director Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Medical College, Thiruvananthapuram, Kottayam,
Alappuzha, Thrissur & Kozhikode
All the District Medical Officers (Health) (through DHS)
Stock file/Office Copy/

Forwarded/By Order

Section Officer



GOVERNMENT OF KERALA

HEALTH & FAMILY WELFARE (S) DEPARTMENT

No. 14931/S2/2009/H&FWD

Date: 19.11.2010

NOTIFICATION

In exercise of powers conferred by Human Organ Transplantation Act and its Rules Government of Kerala hereby issue guidelines for conducting organ transplantations in the State. These guidelines shall be followed by all authorization committees for organ transplantations working in the State of Kerala. The guidelines are appended herewith.

Sd /-

B.S. MAVOJI
SECRETARY TO GOVERNMENT

To

The Director of Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Government Medical College, Thiruvananthapuram/ Alappuzha
Kottayam/ Thrissur/ Kozhikode.
All major Private Hospitals in the State.
Stock File/Office Copy

Appendix

GUIDELINES FOR GRANTING APPROVAL FOR ORGAN TRANSPLANTATION IN THE STATE

1. The donor must be a near relative of the recipient as certified in the 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 in charge of transplant center.
2. 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.
3. 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 Authorization Committee for the said donation has to be obtained.
4. Where the proposed transplantation is between a married couple, the Registered Medical Practitioner in charge of transplant center must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc are kept for records along with the information on the number and age of children and family photograph depicting the entire immediate family birth certificate of children containing particulars of parents.
5. When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committee shall consider all such requests.
6. When the proposed donor and the recipient are not 'near relatives' as defined under clause (i) of section 2 of the Act, the authorization 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 Authorization 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, eg; proof that they have lived together etc.
 - (iii) that there is no middleman tout involved;

- (iv) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing.
 - (v) that the donor is not a drug addict or 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.
7. 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 Authorization Committee as specified in Form 10. The Authorization Committee shall take a decision on such application in accordance with the guidelines in rule 6-A.
8. The Authorization 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 Bonk 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 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, 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.

- (e) Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorization Committee):
The concerned competent authority or authorization 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.
- (f) 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 Authorization 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 eg., 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 next kin of the proposed unrelated donor is interviewed regarding awareness about his/her intention to donate an organ, the authenticity of link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection of such 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) Authorization 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 Authorization Committee an 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 Authorization 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 Authorization 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 tall such medial tests as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question.
 - (iii) 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.
 - (iv) All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.
 - (v) All interviews to be video recorded.

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, and Date of issue & place (Photocopy attached)

and/or

• Passport number and country of issue (Photocopy attached)

and/or

• Driving License 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 purpose/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

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 1-Card number, date of issue, Assembly constituency
(Photocopy attached)
And/or
- Passport number and country of issue
(Photocopy attached)
and/or
- Driving License 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 authorization 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) sign(s) on the Notary Registrar, as well.

- Wherever applicable.

FORM 1 (B)

(Page 1 of 2)

To be completed by the prospective spousal donor)

(see Rule3)

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, licensing authority
(Photocopy attached)
and/or
- Driving License number, Date of issue, licensing authority
(Photocopy attached)
and/or
- PAN
- 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.

(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 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 authorization 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(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 taken 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) sign(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 License 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 License 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

2. I understand the nature of criminal offences referred to 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 authorization 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(organ).
That explanation was given by(name of registered medical practitioner).
5. I under 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 taken 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) sign(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 Authorization Committee/Registered Medical Practitioner ie., incharge of transplant center (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 sea 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 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 result of the tests are attached.

Place :
Date :

Signature
(To be signed by the Head of the laboratory)
Seal

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)]

To be self
attested across
the affixed
photograph

To be self
attested across
the affixed
photograph

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 reasons(s):-

- a) by virtue of being a near relative ie.,
- 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 allurement 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 ie., 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 t 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 Authorization 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 judgment dated 31.03.2005, the approval/No Objection Certificate from the concerned State/Union Territory Government or Authorization 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 Authorization Committee/Registered Medical Practitioner ie., 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 :

Certificate of Altruism

(Sample - to be issued by SP/DY SP of the District having administration where donor and recipient resides)
(For production before the Authorization Committee for Organ Transplantation)

This is to certify that it has been found after due enquiry/investigation that Sri/Smt (name of donor) Years residing at(address of the donor) has voluntarily consented to donate one of his/her kidneys to Sri/Smt name of recipient), upon his/her free will, without any compulsion, influence, or intent of reward or consideration and his altruism is genuine. He has no criminal back ground.

The donor (name) had been associate with the recipient (name) as (specify the nature of association) since the last Specify the period of acquaintance/the degree of association/reciprocity of feelings/gratitude). Enquiries were made about the chances of commercial dealings under the pretext of a Hruistic donation by the DY SP of special branch unit and their report obtained.

The following documents (if any) that support the above facts are attached.

1.
2.

The donor and recipient have been informed about the provisions of THOA 1994 and that any sort of commercial dealings or even an attempt at it will attract primitive action which may extend up to 7 years imprisonment and fine up to Rs.2,00,000/-

Signature with date
Name :
Designation :

(Office Seal)

Affidavit

(Sample - to be attested by the Notary of the District regarding the altruism)

(For production before the Authorization Committee for Organ Transplantation)

I, (name of donor)
son/daughter/wife/husband of aged
..... Years residing at Hereby
solemnly affirm and sincerely state that :-

I am donating one of my kidneys to Sri/Smt.
Aged years residing at without
any compulsion or coercion and without intent for monetary or material gain,
reward or consideration.

I have been associating with the recipient
(name) as (specify the nature of
association) since the last (specify the period of acquaintance/the
degree of association/reciprocity of feelings/gratitude etc..)

The following documents (if any) that support the above facts are attached.

1.
2.

I further declare that I am aware of the Transplantation of Human Organs Act
of 1994 and its penal provisions and I am aware of the penalties imposed should
the provisions of the act be contravened in any way.

I also certify that the above facts are true to the best of my knowledge and
belief.

Date Signature of the donor
Name and Address

Signed before me
Signature

Name & Designation Seal

(Office Seal)