LICENCE CONDITIONS FOR ACUTE HOSPITAL SERVICE AND OUTPATIENT MEDICAL SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE ORGAN TRANSPLANT SERVICE

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1 These licence conditions ("**LCs**") apply to:

(1) all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide:

(a) an acute hospital service ("**AHS**"); and/or

(b) an outpatient medical service ("**OMS**");

(2) that provide or intend to provide as part of the aforementioned service(s), Organ Transplant Services (as defined in paragraph 2.7),

(such persons referred to as "**Licensees**").

1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's licence(s) to provide AHS and/or OMS;

(b) shortening the term of the Licensee's licence(s) to provide AHS and/or OMS;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

1.3 For avoidance of doubt:

(a) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;

(b) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient; and

(c) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definitions

2.1 **"Donor Selection Criteria"** refers to Organ-specific donor selection criteria for Donors.

2.2 **"Donor"** refers to a person (living or deceased) whose Organ, or part of it, is removed for the purpose of its transplantation into the body of another living person.

2.3 **"Good Standing"** refers to a Medical Practitioner:-

(a) Holding a valid practising certificate issued by the Singapore Medical Council ("SMC");

(b) Who has not had a disciplinary tribunal referral issued against him/her in the three years preceding the date of the Licensee's application to perform Organ Transplant Services; and

(c) With the necessary postgraduate degree, qualification or special knowledge of and skill and experience relevant or related to Organ Transplant Services.

2.4 **"Infectious Diseases Screening"** refers to the screening for infectious diseases such as Hepatitis B, Hepatitis C, Human Immunodeficiency Virus (HIV) and Syphilis through the use of screening tests, pre- and post-transplant.

2.5 **"Medical Practitioner"** refers to a person who is registered, or deemed to be registered, as a medical practitioner under the Medical Registration Act 1997.

2.6 **"Organ"** refers to the kidney, liver, heart, lung and/or pancreas of a human body; and/or any part thereof.

2.7 **"Organ Transplant Services"** shall refer to any of the following:

(a) Donor and Recipient selection and evaluation, including but not limited to counselling for living Donors and Recipients, screening of Donors and Recipients, physical examinations, laboratory investigations, interpretation of laboratory results and medical assessments;

(b) Obtaining informed consent from a Donor, Recipient and/or other relevant person;

(c) Surgical procedures that relate to the removal and transplant of the Organ, including but not limited to the removal of an Organ, or part of it, from a living Donor or the transplant of the Organ to a Recipient;

(d) Post-Transplant Care and screening for Recipients; and Post-Transplant Care for living Donors.

For the avoidance of doubt, Organ Transplant Services shall not include tissue banking and storage requirements[1].

2.8 **"Post-Transplant Care"** refers to the immediate care and management of the Donor and/or Recipient within 1 year of the Organ donation/transplant or in the case of a Recipient, until the Recipient is deemed clinically stable on the immunosuppressive medication, whichever is earlier.

2.9 **"Post-Transplant Outcome Monitoring"** refers to the monitoring of key parameters (including through the use of screening tests) related to transplant outcomes for Recipients (as may be communicated to the Transplant Hospital or Transplant Clinic).

2.10 **"Pre-Transplant Screening"** refers to the conduct of screening tests prior to the date of the transplant.

2.11 **"Recipient"** refers to the individual to whose body the Organ is transplanted for the purpose of treating or preventing a human disease.

2.12 **"Reporting Point"** refers to a specific date, by which a Transplant Hospital or the Transplant Clinic is required to submit data for Post-Transplant Outcome Monitoring and Infectious Diseases Screening.

2.13 **"Transplant Clinic"** refers to a permanent premises or temporary premises licensed to provide an OMS under Section 8 of the HCSA and offering Organ Transplant Services.

2.14 **"Transplant Doctor"** refers to (a) a Medical Practitioner who manages a Donor from pre-donation to post-donation; (b) a Medical Practitioner who manages a Recipient from the pre-transplant to post-transplant ("**Transplant Physician**"); or (c) a surgeon who performs any procedure for the removal of an Organ from a Donor and/or transplant of an Organ into a Recipient ("**Transplant Surgeon**").

2.15 **"Transplant Hospital"** refers to a hospital declared by the Minister, by notification in the Gazette, to be a hospital for the purposes of the Human Organ Transplant Act 1987 ("**HOTA**") or any part thereof; and a premises licensed to provide an AHS under Section 8 of the HCSA and offering Organ Transplant Services.

2.16 **"Transplant Programme"** refers to pre-admission, admission, surgery, post-surgical care, discharge and long-term follow-up of the Donor and/or Recipient in relation to the donation and/or transplant of the Organ, including pre-

[1] Tissue banking and storage requirements, and the commercial trading prohibition for tissues (research and therapeutic use) are covered under the Human Biomedical Research Act (No. 30 of 2015) and the MOH Guidelines for Healthcare Institutions Providing Tissue Banking issued in February 2003.

admission medical and surgical evaluation, in-hospital care, post-surgical follow-up within the Transplant Hospital and post-discharge follow-up.

3 Specific Restrictions

3.1 Licensees holding an OMS licence shall only provide Organ Transplant Services through the permanent premises or temporary premises mode of service delivery. Organ Transplant Services must not be provided through the remote mode of service delivery.

4 Governance

4.1 The Licensee shall ensure that its employees, servants and agents comply with these LCs and all relevant laws and guidelines in Singapore. Such relevant laws and guidelines are:

(a) The HOTA & the Human Organ Transplant Regulations 2004;
(b) The Medical (Therapy, Education and Research) Act 1972 ("**MTERA**");
(c) Guidelines on the Evaluation of Living Kidney Donors issued by the National Organ Transplant Unit ("**NOTU**");
(d) Guidelines on the evaluation of recipients of Organs on the national wait list to receive Organs from a deceased Donor; and
(e) All relevant advisories, circulars, directives and national protocols issued by MOH and NOTU namely:
    i. MOH Directive No. 01/2017 – Update to reporting requirements for a case of Living Donor Organ transplant – Directions under Section 15D Human Organ Transplant Act;
    ii. MOH Circular No. 22/2019 – Revised reporting process for adverse events pertaining to organ transplant services;
    iii. MOH Manual on Organ Donation and Transplantation, as updated from time to time ("**MOH Manual**");
    iv. Credentialing Criteria for Medical Practitioners providing Organ Transplant services
    v. Blood Group Incompatible Living Donor Liver Transplants Protocol ("**ABOi LDLT Protocol**");
    vi. Organ Allocation Criteria; and
    vii. MOH Guidelines for Ethical Living Donor Organ Transplant,

    (sub-clauses (a) to (e) collectively referred to as "**Relevant Requirements**").

4.2 The Licensee shall: –

(a) Put in place adequate processes to: -
    i. implement the Transplant Programme(s);
    ii. appoint a multi-disciplinary transplant team (which composition and responsibilities are set out in clause 6 below) and where applicable, ensure that members are clinically privileged to practise in the Licensee's premises;

iii. monitor, identify, report and manage any adverse event or reaction in the Donor and/or Recipient arising from the Organ transplant; and
iv. maintain proper records and reports relating to the Organ Transplant Services.

(b) Ensure that the necessary authorisation(s) and/or consent for the removal, donation and/or transplant of the Organ, are obtained pursuant to sections 4, 5, 6, 15 of the HOTA and/or section 4 of the MTERA; and

(c) Ensure that Organ Transplant Services are carried out by persons with the necessary credentials, qualifications and experience as set out in the Credentialing Criteria for Medical Practitioners providing Organ Transplant Services, and who meet any additional requirements set by the Transplant Hospital and/or Transplant Clinic.

5 Transplant Programme Director and Transplant Centre Director

5.1 Role and Qualifications

Transplant Programme Director

5.1.1 The Licensee shall appoint suitably qualified individuals as Transplant Programme Director(s) to oversee each Transplant Programme in the Transplant Hospital. Each Transplant Programme Director shall oversee only one (1) Transplant Programme in the Transplant Hospital.

5.1.2 For the purposes of clause 5.1.1, an individual is suitably qualified as a Transplant Programme Director overseeing one Transplant Programme, if the individual is a:

(a) Transplant Doctor;
(b) Intensivist with relevant clinical competency in the area of the Organ donated/transplanted in the Transplant Programme; or
(c) Specialist physician of the Organ donated/transplanted in the Transplant Programme, including but not limited to a renal, cardiac, or liver medical specialist, pulmonologist, gastroenterologist or hepatobiliary and pancreatic specialist;

with expertise[2] in any one of the following:

(i) Organ donation;
(ii) Organ transplant;
(iii) Paediatric Organ Transplant where the Transplant Programme Director is overseeing a paediatric Transplant Programme;
(iv) Pre-donation to post-donation; or
(v) Pre-transplant to post-transplant.

[2] Expertise refers to relevant experience in organ donation, organ transplant, pre- to post-donation phases, and pre- to post-transplantation phases and has met the credentialing criteria promulgated by the NOTU, where applicable.

Transplant Centre Director

5.1.3 Where there is more than one Transplant Programme within the Transplant Hospital, the Licensee may appoint a Transplant Centre Director to oversee all Transplant Programmes in the Transplant Hospital.

5.1.4 For the purposes of clause 5.1.3, an individual is suitably qualified as a Transplant Centre Director if the individual is a: -

(a) Transplant Doctor;
(b) Intensivist with relevant clinical competency in the area of Organ Transplant; or
(c) Specialist physician of any Organ to be donated/transplanted in the Transplant Programme;

with expertise in any one of the following:

(i) Organ donation;
(ii) Organ transplant;
(iii) Pre-donation to post-donation; or
(iv) Pre-transplant to post-transplant.

5.1.5 In the event that a Transplant Centre Director overseeing multiple Transplant Programmes in the Transplant Hospital is: -

(a) An Intensivist or specialist physician, and not a Transplant Doctor, that Transplant Centre Director shall ensure that at least one individual in each Transplant Programme is a Transplant Doctor;
(b) A Transplant Doctor or specialist physician, and not an Intensivist (with relevant clinical competency in the area of the Organ donated/transplanted), that Transplant Centre Director shall ensure that at least one individual in each Transplant Programme is an Intensivist (with relevant clinical competency in the area of the Organ donated/transplanted); or
(c) An Intensivist or Transplant Doctor, and not a specialist physician of any Organ to be donated/transplanted within the Transplant Programme, that Transplant Centre Director shall ensure that at least one individual in each Transplant Programme is a specialist physician of any Organ to be donated/transplanted within the Transplant Programme;

5.1.6 In addition to clause 5.1.5, at least one individual in each Transplant Programme must have expertise in any one of the following:

(a) Organ donation;
(b) Organ transplant (at least one individual in the paediatric Transplant Programme must have expertise in paediatric Organ Transplants if there is a paediatric Transplant Programme in the Transplant Hospital);

(c) Pre-donation to post-donation; or
(d) Pre-transplant to post-transplant.

5.2 **Non-delegable Responsibilities**

5.2.1. The Transplant Programme Director and Transplant Centre Director (where appointed) shall have the following non-delegable responsibilities: -

(a) Ensure that the Licensee's employees, servants and agents read, understand and comply with these LCs, and all Relevant Requirements listed under clause 4.1 above;
(b) Ensure that the Transplant Doctors have the necessary credentials and fulfill the substantive requirements set out under the Credentialing Criteria for Medical Practitioners providing Organ Transplant Services;
(c) Put in place suitable and appropriate covering arrangements for the Transplant Doctors in their absence from the Transplant Hospital, to ensure that patient safety is not compromised during this period;
(d) Ensure that the necessary authorisation(s) and/or consent for the removal, donation and/or transplant of the Organ, are obtained pursuant to sections 4, 5, 6, 15 of the HOTA and/or section 4 of the MTERA;
(e) Put in place Donor Selection Criteria, taking into account the local context, availability of the Organ, best practices and guidelines;
(f) Ensure that there is a multi-disciplinary transplant team working on each Transplant Programme;
(g) Maintain a formal record of the composition of each multi-disciplinary transplant team and the roles and responsibilities of each member;
(h) Submit the following information to the Licensee according to the timelines stated below: -
    i. If the living Donor and/or Recipient has been with the Transplant Programme for one year, to submit the one-year survival outcome of the Donor and/or Recipient within one-year of the Visit Date; and
    ii. In addition to (i) above, if the living Donor and/or Recipient has been with the Transplant Programme for three years, to submit the three-year survival outcome of the Donor and/or Recipient within one-year of the Visit Date.

    In this sub-clause (h), Visit Date is defined as the date of the Donor or Recipients' consultation with the Transplant Doctor on or immediately after: -
        a. In the case of sub-clause (h)(i), the living Donor or Recipient having been in the Transplant Programme for one year; and
        b. In the case of sub-clause (h)(ii), the living Donor or Recipient having been in the Transplant Programme for three years.
(i) Put in place and implement adequate processes to: -
    i. Acknowledge and follow up on complaints and feedback received from Donors and/or Recipients;

ii. Monitor, identify, report and manage any adverse event or reaction in the Donor and/or Recipient that may result from the Organ transplant; and

iii. Comply with the MOH Circular No. 22/2019 – Revised Reporting Process for Adverse Events Pertaining to Organ Transplant Services.

(j) Submit the necessary forms and reports to MOH and/or NOTU as directed by MOH and/or NOTU from time to time, including reports on mortality events, serious reportable events and blood-borne infections, including but not limited to the infections listed in the MOH Manual.

5.3 **Evaluation of Medical Suitability for Transplantation**

General

5.3.1 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that a Transplant Doctor: -

(a) Reviews the clinical history of each Donor and Recipient; and

(b) Evaluates the suitability of each Donor and Recipient for the Organ transplant.

5.3.2 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that a multi-disciplinary transplant team carries out a complete clinical evaluation of each Donor and Recipient. The clinical evaluation shall consider the results of laboratory tests, diagnostic scans and additional assessments.

5.3.3 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that laboratory tests, diagnostic scans and additional assessments for the Donor and/or Recipient are carried out in accordance with the (a) MOH Manual, (b) national protocols and (c) guidelines and circulars endorsed and/or issued by MOH and/or NOTU as listed in clause 4.1, for the specific Organ and at the various pre-transplant and post-transplant Reporting Points set out in **Annex A**.

Donor

5.3.4 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that the review of the Donor under clause 5.3.1 is carried out by a Transplant Doctor not directly involved in the care or evaluation of the intended Recipient, as stipulated in the MOH Manual and the “Guidelines on the Evaluation of Living Kidney Donors” issued by the NOTU on 10 July 2019 and other guidelines as may be issued by MOH and/or NOTU from time to time.

5.3.5 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that the potential Donor is screened for all infectious diseases listed in the MOH Manual.

Recipient

5.3.6 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that all potential Recipients are screened for all infectious diseases listed in the MOH Manual.

5.3.7 The Transplant Programme Director and the Transplant Centre Director (where appointed) shall ensure that, after the Organ transplant, a Recipient undergoing follow-up treatment at the Transplant Hospital is screened for all infectious diseases listed in the MOH Manual. Where a Recipient is not undergoing follow-up treatment at the Transplant Hospital, that Recipient's Transplant Doctor shall advise the Recipient to go for such screening.

5.3.8 The screening and subsequent reporting of the outcome of the aforesaid screening tests shall take place in accordance with the Reporting Points set out in **Annex A**, or until death, graft loss or until the Recipient no longer returns for follow-up.

5.4 Counselling and Consent

Counselling

5.4.1 The Transplant Programme Director shall ensure that the living Donor and/or the Recipient is counselled by an appropriately qualified and trained personnel, and that information is explained in a manner best understood by the living Donor and/or Recipient.

Consent by living Donor

5.4.2 The following information shall be provided to the living Donor when obtaining his/her consent for the Organ Transplant Services:

(a) The process of Donor evaluation;
(b) The potential risks and benefits of Donor evaluation;
(c) The process of donating an Organ;
(d) The potential risks and benefits (where applicable) of donating an Organ for both the living Donor and the Recipient;
(e) Alternative options available to the Recipient other than an Organ transplant (if applicable);
(f) The follow-up process after donating an Organ; and
(g) The short and long-term risks, side-effects and complications associated with Organ transplants for both the Donor and the Recipient.

Consent by Recipient

5.4.3 The following information shall be provided to the Recipient when obtaining his/her consent for the Organ Transplant Services:

(a) The short and long-term risks affecting the function of the Organ after it has been transplanted;

(b) The risks of infection from the Donor after the Organ transplant;

(c) The risks of immunosuppression, including the side effects of the drugs prescribed to the Recipient;

(d) The Recipient's survival rate at one year and the survival rate of transplant procedures for that Organ; and

(e) The short and long-term risks, side-effects and complications associated with the transplant of that Organ and organ transplants in general, for both the Donor and the Recipient.

5.5 Equipment, Facilities and Infection Control

5.5.1 The Transplant Programme Director shall ensure that the procedure room/operating theatre is equipped with appropriate equipment and necessary facilities for the provision of Organ Transplant Services.

5.5.2 The Transplant Programme Director shall ensure that there is an infection control policy in place at the Transplant Hospital, and that such a policy is complied with.

6 Multi-Disciplinary Transplant Team

6.1 Each multi-disciplinary transplant team shall: -

(a) Comprise of medical and non-medical personnel, including but not limited to a Transplant Doctor and an intensivist;

(b) Put in place a management plan for each living Donor and/or Recipient, which shall include counselling, pre-and post-operation care and discharge criteria. The management plan shall be clearly recorded in the clinical notes and reviewed by each member of the multi-disciplinary transplant team involved in the patient's care;

(c) Regularly discuss the management plan to ensure that it is updated, relevant, and followed; and

(d) Carry out a complete clinical evaluation of each Donor and Recipient. The clinical evaluation shall include the results of laboratory tests, diagnostic scans and additional assessments.

6.2 Nursing staff responsible for post-operative care of the living Donor and/or Recipient shall be appropriately qualified and trained to provide the necessary nursing care and interventions required in a competent manner.

6.3 Nursing staff shall recognise and escalate deteriorating medical conditions of living Donors and/or Recipients to an appropriate member of the multi-disciplinary transplant team in a timely manner. Upon notification by the nursing

staff, the member of the multi-disciplinary transplant team shall respond in a timely and appropriate manner.

7 Transplant Physician

7.1 The Transplant Physician shall:

(a) Be a specialist accredited by the Specialists Accreditation Board (as defined in the Medical Registration Act 1997);

(b) Have undergone specialised transplant clinical training (fellowship or equivalent acquired clinical experience);

(c) Satisfy the credentialing criteria promulgated by the NOTU as set out in the Credentialing Criteria for Medical Practitioners providing Organ Transplant Services; and

(d) Be in Good Standing.

7.2 The Transplant Physician shall: -

(a) Ensure that each Donor and Recipient is medically and physically suitable for the removal and/or transplant of the Organ according to the Donor Selection Criteria, including but not limited to reviewing the clinical history of each Donor and Recipient;

(b) Ensure compliance with the MOH Manual when carrying out the obligations specified in clause 7.2(a), including but not limited to ensuring that the evaluation of a living Donor is carried out by a Transplant Doctor not involved in the direct care of the Recipient;

(c) Provide appropriate medical care for the living Donor and Recipient before, during and after the surgery;

(d) Advise a Recipient not undergoing follow-up treatment at the Transplant Hospital and/or Transplant Clinic, to be screened for all infectious diseases listed in the MOH Manual; and

(e) Ensure that covering arrangements are made in his absence from the Transplant Hospital or Transplant Clinic, to ensure that patient safety is not compromised during this period.

8 Transplant Surgeon

8.1 The Transplant Surgeon shall:

(a) Be a specialist accredited by the Specialists Accreditation Board (as defined in the Medical Registration Act 1997;

(b) Have undergone specialised transplant surgical training (fellowship or equivalent acquired clinical experience);

(c) Satisfy the credentialing criteria promulgated by the NOTU as set out in the Credentialing Criteria for Medical Practitioners providing Organ Transplant Services; and

(d) Be in Good Standing.

8.2 The Transplant Surgeon shall: -

(a) Ensure that each Donor and Recipient is medically and physically suitable for the removal and/or transplant of the Organ according to the Donor Selection Criteria, including but not limited to reviewing the clinical history of each Donor and Recipient;
(b) Ensure compliance with the MOH Manual when carrying out clause 8.2(a), including but not limited to ensuring that the Transplant Doctor of the Living Donor is not directly involved in the Recipient's transplantation;
(c) Ensure that covering arrangements are made in his absence from the Transplant Hospital or Transplant Clinic, to ensure that patient safety is not compromised during this period; and
(d) Ensure that appropriate sterilised equipment and facilities are used for the provision of Organ Transplant Services.

9 Contractual Agreement Between Transplant Hospital and Transplant Clinic For Organ Transplant Services

9.1 Where a Transplant Clinic uses the facilities of a Transplant Hospital to perform any Organ Transplant Service, the Licensee of the Transplant Hospital shall ensure that the Licensee of the Transplant Clinic agrees in writing to:
(a) Comply with these LCs; and
(b) Grant the Transplant Doctor clinical privileges. The clinical privileges shall at the very least, be subject to the following conditions:
i. The Transplant Doctor has never had his/her clinical privileges revoked or suspended by any hospital in Singapore due to a lapse in patient safety;
ii. The clinical privileges granted herein shall be immediately revoked or suspended upon the revocation or suspension of the Transplant Doctor's clinical privileges with another hospital due to a lapse in patient safety; and
iii. The Transplant Doctor shall inform the Transplant Hospital and/or the Transplant Clinic immediately, upon the revocation or suspension of his/her clinical privileges with another hospital.

10 Quality Assurance

10.1 The Licensee shall establish a Quality Assurance Committee to develop a quality assurance programme.

10.2 The Quality Assurance Committee shall maintain an ongoing quality assurance programme for the purpose of: -
(a) Monitoring and evaluating the overall quality and appropriateness of the patient care that is provided, and the practices and procedures that are carried out;
(b) Identifying and solving problems which may from time to time arise in connection with the provision of Organ Transplant Services; and

(c) Pursuing opportunities to improve patient care.

10.3 The Quality Assurance Committee shall review the quality assurance programme at least once each calendar year. A written report of each review shall be submitted to the Director-General of Health ("**DGH**") at such time and in such form as the DGH shall require. Upon a review of the report, the DGH may require the Licensee to improve its quality assurance programme.

10.4 The Quality Assurance Programme shall contain a framework for receiving, evaluating, investigating, documenting and reporting errors, adverse events, near misses and accidents relating to all Organ Transplant Services.

10.5 The Chair of the Quality Assurance Committee and the Transplant Programme Director shall be jointly accountable for the timely investigation and rectification of any reported error, adverse event, near miss and/or accident relating to Organ Transplant Services.

11 Record Keeping And Reporting

11.1 The Transplant Hospital and/or Transplant Clinic shall submit all necessary information, documents and forms (including but not limited to the survival rate of living Donors and/or Recipients) to NOTU at the timeframes stipulated in these LCs, in the MOH Manual, as well as in the MOH Circular No. 22/2019.

11.2 The clinical notes of each Donor and/or Recipient shall contain: -

(a) Detailed records of pre-operation, intra-operation and post-operation procedures performed in relation to the Organ Transplant Services provided (where applicable);

(b) The name and role of each member of the surgical and medical team (including but not limited to principal and assistant surgeons, implant and recovery surgeons, and physicians) involved in managing the Donor and/or Recipient before, during and after the Organ transplant;

(c) A comprehensive record of the management of the Donor and/or Recipient before, during and after the Organ transplant by the multi-disciplinary transplant team, and the findings, assessment and recommendations made by each Medical Practitioner in the multi-disciplinary transplant team (where applicable); and

(d) Detailed records of care plans discussed between the Medical Practitioners involved in the Organ transplant.

11.3 The Licensee shall maintain and keep all reports made in relation to the Organ Transplant Services, including but not limited to investigation reports, completed consent forms, anaesthetic records, post-operation review report, and pre- and post-discharge records.

11.4 The Licensee shall maintain and keep records of every Donor and Recipient to allow Donor and Recipient tracing. Where applicable, follow-up data on a Donor shall be submitted to the Donor Care Registry.

11.5 The Licensee shall submit data to NOTU in relation to Post-Transplant Outcome Monitoring and Infectious Diseases Screening in accordance with the Reporting Points stipulated in **Annex A**.

Annex A

Reporting Points for Data Submission for Post-Transplant Outcome Monitoring ("PTOM") and Infectious Diseases Screening ("IDS")

Reporting Point / Type of Screening	Pre-Transplant Screening	1 Month Post Transplant	3 Months Post Transplant	12 Months Post Transplant	Annual Data Submission
IDS	Up to 14 days post-transplant	Between 15 days prior to Reporting Point and up to 1 month after Reporting Point	Between 1 month prior to Reporting Point and up to 1 month after Reporting Point	Between 1 month prior to Reporting Point and up to 1 month after Reporting Point	(Not required)
PTOM	Up to 14 days post-transplant	Between 15 days prior to Reporting Point and up to 1 month after Reporting Point	Between 1 month prior to Reporting Point and up to 1 month after Reporting Point	Between 1 month prior to reporting point and up to 1 month after Reporting Point	Between 1 month prior to annual Reporting Point and up to 1 month after annual Reporting Point