

**Policy for Human Organ Donation, 2015****Background**

Organ transplantation is a life-saving treatment of last resort for individuals with organ failure, and can provide dramatic increases in quality of life to the recipients. Organ and tissue transplantation is now established practice worldwide. Improvements in surgical techniques, advances in post-operative care, the introduction of effective organ preservation solutions and the development of good immuno-suppression drugs have all ameliorated Organ Transplantation over the last three decades leading to quality life for recipients of organ.

**Rationale**

The absence of a policy or law governing organ transplants and organ donation could lead to commercial traffic in human organs, particularly from living donors who are unrelated to the recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades in the world and Bhutan is no exception. People with resources and needing organ transplant have been known to influence people having financial difficulties to sell their organs. Therefore, it is essential that policy and procedure are in place to facilitate patients with legitimate donors.

**Objective of the Policy**

- a) To save and improve the quality of life of patients with organ failure
- b) Ensure that the vulnerable groups are not being exploited for monetary consideration
- c) To enable carrying out research and educational measures related to body organ transplant
- d) To cooperate and to obtain assistance from government departments and organizations, international organizations, local and international non-governmental organizations, companies and individuals in body organ transplant.

**Existing Legislations and Regulations**

1. The Penal Code of Bhutan Section 152 and 153 states that a defendant shall be guilty of the offence of illegal selling or buying of human organ, if the defendant sells or buys any human body organ for money or profit and the offence of illegal selling or buying of human organ shall be a misdemeanor.



2. The National Health Policy of 2010 states that human organ and tissue transplantation shall be on voluntary bases with explicit consent of both the donors and recipient and shall comply with the national legal and ethical instruments.
3. Until a National Law on Organ and Tissue transplant is in place, Ministry of Health shall follow Supreme Court order (60)2014/3504 dated 24<sup>th</sup> June 2014.

**Policy Statements**

1. Adult living persons may donate organs (18 years and above). However, living donors should be genetically, legally or emotionally related to the recipients.
2. Cells, tissues and organs should only be donated voluntarily without any monetary payment or other rewards. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next to kin for deceased persons, shall not be allowed.
3. Cells, tissues and Organs 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 may be used or harvested by public hospitals for medical teaching and transplantation purpose.
4. Organs may be removed from a deceased person in performing transplantation or medical education if the person had expressly consented to such removal during his or her lifetime.
5. Public Hospitals and Civil Society Organizations may carry out public campaign organ donation.
6. Public Campaigning for organ donors by or for any specific recipient shall not be allowed.
7. Individuals appealing to the general public for organ donation or raising of funds from general population for organ transplantation shall not be allowed.



**Implementation Procedures****Establishment of Hospital Ethics Committee**

1. The MoH and JDWNRH shall institute a Hospital Ethics Committee to oversee any issues on organ and tissue transplantation.
2. The committee shall review, scrutinize, and authorize organ donation by related or unrelated donors. The committee shall review and scrutinize the following documents:
  - a. Any proof of relationship between the donor and recipient;
  - b. letter of undertaking by both donor and recipient;
  - c. Copy of donor medical fitness;
  - d. Citizenship identity card copies of donor and donor's care takers;
  - e. Evaluate and ensure that there is no financial remuneration, gift or gratification including tangible benefits, threat, fraud, coercion, inducement involving the recipient and the unrelated donor;
  - f. Reason why the donor wishes to donate;
  - g. The 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;
  - h. The next to kin of the proposed unrelated donor must be interviewed regarding the awareness of the donor's intention to donate, the authenticity of the link between the donor and the recipient and the reason for donation, etc
3. The relation of the donor and the recipient will be reviewed by the hospital referral committee and attested by the royal court of justice.
4. In case of un-related donor, the committee shall review and scrutinize following documents over and above those documents mentioned hereinabove:
  - i. Competent (possessing decision making capacity)
  - ii. Willing to donate
  - iii. Free from coercion
  - iv. Fully informed of the risks involved as a donor
  - v. Fully informed of the risks, benefits, and alternative treatment available to the recipient
  - vi. Fully informed of the procedure involved in the transplantation
  - vii. Not be a minor



5. All documents of each organ transplant, including names of ethical committee members who processed the transplant and decision of the committee shall be maintained as separate individual case files.
6. In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Hospital Ethics Committee and minutes of the interview should be recorded.
7. The Committee shall state in writing its reason for rejecting / approving the application of the proposed donor and all approvals should be subject to the following conditions:
  - a. That the approved proposed donor would be subjected to all such medical test as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question.
  - b. 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.
8. The committee shall expedite its decision making process and use its discretion judiciously for all cases where the patient requires immediate transplantation.

#### **Role and Responsibility of MoH and JDWNRH**

1. The MoH and JDWNRH shall maintain a list of living donors who have consented to use of their body or any part of their body for medical education, research or organ transplant upon their demise with medical details for easy reference.
2. The MoH and JDWNRH shall maintain a waiting list of patients requiring organ transplant in the order of dates of diagnosis. When donors or organs are available the patients to receive such organs shall be chosen based on the sequence of the waiting list.
3. The MoH and JDWNRH shall submit the documents in both related and non-related cases of transplantation to the Court wherein the Court shall attest the documents related to proposed transplantation.

#### **Donation of Organ or Tissue by a Living Person**

1. In the case of regenerative tissue, i.e. stem cells, there is no restriction of age between siblings provided that transplantation shall be voluntary, genuinely motivated and without any duress or coercion.



2. 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.
3. Any document with regard to the proof of the residence and particulars of parentage should be relatable to the citizenship identity card 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 Hospital Ethics committee may in its discretion seek such other information or evidence as may be expedient; and desirable in the peculiar facts of the case.

### **Donation after Death by the Individual**

1. Organs may be removed from a deceased person or the body used for medical education or research if the person had expressly consented to such removal or use during his or her lifetime; such consent may be made orally or recorded on a donor card, or in the medical record.
2. Any individual who gives voluntary consent to donate the individual's body or specified organs or tissue after the individual's death for transplantation, education or scientific research may consent:
  - a) in a writing signed by the individual at any time; or
  - b) Orally in the presence of at least two witnesses with contemporaneous documentation of the consent signed by two witnesses.
3. Where the individual consents to donate the individual's organs or tissue after the individual's death for transplantation, the consent is not valid unless the individual is provided with the following information before consenting.
  - a) an explanation of the donation process;
  - b) an explanation of the determination of death process;
  - c) an explanation of pre-death transplantation optimizing interventions and why they are used;
  - d) what organs or tissue can be donated;
  - e) that by consenting to donation after death for transplantation, the individual authorizes the information sharing of the individual's personal information between persons and organizations engaged in the donation, procurement or transplantation of organs and tissues for the purpose of facilitating organ and tissue donation and transplantation across jurisdictions; and
  - f) an explanation of additional tests and procedures conducted to determine medical suitability and confidentiality protections and potential notification requirements regarding this information.



### Donation after Death by Close-Relatives

1. The cells, tissues or organs after the individual's death shall be donated for transplantation, education or scientific research by any of the close-relatives of decease under such circumstances:
  - a) the deceased has given his consent in writing signed by the deceased prior to death in the presence of at least two witnesses to donate organ from his body and has not revoked or withdrawn the consent;
  - b) Where an individual of any age who has not given a consent dies or, in the opinion of a Close-relatives, is incapable of giving a consent by reason of injury or disease;
  - c) Where the close-relatives consents on the deceased's behalf to donate the individual's organs or tissue after the individual's death for transplantation, the consent is not valid unless the close-relative is provided with the following information before consenting:
    - i. an explanation of the donation process;
    - ii. an explanation of the determination of death process;
    - iii. an explanation of pre-death transplantation optimizing interventions and why they are used;
    - iv. what organs or tissue can be donated;
    - v. that by consenting to donation after death for transplantation, the individual authorizes the information sharing of the individual's personal information between persons and organizations engaged in the donation, procurement or transplantation of organs and tissues for the purpose of facilitating organ and tissue donation and transplantation across jurisdictions; and
    - vi. an explanation of additional tests and procedures conducted to determine medical suitability and confidentiality protections and potential notification requirements regarding this information.
2. When the deceased has neither consented nor clearly expressed opposition to organ removal, permission should be obtained from a family member.

### Monitoring and Evaluation

- i. Adherence to this policy shall be ensured through a comprehensive systematic auditing and monitoring process.
- ii. A checklist shall be designed and followed before pursuing the organ donation procedures.



- iii. Ministry of Health may campaign for organ donor who would like to donate their organ for medical education or for transplantation to other individuals in need on their dead. A system of recording and retrieving such information shall also be established in the region.
- iv. Ministry of Health shall institute a national level committee to oversee any issues on human organ and tissue transplantation.

\*\*\*\*\*

