



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 03 2021

ADMINISTRATIVE ORDER

No. 2021 - 0059

SUBJECT: Guidelines on Ethical Organ Donation and Transplantation from Living Donors

I. RATIONALE

Republic Act No.7170, as amended, otherwise known as the "Organ Donation Act of 1991" emphasizes the importance of pursuing deceased organ donation. Further, this Act states that "the Secretary of Health shall endeavor to persuade all health professionals, both government and private, to make an appeal for human organ donation." The Department of Health (DOH) strongly pushes to end the unethical and illegal practices on organ donation by unscrupulous individuals, especially among living non-related donations or from living donors not related by blood to the recipients.

Organ transplantation when deemed appropriate has become the preferred option for patients with End Stage Organ Disease. Administrative Order 2010-0018 entitled Revised National Policy on Living Non-Related Donation and Transplantation and Its Implementing Structure Amending for the Purpose Administrative Order No. 2008-004-A mandates the National Transplant Ethics Committee (NTEC) to formulate national ethical standards/guidelines on organ donation and transplantation for approval by the DOH. Both Living Related and Living Non-Related donors shall be covered by these ethical guidelines since they are healthy individuals and the surgical removal of a part or the whole organ is an invasive procedure that may have later effects on their health and physical, emotional and social circumstance. The guidelines shall uphold the protection and best interests of any Living Donor and Recipient. These shall ensure the voluntariness of the donation and the protection of the rights, welfare and safety of the organ donor.

II. OBJECTIVE

This Order establishes the principles, policies and guidelines on ethical organ donation and transplantation from living donors for the reference of health professionals and transplant facilities performing organ donation and transplantation and other related health facilities. Additionally, this Order seeks to ensure the protection of the rights, welfare and safety of the organ donors and recipients.

III. SCOPE AND COVERAGE

This Order shall apply to all government and private hospitals engaged in organ donation and transplantation, the National Transplant Ethics Committee (NTEC), Hospital Transplant Ethics Committee (HTEC), and all others concerned.

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This shall also govern the conduct of practice of all those engaged in organ donation and transplantation from living donors.

IV. DEFINITION OF TERMS

- A. **Attending Physician** – the doctor primarily attending to the recipient and his donor.
- B. **Donor Advocate** – a physician or a collegial body that has no relationship in any way with the recipient and the donor, who can assess and ascertain the medical and surgical suitability of the donor for the recipient.
- C. **Filipino Dual Citizen (FDC)** - a natural-born Filipino who had become a citizen of another country by reason of naturalization and who retained or re-acquired his/her Philippine citizenship or who was granted recognition as a Filipino citizen by virtue of Republic Act. (RA) No. 9225, otherwise known as the “Citizenship Retention and Reacquisition Act of 2003” and its Implementing Rules and Regulations (IRR). Also, FDC is a foreign national, who has been acknowledged or recognized as a Filipino citizen, because his father and/or mother was/were Filipino citizen(s) at the time of the FDC’s birth.
- D. **Foreigner** - a person also referred to as an alien who does not fall in any of the categories as enunciated in Section 1, Article IV of the 1987 Constitution of the Republic of the Philippines.
 - 1. Those who are citizens of the Philippines at the adoption of this Constitution;
 - 2. Those whose fathers or mothers are citizens of the Philippines;
 - 3. Those born before January 17, 1973, of Filipino mothers, who elect Philippine citizenship upon reaching the age of majority, and
 - 4. Those who are naturalized in accordance with the law.
- E. **Hospital Ethics Committee** - a group of individuals trained in ethics from different disciplines, age groups, gender, and professions, established by a hospital or health care institution, whose main function is to address ethical issues involving patient care.
- F. **Hospital Transplant Ethics Committee** – is a trained multi-sectoral committee that attends to ethical issues surrounding organ transplantation within the transplant facility.
- G. **Living Donors** - persons of 21 years of age and above, and who are mentally competent:
 - 1. **Living Related Donors (LRD)** – living donors who are related to the recipient by blood within the fourth degree of consanguinity (e.g. parents, children, siblings, nephew/nieces, first cousins).
 - 2. **Living Non-Related Donors (LNRD)** – living donors who are not related to the donors by blood. Relatives who are beyond the fourth degree of consanguinity are also considered to be LNRD.

LNRDs are classified as:

- a. "Emotionally Related" Donors – not related by blood to the recipient but bear close emotional ties with him/her that are proven beyond question (e.g. spouses, relatives by affinity, friends, colleagues, fiancé/fiancée and adoptive parents or children, employee - employer relationships).
- b. Commercial Donors (organ vendors) – offer their organs with monetary or other payments as precondition and prerequisite to the organ donation. Commercial donors are prohibited.

LNRDs can also be classified as:

- a. Directed Organ Donor – a living donor who has a specific recipient in mind to whom he/she would like to donate. This follows the principle known as donor designation wherein the donor's wishes are given due consideration.
- b. Non-Directed Organ Donor – a living donor who does not have a specific recipient in mind but would donate to anyone in the list of waiting patients for organ transplant. This is not in conformity with ethical guidelines and protocol on organ donation and is therefore prohibited.

- H. **National Transplant Ethics Committee** – is a collegial body created internally by the DOH and is an integral operational component of the PODTP that shall serve as the national oversight of the HTECs on ethical issues and dilemmas regarding organ donation and transplantation.
- I. **Organ** – differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularization and capacity to develop physiologic functions with an important level of autonomy (World Health Organization).
- J. **Organ Donation** – an act of liberality, whereby one disposes gratuitously of one's organ in favor of another, who accepts it.
- K. **Organ Sale** – an act when a person (the seller) obligates himself/herself to give his/her organ to another (the buyer) for a monetary price or its equivalent.
- L. **Recipient** – receiver of the organ directly from a donor; can also mean the transplant candidate or a donee. For the purpose of this AO, recipients include Filipino citizens, Filipino dual citizens and foreigners.
- M. **Transplant Team** – group of healthcare providers responsible for the actual retrieval and transfer of the organ.
- N. **Vulnerable Person** – any person who is susceptible to undue influence or other factors that may impair consent to the donation (e.g. elderly, persons with disabilities or mental health conditions, prisoners, members of the military, and indigenous peoples; or any person disadvantaged economically, professionally or socially directly or indirectly in relation to the recipient). If the donor is a

vulnerable person extra measures shall be undertaken to guard against exploitation. These measures include ensuring that:

1. The donor is able to comply with all the requirements of an informed consent.
2. The emotional relationship with the donor is established without question.

V. GENERAL GUIDELINES

- A. Organ donation and transplantation shall be guided by the principles and values which aspire to manifest fidelity and achieve trustworthiness in organ donation and transplantation. (See Annex A) <https://bit.ly/NTEC-AO>
- B. The National Transplant Ethics Committee shall serve as the national oversight of the HTEC on ethical issues and dilemmas regarding organ donation and transplantation.
- C. The Hospital Transplant Ethics Committee shall be required for the accreditation of all transplant facilities. An existing Hospital Ethics Committee (HEC) may perform the functions of the HTEC. It shall abide by the norms and expectations required for HTEC which may be more than what HEC does in its usual work, processes or procedures. There shall be a separate HTEC supported by a secretariat. The hospital administration shall provide administrative support and the honoraria of the HTEC members. (See Annex B)

VI. SPECIFIC GUIDELINES

A. National Transplant Ethics Committee

1. The NTEC shall be composed of a Chairperson, Co-Chairperson, and seven (7) Cluster Expert Members to be designated by the Secretary of Health from representatives of the hospitals, academe, socio-civic organization, government organization and religious organization and who shall serve for a term of 3 years. The members shall continue to serve on a holdover capacity at the end of their terms until such a time a replacement has been appointed. A Department Personnel Order (DPO) shall be issued for this purpose.
2. The NTEC shall report to the Secretary of Health.
3. The Philippine Network for Organ Sharing (PhilNOS) under Philippine Organ Donation and Transplantation Program (PODTP) shall serve as the secretariat of the NTEC as mandated by DPO No. 2018-4821 "Reconstitution of the National Transplant Ethics Committee (NTEC) under the Department of Health" and its amendments DPO No. 2018-4821-A and 2018-4821-B.

4. The operating expenses for the NTEC shall come from the Department of Health Disease Prevention and Control Bureau in accordance with DPO 2018-4821-B.

B. Organ Donors

1. A potential donor shall be 21 years old or above who voluntarily offers his/her organ. The potential donor must be ascertained to be an appropriate donor in accordance with standard medical practice and with the principles and provisions of this Order (See Annex D). He/she should be related to the recipient up to the 4th degree of consanguinity or at least have established emotional ties with the recipient. (See Annexes C.1 and C.2)
2. Potential LRDs shall be given priority over LNRDs. A document indicating the reason for the selection of the donor shall be submitted by the attending physician of the recipient. In the event that a recipient has several donors who do not have any distinct physical or compatibility advantage, the donor who is more emotionally and psychologically mature shall be selected. This shall be determined by the donor advocate or a person with the same qualifications designated by the transplant facility.
3. The potential donor and his/her spouse or if not married, a member of his/her family shall attend a Pre-Transplant Orientation in any DOH licensed and PhilHealth accredited transplant hospital. The orientation shall include among others an overview of the organ donation and transplantation procedure, importance of informed consent, benefits and risks to the donor and recipient, recognition and management of adverse effects, policies and guidelines related to the procedure, responsibilities of donors, recipients, transplant team and hospital, long term follow-up requirements, previous outcomes and alternatives to transplantation. A certificate of attendance shall be included in the evaluation of the donor by the HTEC.
4. The transplant facility/institution shall designate a donor advocate for the potential donor.
5. If the potential donor passes the initial matching tests, he/she shall be evaluated by a psychiatrist or clinical psychologist for competence in decision-making, motive for the donation, coercion or any limitation to free choice, and clarification of personal values. The psychiatrist/psychologist shall ensure that the donor is able to give free and informed consent. A corresponding report of this evaluation shall be submitted to the HTEC.
6. The potential donor shall be evaluated by a social worker to check the socio economic status and for any financial inducement. The social worker shall make a home visit to ascertain the motivation for the donation, real living conditions, family situation and actual address of

the donor. The written report of the social worker shall be included in the HTEC deliberation.

7. The eventual outcome of the evaluations and the decision to pursue or not to pursue the match and the basis for the decision shall be communicated to the transplant coordinator, attending physician and to the potential donor. (See Annexes D, D.1)
8. If approved as a potential donor, informed consent shall be obtained by the surgeon. His/her spouse or if not married, a member of his/her family shall again be given the same information as during the orientation. The patient shall be given time to reflect, discuss and ask questions. If he/she chooses to donate, consent forms and a Deed of Donation as required by the IRR of RA 9208 written in a dialect/language that is understandable to the donor are signed and witnessed. The informed consent process shall be documented and witnessed by persons unrelated to either the donor or the recipient and is not a member of the transplant team of the recipient. At any time before the donation, the potential donor is made to understand that he/she is free to change his/her mind and may withdraw his/her offer to donate. It shall also be made clear to the donor that he/she will not be charged for any procedure related to the donation.
9. The HTEC shall be provided with all the pertinent documentation during the time of their interview with the potential donor. The HTEC shall evaluate, then approve or disapprove the proposed donation based on this Administrative Order. The HTEC Certificate of Approval/Disapproval shall be given and included in the donor's and recipient's charts. A total of seven copies shall be made and a copy be given to the donor, recipient, attending physician, transplant surgeon, transplant coordinator, national registry and HTEC. Additional copies may be submitted to fulfill other administrative requirements. (See Annexes D, D.1 and E)
10. The donor shall be admitted and given the appropriate pre-operative, peri-operative and post-operative hospital care including treatment of any post-operative complications.
11. Upon discharge, the attending physician shall again explain to the donor and his/her spouse or a close relative or social relationship if not married, what was done, risks present, the importance of lifestyle conditions and follow-up monitoring as required by good clinical practice. The follow-up of the donor may be done by his/her attending physician. He/she may also be referred back to his/her original physician for further follow-up once the patient is considered to be completely stable. The HTEC shall ensure that there is a monitoring system within the institution that the donor is being followed-up over his/her lifetime. Donor follow-up shall be done according to the DOH guidelines on donor monitoring.

12. All medical expenses related to the donation including donor care and follow-up shall not be charged to the donor by the transplant facility.
13. Consistent with the provisions of the RA 10173 or the Data Privacy Act of 2012, all personal information regarding the organ donor shall be kept confidential except when regulatory authorities request information regarding the donation.

C. Organ Recipient

1. A transplant candidate bearing a certificate from his/her attending physician of the patient's need and suitability for an organ transplant shall be submitted to the registry of recipients that is to be found in the Philippine Organ Donor and Recipient Registry System (PODRRS).
2. If enrolled in the PODRRS, he/she shall be eligible to receive an organ from a deceased donor following the guidelines for organ allocation from deceased donors (AO 2010-0019 and AO 2010-0019-A). However, if a Living Donor is willing and available, the recipient can opt for this instead and shall inform PhilNOS of their availment.
3. The potential recipient and his/her spouse or if not married, a member of his/her family shall attend a Pre-Transplant Seminar Orientation in any DOH licensed and PhilHealth accredited transplant hospital. The seminar shall include among others an overview of the organ donation and transplantation procedure, importance of informed consent, benefits and risks to the donor and recipient, recognition and management of adverse effects, policies and guidelines related to the procedure, responsibilities of donors, recipients, transplant team and hospital, long-term follow-up requirements, previous outcomes and alternatives to transplantation. A certificate of attendance shall be provided to the HTEC during the evaluation.
5. Records of the recipient shall be submitted to the HTEC along with other relevant documents for evaluation and approval or disapproval of the proposed donation based on this Order and the implementing guidelines of the Administrative Order on Living Donation (DOH AO 2010-0018). The HTEC Certificate of Approval shall be given to the recipient and to the national registry.
6. The recipient shall be admitted for the transplant and shall be given the appropriate pre-, peri- and post-operative hospital care including treatment of any post-operative complications.
7. Upon discharge, the attending physician shall again explain what was done, risks present and the importance of follow-up care. He/she shall also refer the recipient back to his/her original physician.

8. The attending physician shall submit to the HTEC an abstract of the patient's records as well as the name of his/her assigned attending physician.
9. Consistent with the provisions of the RA 10173 or the Data Privacy Act of 2012, all personal information shall be kept confidential except when regulatory authorities request information regarding the transplantation.

D. Foreign Organ Donors and Recipients

1. Foreigners shall be eligible to receive professional medical care including organ transplantation in the Philippines. However, foreign patients cannot receive organs from living non-related Filipino donors as stipulated in the RA 9208, otherwise known as the Anti-Trafficking in Persons Act of 2003.
2. For foreign patients, the organ donor shall be a:
 - a. Related donor – up to 4th degree of consanguinity (parents, siblings, children, and first cousins of the recipient)
 - b. Spousal donor - at least (3) years legally married.
3. In addition, the following guidelines shall apply to foreign recipients and foreign related donors to ensure that human trafficking for organ donation does not occur.
 - a. The patient and/or patient's doctor shall communicate with a Philippine hospital and accredited transplant surgeon regarding medical status of recipient and donor. The hospital or surgeon shall inform them of the Philippine requirements.
 - b. Before going to the Philippines, the patient and donor shall be evaluated by a hospital ethics committee in their country.
 - c. Required documents to be submitted to the HTEC before surgery shall be authenticated by the Consular Office/Embassy or the appropriate Ministry of the foreign country and should have an accompanying English translation (see Annex C.2).
4. In addition to the requirements, the transplant candidate and donor upon coming to the Philippines shall be interviewed separately by the HTEC of the hospital where surgery will be performed. This interview shall be documented. (See Annex C.2)
5. Based on the guidelines, the HTEC shall decide whether to approve or disapprove the case. If disapproved, the reasons shall be clearly stated and documented. (See Annex D, D.1 and E)
6. If HTEC approves the donation, it shall inform NTEC of the case within 24 working hours. The NTEC has the right to review and overrule the decision of the HTEC within 24 working hours from receipt of HTEC information. If NTEC does not respond within the time period, it is presumed that the case has been approved and the transplant facility shall proceed with the surgery.

7. The HTEC shall consult with NTEC in cases where the HTEC has questions or unresolved issues related to this matter.
8. The NTEC shall conduct an audit of the HTEC with regard to organ transplantation and donation cases involving foreign recipients and donors as deemed necessary.
9. The HTEC shall include required documents (together with the interview documentation) of foreign patients and donors when it submits its quarterly report to the NTEC.

VII. ROLES AND RESPONSIBILITIES

A. Department of Health - Central Office shall develop systems, policies and guidelines that will facilitate the implementation of organ donation and transplantation from living donors at all levels. As such, the following offices shall have the following responsibilities:

1. National Transplant Ethics Committee shall:
 - a. Formulate the national ethical standards and guidelines on organ donation and transplantation;
 - b. Assist in the development of legislation, rules, and regulations regarding organ donation and transplantation;
 - c. Provide opinions, recommendations and final resolution of cases referred by HTECs;
 - d. Foster awareness on organ donation and transplantation ethical healthcare issues;
 - e. Participate in international discussions through interaction and collaboration with similar committees and organizations working in this field;
 - f. Provide technical assistance and monitor HTECs in the performance of their functions, helps in the accreditation of the transplant facility by the HFSRB by assessing the HTECs of the transplant facility to ensure compliance with ethical standards and guidelines; and,
 - g. Perform other functions assigned by the Secretary of Health.
2. Public Health Services Team (PHST) through
 - a. The Philippine Organ Donation and Transplantation Program (PODTP) shall:
 1. Oversee the organ donation and transplantation system in the country;
 2. Monitor compliance of the transplant facilities to policies set forth by this order and other operational guidelines that may be formulated;

3. Perform other functions assigned by the Secretary of Health of Health related to its primary function.

b. Philippine Network for Organ Sharing (PhilNOS) shall:

1. Act as the central coordinating body to ensure that all donor kidneys/organ from deceased donors are allocated according to established criteria;
2. Maintain the Philippine Organ Donor and Recipient Registry System (PODRRS);
3. Shall serve as the secretariat of the NTEC.

3. Health Facility Development Bureau (HFDB) shall:

- a. Provide technical assistance to transplant facilities in alignment with the Philippine Health Facility Development Plan (PHFDP) 2020-2040, and;
- b. Ensure the alignment to the requirements (human resource for health, equipment, and infrastructure) in organ donation and transplantation guidelines with Resource Stratified Framework for renal care and transplant

4. Health Facilities and Services Regulatory Bureau (HFSRB) shall:

- a. Ensure compliance of Accredited Kidney Transplant Unit's HTEC to the guidelines of the NTEC;
- b. Impose sanctions and penalties for ethical violations recommended by the NTEC.

B. The **Transplant Hospitals** shall establish a Hospital Transplant Ethics Committee in their respective hospitals and shall comply with the rules and regulations governing their accreditation and operation.

C. The **HTEC** shall fulfill the requirements for national and international assurances as it functions in accordance with the national laws and relevant rules and regulations. (Annex B)

VIII. VIOLATIONS AND SANCTIONS

1. Non-compliance of the transplant facilities with the standards and policies of this Administrative Order shall be investigated and sanctioned by the DOH in accordance with the existing relevant issuances.
2. Furthermore, any violations by erring professionals shall be forwarded to the DOH and to the Professional Regulatory Commission (PRC), as applicable, for appropriate sanctions. The referral of the said violations to the DOH and PRC shall be without prejudice to the filing of appropriate civil or criminal charges whenever warranted.

IX. REPEALING CLAUSE

The Provision in this *Order* shall supersede any sections in existing provisions or administrative issuances that are not consistent with the contents of this Order.

X. SEPARABILITY CLAUSE

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law of competent authority, those provisions not affected by such declaration shall remain valid and effective.

XI. EFFECTIVITY

This order shall take effect fifteen (15) days following its publication in the Official Gazette or a newspaper of general circulation and upon filing with the University of the Philippines Law Center of three (3) certified copies of this Order.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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ANNEX A PRINCIPLES AND VALUES

Organ donation and transplantation shall be guided by the principles and values as outlined in AO 2010-0018. These guidelines aspire to manifest fidelity and achieve trustworthiness in organ donation and transplantation.

1. Common good and solidarity

The organ donation shall be done, first and foremost, to save and improve the quality of life of another.

2. Non-Maleficence

Benefits shall outweigh the risks. Conflict of interests shall be avoided at all times. There shall be no exploitation of donor or recipient.

3. Respect for Person

No one shall be hastily judged based on another's personal beliefs, or socioeconomic status.

Informed consent shall be obtained from the donor and the recipient. They shall be provided with truthful information regarding the procedures, possible risks and its consequences in a language with which they are familiar. They shall be protected against any coercive force, which may prevent their free and voluntary decision. They must be mentally and emotionally competent.

A substitute decision maker cannot authorize the donation of an organ. This statement especially applies to those who are vulnerable and those with diminished autonomy.

Organ sale is **not allowed**. Respect for the donor also requires that his/her dignity shall be protected. Organ commodification/commercialism (wherein the giving of the organ is conditioned on the financial or material gain for the donor) violates human dignity, and has no place in organ donation.

4. Justice and Equality

All efforts must be exerted so that benefits and burdens are equally distributed. Transplant recipients are the main beneficiaries of transplantation procedures. However, the donors stand to gain equally when the donation is altruistic. The past experience of recruitment and exploitation of vulnerable living non-related donors from vulnerable sectors of society shall be avoided.

5. Beneficence

Beneficence refers to a charitable act or a gift. Organ donation and transplantation is a way of caring for the other. It is also a manifestation of generosity and compassion.

ANNEX B CONSTITUTING THE HOSPITAL TRANSPLANT ETHICS COMMITTEE

RATIONALE

The HTEC is guided by the ethical principles expressed in AO 2010-0018 of the Department of Health (Philippines) and other relevant national guidelines and international guidelines. The functions of the HTEC shall be in accordance with DOH guidelines and policies. The HTEC shall fulfill the requirements for national and international assurances as it functions in accordance with the national laws and relevant rules and regulations. Although the members are appointed by the Hospital Director, the HTEC shall ensure its independence from political, institutional, professional, and market influences. HTEC members shall undergo regular training on topics related to the ethical aspect of organ donation and transplantation. They shall have their own documented Standard Operating Procedures (SOPs).

OBJECTIVE

This SOP describes the appointment or Terms of Reference (TOR) which provide the framework for the constitution of the HTEC.

SCOPE AND COVERAGE

This SOP will cover the description of the general functions, composition, appointment, resignation and disqualification of HTEC members. It will also include a description of the officers of the HTEC.

1. Functions of the HTEC

- 1.1 Monitor and resolve ethical issues that may arise in the process of organ donation and transplantation in the hospital.
- 1.2 Evaluate living donors and approve or disapprove according to its assessment of the competence, willingness and absence of undue influence (compensation, pressure, etc.) of the donor
- 1.3 Ensure mechanisms for and implementation of post-transplant monitoring of the donors are in place and functioning within the institution.
- 1.4 Recommend sanctions for violation of the guidelines to the hospital administration. The hospital shall determine the proper sanction to be given to whoever is deemed culpable for the violation in accordance with the A.O.
- 1.5 Report to NTEC all HTEC resolution of cases, particularly violations and any recommended sanctions.
- 1.6 Report directly to authorized bodies such as the IACAT or PNP any suspected organ trafficking activities in accordance with RA 9208.
- 1.7 Perform such other functions as may be ordered by NTEC.

2. Composition of the HTEC

- 2.1 The HTEC shall comprise at least five members.

- 2.2 The members shall come from various backgrounds to ensure unbiased and comprehensive review.
- 2.3 The HTEC or HEC shall be a multi sectoral committee that should include at least any three of the following occupations: physician, psychiatrist, nurse, social worker, religious leader, lay person, ethicist, and a lawyer.
- 2.4 The membership shall include at least one member who is not affiliated with the hospital.
- 2.5 The HTEC must have an adequate balance of members with regard to age and gender.

3. Designation of HTEC Members

- 3.1 The HTEC members are appointed by the Hospital Director or Medical Center Chief.
- 3.2 Members are selected according to their professional and personal capacity, background interest and commitment and willingness to volunteer their time and effort for the HTEC's work.
- 3.3 Members shall submit their CVs which should be filed together with other documents of the HTEC. The CVs shall be updated every 2 years and whenever there is change in their professional competence or prior to HTEC re-accreditation whichever comes first.
- 3.4 Members are appointed for a period of 1-3 years, in accordance with the terms of reference of their appointment, preferably on a staggered basis. They can be re-appointed by the Medical Center Chief or Hospital Director.
- 3.5 Members shall disclose any conflict of interest (COI) annually and whenever there is a change in circumstances affecting the members interests.
- 3.6 Members shall undergo training for their functions as HTEC members at the expense of the hospital at least once a year. Attendance is required for training programs held by the Department of Health. Participation in non-DOH sponsored programs is highly encouraged.
- 3.7 Provision of honoraria to HTEC members shall be subject to existing law and DBM issuances as well as government accounting rules and regulations as applicable. The HTEC members from private health facilities shall be provided honorarium based on the institutional guidelines and policies, provided that, honoraria for government employees who are members of HTEC in private institutions shall be provided in accordance with pertinent government rules and regulations.

4. Duties of the HTEC Members

To fulfill its roles and functions, the HTEC shall:

- 4.1 Interview separately both the donor and the recipient in cases involving emotionally related donations. They should have standard operating procedures (SOPs) in the conduct of the interview. These SOPs shall be documented in writing and be made easily available to NTEC on request. Please see Annex B (SOP No. 2) and Annex D (SOP No. 4).

- 4.2 Evaluate every proposed donation and transplantation involving living organ donors and come to a decision to either approve or disapprove the donation by votation. A quorum for deliberation shall constitute 50% plus 1 of the total members of the HTEC while the required number of members to make a decision shall be 50% plus 1 of the total members of the HTEC present at the deliberation.
 - 4.2.1 Rules of quorum must be established and observed by the committee for each meeting.
 - 4.2.2 For a particular case, any member with a perceived conflict of interest shall abstain from the deliberation;
 - 4.2.3 Experts may be invited to act as a resource person.
 - 4.2.4 Difficult cases that cannot be resolved by the HTEC shall be referred to the NTEC for proper disposition.
- 4.3 Protect the best interests of both donor and recipient.
 - 4.3.1 It shall ascertain that the institution shall have a donor advocate that can ensure that the donation is beneficial for both donor and recipient.
 - 4.3.2 It shall ensure that the institution has mechanisms for post-donation health care and follow up to allow for monitoring long-term outcomes of the donation.
 - 4.3.3 It shall exert efforts to prevent his/her discrimination or stigmatization because of the donation.
- 4.4 Report ethical issues which arise from organ donation and transplantation that requires corrective action to the appropriate authoritative body.
- 4.5 Recommend sanctions for violations of these guidelines to the Hospital Administration and obtain information regarding the action of the administration.
- 4.6 Organize and keep records of cases, minutes of meetings, actions, clinical outcomes, ethical issues and reports of other committees involved in organ donation and transplantation. These shall be available to the NTEC for auditing. Please see Annex F (SOP No. 6).
- 4.7 Submit to the NTEC its updated composition together with brief curriculum vitae and training of HTEC members and the quarterly and annual reports of cases reviewed, actions, clinical outcomes, issues and recommendations. Please see Annex G (SOP No. 7).
- 4.8 Comply with all approved guidelines and requirements of NTEC and other regulatory authorities.
- 4.9 Be available and have documents ready for any on-site visit and audit by the NTEC. Please see Annex H (SOP No. 8).

5. Resignation and disqualification of members

- 5.1. A member may resign his/her position by submitting a letter of resignation.

- 5.2. A member may be disqualified due to proven practices that will compromise the work of the HTEC.
- 5.3. A member who has resigned or has been disqualified should be replaced to maintain quorum.
- 5.4. The terms of replacement shall be limited to that of the remaining term of the member that he/she has replaced.

6. Officers of the HTEC

The following are the officers to ensure the smooth functioning of the HTEC. The designation of positions is determined by the hospital's internal policies.

6.1. Chair

- 6.1.1 Responsible for preparing the agenda, calling, and presiding the meetings.
- 6.1.2 Liaise directly with the Hospital Director and the NTEC.
- 6.1.3 Responsible for preparing and submitting the reports to NTEC on time.

6.2. Co-chair

- 6.2.1 Responsible for presiding over the meetings in the absence of the Chair.
- 6.2.2 The Co-chair may be delegated by the Chair to do other relevant tasks.

6.3. Member Secretary

- 6.3.1 The secretary is responsible for the administrative aspects of the HTEC. She/He may designate staff to help out with the following functions of the Member Secretary:
 - 6.3.1.1 Organizes and prepares meeting agendas in consultation with the Chair.
 - 6.3.1.2 Takes the minutes of the meeting and submits the written minutes for HTEC Chair's approval after which they are filed.
 - 6.3.1.3 Organizes the HTEC files and maintains its confidentiality.
 - 6.3.1.4 Provides the necessary administrative support to the Chair for HTEC related activities.
 - 6.3.1.5 Submits quarterly and annual reports to the NTEC.

ANNEX C MANAGEMENT OF INITIAL REQUEST FOR HTEC REVIEW

RATIONALE

When the request for an interview is made, the HTEC must have clear guidelines on how to handle the request.

OBJECTIVE

This SOP describes the steps for managing the initial request for a donor interview.

SCOPE AND COVERAGE

This SOP describes how the HTEC Secretary manages the initial request for HTEC review made by those authorized or in charge of the Hospital Organ Donation and Transplantation Program (Hospital Transplant Coordinator - HTC). It covers the steps to be done from the time of submission of the letter of request to the filing of documents and the notification of a meeting to HTEC members.

It is the responsibility of the Secretary to inform the HTEC about the list of documents that are needed for submission to the HTEC. The secretary shall receive, record and file pertinent documents and ensure that all documents are complete. The secretary shall inform the Chair of such request.

STEPS:

The Secretary:

1. Gives the list of all documents that should be submitted to the HTEC (Form No. __: Checklist of documents for submission).
2. Logs (in an electronic database if available) the name of donor, recipient, person who submitted the documents, date of submission and the pertinent documents.
3. Files all documents in a secured cabinet.
4. Ensures that documents are complete.
5. Informs the Chair of the submission of the request.
6. Schedules an HTEC meeting upon the instruction of the Chair.

*Evaluation should include the donor's voluntariness and that ethical issues such as informed consent, non-payment of the donor and post-surgery follow-up have been considered and found to be within the ethical framework of organ donation.

For Foreign Transplant Patients with their Living Related Donors:

The patient / patient's doctor shall communicate with a Philippine hospital and accredited transplant surgeon regarding medical status of recipient and donor. The hospital or surgeon shall inform them of the Philippine requirements. Documents required to be submitted to HTEC before the surgery shall be authenticated by the Consular Office/Embassy or the appropriate Ministry of the foreign country.

ANNEX C.1 Checklist of Documents for Submission prior to HTEC Evaluation of Transplant Candidate and Donor Candidate

Checklist of Documents for Submission prior to HTEC Evaluation of Transplant Candidate and Donor Candidate		
Name of person submitting Address:		Contact No.
Name of Donor Address:		Contact No.
Name of Attending Physician/Nephrologist:		Contact No.
Name of Recipient Address		Contact No.
Name of Nephrologist:		Contact No.
Documents	Date of Submission (NA if not applicable)	Signature
Letter of Request		
Medical abstract of patient		
Medical abstract of donor		
Reports from the Social Service (donor)		
Reports from the Psychiatrist (donor)		
Certified true copy of original Birth Certificates of patient		
Certified true copy of original Birth Certificates of donor		
Certified true copy of birth certificates of parents of patient		

Certificate of relationship between transplant patient and donor		
Deed of donation		
Proof showing that transplant candidate and potential donor have known each other substantially e.g. such as pictures showing them together when they were younger.		
Marriage certificate if applicable		
Informed Consent of donor		
Pre-transplantation orientation certificate		
Notarized oath of undertaking		

Date: _____

OATH OF UNDERTAKING

I, _____, _____, _____

(name of recipient)

(age)

(address)

KIDNEY RECIPIENT , pledge to provide medical support pertaining to Kidney Donation

of, _____, _____, _____

(name of donor)

(age)

(address)

KIDNEY DONOR to _____ hereby accept the terms and

(name of recipient)

condition implied below.

TERMS AND CONDITION

1. _____ guaranties that the DONOR _____

(name of recipient)

(name of donor)

Will not be charged of any medical bills during the KIDNEY TRANSPLANT OPERATION.

2. _____ will receive free Kidney Check- up from

(name of donor)

(name of recipient)

As follows:

a.

FOLLOW – UP SCHEDULE	EXAMINATION TO BE DONE
1 week after donation	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN), Creatinine

1 month after donation	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN), Creatinine
3 months after donation	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN) , Creatinine
6 months after donation	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN) , Creatinine
1 year after donation • if w/ blood in the urine – RBC morphology • if w/ protein in the urine – Urine TP; Crea Ratio	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN) , Creatinine, Whole Abdomen Ultrasound, 12 Leads ECG, Chest X-ray
Yearly after x 10 years	Complete Blood Count (CBC); Urinalysis; Triglycerides; Blood Urea Nitrogen (BUN) , Creatinine, Whole Abdomen Ultrasound, 12 Leads ECG, Chest X-ray

b. Medical consultations, medications and hospitalization and PhilHealth membership payment whenever necessary that is related to Kidney Donation.

I have read and understood the above information and it was fully explained to me. I have had the opportunity to ask questions I have and all have been answered.

(Name of Donor)

witness / date

(Name of Recipient)

witness / date

ANNEX C.2 Checklist of Documents for Submission of Foreign Transplant Candidates with their Living Related Donors

Checklist of Documents for Submission of Foreign Transplant Candidates with their Living Related Donors

	Documents	Date of Submission (NA if not applicable)	Signature
1	Letter of Request		
2	Medical abstract of patient		
3	Medical abstract of donor		
4	Reports from the Social Service (donor)		
5	Reports from the Psychiatrist (donor)		
6	Certified true copy of original Birth Certificates of patient		
7	Certified true copy of original Birth Certificates of donor		
8	Certified true copy of birth certificates of parents of patient		
9	Certified True copy of Marriage certificate of parents of patient if no. 8 is not available		
10	Certified true copy of birth certificates of parents of donor		
11	Certified True copy of Marriage certificate of parents of donor if no. 10 is not available		
12	Certificate of consanguinity; family tree		
13	Deed of donation		

14	Certification by an ethics committee in the country of origin		
15	Proof showing patient and donor have known each other such as pictures together when they were younger		
16	Marriage Certificate (if the donor is the spouse)		

ANNEX D DONOR EVALUATION

RATIONALE

The way a potential donor is evaluated by the HTEC must be in accordance with the principles and provisions of this Order.

OBJECTIVE

This SOP describes the procedures to be followed upon receiving a request for Organ Donor evaluation.

SCOPE AND COVERAGE

This SOP covers the procedures for evaluating potential donors. This step in the donor matching takes place parallel to the clinical evaluation and should neither be at the very start nor at the very end of the process (e.g. before HLA typing). Required Documents to be evaluated should be complete before the HTEC meeting.

STEPS:

1. The HTEC Secretary through his/her staff shall check the submitted documents prior to the meeting to determine their completeness. If not complete or unsatisfactory, the secretarial staff shall inform the Hospital Transplant Coordinator (or whoever submitted the documents) of the deficiencies. Only when all pertinent requirements are complete shall the HTEC Secretary inform the HTEC Chair of the request for organ donor evaluation.
2. HTEC Chair shall check the submitted documents prior to the meeting to determine their completeness.
3. HTEC Chair shall call the HTEC meeting after making sure of the availability of the organ donor and the patient recipient for the interviews. If a resource person, including an interpreter, is needed, the HTEC Chair shall also ensure his/her availability during the meeting.
4. Before the interview, HTEC shall examine the documents, especially the psychiatrist's and social worker's reports.
5. The recipient and donor shall be interviewed separately.
6. The interview shall be recorded and a written summary of the important points shall be prepared. Using the interview questionnaire checklist, the HTEC shall elicit appropriate and truthful answers regarding the relationship of recipient and donor, motive for donation and appropriate knowledge of the donor about procedures to be done, risks involved, and the need for follow-up. The HTEC shall ensure that the donor is able to explain rather than just answer yes or no to their questions.
7. The HTEC shall take special care in the interview of "emotionally" related donors as they may be paid organ donors claiming a relationship with the recipient. HTEC can

use the social worker's or psychiatrist's report to help them to ask additional questions that may show the true motive of the donor.

8. HTEC shall ask the donor if she/he has offered to be a donor to another recipient or if she/he has been interviewed at another hospital (if yes, which hospital and the reason why she/he is now a donor for the present recipient).
9. HTEC shall validate the answers obtained from donor or recipient without telling the other (recipient or donor) the answer given to the question by either donor or recipient.
10. After the interview, the donor and recipient shall leave the room.
11. The HTEC shall evaluate if the answers of donor and recipient correspond well and do not conflict with each other. Discrepancy in the answers may be the basis for disapproval of the donor.
12. HTEC shall consult with the social worker and/or psychiatrist to clarify issues or if they have questions about the donor.
13. On the basis of the interviews and assessment of submitted documents, HTEC shall approve or disapprove the donation. If disapproved, reason for disapproval shall be stated. If there are concerns to watch for in approved cases, these shall also be included in the minutes.
14. A Certificate of HTEC approval or disapproval of the donation signed by the HTEC Chair shall be prepared and given to concerned authorities. A total of seven (7) copies shall be made and a copy be given to the donor, recipient, attending physicians, transplant surgeon, national registry, and HTEC.

ANNEX D.1 Sample Certificate of Outcome of HTEC Interview

Name of Hospital
Hospital Transplant Ethics Committee
Transplant Interview Outcome

This is to certify that the case of the transplant pair involving ____ (name of donor) ____ for organ recipient ____ (name of recipient) ____ was presented to the Hospital Transplant Ethics Committee this ____ day of ____ (month) ____, 20__ at the ____ (name of hospital) ____ . A thorough review and investigation of the circumstances surrounding the organ donation was done.

OUTCOME OF EVALUATION:

DISPOSITION of Ethics Committee Member No. 1

____ Approved as stands

____ For further investigation, with request for the following requirements

____ Disapproved because _____

Name and Signature of Committee Member

DISPOSITION of Ethics Committee Member No. 2

____ Approved as stands

____ For further investigation, with request for the following requirements

____ Disapproved because _____

Name and Signature of Committee Member

DISPOSITION of Ethics Committee Member No. 3

____ Approved as stands

____ For further investigation, with request for the following requirements

____ Disapproved because _____

Name and Signature of Committee Member

FINAL DECISION OF HTEC

____ Approved as stands

____For further investigation, with request for the following requirements

____Disapproved because _____

Name and Signature of Committee Chairperson

ANNEX E CONDUCT OF HTEC MEETING

RATIONALE

HTEC meetings are important as this is the time when decisions regarding organ donations and other HTEC-related work are made. Proper decorum of meetings and documentation are vital components of HTEC work.

OBJECTIVE

This SOP will describe the procedures to be followed by HTEC in the conduct of meetings.

SCOPE AND COVERAGE

This SOP covers the procedures to follow once the meeting is convened until such time the said meeting is adjourned.

STEPS:

1. HTEC shall decide if they shall have regular meetings at a particular date and time and venue especially if the number of transplants being done at hospital is substantial. This will enable the other concerned parties to do their own scheduling of cases and the availability of HTEC members in meetings will be ensured. However, if the cases occur sporadically, then the HTEC may schedule their meetings accordingly.
2. Decision making shall be determined by HTEC beforehand in the SOP, whether it will be by consensus or by voting.
3. The HTEC Chair shall instruct the Secretary to send the notice of meeting and agenda for the meeting. The Secretary shall inform the Chair if there will be a quorum or not; if no quorum, another schedule shall be set.
4. The Secretary shall inform the Organ Donation and Transplantation office or Hospital Transplant Coordinator (HTC) so that the potential donor and recipient can be informed and be available for the meeting.
5. Conduct of meeting:
 - 5.1 Determination of quorum. A suggested quorum of 50% plus one (1) of HTEC members in the meeting shall be noted. The lay person and/or the member not affiliated with the institution should be present.
 - 5.2 HTEC Chair (or Co-Chair) shall call the meeting to order
 - 5.3 Disclosure of conflict of interest
 - 5.4 Approval of Agenda
 - 5.5 Approval of Minutes of Previous Meeting
 - 5.6 Business Arising from Minutes of Previous Meeting
 - 5.7 Review of documents of the cases to be discussed

- 5.8 Interview of Donor alone
 - 5.9 Interview of Recipient alone
 - Note: The potential donor and recipient are called into the meeting only during the actual interview with the HTEC and are subsequently excused from the succeeding parts of the meeting. Donor and recipient shall be interviewed separately from each other
 - 5.10 Discussion of the case and action of HTEC regarding the case.
 - 5.11 If there is more than one case, the same procedure shall be observed.
 - 5.12 Discussion of other matters (e.g. current issues on ODT, Administrative orders, etc.)
 - 5.13 Adjournment of meeting
6. The Secretary shall keep an audio recording of the meeting, time started and time ended.
7. Minutes of the meeting shall be completed within 2 weeks of the HTEC meeting. A template may be developed as a standard form for HTEC meetings. It shall include:
- 7.1 Determination of quorum
 - 7.2 Agenda
 - 7.3 Disclosure of Conflict of Interest
 - 7.4 Title of Meeting, Date and Venue of Meeting
 - 7.5 Members present
 - 7.6 Presider and time of start of meeting
 - 7.7 Approval of Agenda
 - 7.8 Business Arising from Previous Minutes
 - 7.9 Cases reviewed – including names of Donor and Transplant Recipient
 - 7.10 Interview
 - 7.11 Issues/Matters discussed in each case
 - 7.12 Decision taken (if by voting, members who voted are noted)
 - 7.13 Other Matters Discussed
 - 7.14 Time of Adjournment
8. All minutes of the meeting should be signed by the Presider of the meeting and the secretary who made the report.
9. All documents of the cases discussed shall be filed according to office procedures. The confidentiality of the files should be strictly maintained.

ANNEX F MANAGEMENT OF APPEALS, COMPLAINTS AND VIOLATIONS

RATIONALE

The HTEC must be ready to manage appeals regarding its decisions and complaints from various parties. In the pursuit of its work, the HTEC must ensure its objectivity, fairness and transparency since the health of patients may be affected by its decisions.

OBJECTIVE

This SOP will describe the steps the HTEC can take to manage appeals, complaints or violations that are brought to the attention of the HTEC.

SCOPE AND COVERAGE

This SOP will cover the steps the HTEC will take to address appeals, complaints and violations regarding decisions or actions from the time they are brought to the attention of the HTEC to the time of the disposition of these.

STEPS:

A. Management of Appeals

1. HTEC shall consider only written and signed communications of appeal.
2. The clerical staff shall log the appeal upon receipt, make a copy for office files and shall inform and send the letter to the HTEC Chair.
3. The HTEC Chair shall evaluate the appeal whether she/he could answer it based on the discussion of the case during the HTEC meeting.
4. If unable to make a decision on his/her own, the HTEC Chair shall either consult the other HTEC members for their opinions during the regular HTEC meeting; or if urgent, call a special meeting.
5. If needed, the HTEC Chair can consult others outside HTEC or invite resource persons to the meeting. NTEC can also be consulted if deemed necessary.
6. The HTEC Chair shall answer the letter as soon as possible. In addition to the letter to the appellant, copies shall be provided to the HTC and attending physicians.

B. Management of Complaints

1. HTEC shall consider only written and signed communications of complaint.
2. Complaints shall be specific and state the nature of the complaint, and where applicable, the specific persons involved in the complaint (e.g. HTEC members, staff, physicians, HTC, transplant facility or others). It shall state facts – date, time, persons involved, source of conflict, etc.
3. If HTEC members, personnel or processes are the subject of the complaint, the HTEC shall respond in writing after a thorough investigation.

C. Management of Violations

1. Non-compliance to the standards and ethical guidelines by those involved in organ donation and transplantation in the hospital shall be considered a violation.
2. Once informed of a violation, HTEC shall report it to the hospital authorities.
3. The reported violation shall be investigated according to standard hospital policies.
4. The HTEC can recommend to hospital authorities appropriate sanctions according to the hospital's established rules or in the absence of these, according to their collective judgment.
5. The HTEC shall report to NTEC all violations and any recommended sanctions.

ANNEX G MANAGEMENT OF DOCUMENT FILES

RATIONALE

Documents of the HTEC must be organized and easily retrievable while maintaining confidentiality at all times.

OBJECTIVE

This SOP shall describe the procedures regarding the handling and management of HTEC files related to Organ Donation and Transplantation.

SCOPE AND COVERAGE

This SOP covers the maintenance of the files, the archiving and the maintenance of confidentiality.

The HTEC Secretary has the main responsibility to maintain files and archives for its work.

1. The HTEC meetings/work must be properly documented.
2. Forms and Templates for various documents needed in HTEC work shall be made available for standardized appearance and text content.
3. A filing system must be established.
4. Documents must be kept for at least five (5) years after which electronic archiving must be done including follow-up medical reports on the organ donors.
5. Access to documents must be limited to authorized personnel whose names and designations are decided upon beforehand by the HTEC and a list of these posted near the said documents.
6. The Secretary must sign a confidentiality agreement with the hospital with regards to all organ and transplant records.

STEPS:

1. HTEC shall have an office space with secured filing cabinets which can be secured so that only authorized person or staff can have access to the files.
2. The Secretary shall organize the office files for HTEC:
 - 2.1 CV and appointment papers, training of HTEC members
 - 2.2 Donor Files – Filipino living related and non-related donors; deceased donors
 - 2.3 Recipient Files – Filipino Patients
 - 2.4 Foreign Recipient and Foreign Donor files
 - 2.5 Minutes of HTEC meetings
 - 2.6 Quarterly and Annual Reports to NTEC
 - 2.7 DOH ODT Operating Procedures Manual
 - 2.8 HTEC Standard Operating Procedures (SOPs)
 - 2.9 Logbooks of donors/recipients, including post-surgery follow-up
 - 2.10 National (DOH, NTEC) and international guidelines, other references
 - 2.11 Forms, checklists, templates used by HTEC

- 2.12 Logbooks and database (electronic if possible)
- 2.13 Other relevant HTEC Communications
- 3. Coding System – The Secretary shall develop a coding (numbering) system for its database to facilitate the access and retrieval of documents.
- 4. Tracking System
 - 4.1. Each application shall contain a log page that contains the date, progress and decisions regarding said application.
 - 4.2. The tracking system shall be linked to the database through the coding system.
- 5. Confidentiality of records shall be observed accordingly and access limited to authorized persons only.

ANNEX H SUBMISSION OF REPORTS

RATIONALE

HTEC is required by NTEC to submit quarterly and annual reports. These contain important information which shall provide statistics and issues of concern on organ donation and transplantation in the country. Submission shall be prompt and on or before the required deadline (quarterly and annual).

OBJECTIVE

This SOP describes the manner by which reports of the HTEC are submitted to the DOH NTEC.

SCOPE AND COVERAGE

This SOP covers the kind of reports to be used and how it is to be turned over and received by the NTEC.

STEPS:

1. The Secretary shall use the DOH NTEC template and encode the required data contained therein including:
 - 1.1 Filipino recipient with Living Related Donor
 - 1.2 Filipino recipient with Living Non-Related Donor
 - 1.3 Foreign recipient with Foreign Living Related Donor
2. The report shall also include reports of complaints, appeals and violations and how the HTEC managed and resolved these matters. HTEC shall also include other relevant matters which should be brought to the attention of NTEC.
3. Upon completion, the report shall be approved and signed by the HTEC Chair.
4. The report shall be emailed or sent to the NTEC office.
5. Failure to comply with this requirement shall be subject to sanctions by NTEC.
7. NTEC must issue a Certificate of Compliance to renewal of accreditation.

ANNEX H.1 NTEC Report Template

DEPARTMENT OF HEALTH

NATIONAL TRANSPLANTATION ETHICS COMMITTEE

HOSPITAL TRANSPLANT ETHICS COMMITTEE REPORT

NAME OF INSTITUTION :

ADDRESS :

TELEPHONE NUMBER :

FAX NUMBER :

EMAIL ADDRESS :

DATE OF REPORT :

PERIOD COVERED BY THIS REPORT: _____

I. COMPOSITION OF HOSPITAL TRANSPLANT ETHICS COMMITTEE:

Name	Address	Tel. No./ Mobile No./ Email Address	Age	Sex	Occupation	Hospital / Institutional Affiliation

II. MEETINGS OF HOSPITAL TRANSPLANT ETHICS COMMITTEE: (NOTE:
Please attach minutes of HTEC meeting with report)

Date of Meeting	Number of HTEC Members Attending	Venue of Meeting	Number of Donors Discussed	Number of Donors Approved	Number of Donors Disapproved

III. NUMBER OF ORGAN TRANSPLANTATION PROCEDURES DONE BY DONOR CATEGORY

A. Filipino Recipients

Donors Category	Filipino Recipients
Filipino Living Related Donors	
Filipino Living Non-Related Donors	
Deceased Organ Donors	
Total Number	

B. Recipients (whose either parent is a Filipino, who were born in the Philippines, or who carry a Filipino passport):

Donors Category	Filipino Recipients
Filipino Living Related Donors	
Filipino Living Non-Related Donors	
Deceased Organ Donors	
Total Number	

C. Foreign Recipients

Donors Category	Foreign Recipients
Foreign Living Related Donors	

Foreign Living Non-Related Donors	
Filipino Living Related Donors	
Filipino Living Non-Related Donors	
Deceased Organ Donors	
Total Number	

IV. ETHICAL ISSUES DISCUSSED:

<i>Date of Meeting</i>	<i>Issue/s Discussed</i>	<i>HTEC Action</i>	<i>Implemented (Yes/No)</i>	<i>Consultation with NTEC</i>

V. VIOLATIONS/SANCTIONS

Date of Incident	Type of Violation	Date of HTEC Meeting	Action of HTEC	Implemented

SANCTIONS: *Reprimand*

Suspension of Hospital Privileges

Dismissal

VI. COMMENTS / RECOMMENDATIONS:

1.

2.

3.

REPORT PREPARED BY: _____
Name in Print and Signature

Date: _____

REPORT APPROVED BY: _____
Name in Print and Signature
HEC Chair

Date: _____

ANNEX I SITE VISIT BY NTEC

RATIONALE

The NTEC has the mandate to assist in the monitoring of HTECs to ensure compliance with national policies, ethical standards and guidelines. An NTEC representative joins the DOH accreditation team in the site visit of the hospital transplant facility including its Hospital Ethics Committee or HTEC. HTECs shall have a designated, secure place in the transplant facility where HTEC files and documents can be easily retrieved if needed. Security and confidentiality of records in accordance with the provisions of the Data Privacy Act of 2012 shall be ensured at all times.

OBJECTIVE

This SOP describes the steps to take when an HTEC is to be visited for accreditation by the NTEC.

SCOPE AND COVERAGE

The SOP includes the preparations that need to be made prior to an NTEC visit, the day of the actual visit, including the observation of an actual HTEC meeting.

STEPS:

A. Preparation for the NTEC Visit

1. Prior to the scheduled visit set by the DOH HFSRB, the HTEC shall review and fill up the assessment checklist for HTEC (see Annex H.1) and submit it to NTEC before the scheduled visit. This will assist the HTEC in making a self-assessment of the committee and its compliance with the NTEC guidelines. This will also give them the opportunity to address any deficiencies that it may have before the visit.
2. HTEC Chair shall inform the members to be available for the scheduled visit. They shall be ready for an interview by the NTEC.
3. The HTEC Secretary shall be available during the site visit to provide the relevant documents. NTEC shall include the clerical staff in the interview.
4. If possible, HTEC shall schedule a meeting during the visit so the NTEC can observe how they conduct its meeting, especially the interview.

B. Actual Visit

1. Inspection of HTEC Office and Files
 - 1.1. CV and appointment papers, training of HTEC members

- 1.2. Donor Files – Filipino living related and non-related donors; deceased donors
 - 1.3. Recipient Files – Filipino Patients
 - 1.4. Foreign Recipient and Foreign Donor files
 - 1.5. Minutes of HTEC meetings
 - 1.6. Quarterly and Annual Reports to NTEC
 - 1.7. DOH ODT Operating Procedures Manual
 - 1.8. HTEC Standard Operating Procedures (SOPs)
 - 1.9. Log books of donors/recipients, including post-surgery follow-up
 - 1.10. National (DOH, NTEC) and international guidelines, other references
 - 1.11. Forms, checklists, templates used by HTEC
 - 1.12. Log books and database (electronic if possible)
 - 1.13. Other relevant HTEC Communications
2. Interviews – NTEC may ask any of the following persons for the interview
 - 2.1. HTEC Chair
 - 2.2. HTEC Secretary
 - 2.3. HTEC Member – non-affiliated
 - 2.4. Donor if possible, even a post-donor
 - 2.5. Recipient if possible
3. Observation of an HTEC Meeting (NTEC can ask date of next HTEC meeting and may decide to attend)

NOTE: NTEC can visit at any other time but this shall be communicated to HTEC. A past or potential donor may be requested to come for an interview by NTEC.

ANNEX I. 1: HTEC Site Visit Checklist

**NATIONAL TRANSPLANT ETHICS COMMITTEE
ASSESSMENT CHECKLIST FOR HOSPITAL (TRANSPLANT)
ETHICS COMMITTEE (HEC /HTEC)**

NAME OF TRANSPLANT FACILITY: _____

ADDRESS: _____

NAME OF HTEC MAIN CONTACT: _____

CONTACT NUMBER: _____

YEAR HTEC ESTABLISHED: _____

NAME	PROFESSION/ CREDENTIALS	AFFILIATION		GENDER	
		YES	NO	M	F
Chair:					
Vice-Chair					
Secretary					
Members:					

A. STRUCTURE AND COMPOSITION:

Does HTEC have	HTEC	NTEC	Remarks
At least 5 members?			
A diversity of members (age, gender, profession, etc.)			
Responsibilities/duties clear in their appointment letter?			
The duration/term of their appointment stated?			
members who have the necessary training/knowledge about organ donation and transplantation?			
A non-affiliated member?			
A lay/community member?			
Procedure for disclosure and addressing conflict of interest?			
Confidentiality agreement signed by members?			

ADMINISTRATIVE SUPPORT:

Does HTEC have	HTEC	NTEC	Remarks
Office space?			
Necessary office equipment to do its work including locked filing cabinets?			
Adequate staff to do its functions?			
Clear duties and responsibilities of the staff?			
Staff who understand the confidentiality of its work?			
A budget?			
Orderly and organized files of its documents (minutes, donor/recipient files, complaints, communications, etc)?			

B. COMPLIANCE TO NATIONAL LAWS, POLICIES AND REGULATIONS, SOPs)

Does HTEC have	HTEC	NTEC	Remarks
Copies of the necessary documents on ODT which it can use as reference? RA 7170, RA 9208 DOH AOs (current) NTEC guidelines PBODT Manual of Procedures WHO Guiding Principles on ODT Declaration of Istanbul			

Its own written manual of SOPs?			
SOPs that cover all necessary procedures?			
Proof of compliance with its SOPs and national guidelines?			
Regular review, updating and revision of SOPs?			

C. ASSESSMENT / EVALUATION OF DONORS / RECIPIENTS

1. PROCEDURES:

Does the HTEC have	HTEC	NTEC	Remarks
A procedure on request for donor/recipient evaluation?			
Clear procedures known to concerned parties? Is the written procedure available to them?			
A standard submission form for evaluation request?			
A checklist of standard list of documents to be submitted with the request?			
Template for the informed consent document?			
An interview checklist for donor and recipient?			

A registration /logging procedure for requests made?			
A tracking procedure for all requests and HTEC actions			

2. HTEC MEETING/EVALUATION

Does the HTEC have	HTEC	NTEC	Remarks
Regularly set HTEC meetings? How often? Are meetings called only to evaluate donors and recipients on a need basis?			
Notification procedure re date and agenda of meetings?			
An established procedure how to conduct their meetings?			
Definition of the quorum to be observed during the meeting?			
Provision for disclosure of conflict of interest during the meeting? Does HTEC ensure that persons with possible conflict of interest are not present during deliberation concerning donors?			
All the relevant documents available to the members during the meeting?			
A checklist for donor evaluation?			

An established procedure how to conduct the interview of donors and recipients? Does HTEC conduct interviews <i>en banc</i> ?			
Special questions to be asked of LNRDs during the interview?			
Provision to discuss contents of the informed consent during the interview?			
Interviews recorded and transcripts available?			
Process of decision making during the meeting? Is the method of decision making by vote or by consensus?			
Decisions made in meetings where there is a quorum?			
Relevant concerns/opinions duly noted in the minutes?			
Clear explanation for disapproval?			
Minutes which follow a standard format which includes the date, time and venue of meeting, the members present, the matters discussed, donors evaluated, HTEC action/decision?			
The Certificate of Approval of Donation issued only after the HTEC meeting?			

Procedure for communicating the written decision to persons concerned?			
The decision letter which states HTEC requirements after donation esp re submission of medical abstracts and follow-up?			

FOREIGN DONORS AND RECIPIENTS

Does HTEC	HTEC	NTEC	Remarks
Evaluate foreign recipients and donors?			
Have special procedure for evaluating these cases?			
Have an evaluation checklist for foreign cases?			
Comply with the policies and guidelines re these cases?			
Submit reports on these cases to NTEC within the set time period?			
Ensure that it is informed re follow-up of these cases after ODT?			

D. AFTER HTEC APPROVAL AND ORGAN DONATION

Does HTEC	HTEC	NTEC	Remarks
-----------	------	------	---------

Have a procedure for following up donors?			
Get medical abstracts of donors/recipients after surgery?			
Remind transplant facility or doctors concerned if there is no follow-up report on donors?			
Submit quarterly reports to NTEC?			
Submit annual reports to NTEC?			
Communicate or refer special concerns to NTEC?			

E. D. DOCUMENTATION AND ARCHIVING PROCEDURES

Does HTEC have	HTEC	NTEC	Remarks
A log book / registry of all donors and recipients?			
An electronic database registry of donors and recipients?			
Complete donor files – on-going and archived?			
A procedure for record keeping and archiving all records and communication documents?			

Provision for security and confidentiality of files except to authorized individuals/agencies?			
Orderly and organized files that can be easily retrieved?			

COMMENTS:

RECOMMENDATION/S:

SIGNED: _____
NTEC

DATE: _____

ANNEX J DUAL CITIZENSHIP

In recent years, permanent overseas Filipinos, either natural-born or naturalized in their countries of permanent residence, who themselves are organ transplant candidates (OTCs) have resorted to travel for transplantation to the Philippines relying on familial and emotional ties that would potentially provide them relief through organ donations, mostly coming from living non-related organ donors (LNRDs). The same may be true with aliens who were granted Philippine citizenship.

Filipino Dual Citizens (FDCs) are those natural-born Filipinos who retained and reacquired their Philippine citizenship or those granted recognition as Filipino citizens by virtue of Republic Act. No. 9225, otherwise known as the “Citizenship Retention and Reacquisition Act of 2003” and its Implementing Rules and Regulations. Also, a foreign national, who has been acknowledged/recognized as a Filipino citizen, whose father and/or mother was/were Filipino citizen(s) at the time of birth. Furthermore, pursuant to Bureau of Immigration Operations Order No. SBM-2014-045 dated 30 September 2014 entitled, “Formalities in the Arrival and Departure of Philippine Citizen with Dual or Multiple Citizenship.” FDCs traveling to the Philippines shall be able to present the following proofs of Philippine citizenship: (1) a valid Philippine Passport; (2) Identification Certificate (IC); or (3) Certificate of Retention/Reacquisition of Philippine Citizenship (CRPC). Hence, an FDC, upon arrival or departure, may or may not possess a Philippine passport along with a foreign passport but is expected to have only either an IC or a CRPC.

In order to ensure that hospital transplant ethics committees (HTECs) discharge their duties and obligations to protect both donor and recipient from exploitative practices, below are guidelines in determining the eligibility of Filipino Dual Citizens (FDCs) for organ and tissue donation and transplantation subject to existing Philippine laws and DOH policies, rules, and regulations along with entitlement to benefits pursuant to the policies and guidelines of the Philippine Health Insurance Corporation (PhilHealth).

A. ENTITLEMENT TO PHILHEALTH BENEFITS

Pursuant to PhilHealth Circular No. 2017-0004 dated January 10, 2017, entitled “Enrolment/Coverage of Filipinos with Dual Citizenship,” Section III.4 provides that:

“FDCs and their qualified dependent/s are entitled to avail PhilHealth benefits, provided they have paid premium contributions of at least 3 months within the 6-month period prior to the first day of availment, subject to PhilHealth Circular No. 032-2014 and/or as may be prescribed by the Corporation.”

Note: Foreign spouses are not qualified dependents of FDCs.

B. CONDITIONS FOR PROPER TRAVEL FOR TRANSPLANTATION *(lifted verbatim from Gill, J. S., & Delmonico, F. L. (2015). Transplant tourism versus*

proper travel for transplantation. Clinical Liver Disease, 6(4), 90–91. doi: 10.1002/cld.503)

Proper travel for transplantation should include the referral of either a donor or a recipient or a donor–recipient pair to a center that is compliant with the Declaration of Istanbul (DOI) and World Health Organization (WHO) principles of care before such a transplant occurs in a foreign destination.

Proper travel for transplantation may be acceptable if, for example, the following conditions are fulfilled for organ transplantation from a [living]* donor:

1. If the recipient has a dual citizenship (in the country of residence and also in the destination country) and wishes to undergo transplantation from a [living] donor who is a family member in the destination country of citizenship that is not their residence;
2. If the donor and recipient are genetically- or emotionally-related and wish to undergo donation and transplantation in a country not of their residence to gain access to better health services.

*Note: Original term used by the article was “live”

C. GUIDELINES TO DETERMINE ELIGIBILITY OF FDCs FOR ORGAN AND TISSUE TRANSPLANTATION

To ensure that healthcare providers’ fiduciary and legal obligations are met for OTCs who are FDCs, these guidelines shall provide the requisites to determine eligibility for transplantation of FDCs along with their potential Filipino living organ donors.

As citizens of the Philippines, FDCs are subject to existing Philippine laws and DOH policies, rules and regulations governing organ and tissue donation and transplantation.

1. Requirements Prior to Travel for Transplantation to the Philippines of the FDC-Organ Transplant Candidate (OTC)

- a. The reason(s) for travel for transplantation to a destination outside the FDC-OTC’s country of residence must be clarified prospectively IN WRITING to the preferred Attending Physician (AP) in the Transplant Center (TxC) of choice in the Philippines. Said document shall be submitted to the HTEC along with the other documentary requirements.
- b. The FDC-OTC may be accompanied by a potential living donor identified for evaluation in the foreign destination.

- c. The FDC-OTC shall provide certified and authenticated documentary proof(s) of medical evaluation(s)
- d. The FDC-OTC shall produce evidence that s/he has exhausted all eligible family members in full compliance to Section 9, Article IV of Republic Act No. 9208, otherwise known as the "Anti-Trafficking in Persons Act of 2003," as amended by Republic Act. No. 10364 and its Implementing Rules and Regulations, which states that:

"xxx Provided, however, that in case of non-related voluntary donor, a medical evaluation has been made showing that all other members of the immediate family of the donee-recipient have been eliminated, for medical or for other reasons, as potential donors. xxx"

- e. With documentary requirements completed, the donor-recipient pair opting for transplantation shall submit such for evaluation to the HTEC of the TxC of choice.

2. Documentary requirements to be submitted by the FDC-OTC for HTEC evaluation as proof of Philippine citizenship.

For an FDC-OTC who is a former Philippine citizen who has been naturalized in another country and who retained or reacquired his/her Philippine citizenship by virtue of RA No. 9225.

- a. Certificate of Retention/Reacquisition of Philippine Citizenship (CRPC);
- b. Order of Approval;
- c. Oath of Allegiance (Philippines);
- d. PSA-Authenticated Birth Certificate;
- e. Bio-page of valid Philippine passport;
- f. Medical evaluation report

For an FDC-OTC who is a foreign national, whose father and/or mother was/were Filipino citizen(s) at the time of the OTC's birth and who has been acknowledged/recognized as a Filipino citizen.

- a. Identification Certificate (IC);
- b. PSA-Authenticated Birth Certificate/ Report of Birth
- c. Bio-page of valid Philippine Passport;
- d. Medical evaluation report

3. Documentary requirements to be submitted by the prospective/potential Filipino living organ donor, either accompanying the OTC or permanently residing in the Philippines.

- a. PSA-Authenticated Philippine Birth Certificate;
- b. Any acceptable valid Philippine government-issued ID
- c. Bio-Page of valid Philippine Passport (optional)

Summary Table of Required Documentary Proofs and Issuing Authorities				
Type of Documentary Proof	Bureau of Immigration (BI)	Department of Foreign Affairs (DFA)	Philippine Statistical Authority (PSA)	Foreign Service Post (FSP)*
Birth Certificate (BC) / Report of Birth (ROB) in Security Paper (SECPA)			x	
Philippine Passport		x		x
Certificate of Retention/Reacquisition of Philippine Citizenship (CRPC)	x			x
Identification Certificate (IC)	x			x
Order of Approval	x			x
Oath of Allegiance (Philippines)	x			x

**A Foreign Service Post refers to a Philippine Embassy or a Philippine Consulate General. (Department of Foreign Affairs Department Order No. 11-2015, "Jurisdiction of Foreign Service Posts" dated 22 June 2015.)*

Note: Certified true copies (CTCs) of the above-mentioned documents are to be submitted along with presentation of originals for authentication. The HTEC reserves the right to require additional documents from the FDC-OTC or his/her Filipino living organ donor, to prove his/her identity and/or citizenship.