STANDARDS FOR HUMAN ORGANS AND TISSUES DONATION SERVICES (LIVING DONOR)

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Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

The Standard for Human Organs and Tissues Donation Services (Living Donor) aims to fulfill the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

EXECUTIVE SUMMARY

Human organ and tissue donation services are considered critical support areas to the healthcare system. Living donation is the removal of an organ from a living person who willingly chooses to donate an organ or tissue for transplantation. This includes the recovery of a kidney or a segment of liver from a living person and transplanting it into an individual with end-stage kidney or liver disease. Living donation can be favourable since it can reduce a candidate's time waiting for transplant. Living donors may be blood relatives, emotionally related individuals, or altruistic strangers. This document is developed to ensure that living donor workup, consent, recovery, and post-operative services provided in Dubai Health Authority (DHA) licensed health facilities are of the highest quality standards and aligned with current international best practices.

This document elaborates the licensing requirements of a hospital aiming to assess and workup potential living donors, recover living donor organs for transplant, provide post-operative follow-up care. These requirements include the health facility requirements, the healthcare professional requirements, the consent for living organ donation, medication requirements, assessment and workup of living donor candidate, pre-operative assessment, and post-operative care of living donors. This standard is aligned with all the applicable United Arab Emirates (UAE) laws and legislations related to the subject.

These Standards shall align with the following:

- Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.
- Federal Decree Law (18) of 2023 concerning the Medical Liability.
- Federal Law no. (8) of 2023 amending some provisions of Federal Law no (4) of 2015 concerning the Private Health Facilities.
- Cabinet Decision No. (25) of 2020 concerning Federal Decree No. (5) of 2016 concerning regulating the transfusion and transplantation of human organs and tissues.
- DHA Guidelines for Organ and Tissue Donation Registry and KPIs.

DEFINITIONS

Donation is a legal act indicating that a living individual has legally accepted to donate, during his/her lifetime or after death when formally documented either by the notary public, through Emirates identify card, under a legal will left for his/her heirs or permitted successors, or through consent from next of kin in accordance with published DHA standards, to donate with no compensation one or more of his/her body organs or part thereof or tissues to someone by way of transplantation operation.

Donor is a human being, living or deceased, who is a source of organs, tissues or cells which are to be used for the purpose of transplantation.

Health Facility is a facility licensed by DHA to provide medical services to individuals, including areas of prevention, treatment, and convalescence owned and managed by natural or corporate body.

Healthcare Professional are healthcare personnel working in health care facilities and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

Independent Living Donor Advocate (ILDA) a person (preferably the Medical Director of the Hospital or Director of the service, with a capacity to take challenging decisions, when required) or team of individuals that advocates on behalf of the donor to help ensure the potential donor understands the evaluation process, recovery surgery, its risks, and its benefits. The ILDA protects the donor's rights and decisions. The ILDA must be knowledgeable

regarding the transplant process but independent of transplant recipient services and any pressure to move forward based on individual or system transplant needs.

Informed Consent refers to an agreement or permission accompanied by full information on the nature, risks, and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

Living Donor is a living human being from whom organs tissues or cells have been retrieved for the purpose of transplantation and who has one of the following possible relationships with the recipient:

- Genetic Relative up to fourth degree of kinship;
- Emotionally Related: Spouse up to fourth degree of kinship;
- Reciprocal donor in accordance with Federal Decree No. (25) of 2023; or
- Unrelated or Non-Related: Not genetically or emotionally related, approved by special Committee as coordinated by the National Center.

Living Donor Coordinator serves as a facilitator, educator and point of contact as well as assisting patients with all details of care involved in preparing for evaluation, organ recovery, and post-transplant care.

National Center for Donation and Transplantation (The National Center) is the federal center under the Ministry of Health and Prevention responsible to regulate and coordinate organ and tissue donation and transplantation in UAE.

Next of Kin: a person authorized to make decisions on behalf of the patient, in cases where the patient is incompetent, or the relatives up to the fourth degree available in the country or by telephone or computer visual and audio/sign language communication, based on the below order:

A. The father.

B. The mother.

C. The offsprings (adult).

D. The spouse.

E. The grandfather.

F. The siblings.

G. The paternal uncle and the full uncle is precedent to the half uncle.

Organ Transplant Unit (OTU) is an area in the hospital dedicated to Organ Transplant with privileged healthcare professionals and administrative staff like the Kidney (organ) Transplant Coordinator to ensure a seamless and efficient provision of Organ Transplant Services.

Potential Living Donor is a human under evaluation for organ donation. This individual may be in a stage of assessment in the workup process and up until organ recovery occurs.

Transplant Candidate is a person registered on the organ transplant wait list awaiting a transplant. When an organ is offered on behalf of the candidate, they are then called a Potential Transplant Recipient.

Workup is a thorough potential donor or recipient review, which may include diagnostic assessments such as laboratory tests, imaging, cancer screening, psychosocial assessment, and other evaluations for the purpose of ensuring successful donation and transplant outcomes.

ABBREVIATIONS

ALP	:	Alkaline Phosphatase
ALT	:	Alanine Transaminase
AST	:	Aspartate Aminotransferase
BMI	:	Body Mass Index
BUN	:	Blood Urea Nitrogen
CKD	:	Chronic Kidney Disease
CMV	:	Cytomegalovirus
CT	:	Computed Tomography
DHA	:	Dubai Health Authority
ECG	:	Electrocardiogram
ERCP	:	Endoscopic Retrograde Cholangiopancreatography
ESRD	:	End Stage Renal Disease
GFR	:	Glomerular Filtration Rate
GGT	:	Gamma Glutamyl Transpeptidase
HBV	:	Hepatitis B Virus
HCV	:	Hepatitis C Virus
HDL	:	High Density Lipoproteins
HFG	:	Health Facility Guidelines
HIV	:	Human Immunodeficiency Virus
HLA	:	Human Leukocyte Antigens
HRS	:	Health Regulation Sector

HRQOL	:	Health-Related Quality of Life
HTK	:	Histidine–Tryptophan–Ketoglutarate
HTLV	:	Human T-Lymphotropic Virus
ICU	:	Intensive Care Unit
IgG	:	Immunoglobulin G
IgM	:	Immunoglobulin M
ILDA	:	Independent Living Donor Advocate
LDC	:	Living Donation Coordinator
LDH	:	Lactate Dehydrogenase
LDKD	:	Living Donor Kidney Donation
LDL	:	Low Density Lipoproteins
LDLD	:	Living Donor Liver Donation
MOHAP	:	Ministry of Health and Prevention
MRCP	:	Magnetic Resonance Cholangiopancreatography
MRI	:	Magnetic Resonance Imaging
NCDT	:	National Center for Donation and Transplantation
OT	:	Operating Theatre
OTU	:	Organ Transplant Unit
OTUC	:	Organ Transplant Unit Coordinator
PT	:	Prothrombin Time
PTT	:	Partial Thromboplastin Time
RN	:	Registered Nurse

RNA	:	Ribonucleic Acid
SOP	:	Standard Operating Procedure
TPHA	:	Treponema Pallidum Hemagglutination
UAE	:	United Arab Emirates
UTI	:	Urinary Tract Infection
VDRL	:	Venereal Disease Research Laboratory

1. BACKGROUND

In 2016 the United Arab Emirates (UAE) issued a law to allow transplantation of human organs and tissues from both living donors and the deceased. In 2023 this law was replaced as the Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.

In September 2020, The National Center to Regulate Human Organs and Tissues Transplantation (The National Center) was established. The National Center aims to unify the national efforts in the field of transplantation of human organs and tissues, regulate and coordinate organ transplant surgeries across the country.

This standard is developed to regulate living donation services, with an aim to assure the provision of the highest levels of safety and quality for providing living kidney donation and living liver donation in Dubai Health Authority (DHA) licensed hospitals.

Living donor organ recovery surgery is done to remove a healthy kidney or partial liver segment from a living human donor that may then be transplanted into a recipient whose kidneys or liver no longer functions well enough to support the body independently.

2. SCOPE

2.1. Living Donation services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality Living Donation services in DHA licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Living Donation services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Living Donation services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities opting to provide Living Donation services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.3. Licensed health facilities opting to add Living Donation services shall inform Health Regulation Sector (HRS) and submit an application to HRS to obtain permission to provide the required service.

5.3.1. Licensed health facilities opting to provide Living Donation services must have prior permission by HRS to provide transplant services for the organ(s) the hospital intends to retrieve through living donation, in order to obtain licensure for Living Donation services.

5.4. Accreditation

5.4.1. The hospital shall be accredited as per the DHA Hospital accreditation policy before the commencement of living donor organ retrieval services.

5.4.2. The hospital laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy before the commencement of living donor organ retrieval services.

5.5. The hospital shall employ trained and experienced healthcare professionals as identify and described in this document.

5.6. The health facility shall have Standard Operating Procedures (SOPs) related to the living donor organ recovery services. The relevant staff shall be trained to abide by these SOPs. The SOPs shall be made available to HRS upon request.

5.7. The health facility shall develop the following policies and procedures at minimum and provide documented evidence to HRS upon request:

5.7.1. Patient Continuity of Care

5.7.2. Living donor acceptance criteria.

5.7.3. Patient education and informed consent, including the requirements listed in **Appendix 1.**

5.7.4. Living donor exclusion criteria as elaborated in **Appendix 2 (kidney) and Appendix 3 (liver)**.

5.7.5. Blood type determination of the candidate, which must include the requirements listed in **Appendix 4**.

5.7.6. Pre-operative living donor assessment and evaluation, which must include the requirements listed in **Appendix 4 (clinical) and Appendix 5 (psychosocial)**.

5.7.7. Post-recovery follow-up protocol, including the requirements listed in **Appendix 6 (kidney) and Appendix 7 (liver).**

5.7.8. Patient health records must be maintained and demonstrate that all policies and procedures were followed.

5.7.9. Infection control measures including post-donation follow-up testing detailed in **Appendix 6 (kidney) and Appendix 7 (liver)** and hazardous waste management.

5.7.10. Adverse event reporting to the DHA in accordance with **Appendix 8**.

5.7.11. Patient privacy.

5.7.12. Medication management.

5.7.13. Emergency action plan.

5.7.14. Patient discharge/transfer.

5.8. The health facility shall provide documented evidence of the following:

5.8.1. Transfer of critical/complicated cases when required.

5.8.2. Patient discharge.

5.8.3. Clinical laboratory services.

5.8.4. Equipment maintenance services.

5.8.5. Laundry services.

5.8.6. Medical waste management as per Dubai Municipality (DM) requirements.

5.8.7. Housekeeping services.

5.9. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premises in two languages (Arabic and English).

5.10. The health facility shall have in place a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects. This written plan shall be provided upon request.

5.11. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets, and communications.

5.12. The health facility shall allocate sufficient operating and recover room resources, intensive care resources, surgical beds, and personnel to the living donor organ recovery services.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. Living Donation recovery services shall only be performed in DHA organ transplant licensed hospitals.

6.2. The hospital shall have the clinical resources available to assess the medical condition of and specific risks to the living donor during a living donor workup.

6.3. The hospital shall have the clinical resources to perform a psychosocial evaluation of the living donor, in accordance with **Appendix 5**.

6.4. The hospital shall make available an independent living donor advocate (individual or team) to the donor throughout the entire evaluation process, in accordance with **Appendix 9**.

6.5. The hospital providing living donor recovery services shall have the following services:

6.5.1. Psychiatry, Clinical Psychology, or Social Work

6.5.2. Cardiology

6.5.3. Gastroenterology with endoscopy

6.5.4. Pulmonology with bronchoscopy

6.5.5. Radiology

6.5.6. Haematology

6.5.7. Pathology Laboratory

a. All routine investigations necessary for the patients before or after donation must be available.

b. Facilities to do tissue typing, cytotoxic antibodies and blood levels of drugs including cyclosporine or similar drugs should be available.

6.5.8. Biochemistry Laboratory

6.5.9. Nephrology with haemodialysis unit (preferably with portable dialysis machines).

6.5.10. Intensive Care Unit (ICU).

6.5.11. Quality Management.

6.5.12. Blood banking services.

6.5.13. Microbiology services.

6.6. The hospitals shall provide the following:

6.6.1. Minimum of two Operating Theatres (OTs).

6.6.2. Minimum of two (2) rooms for the management of patients both before and after organ recovery.

6.7. The hospital shall install and operate equipment required for provision of the proposed services in accordance with the manufacturer's specifications.

6.8. The hospital shall ensure easy access to the health facility and treatment areas for all patient groups.

6.9. The health facility design should provide assurance of patient and staff health and safety.

6.10. The health facility shall have appropriate emergency medications as defined in the published DHA Policy for Emergency Medications, equipment, and trained healthcare professionals to manage critical and emergency cases.

6.11. The health facility's design shall align with the health facility requirement as per the DHA Health Facility Guidelines (HFG) 2019, Part B – Health Facility Briefing & Design, for all the above-mentioned categories of services.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS FOR LIVING DONOR KIDNEY RECOVERY

7.1. A DHA licensed hospital providing living kidney donor assessment and organ recovery services shall have a team of healthcare professionals to ensure the smooth functioning of the service to ensure patient continuity of care.

7.2. A DHA licensed health facility providing living kidney donor assessment and organ recovery services shall have a qualified consultant living donor surgeons such as General Surgeon/Vascular Surgeons/Renal Transplant Surgeons/Urologist, with training and experience in living donor kidney retrieval, as described below and privileged by the health facility.

7.3. The consultant living donor surgeons are responsible for ensuring the operation and compliance of living donor recovery services with requirements set forth in this document.

7.4. To perform open living donor nephrectomies, the hospital must have a qualified consultant surgeon as mentioned above, who shall meet the following conditions:

7.4.1. The surgeon must have performed:

a. At least ten (10) open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, within the last five (5) years as primary surgeon, co-surgeon, or first assistant.

b. At least five (5) of these open nephrectomies must have been performed as the primary surgeon or co-surgeon.

c. This experience must be documented in a log including date of recovery, the role of the surgeon in the procedure, the type of procedure, and the medical record number or other unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

7.5. To perform laparoscopic living donor nephrectomies, the hospital must have a qualified consultant laparoscopic living donor kidney surgeon. The consultant laparoscopic living donor kidney surgeon must meet the following criteria:

7.5.1. The surgeon must have performed:

a. At least fifteen (15) laparoscopic nephrectomies within the last 3 years as primary surgeon, co-surgeon, or first assistant.

b. At least seven (7) of these nephrectomies must have been performed as the primary surgeon or co-surgeon.

c. This experience must be documented in a log including date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or other unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

7.5.2. The surgeon must provide a letter from an individual in a supervisory position from the hospital where the surgeon acquired transplant

experience verifying that the surgeon has met the requirements outlined above, is qualified to lead kidney donation and transplant services, is a person of honesty and integrity, and has experience adhering to regulatory obligations.

7.6. A DHA licensed health facility providing kidney living donor assessment and organ recovery services shall have the following DHA licensed healthcare professionals.

7.6.1. **Nephrologists** experienced and trained to manage and provide care for patients during evaluation, recovery, and post-organ donation, with at least one (1) year of training in transplant nephrology (lead).

7.6.2. **Registered Nurses (RNs)** experienced and trained to care for patients during evaluation, recovery, and post-organ donation.

7.6.3. **Living Donor Coordinator** to work with patients and their families to coordinate care, beginning with evaluation and continuing through and after donation. The coordinator shall be a registered nurse or other licensed clinician with minimum of three (3) years of acute care or dialysis experience required. Experience relevant to nephrology transplant subspecialty is preferred.

7.6.4. **Clinical Pharmacist** to provide comprehensive medication management to living donors.

7.6.5. **Clinical Social Worker** to coordinate psychosocial needs of living donors, living donor candidates, and their families.

7.6.6. **Clinical Dietician** to provide nutritional services to living donors.

7.7. Living donor kidney recovery services shall collaborate with medical experts in these fields; including but not limited to:

7.7.1. Anaesthesiology (with experience in intra-operative management of living organ donors).

7.7.2. Histocompatibility and immunogenetics.

7.7.3. Immunology.

7.7.4. Infectious Disease.

7.7.5. Pathology.

7.7.6. Physical therapy and rehabilitation medicine.

7.7.7. Radiology.

7.7.8. Pharmacy.

7.7.9. Cardiology, as appropriate.

7.7.10. Hepatology, as appropriate.

7.7.11. Pulmonary medicine, including respiratory therapy support, as appropriate.

7.7.12. Paediatrics, if applicable.

7.8. Living Donor Coordinators (LDC) shall be assigned in the hospital OTU providing kidney living donor recovery services, with the following responsibilities:

7.8.1. Acts as liaison between the National Center and the hospital OTU.

7.8.2. Work closely with coordinator(s) of the National Center and the Organ Transplant Unit Coordinator (OTUC) to facilitate subsequent transplant after living donor organ recovery.

7.8.3. Ensure that all potential living donors meet donation criteria and maintain documentation to support that these requirements are met.

7.8.4. Ensure that all policies and procedures for the OTU related to living donation are up to date and aligned with current international best practice.

7.8.5. Ensure that all activities of the OTU adhere to policies and procedures for living donation and assume responsibility for maintaining all supportive documentation in patients' medical records.

7.9. The health facility shall provide effective communication and coordination of the donation and transplantation process without compromising the privacy and autonomy of either the potential living donor or the organ transplant candidate.

7.9.1. An Independent Living Donor Advocate (ILDA) is an individual or team not involved with the potential organ transplant candidate's evaluation that will serve in a supportive role to the potential living donor in receiving and understanding this communication and support the living donor through the decision-making process. Criteria for an ILDA is elaborated in **Appendix 9**.

7.10. A DHA licensed health facility providing Living Kidney Donation services shall have a Living Kidney Donation Committee to ensure efficiency and safe living donor organ recovery services. The Living Kidney Donation Committee shall meet on a regular basis to ensure smooth operation of the OTU's living donation services and shall consist of the following members:

7.10.1. Consultant Living Donor Kidney Surgeon(s) (could be the lead).

7.10.2. Nephrologist (could be the lead).

7.10.3. Independent Living Donor Advocate.

7.10.4. Living Donor Coordinator.

7.10.5. Registered Nurse Representative.

7.10.6. Anaesthesiologist.

7.10.7. Psychiatrist or Clinical Psychologist.

7.10.8. Cardiologist (optional).

7.10.9. Paediatric Nephrologist (optional).

7.10.10. Urologist (optional).

7.10.11. Legal Representative (optional).

7.11. The responsibilities of the Living Kidney Donation Committee are as follows:

7.11.1. Review the health records of patients assessed for living donation.

7.11.2. Make clinical decisions regarding the appropriateness of living donation based on their clinical and psychosocial workup.

7.11.3. Review aggregate reporting on annual living donor follow-up and any individual adverse event reporting as elaborated in **Appendix 8**.

7.11.4. Ensure that living donation activities abide to the highest ethical and legal standards.

7.11.5. Facilitate multi-disciplinary decision-making to provide the best possible care for living donors.

7.11.6. Create a process of living donor evaluation and clinical care that is efficient, effective, and transparent.

7.11.7. Develop and regularly update Policies and Procedures related to Living Donation services to ensure efficient and safe provision of services.

7.12. The Privileging Committee and/or Medical Director of the health facility must privilege the physicians listed above aligned with her/her education, training, experience, and competencies. The privilege shall be reviewed and revised on regular intervals aligned with the DHA Clinical Privileging Policy.

8. **STANDARD FOUR:** HEALTHCARE PROFESSIONALS REQUIREMENTS FOR LIVING DONOR LIVER RECOVERY

8.1. A DHA licensed hospital providing living Liver donor assessment and organ recovery services shall have a team of healthcare professionals to ensure the smooth functioning of the service to ensure patient continuity of care.

8.2. A DHA licensed health facility providing living liver donor assessment and organ

recovery services shall have a qualified consultant General Surgeon/Visceral Surgeon/Gastroenterologist with training and experience in living donor liver retrieval, as described below and privileged by the health facility.

8.3. The consultant surgeons are responsible for ensuring the operation and compliance of living donor recovery services with requirements set forth in these standards.

8.4. To perform the open surgery to recover livers for transplantation from living donors, the health facility must have two (2) DHA licensed consultant surgeons trained and experienced in open living donor liver. The consultant shall meet the following conditions:

8.4.1. The surgeon must have:

a. Performed forty-five (45) liver transplants as primary surgeon, co-surgeon or first assistant within the last ten (10) years at a hospital designated to perform liver transplants.

b. Participated in pre-operative assessment of liver transplant candidates and post-operative care of these recipients.

c. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or another unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

8.4.2. The surgeon must have:

a. Performed at least one (1) liver transplant within the last two (2) years.

   (i) These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or another unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

b. Performed at least twenty (20) liver procurements as primary surgeon or first assistant under the supervision of a qualified liver transplant surgeon.

   (i) These procedures must be documented in a log that includes the date of procurement and a unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

c. Performed at least twenty (20) major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past five (5) years.

   (i) Of these, at least ten (10) must have been performed as the primary surgeon or co-surgeon.

(ii) In addition, seven (7) must have been live donor procedures, of which at least four (4) much have been performed as the primary or consultant surgeon, or co-surgeon.

(iii) The procedures must be documented in a log that includes the date of the procedure, the type of procedure, the role of the surgeon in the procedure, and the medical record number or other unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

8.5. To perform laparoscopic living donor hepatectomies, the hospital must have a DHA licensed consultant General Surgeon with training and experience in laparoscopic intervention in living donor liver and privileged by the health facility aligned with the DHA Privileging Policy. The consultant general surgeon shall meet the following criteria:

8.5.1. The surgeon must meet all the qualifications for the consultant open living donor liver surgeon.

8.5.2. In addition, the surgeon must have performed:

a. An additional six (6) open living donor procurements as primary or consultant surgeon, or co-surgeon within the past five (5) years, for a total of ten (10) open living donor procurements as primary.

b. At least ten (10) formal laparoscopic right hepatectomies and ten (10) formal laparoscopic left hepatectomies for non-transplant indication.

c. At least three (3) laparoscopic living donor liver procurements that are proctored by an established robotic living donor liver surgeon.

d. This experience must be documented in a log including date of recovery, the role of the surgeon in the procedure, the type of procedure (laparoscopic vs. open), and the medical record number or other unique identifier that can be identified. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

8.5.3. The surgeon must provide a letter from an individual in a supervisory position from the hospital where the surgeon acquired transplant experience verifying that the surgeon has met the requirements outlined above, is qualified to lead donation and liver transplant services, is a person of honesty and integrity, and has experience adhering to regulatory obligations.

8.6. A DHA licensed health facility providing liver living donor assessment and organ recovery services shall also have the following DHA licensed healthcare professionals to support the above physicians:

8.6.1. **Hepatologists** experienced and trained to manage and provide care for patients during evaluation, recovery, and post-organ donation.

8.6.2. **Registered Nurses (RNs)** experienced and trained to care for patients during evaluation, recovery, and post-organ donation.

8.6.3. **Living Donor Coordinator** to work with patients and their families to coordinate care, beginning with evaluation and continuing through and after donation. The coordinator shall be a registered nurse or other licensed clinician with minimum of three (3) years of acute care experience required. Experience relevant to hepatology transplant subspecialty is preferred.

8.6.4. **Clinical Pharmacist** to provide comprehensive medication management to living donors.

8.6.5. **Clinical Social Worker** to coordinate psychosocial needs of living donors, living donor candidates, and their families.

8.6.6. **Clinical Dietician** to provide nutritional services to living donors.

8.7. Living donor liver recovery services shall collaborate with medical experts in these fields; including but not limited to:

8.7.1. Anaesthesiology (with experience in intra-operative management of living organ donors).

8.7.2. Histocompatibility and immunogenetics.

8.7.3. Immunology.

8.7.4. Infectious Disease.

8.7.5. Pathology.

8.7.6. Physical therapy and rehabilitation medicine.

8.7.7. Radiology.

8.7.8. Pulmonary medicine, including respiratory therapy support, as appropriate.

8.7.9. Cardiology, as appropriate.

8.7.10. Nephrology, including dialysis capability, as appropriate.

8.7.11. Paediatrics, if applicable.

8.8. Living Donor Coordinators shall be assigned in each OTU providing liver living donor recovery services, with the following responsibilities:

8.8.1. Acts as liaison between the National Center and the hospital OTU.

8.8.2. Work closely with coordinator(s) of the National Center and the Organ Transplant Unit Coordinator to facilitate subsequent transplant.

8.8.3. Ensure that all potential living donors meet donation criteria and maintain documentation to support that these requirements are met.

8.8.4. Ensure that all policies and procedures for the OTU related to living donation services are up to date and aligned with current international best practice.

8.8.5. Ensure that all activities of the OTU adhere to policies and procedures for living donation and assume responsibility for maintaining all supportive documentation in patients' medical records.

8.9. The health facility shall provide effective communication and coordination of the donation and transplantation process without compromising the privacy and autonomy of either the potential living donor or the organ transplant candidate.

8.9.1. An Independent Living Donor Advocate (ILDA) is an individual or team not involved with the potential organ transplant candidate's evaluation that will serve in a supportive role to the potential living donor in receiving and understanding this communication and support the living donor through the decision-making process. Criteria for an ILDA is elaborated in **Appendix 9**.

8.10. A DHA licensed health facility providing Living Donation services shall have a Living Liver Donation Committee to ensure efficiency and safe living donor organ recovery services. The Living Liver Donation Committee shall meet on a regular basis to ensure smooth operation of the OUT's living donation services and shall consist of the following members:

8.10.1. Consultant Surgeons for Living Donor Liver (lead).

8.10.2. Hepatologist.

8.10.3. Independent Living Donor Advocate.

8.10.4. Living Donor Coordinator.

8.10.5. Registered Nurse Representative.

8.10.6. Anaesthesiologist.

8.10.7. Psychiatrist or Clinical Psychologist.

8.10.8. Paediatric Hepatologist (optional).

8.10.9. Cardiologist (optional).

8.10.10. Nephrologist (optional).

8.10.11. Legal Representative (optional).

8.11. The responsibilities of the Living Liver Donation Committee are as follows:

8.11.1. Review the health records of patients assessed for living donation.

8.11.2. Make clinical decisions regarding the appropriateness of living donation based on their clinical and psychosocial workup.

8.11.3. Review aggregate reporting on annual living donor follow-up and any individual adverse event reporting as elaborated in **Appendix 8**.

8.11.4. Ensure that living donation activities abide to the highest ethical and legal standards.

8.11.5. Ensure that each potential living donor has access and fair opportunity to be assessed for organ donation.

8.11.6. Facilitate multi-disciplinary decision-making to provide the best possible care for living donors.

8.11.7. Create a process of living donor evaluation and clinical care that is efficient, effective, and transparent.

8.11.8. Develop and regularly update Policies and Procedures related to Living Donation services to ensure efficient and safe provision of services.

8.12. The Privileging Committee and/or Medical Director of the health facility must privilege the physicians listed above aligned with her/her education, training, experience, and competencies. The privilege shall be reviewed and revised on regular intervals aligned with the DHA Clinical Privileging Policy.

9. **STANDARD FIVE:** INFORMED CONSENT FOR LIVING DONATION

9.1. Living donors shall sign the consent before the donor workup begins and the consent shall be documented in his or her health record. Full requirements for informed consent are elaborated in **Appendix 1.**

9.1.1. Exclusion criteria for Living-Donor Kidney Donation (LDKD) are elaborated in **Appendix 2.**

9.1.2. Exclusion criteria for Living Donor Liver Donation (LDLD) are elaborated in **Appendix 3.**

10. **STANDARD SIX:** MEDICATION REQUIREMENTS

10.1. Health facilities providing living donor kidney or liver organ recovery services shall ensure the in-house availability of the following drugs, but not limited to:

10.1.1. Commonly used intra-operative drugs:

a. Lasix and/or Mannitol.

b. Heparin.

c. Diuretics.

d. Prophylactic antibiotics.

e. Anaesthetics.

10.1.2. Commonly used post-operative drugs:

a. Narcotics for pain.

b. Anti-inflammatories.

c. Prophylactic antibiotics.

d. Treatment for nausea, reflux, stool softeners, insomnia as needed.

10.1.3. Solutions for perfusing the organs such as University of Wisconsin solution, HTK solution, KPS solution, or Euro Collins solution.

10.1.4. Drugs for treating bacterial, viral, fungal, or parasitic infections.

11. STANDARD SEVEN: PRE-OP ASSESSMENT AND EVALUATION OF LIVING DONOR

11.1. The pre-operative assessment and workup of a potential living donor is elaborated in **Appendix 4**.

11.1.1. The pre-operative assessment must ensure that each living donor's blood type is determined by testing at least two donor blood samples. These samples must be drawn on two separate occasions and be submitted as separate samples with different collection times.

11.1.2. The organ recovery hospital shall have a process to address conflicting or indeterminate primary blood type results in their written protocol.

11.2. The psychosocial assessment and workup of the potential Living Donor is elaborated in **Appendix 5**.

11.3. Each case of non-related living donation shall be approved by the National Committee.

12. STANDARD EIGHT: POST-OPERATIVE AND FOLLOW-UP MANAGEMENT OF LIVING DONOR

12.1. The post operative management and follow-up of living kidney donors is elaborated in **Appendix 6.**

12.2. The post operative management and follow-up of living liver donors is elaborated in **Appendix 7.**

13. STANDARD NINE: LIVING DONOR DATA SUBMISSION AND REPORTING REQUIREMENTS

13.1. Minimum requirements for submitting living donor follow-up data and the reporting of donation-related adverse events is elaborated in **Appendices 6, 7, and 8.**

14. STANDARD TEN: KEY PERFORMANCE INDICATORS

14.1. The Key Performance Indicators (KPIs) are elaborated in **Appendix 10**.

14.2. The health facility shall report the KPIs (quarterly) and all donation related information defined by the National Center to the National Center at ncdt@mohap.gov.ae and HRS at MonitoringKPIs@dha.gov.ae

14.3. The information shall be as follows, but not limited to:

14.3.1. Donor- full name, date of birth, emirates ID, nationality, country of residence, date of donation, visa number and passport number.

14.3.2. Transplant Recipient- full name, date of the transplant, nationality of the recipient, if related describe the type of relation (parent, siblings, etc), visa number and passport number.

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APPENDICES

APPENDIX 1: INFORMED CONSENT REQUIREMENTS FOR LIVING DONATION

1. The following conditions should be fulfilled BEFORE performing organ recovery surgery on a living donor:
    1.1. Recovery of single organs on which the life of the living donor is dependent is prohibited.
    1.2. Always ensure donor and recipient confidentiality.
    1.3. The living donor shall sign a separate form to indicate informed consent for living donor evaluation in addition to signing a separate form to indicate surgical consent if selected to proceed as a living donor.
    1.4. Organ donation shall be pursued without any social or financial pressure.
    1.5. Relevant medical examinations should be performed on the living donor and organ recipient.
2. The following are the requirements for obtaining informed consent for **all potential living donors**. Each section must be completed, including evaluation for and assessment of the information listed.
    2.1. Organs-specific assessments follow in subsequent tables within this appendix.
    2.2. The health facility must maintain documentation in the potential donor's record that this evaluation has been completed.

3. Living donor informed consent checklist:

Elements for ALL Potential Living Donors to be discussed and clearly acknowledged:	Check
Provide to all living donors:	
• An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential.	
• Acknowledgment that the ILDA must be available to assist the living donor during the consent process.	
• Instruction about all phases of the living donation process, which includes: ○ Consent. ○ Medical and psychosocial evaluations. ○ Pre- and post-operative care. ○ Required post-operative follow-up as outlined in **Appendices 6** and **7**. (Reporting requirements for the hospital are outlined in **Appendix 8)** • Teaching or instructional material can include any media, one-on-one or small group interaction. • Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with the recovery hospital's staff.	
General disclosures regarding living donation:	
• It is a crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value, including but not limited to cash, property, and vacations.	
• The recovery hospital must provide an ILDA.	
• Share any alternate procedures or courses of treatment for the recipient, including deceased donor transplantation.	
• If the living donor candidate is not related to the recipient (genetically, by marriage, or through reciprocal donation), the living donor must be approved by a special Committee as coordinated by the National Center before donation.	
• A deceased donor may become available for the candidate before the recovery hospital completes the living donor's workup or the living donor transplant occurs.	
• Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment.	

• The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient.	
• Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: ○ Exceed local or national averages, ○ Do not necessarily prohibit transplantation, ○ Are not disclosed to the living donor,	
• The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: ○ The reason for a transplant candidate's increased likelihood of adverse outcomes, ○ Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law.	
• Health information obtained during the living donor evaluation is subject to same regulations as all medical records and could reveal conditions that must be reported to public health authorities.	
• The recovery hospital is required to: ○ Report living donor follow-up information at the time intervals specified in **Appendix 8**. ○ Have the donor commit to post donation follow-up testing coordinated by the recovery hospital. ○ Obtain and store a living donor blood specimen for three (3) years, only to be used for investigation of potential donor-derived disease.	
• Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care: ○ May need to be reported to public health authorities. ○ Will be disclosed to the recipient's transplant hospital. ○ Will be reported to the Living Donor Committee, who will report to the National Center for Donation and Transplantation.	
• A living donor must undergo a medical evaluation and a psychosocial evaluation as outlined in **Appendices 4 and 5**.	

• The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria.	
• The following are inherent risks associate with evaluation for living donation: ○ Allergic reactions to contrast. ○ Discovery of reportable infections. ○ Discovery of serious medical conditions. ○ Discovery of adverse genetic findings unknown to the living donor. ○ Discovery of certain abnormalities that will require more testing at the living donor's expense.	
Potential psychosocial risks of donation:	
• Problems with body image.	
• Post-surgery depression or anxiety.	
• Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease, the transplant fails, or if the transplant recipient dies.	
• Changes to the living donor's lifestyle from donation.	
Potential medical or surgical risks:	
• Death.	
• Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure.	
• Abdominal symptoms such as bloating, nausea, and developing bowel obstruction.	
• That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions.	
Potential financial impacts:	
• Personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs.	
• Need for life-long follow up at the living donor's expense.	
• Loss of employment or income.	
• Negative impact on the ability to obtain future employment.	
• Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance.	

• Future health problems experienced by living donors followed by donation may not be covered by the organ recipient's insurance.	
A detailed medical history with respect to any previous disease, drug intake, and prior surgical procedures has been taken. Known contraindications shall be considered (and their absence) and noted in the health records.	
A detailed psychosocial evaluation has been completed. Known contraindications shall be considered (and their absence) and noted in the health records.	
Donor signature on a document that confirms that: • Donor is willing to donate; and • Donors have the right to opt out of donation at any time during the living donation process. Living donors can unconditionally withdraw consent at any time, up until the kidney is removed, after which they cease to have jurisdiction; and • Donor has read and understood the donation process and the possible and probable hazards resulting from organ removal and this should be documented in his/her health record; and • Donor is free from inducement, coercion, and social and financial pressure.	
Additional elements for Potential Living KIDNEY Donors to be discussed and clearly acknowledged:	
Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:	
• Inform donor that living donors will have a 25-35% permanent loss of kidney function after donation.	
• Inform donor that, although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.	
• Inform donor that living donor risks must be interpreted considering the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in midlife (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD.	

• Inform donor that living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.	
• Inform donor that dialysis is required if the living donor develops ESRD.	
• Inform donor that current practice is to prioritize prior living kidney donors who become kidney transplant candidates.	
• Inform donor of potential surgical and medical risks that apply to living kidney donation, including: ○ Decreased kidney function. ○ Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period. ○ Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation (for females).	
Additional elements for Potential Living LIVER Donors to be discussed and clearly acknowledged:	
• The following surgical and medical risks apply for living liver donors: ○ Acute liver failure with need for liver transplant. ○ Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. ○ Risk of red cell transfusions or other blood products. ○ Biliary complications, including leak or stricture that may require additional intervention. ○ Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.	

APPENDIX 2: EXCLUSION CRITERIA FOR LIVING-DONOR KIDNEY DONATION (LDKD)

1. Age younger than 18 years.
2. Incompetence to provide an explicit informed consent to donation.
3. Psychiatric disorders or psychological concerns related to donation.
4. Evidence of some form of coercion to donation.
5. Drug abuse.
6. Malignant neoplasia.
    - 6.1. Screening for malignant neoplasia is mandatory since it represents an absolute contraindication.
    - 6.2. History of melanoma, testis cancer, renal cancer, choriocarcinoma, leukaemia, lymphoma, monoclonal gammopathy, bronchial cancer or breast cancer are an absolute contraindication although considered cured.
    - 6.3. History of other malignant neoplasms with a negative follow-up for disease recurrence of at least 3-5 years may not represent an absolute contraindication.
    - 6.4. A history of low-grade skin cancers (excluding melanoma) is not a contraindication.
7. Major respiratory disease.
8. Cardiovascular diseases (heart failure, coronary disease, valve disease, arrhythmia).
9. Current pregnancy.
10. Diabetes mellitus:
    - 10.1. Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L).
    - 10.2. 2-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance.

10.3. A1C ≥6.5%.

11. Renal diseases or abnormal renal function:

11.1. Renal scintigraphy: a radioisotope clearance < 80 ml/min/1.73 m^2;

11.2. Proteinuria over 300 mg in 24 hours;

11.3. Haematuria: in presence of either haematuria, proteinuria <300mg in 24hrs, anomalies in the urine sediments, kidney biopsy may be indicated to exclude an underlying nephropathy.

12. Nephrolithiasis:

12.1. A history of nephrolithiasis may not be a contraindication to donation if there are no stones in the kidney or ureter, signs of urinary infection, or crystals in the urine sediment.

12.2. A single, small (diameter <1.5cm), uncomplicated stone which can be removed at back table may not be a contraindication to donation.

13. Systemic diseases with renal involvement.

14. Thrombophilia.

15. BMI over 35:

15.1. A BMI lower than 35 but higher than 30 is considered a relative contraindication and the donor candidate should be enrolled in a dietary program to target a BMI<30.

15.2. Dyslipidaemia is considered a relative contraindication and becomes relevant if associated with other risk factors.

16. Active infections:

16.1. Recurrent pyelonephritis is an absolute contraindication.

16.2. Active tuberculosis is an absolute contraindication while a history of adequately treated and cured infection is a relative contraindication.

16.3. A history of renal tuberculosis is an absolute contraindication.

16.4. Uncomplicated urinary tract infection (UTI) must be treated, and urine sterility must be assessed before donation.

17. HBV, HCV, HIV infections.

18. Hypertension:

18.1. Arterial pressure values over 140/90 mmHg.

18.2. Borderline arterial pressure values without therapy but associated with other risk factors (smoking, obesity, dyslipidaemia, diabetes), borderline renal function or microalbuminuria.

18.3. Pharmacological therapy.

18.4. Presence of secondary organ damage.

19. Chronic illness, particularly pulmonary, liver, autoimmune, neurologic, or cardiac.

APPENDIX 3: EXCLUSION CRITERIA FOR LIVING-DONOR LIVER DONATION (LDLD)

1. Age younger than 18 years or over 60 years.
2. Incompetence to provide an explicit informed consent to donation.
3. Psychiatric disorders or psychological concerns related to donation.
4. Evidence of some form of coercion to donation.
5. Drug abuse.
6. Malignant neoplasia.
    6.1. Screening for malignant neoplasia is mandatory since it represents an absolute contraindication.
    6.2. History of melanoma, testis cancer, renal cancer, choriocarcinoma, leukaemia, lymphoma, monoclonal gammopathy, bronchial cancer or breast cancer are an absolute contraindication although considered cured.
    6.3. History of other malignant neoplasms with a negative follow-up for disease recurrence of at least 3-5 years may not represent an absolute contraindication.
    6.4. History of low-grade skin cancers (excluding melanoma) is not a contraindication.
7. Pre-existing chronic liver disease, which includes:
    7.1. Hepatitis C (HCV) RNA positive.
    7.2. Successfully treated Hepatitis C with sustained viral response at 12 weeks post-treatment, having any fibrosis.
    7.3. Hepatitis B (HBsAG) positive.
8. HIV.

9. HTLV.
10. Any chronic disease needing active immunosuppressive/biological treatments.
11. Donors with ZZ, Z-null, null-null, and S-null aplpha-1-antitrypsin phenotypes, and untype-able phenotypes.
12. Expected donor liver remnant volume less than 30% of native liver volume.
13. Prior living liver donor.
14. Prior liver surgery or resection.
15. Macrovesicular steatosis greater than 30%. Patients with predisposing factors for fatty liver and/or imaging findings consistent with fatty liver should undergo biopsy to assess the extent of macrovesicular steatosis.
16. Current pregnancy and up to 6 months post-partum.
17. Major respiratory disease.
18. Cardiovascular diseases (heart failure, coronary diseases, valve disease, arrhythmia).
19. Thrombophilia.
20. BMI over 35:
    - 20.1. A BMI lower than 35 but higher than 30 is considered a relative contraindication and the donor candidate should be enrolled in a dietary program to target a BMI<30.
    - 20.2. Dyslipidaemia is considered a relative contraindication and becomes relevant if associated with other risk factors.
21. Active tuberculosis is an absolute contraindication.

21.1. A history of adequately treated and cured tuberculosis infection is a relative contraindication.

APPENDIX 4: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF LIVING DONOR CANDIDATES

Living donor evaluation and follow up is the responsibility of the Organ Transplant Unit. It must be conducted by a DHA licensed Nephrologist trained and experiences in transplant services (for Kidney), DHA licensed Hepatologist trained and experiences in transplant services (for liver) and transplant coordinators.

1. The following are the requirements for the medical evaluation of **all potential living donors**. Organs-specific assessments follow in subsequent tables within this appendix.
2. The hospital must maintain documentation in the potential donor's record that this evaluation has been completed.
3. Prior to bringing potential living donors into the hospital or clinic for assessment and workup, the living donor coordinator may find it helpful to provide the potential living donor with a self-evaluation to complete and return prior to the first clinic visit.
   3.1. Examples of living kidney (resource 1) and living liver donor (resource 2) self-assessment questionnaires are included at the end of this appendix.

LIVING DONOR PRE-OPERATIVE MEDICAL ASSESSMENT AND EVALUATION CHECKLIST

Required Assessments for ALL Potential Living Donors. **(Organ specific testing follows in subsequent tables.)**	**CHECK**
General Donor History	
Medical Examination	
• Height.	
• Weight.	
• Body Mass Index (BMI).	

• Vital Signs.	
• Examination of all major organ systems.	
Personal history of significant medical conditions which include but are not limited to:	
• Hypertension.	
• Diabetes.	
• Lung Disease.	
• Heart Disease.	
• Gastrointestinal Disease.	
• Neurological Disease.	
• Autoimmune Disease.	
• Genitourinary Disease.	
• Hematologic Disorders.	
• Bleeding or clotting disorders.	
• History of cancer including melanoma.	
History of infections: • If there is risk or family history of tuberculosis, screening must include blood testing in addition to MANTOUX.	
Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medications.	
Allergies.	
Evaluation for coronary artery disease.	
General Family History	
• Coronary artery disease.	
• Cancer.	
Social History	
• Occupation.	
• Employment status.	
• Health insurance status.	
• Living arrangements.	
• Social support.	
• Smoking (if yes, frequency and packs per day).	
• Alcohol use or abuse.	
• Drug use or abuse.	

• Psychiatric illness, depression, suicide attempts.	
• Risk criteria for acute HIV, HBV, and HCV infection.	
Laboratory Tests	
• Blood group (Subtyping is mandatory): ○ Draw one (date and time). ○ Draw two (date and time; must be different date than first draw).	
• Complete blood count.	
• Serum creatinine, blood urea nitrogen (BUN), Sodium, potassium, calcium, chloride, glucose, Cystatin C.	
• Creatinine clearance with Glomerular Filtration Rate (GFR) measurement, at least 3 times: ○ Measurement one (date and time). ○ Measurement two (date and time). ○ Measurement three (date and time). ○ Additional measurements (dates and times).	
• Full urine test with urine sediment examination, proteinuria in 24 hours.	
• Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH).	
• Serum total and direct bilirubin.	
• Serum HDL and non-HDL Cholesterol, Triglyceride.	
• Plasma protein levels and protein electrophoresis.	
• PT, PTT, Fibrinogen.	
• Fecal occult blood test.	
Microbiology Tests	
• Urine culture tests (2 times): ○ Result 1 (day/time collected). ○ Result 2 (day/time collected). ○ Additional Result (day/time collected).	
Infectious Disease Tests	
• HBV markers: HBsAg, HBsAb, HBcAb, HBeAg, HbeAb as close as possible but within 28 days prior to organ recovery .	
• HCV-RNA and HCV antibody; and	

• HIV-RNA and HIV antibody as close as possible but within 28 days prior to organ recovery.	
• Serology test for: ○ Cytomegalovirus (CMV) IgG and IgM, ○ Toxoplasma, ○ Epstein Barr antibody, and ○ HTLV I and II.	
• Screening for syphilis (VDRL, TPHA).	
• Additional testing may be considered in selected cases where clinically indicated such as endemic or geographic risks: ○ Coccidiomycosis antibody. ○ Malaria blood film. ○ Schistosomiasis antibody, urine microscopy. ○ Trypanosoma cruzi antibody. ○ Strongyloides steracoralis antibody. ○ West Nile Virus antibody/RNA.	
MANTOUX • If potential living donor is at increased risk for tuberculosis (as noted in social history above), testing must include blood testing for latent infection.	
Immunologic Tests	
• HLA typing.	
• Donor/Recipient Cross Match.	
Other Preliminary Examinations	
• ECG, echocardiography, cardiologic examination.	
• Chest x-ray.	
• Psychosocial examination (see **Appendix 5** for check list).	
Second-Level Investigations	
• Specific examinations for previously suspected or diagnosed pathologies (chest CT scan, abdominal US, mammography and US, gynaecologic exam).	
• Angio-CT scan or Angio-MR imaging.	
• Uro-CT scan or perfusion urography.	
• Renal scintigraphy.	

4. The following additional requirements apply specifically to the medical evaluation of all potential **living kidney donors**:

Medical evaluation of living kidney donors:	**CHECK**
Kidney-specific donor history to include a personal history of significant medical conditions which include, but are not limited to:	
• Genetic renal disease.	
• Kidney disease, proteinuria, haematuria.	
• Kidney injury.	
• Diabetes including gestational diabetes.	
• Nephrolithiasis.	
• Recurrent urinary tract infections (UTI).	
Kidney specific family history of:	
• Kidney disease.	
• Diabetes.	
• Hypertension.	
• Kidney cancer.	
Physical exam	
• Blood pressure taken on at least two different occasions or 24-hr overnight blood pressure monitoring. o Report 1 (including date and time). o Report 2 (including date and time).	
Other metabolic testing	
• Fasting blood glucose.	
• Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol).	
• Glucose tolerance test or glycosylated haemoglobin in first degree relatives of diabetics and in high-risk individuals.	
Kidney-specific tests	
• Urinalysis or urine microscopy.	
• Urine culture if clinically indicated.	
• Measurement of urinary protein and albumin excretion.	

• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection.	
• OTUs must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history.	
• Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:	
o Calcium.	
o Oxalate.	
o Uric acid.	
o Citric acid.	
o Creatinine.	
o Sodium.	
Anatomic assessment to determine:	
• Whether the kidneys are of equal size.	
• If the kidneys have masses, cysts, or stones.	
• If the kidneys have other anatomical defects.	
• Which kidney is more anatomically suited for transplant.	

5. The following additional requirements apply specifically to the medical evaluation of all potential **living liver donors**:

Medical evaluation of living liver donors:	Check
Liver-specific family history.	
Liver diseases.	
Bleeding or clotting disorders (Thrombophilia screen should be considered in donors with any previous history of venous thromboembolism).	
General laboratory and imaging tests.	
Liver-specific tests.	
Hepatic function panel: • Biopsy shall be considered to investigate any unexplained elevations in liver function tests before proceeding any further.	
Ceruloplasmin in a donor with a family history of Wilson's Disease.	
Iron, iron binding capacity, ferritin.	

Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin level should have a phenotype.	
Anatomic assessment: A radiological assessment must be performed to determine if the liver is suitable for transplantation and to assess safety of resection for the donor, including: • Dual phase CT to estimate residual liver volume and graft volume/weight . • MRI/MRCP quality images with 3D reconstruction shall be the standard for clarification of biliary anatomy. Endoscopic Retrograde Cholangiopancreatography (ERCP) is never indicated. This evaluation must include all the following: • Assessment of projected graft volume. • Donor's remnant volume. • Vascular anatomy. • Presence of steatosis o Liver biopsy shall be considered to quantify or rule out steatosis if the imaging is suspicious. At present, MR assessment of steatosis is superior to un-enhanced CT attenuation index. Hospitals may use one or the other according to availability and clinical experienced gained with their use. MR is recommended if fat fraction is over 5%.	

6. The following resource is a potential living kidney donor self-assessment.

Living Donor Kidney Program

Donor Self-Assessment - Health History

Please submit this form along with a copy of your blood type (if known) to the living donor coordinator prior to your first assessment:

Name

Office use only

Date Received: _____

Date Reviewed: _____

DEMOGRAPHICS			
ID NO: (if known)		Date of Birth:	Age:
Marital Status: Married / Single / Divorced / Widowed / Other		Blood Type: A / B / AB / O / positive / Negative / Not known □ I can produce evidence of blood group □	
Sex: Male / Female	Height: inch / cm	Weight: lbs/kg	Office use only BMI:
Country of Birth:	Citizenship:	Race/Ethnicity:	
Street No and Name City Post Code Address:			
Home Telephone: ( )		Mobile:	
Email Address:			
Occupation:		Work Telephone: ( ) Can we contact you at work? □ Yes □ No	
Family Doctor/GP		Telephone: ( )	
Street No and Name City Post Code Address:			
Please indicate the name of the recipient (if known) to whom you wish to direct your donation:			Office use only ABO

Date of Birth:	
What is your relationship to the recipient?	□ Anonymous

Legal Name:
Have you discussed your wish to donate With the intended recipient? □ Yes □ No
Have you discussed your wish to donate With your family / friends? □ Yes □ No
Why do you wish to donate?

Medical History:

These questions are used to gather important information about your health and lifestyle that might impact on your potential to become a living donor. This information will be used by the health care professionals on our team to determine your overall well-being. All information on this questionnaire is kept strictly confidential.

GENERAL HEALTH:		
1.	Have you ever had any abdominal surgery? (kidney, liver, gallbladder, appendix, bowel) If yes what type, when?	□ Yes □ No
2.	Have you ever had any other surgery? If yes, what, and when?	□ Yes □ No

3.	Did you have any problems after surgery/anaesthetic? If yes, what were the problems?	□ Yes □ No
4.	Have you had any hospitalisation for other reasons? If yes, when, and why? Name of Hospital:	□ Yes □ No
5.	Do you routinely take any medications (including over the counter & herbal)? If yes, list:	□ Yes □ No
6.	Do you have any allergies? If yes, to what? If yes, is your reaction life-threatening (i.e. anaphylaxis)?	□ Yes □ No
7.	Do you currently smoke or have you ever smoked? If yes, what (cigarettes, pipe, cigars)? How many per day? For how long? Years If you have quit, when did you quit?	□ Yes □ No
8.	Do you drink alcohol? How many drinks per week (1 drink = 1 bottle of beer, 1 glass of wine or 1 measure of spirits? For how long?	□ Yes □ No
9.	Have you had any recent unexplained weight loss? If yes, explain.	□ Yes □ No
KIDNEY HEALTH		
10.	Have you ever had a kidney stone? If yes, when?	□ Yes □ No
11.	Have you ever had kidney infections or blood in your urine? If yes, what, and when?	□ Yes □ No
12.	Have you ever been diagnosed as pre-diabetic or as having diabetes?	□ Yes □ No

	If yes, when?	
13.	Is there a family history of kidney problems? If yes, what?	□ Yes □ No
CANCER HISTORY		
14.	Have you had cancer? If yes, Type? When? Treatment: Radiation □ Chemo □ Surgery □ Other:	□ Yes □ No
15.	Do you have a family history of cancer? If yes, who? What of type of cancer?	□ Yes □ No
INFECTION RISKS		
16.	Have you ever received a blood transfusion or other blood product? If yes, type? When?	□ Yes □ No
17.	Have you, in the last 12 months, had a tattoo, cosmetic permanent make-up, ear piercing, or body piercing, in which sterile procedures were not used (e.g. contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used)? If yes, what? When?	□ Yes □ No
18.	Do you have a chronic infection of any type? If yes, what, and when?	□ Yes □ No
19.	Have you ever had a communicable disease (such as Epstein-Barr virus, Cytomegalovirus, Herpes) If yes, what, and when?	□ Yes □ No

20.	Do you have or have you ever had any history of a sexually transmitted infection e.g. syphilis, gonorrhoea, genital herpes, genital warts? If yes, when?	□ Yes □ No
21.	In the past 12 months have you had close contact with another person having clinically active viral hepatitis (e.g. living in the same household, where sharing of kitchen and bathroom facilities occurs regularly)?	□ Yes □ No
22.	Do you currently use, or have you ever used nonmedical or recreational/ street drugs (ingested, inhaled, e.g. LSD, marijuana, hash, cocaine)? If yes, what, and when? Have you ever had treatment for this? Have you ever taken these drugs by other means subcutaneous, intramuscular, or intravenous?	□ Yes □ No □ Yes □ No
23.	Have you been treated for any infection in the past 12 months? If yes, what? When?	□ Yes □ No
24.	Have you ever tested positive for HIV? If yes, when?	□ Yes □ No
25.	Have you had routine childhood immunizations? State which ones.	□ Yes □ No
26.	Have you had any recent vaccinations? If yes, what, and when?	□ Yes □ No
27.	Have you been vaccinated for Hepatitis B? If yes, when or at what age?	□ Yes □ No
28.	Have you ever travelled or lived outside the country in the past 6 months? If yes, where, and when?	□ Yes □ No
29.	In the last twelve months have you been in close contact with a bat anywhere in the world or been bitten by an animal whilst abroad?	□ Yes □ No

	If YES, give details of animal and place of treatment.	
30.	Have you ever had any other serious infection such as tuberculosis, malaria, West Nile virus, SARS, typhoid fever, toxoplasmosis, rabies, encephalitis, Lyme disease or brucellosis?	□ Yes □ No
31.	Have you ever received human growth hormone?	□ Yes □ No
NEUROLOGICAL /PSYCHOLOGICAL		
32.	Do you have a seizure disorder / epilepsy? Please provide details.	□ Yes □ No
33.	Have you ever had a stroke/transient ischemic attack? If yes when?	□ Yes □ No
34.	Have you been diagnosed with or been investigated for any degenerative neurological diseases such as dementia, Alzheimer's, Creutzfeldt-Jakob disease (Mad Cow), brain tumours, Parkinson's disease, Lou Gehrig's, Multiple Sclerosis? If yes, what, and when?	□ Yes □ No
35.	Have you had treatment for depression? When? Treatment:	□ Yes □ No
36.	Have you ever had treatment for a psychiatric problem? When? Treatment:	□ Yes □ No
CARDIOVASCULAR		
37.	Do you have a history of heart disease or chest pain? If yes, elaborate:	□ Yes □ No
38.	Have you ever had high blood pressure?	□ Yes □ No

	If yes, when? Type of treatment:	
39.	Have you had a heart attack? If yes, when?	□ Yes □ No
40.	Have you ever had rheumatic fever, or been told you have a heart murmur? If yes, when?	□ Yes □ No
41.	Have you ever had palpitations or been told that you have a heart arrhythmia? If yes, when?	□ Yes □ No
HAEMATOLOGY/BLOOD		
42.	Do you and/or a family member have haemophilia or a clotting problem? If yes, what?	□ Yes □ No
43.	Have you ever received human-derived clotting factor concentrates? If yes, when?	□ Yes □ No
44.	Have you or any of your family members had a problem with excessive bleeding? If yes, when?	□ Yes □ No
45.	Have you had excessive bleeding with any surgery or dental extractions? If yes, when?	□ Yes □ No
46.	Have you and/or a family member ever had a blood clot in your lungs or legs? If yes, what? When?	□ Yes □ No
RESPIRATORY		
47.	Have you ever had any lung disease such as asthma or emphysema? If yes, what? When? Any treatment?	□ Yes □ No

48.	Have you ever been exposed to someone with tuberculosis or had a positive TB skin test yourself? If yes, when?	□ Yes □ No
49.	Do you routinely use any inhalers or take medications to help your breathing? If yes, what?	□ Yes □ No
50.	Have you ever been suspected of having SARS (severe acute respiratory syndrome) or been diagnosed with SARS? If yes, when?	□ Yes □ No
51.	Do you have sleep apnoea or use a CPAP machine? If yes, please describe:	□ Yes □ No
GASTROINTESTINAL		
52.	Do you have any stomach or intestinal problems? If yes, what?	□ Yes □ No
53.	Have you ever had gallbladder problems or gallstones? If yes, when?	□ Yes □ No
54.	Have you ever had a colonoscopy or gastroscopy? If yes, when?	□ Yes □ No
GENITOURINARY		
55.	Have you ever had problems with your kidneys (such as infections or stones)? If yes, what, and when?	□ Yes □ No
56.	Have you ever had any problems with your bladder (such as infections, incontinence, or difficulty voiding)? If yes, please describe. When?	□ Yes □ No

57.	**For Men Only:** Do you have any problems related to an enlarged prostate? If yes, what?	□ Yes □ No □ **N/A**
58.	**For Females Only:** Have you ever had a gynaecologic problem? Date of Last Menstrual Period: Date of last PAP smear: Date of last breast exam or mammogram:	□ Yes □ No □ **N/A**
59.	**For Females Only:** Did you experience any problems with pregnancies or deliveries (such as high blood pressure, toxaemia, or high blood sugar)? If yes, what?	□ Yes □ No □ **N/A**
ENDOCRINE		
60.	Do you have diabetes? Type? Onset?	□ Yes □ No
61.	Do you have a family history of diabetes? If yes, who?	□ Yes □ No
62.	Have you ever had increased blood sugars (i.e. with pregnancy)? If yes, please describe:	□ Yes □ No
63.	Have you ever been diagnosed with thyroid disease? If yes, what, and when?	□ Yes □ No
SOCIAL		
64.	Does your family have a history of any serious health issues? (i.e. heart disease, strokes, Creutzfeldt-Jakob (Mad Cow disease) If yes, please outline:	□ Yes □ No
65.	Are you the sole wage earner in your household?	□ Yes □ No

66.	Donating part of your liver required approximately 4-12 weeks' time off work to recover. Do you think you are able to take time off work?	□ Yes □ No
OTHER		
66.	Is there any other health information that we should know? If yes, what?	□ Yes □ No
68.	Having answered all questions about medical conditions and behavioural risk factors is there any reason why you think you should not be an organ donor? **You do not have to explain your answer.**	□ Yes □ No

I have answered these questions to the best of my ability.

Name of Potential Donor	Signature of Potential Donor	dd/mm/yyyy

Office Use Only:

Name of Person Administering Questionnaire	Signature of Potential Donor	dd/mm/yyyy

7. The following resource is a potential living liver donor self-assessment.

Living Donor Liver Program

Donor Self-Assessment Health History

Please submit this form along with a copy of your blood type (if known) to the living donor coordinator prior to your first assessment:

Name

Office use only

Date Received: _____

Date Reviewed: _____

DEMOGRAPHICS			
ID NO: (if known)		Date of Birth:	Age:
Marital Status: Married / Single / Divorced / Widowed / Other		Blood Type: A / B / AB / O / positive / Negative / Not known □ I can produce evidence of blood group □	
Sex: Male / Female	Height: inch / cm	Weight: lbs/kg	Office use only BMI:
Country of Birth:	Citizenship:	Race/Ethnicity:	
Street No and Name City Post Code Address:			
Home Telephone: ( )		Mobile:	
Email Address:			
Occupation:		Work Telephone: ( ) Can we contact you at work? □ Yes □ No	
Family Doctor/GP		Telephone: ( )	
Street No and Name City Post Code Address:			
Please indicate the name of the recipient (if known) to whom you wish to direct your donation: **Date of Birth:**			Office use only ABO
What is your relationship to the recipient?		□ Anonymous	

Legal Name:
Have you discussed your wish to donate With the intended recipient? □ Yes □ No
Have you discussed your wish to donate With your family / friends? □ Yes □ No
Why do you wish to donate?

Medical History:

These questions are used to gather important information about your health and lifestyle that might impact on your potential to become a living donor. This information will be used by the health care professionals on our team to determine your overall well-being. All information on this questionnaire is kept strictly confidential.

GENERAL HEALTH:		
1.	Have you ever had any abdominal surgery? (gallbladder, appendix, bowel) If yes what type, when?	□ Yes □ No
2.	Have you ever had any other surgery? If yes, what, and when?	□ Yes □ No
3.	Did you have any problems after surgery/anaesthetic? If yes, what were the problems?	□ Yes □ No

4.	Have you had any hospitalisation for other reasons? If yes, when, and why? Name of Hospital:	□ Yes □ No
5.	Do you routinely take any medications (including over the counter & herbal)? If yes, list:	□ Yes □ No
6.	Do you have any allergies? If yes, to what? If yes, is your reaction life-threatening (i.e. anaphylaxis)?	□ Yes □ No
7.	Do you currently smoke or have you ever smoked? If yes, what (cigarettes, pipe, cigars)? How many per day? For how long? Years If you have quit, when did you quit?	□ Yes □ No
8.	Do you drink alcohol? How many drinks per week (1 drink = 1 bottle of beer, 1 glass of wine or 1 measure of spirits? For how long?	□ Yes □ No
9.	Have you had any recent unexplained weight loss? If yes, explain.	□ Yes □ No
LIVER HEALTH		
10.	Have you ever had jaundice (yellow skin)? If yes, when?	□ Yes □ No
11.	Have you ever had a liver problem? If yes, what, and when?	□ Yes □ No

12.	Have you ever had an inflamed liver - hepatitis? If yes, when?	□ Yes □ No
13.	Is there a family history of liver problems? If yes, what?	□ Yes □ No
CANCER HISTORY		
14.	Have you had cancer? If yes, Type? When? Treatment: Radiation □ Chemo □ Surgery □ Other:	□ Yes □ No
15.	Do you have a family history of cancer? If yes, who? What of type of cancer?	□ Yes □ No
INFECTION RISKS		
16.	Have you ever received a blood transfusion or other blood product? If yes, type? When?	□ Yes □ No
17.	Have you, in the last 12 months, had a tattoo, cosmetic permanent make-up, ear piercing, or body piercing, in which sterile procedures were not used (e.g. contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used)? If yes, what? When?	□ Yes □ No
18.	Do you have a chronic infection of any type? If yes, what, and when?	□ Yes □ No

19.	Have you ever had a communicable disease (such as Epstein-Barr virus, Cytomegalovirus, Herpes) If yes, what, and when?	□ Yes □ No
20.	Do you have or have you ever had any history of a sexually transmitted infection e.g. syphilis, gonorrhoea, genital herpes, genital warts? If yes, when?	□ Yes □ No
21.	In the past 12 months have you had close contact with another person having clinically active viral hepatitis (e.g. living in the same household, where sharing of kitchen and bathroom facilities occurs regularly)?	□ Yes □ No
22.	Do you currently use, or have you ever used nonmedical or recreational/ street drugs (ingested, inhaled, e.g. LSD, marijuana, hash, cocaine)? If yes, what, and when? Have you ever had treatment for this? Have you ever taken these drugs by other means subcutaneous, intramuscular, or intravenous?	□ Yes □ No □ Yes □ No
23.	Have you been treated for any infection in the past 12 months? If yes, what? When?	□ Yes □ No
24.	Have you ever tested positive for HIV? If yes, when?	□ Yes □ No
25.	Have you had routine childhood immunizations? State which ones.	□ Yes □ No
26.	Have you had any recent vaccinations? If yes, what, and when?	□ Yes □ No

27.	Have you been vaccinated for Hepatitis B? If yes, when or at what age?	□ Yes □ No
28.	Have you ever travelled or lived outside the country in the past 6 months? If yes, where, and when?	□ Yes □ No
29.	In the last twelve months have you been in close contact with a bat anywhere in the world or been bitten by an animal whilst abroad? If YES, give details of animal and place of treatment.	□ Yes □ No
30.	Have you ever had any other serious infection such as tuberculosis, malaria, West Nile virus, SARS, typhoid fever, toxoplasmosis, rabies, encephalitis, Lyme disease or brucellosis?	□ Yes □ No
31.	Have you ever received human growth hormone?	□ Yes □ No
NEUROLOGICAL /PSYCHOLOGICAL		
32.	Do you have a seizure disorder / epilepsy? Please provide details.	□ Yes □ No
33.	Have you ever had a stroke/transient ischemic attack? If yes when?	□ Yes □ No
34.	Have you been diagnosed with or been investigated for any degenerative neurological diseases such as dementia, Alzheimer's, Creutzfeldt-Jakob disease (Mad Cow), brain tumours, Parkinson's disease, Lou Gehrig's, Multiple Sclerosis? If yes, what, and when?	□ Yes □ No
35.	Have you had treatment for depression? When? Treatment:	□ Yes □ No
		□ Yes □ No

36.	Have you ever had treatment for a psychiatric problem? When? Treatment:	
CARDIOVASCULAR		
37.	Do you have a history of heart disease or chest pain? If yes, elaborate:	□ Yes □ No
38.	Have you ever had high blood pressure? If yes, when? Type of treatment:	□ Yes □ No
39.	Have you had a heart attack? If yes, when?	□ Yes □ No
40.	Have you ever had rheumatic fever, or been told you have a heart murmur? If yes, when?	□ Yes □ No
41.	Have you ever had palpitations or been told that you have a heart arrhythmia? If yes, when?	□ Yes □ No
HAEMATOLOGY/BLOOD		
42.	Do you and/or a family member have haemophilia or a clotting problem? If yes, what?	□ Yes □ No
43.	Have you ever received human-derived clotting factor concentrates? If yes, when?	□ Yes □ No
44.	Have you or any of your family members had a problem with excessive bleeding? If yes, when?	□ Yes □ No
45.	Have you had excessive bleeding with any surgery or dental extractions? If yes, when?	□ Yes □ No

46.	Have you and/or a family member ever had a blood clot in your lungs or legs? If yes, what? When?	□ Yes □ No
RESPIRATORY		
47.	Have you ever had any lung disease such as asthma or emphysema? If yes, what? When? Any treatment?	□ Yes □ No
48.	Have you ever been exposed to someone with tuberculosis or had a positive TB skin test yourself? If yes, when?	□ Yes □ No
49.	Do you routinely use any inhalers or take medications to help your breathing? If yes, what?	□ Yes □ No
50.	Have you ever been suspected of having SARS (severe acute respiratory syndrome) or been diagnosed with SARS? If yes, when?	□ Yes □ No
51.	Do you have sleep apnoea or use a CPAP machine? If yes, please describe:	□ Yes □ No
GASTROINTESTINAL		
52.	Do you have any stomach or intestinal problems? If yes, what?	□ Yes □ No
53.	Have you ever had gallbladder problems or gallstones? If yes, when?	□ Yes □ No
54.	Have you ever had a colonoscopy or gastroscopy? If yes, when?	□ Yes □ No

GENITOURINARY		
55.	Have you ever had problems with your kidneys (such as infections or stones)? If yes, what, and when?	□ Yes □ No
56.	Have you ever had any problems with your bladder (such as infections, incontinence, or difficulty voiding)? If yes, please describe. When?	□ Yes □ No
57.	**For Men Only:** Do you have any problems related to an enlarged prostate? If yes, what?	□ Yes □ No □ **N/A**
58.	**For Females Only:** Have you ever had a gynaecologic problem? Date of Last Menstrual Period: Date of last PAP smear: Date of last breast exam or mammogram:	□ Yes □ No □ **N/A**
59.	**For Females Only:** Did you experience any problems with pregnancies or deliveries (such as high blood pressure, toxaemia, or high blood sugar)? If yes, what?	□ Yes □ No □ **N/A**
ENDOCRINE		
60.	Do you have diabetes? Type? Onset?	□ Yes □ No
61.	Do you have a family history of diabetes? If yes, who?	□ Yes □ No
62.	Have you ever had increased blood sugars (i.e. with pregnancy)? If yes, please describe:	□ Yes □ No

63.	Have you ever been diagnosed with thyroid disease? If yes, what, and when?	□ Yes □ No
SOCIAL		
64.	Does your family have a history of any serious health issues? (i.e. heart disease, strokes, Creutzfeldt-Jakob (Mad Cow disease) If yes, please outline:	□ Yes □ No
65.	Are you the sole wage earner in your household?	□ Yes □ No
66.	Donating part of your liver required approximately 4-12 weeks' time off work to recover. Do you think you are able to take time off work?	□ Yes □ No
OTHER		
66.	Is there any other health information that we should know? If yes, what?	□ Yes □ No
68.	Having answered all questions about medical conditions and behavioural risk factors is there any reason why you think you should not be an organ donor? **You do not have to explain your answer.**	□ Yes □ No

I have answered these questions to the best of my ability.

Name of Potential Donor	Signature of Potential Donor	dd/mm/yyyy

Office Use Only:

Name of Person Administering Questionnaire	Signature of Potential Donor	dd/mm/yyyy

APPENDIX 5: REQUIREMENTS FOR LIVING DONOR PSYCHOSOCIAL EVALUATION

1. The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, Masters-prepared social worker, or licensed clinical social worker prior to organ recovery.
2. Documentation of the psychosocial evaluation must be maintained in the living donor medical record and include all the following components:
    2.1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome.
    2.2. An assessment of risk criteria for acute HIV, HBV, and HCV infection.
    2.3. A review of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder.
    2.4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision.
    2.5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation.
    2.6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.
    2.7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating

whether the donor has a realistic plan for donation and recovery, with social, emotional, and financial support available as recommended.

2.8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support.

2.9. The determination that the living donor understands the potential financial implications of living donation.

APPENDIX 6: POST-OPERATIVE AND FOLLOW-UP MANAGEMENT OF LIVING KIDNEY DONOR

1. The Organ Transplant Unit (OTU) will provide post-operative care and follow-up of all Living Kidney Donors as outlined below.
2. Any Adverse Living Donor Event(s), as outlined in **Appendix 8** must be reported to the Living Donation Committee in the time requirements specified.

Post-Operative Follow-up and Management of Living Kidney Donors	
At discharge:	Provide living donor with: • Appropriate advice regarding wound care, pain relief, and general rehabilitation. • Prescribed medication and wound dressings as required. • Discharge summary from hospital stay. • Contact number for the Living Kidney Coordinator or team. • Routine follow-up appointment within two (2) weeks in the OTU clinic with the operating surgeon (when possible).
Seven (7) to ten (10) days post-donation:	Bring donor into clinic for routine follow-up appointment for • Weight, BP. • CBC. • Basic Metabolic Panel. • Urinalysis with culture. • Evaluation for early detection of problems with wound healing or infection. • General psychosocial wellbeing check (especially important if transplant was not successful). • Evaluate to determine donor is receiving appropriate caregiver support as needed. • Arrange additional follow-up appointment if clinically indicated. • Discuss importance of long-term follow up following living organ donation for specific clinical review as well as a general health and

	wellbeing check, including psychosocial aspects. • Set referral appointment for six (6)-month follow up.
Six (6) months post-donation	Bring donor into clinic for routine follow-up appointment to evaluate: • Weight, BMI, BP. • CBC. • Basic Metabolic Panel. • Urinalysis with culture. • Urine protein: creatinine. • Micro albumin. • Set appointment for annual follow-up at clinic or with primary care physician.
Approximately one (1)-year post-kidney recovery and annually thereafter:	OTU will track their living kidney donors and share their data with the National Center for Donation and Transplantation. Required living kidney donor status and clinical information includes all the following: • Patient status: o Alive. o Deceased – cause and date of death if applicable and known. • Weight, BMI, BP. • CBC. • Basic Metabolic Panel. • Urinalysis with culture. • Urine protein creatinine. • Micro albumin. • Is the donor working for income, and if not working, reason for not working? • Has the donor lost medical (health, life) insurance due to donation? • If female, has the donor considered pregnancy, become pregnant or given birth in the last year? o Provide appropriate counselling regarding potential increased risk of pregnancy-induced hypertension following kidney donation. This may require specialist prenatal care.

	Advise close monitoring of blood pressure, creatinine, and foetal well-being. • Has the donor been readmitted to a hospital since discharge from organ donation surgery? • Is the donor experiencing any kidney complications? • Has the donor been on dialysis since donation? • Has the donor developed hypertension or diabetes requiring medication since donation? • Set next annual follow-up referral/appointment.
At any time post-transplant:	Report any adverse event as listed in **Appendix 8** to the Living Donation Committee within the outlined time requirement.

APPENDIX 7: POST-OPERATIVE AND FOLLOW-UP MANAGEMENT OF LIVING LIVER DONOR

1. The Organ Transplant Unit (OTU) will provide post-operative care and follow-up of all Living Kidney Donors as outlined below.
2. Any Adverse Living Donor Event(s), as outlined in **Appendix 8**, must be reported to the Living Donation Committee in the time requirements specified.

Post-Operative Follow-up and Management of Living Liver Donors	
At discharge:	Provide living donor with: • Appropriate advice regarding wound care, pain relief, and general rehabilitation. • Prescribed medication and wound dressings as required. • Discharge summary from hospital stay. • Contact number for the Living Liver Donor Coordinator or team. • Routine follow-up appointment in the OTU clinic with the operating surgeon (when possible).

No more than four (4) to six (6) weeks after surgery:	Bring donor into clinic for routine follow-up appointment to review:
	• Weight, BP.
	• CBC.
	• Liver function tests, including:
	  ○ Alanine aminotransferase.
	  ○ Alkaline phosphate.
	  ○ Platelet count.
	  ○ Total bilirubin.
	• Complete Metabolic Panel.
	• Coagulation profile.
	• Evaluation for early detection of problems with wound healing or infection.
	• General psychosocial wellbeing check (especially important if transplant was not successful).

	• Evaluate to determine donor is receiving appropriate caregiver support as needed. • Arrange additional follow-up appointment if clinically indicated. • Discuss importance of long-term follow up following living organ donation for specific clinical review as well as a general health and wellbeing check, including psychosocial aspects. • Set referral appointment for three (3) and six (6) month follow-ups.

Three (3) and six (6) months post-liver recovery	Bring donor into clinic for routine follow-up appointment to review:
	• Weight, BMI, BP.
	• Full blood count.
	• Liver function tests, including:
	  ○ Alanine aminotransferase.
	  ○ Alkaline phosphate.
	  ○ Platelet count.
	  ○ Total bilirubin.
	• Complete Metabolic Panel.
	• Coagulation profile.
	• Set appointment for one (1) year follow up.

Approximately one (1) year post-liver recovery and annually thereafter:	OTU will track their living donors and share their data with the National Center for Donation and Transplantation. Required living liver donor status and clinical information includes all the following:
	• Patient status:
	  ○ Alive.
	  ○ Deceased – cause and date of death if applicable and known.
	• Is the donor working for income, and if not working, reason for not working?
	• Has the donor lost medical (health, life) insurance due to donation?
	• Has the donor been readmitted to a hospital since discharge from organ donation surgery?
	• Has the donor experienced any liver complications, including:
	  ○ Abscess.

	○ Bile leak. ○ Hepatic resection. ○ Incisional hernias due to organ recovery surgery. ○ Liver failure. ○ Listing for a liver transplant. • Weight, BMI, BP. • Full blood count. • Liver function tests, including: ○ Alanine aminotransferase. ○ Alkaline phosphate. ○ Platelet count. ○ Total bilirubin. • Complete Metabolic Panel. • Coagulation profile. • Fasting lipid profile. • Fasting blood glucose. • HBA1c. • Set next annual follow-up referral/appointment.
At any time post-transplant:	Report any adverse event as listed in **Appendix 8** to the Living Donation Committee within the outlined time requirement.

APPENDIX 8: LIVING DONOR DATA SUBMISSION AND REPORTING REQUIREMENTS

1. The Organ Transplant Unit (OTU) will follow Living Donors for a minimum of two (2) years, with reporting completed at least annually.
2. Ideally, Living Donors should be followed for the remainder of their lives.
3. OTUs will track their living donors and share their data, as outlined in **Appendices 6, 7 and 8**, with the National Center for Donation and Transplantation.
4. Certain living donor adverse events require immediate reporting, as outlined in the table below.

Organ Transplant Unit (OTU) must report if:	**To the:**	**Within seventy-two (72) hours after:**
A living donor organ recovery procedure is aborted after the donor has begun to receive general anaesthesia.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The aborted organ recovery procedure.
A living donor dies during surgery for donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.
A living donor dies within thirty (30) days after organ donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.
A living donor dies within two (2) years after organ donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.

A living donor is listed on the waitlist within two (2) years after organ donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.
A living kidney donor begins regularly administered dialysis as an ESRD patient within two (2) years after organ donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.
A living donor organ is recovered but not transplanted into any recipient.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	Organ recovery.
A living donor organ is recovered and transplanted into someone other than the intended recipient.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	Organ recovery.
A living donor malignancy develops within one (1) year of donation.	Living Donor Committee, who will report to the National Center for Donation and Transplantation.	The OTU becomes aware.

APPENDIX 9: INDEPENDENT LIVING DONOR ADVOCATE (ILDA) REQUIREMENTS AND PROTOCOL

1. For any living donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.
2. The ILDA may be one person or an ILDA team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor.
    2.1. The individual serving as the ILDA or the director of the ILDA team must be accredited to serve at the level of a hospital service director for a department not involved in organ transplant.
3. All ILDA requirements must be completed prior to organ recovery.
4. The ILDA must:
    4.1. Function independently from the transplant candidate's team.
    4.2. Advocate for the rights of the living donor.
    4.3. Fulfil the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate.

4.4. Review and document whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:

4.4.1. Informed consent process as described in **Appendix 1**: Informed Consent Requirements for Living Donation.

4.4.2. Evaluation process according to **Appendix 4**: Pre-operative Assessment and Evaluation of Living Donor Candidates and **Appendix 5**: Living Donor Psychosocial Evaluation Requirements.

4.4.3. Surgical procedure.

4.4.4. Follow-up requirements, and the benefit and need for participating in recovery hospital's requirements according to **Appendix 8**: Living Donor Data Submission and Reporting Requirements.

5. The living donor recovery hospital must develop and comply with written protocols for:

5.1. The composition of the ILDA team, if the hospital uses a team.

5.2. The qualifications and training (both initial and ongoing) required for the ILDA, and documentation that each requirement has been met. Minimum qualifications must include knowledge of:

5.2.1. Living organ donation.

5.2.2. Transplantation.

5.2.3. Medical ethics.

5.2.4. Informed consent.

5.2.5. The potential impact of family or other external pressures on the potential living donor's donation decision.

5.2.6. The duties and responsibilities of the ILDA, which must include at least the functions outlined in DHA Standards for Human Organs and Tissues Donation Services (Living Donor).

5.2.7. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.

5.2.8. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

APPENDIX 10: KEY PERFORMANCE INDICATORS

1. Process.

1.1. Average Time to Evaluate a Donor Candidate.

Average Time to Evaluate a Donor Candidate	
Main Domain:	Process.
Subdomain:	Efficiency.
Indicator Definition:	Average number of days from the date a person identifies as a potential living donor to when suitability is determined.
Calculation:	Numerator: The sum of the number of days from the date a person identifies as a potential living donor to when suitability is determined, across all living donor candidates for the past year. Denominator: The total number of potential living donor candidates for the past year.
Target:	90 days
Methodology:	Median calculation.
Measuring Unit:	Number of days between identification to determination of suitability.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to donation and transplant.
KPI Source:	DHA Standards for Living Donor Services.

1.1. Average Time from Suitability Determination Until Donation.

Average Time from Suitability Determination Until Donation	
Main Domain:	Process.
Subdomain:	Efficiency.
Indicator Definition:	Average number of days from the date a person is deemed suitable as a living donor, until the date of donation.
Calculation:	Numerator: The sum of the number of days from the date a person is deemed a suitable living donor, to the date of donation, across all living donors for the past year. Denominator: The total number of living donors for the past year.
Target:	30 days
Methodology:	Median calculation.
Measuring Unit:	Number of days between suitability determination and donation.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to donation and transplant.
KPI Source:	DHA Standards for Living Donor Services.

2. Outcomes

2.1. ICU Length of Stay – Living Liver Donation

ICU Length of Stay – Living Liver Donation	
Main Domain:	Outcomes.
Subdomain:	Effectiveness and efficiency.
Indicator Definition:	Median number of days in the ICU after living liver donation surgery.
Calculation:	Arrange the data points from smallest to largest. If the number of data points is odd, the median is the middle data point in the list. If the number of data points is even, the median is the average of the two middle data points in the list.
Target:	<= 2
Methodology:	Median calculation.
Measuring Unit:	Calendar days.
Reporting Frequency:	Monthly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and effectiveness.
KPI Source:	DHA Standards for Living Donation Services.

2.2. Hospital Length of Stay – Living Kidney Donation

Hospital Length of Stay – Living Kidney Donation	
Main Domain:	Outcomes.
Subdomain:	Effectiveness and efficiency.
Indicator Definition:	Median number of days from admission to discharge after living kidney donation surgery.
Calculation:	Arrange the data points from smallest to largest. If the number of data points is odd, the median is the middle data point in the list. If the number of data points is even, the median is the average of the two middle data points in the list.
Target:	<= 2
Methodology:	Median calculation.
Measuring Unit:	Calendar days.
Reporting Frequency:	Monthly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and effectiveness.
KPI Source:	DHA Standards for Living Donation Services.

2.3. Early Hospital Readmission

Early Hospital Readmission	
Main Domain:	Outcomes.
Subdomain:	Patient safety.
Indicator Definition:	Percentage of patients readmitted to the hospital within 14 days post-donation.
Calculation:	Numerator: Total number of living donors readmitted to the hospital within 14 days after discharge post-donation. Denominator: The number of living donors.
Target:	< 5%
Methodology:	Numerator / Denominator x 100.
Measuring Unit:	Percentage of early hospital readmissions.
Reporting Frequency:	Quarterly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and patient safety.
KPI Source:	DHA Standards for Living Donation Services.

2.4. Living Donor Quality of Life Post-Donation

Living Donor Quality of Life Post-Donation	
Main Domain:	Outcomes.
Subdomain:	Patient satisfaction.
Indicator Definition:	Percentage of living donors who report an excellent health-related quality of life (HRQOL) after donation, using a generic tool such as SF-36, RAND-36, or PROMIS Global Health.
Calculation:	Numerator: The total number of living donors who report excellent HRQOL in the past year. Denominator: The number of living donors in the past year.
Target:	> 90%
Methodology:	Numerator / Denominator x 100.
Measuring Unit:	Percentage of living donors reporting excellent HRQOL post-donation.
Reporting Frequency:	Annually.
Desired Direction:	Higher is better.
Rationale:	Metric of outcomes and patient satisfaction.
KPI Source:	DHA Standards for Living Donation Services.