

## Annex

# As attached to the Cabinet Resolution No. 25 of 2020 on the Executive Regulation of Decree-Federal Law No. 5 of 2016 on the Regulation of Human Organs and Tissue Transplantation

## Requirements for Private Health Facilities Authorization to Perform Human Organs and Tissue Transplantation

### First: Kidney Transplantation

#### 1. Requirements of the Technical Staff:

##### The technical staff shall consist of:

- a. Consultant kidney transplant surgeon: provided that he has at least one year's experience from a recognized kidney transplant center.
- b. Consultant nephrologist: provided that he has at least one year's experience from a recognized kidney transplant center.
- c. Nursing staff: They should be well trained with high experience in taking care of patients during and after kidney transplantation.
- d. Kidney transplant coordinator: This individual must have an adequate experience in order to perform the previously mentioned duties. The coordinator can also be appointed from the above-mentioned staff.
- e. A dietitian.
- f. A social worker.

#### 2. Requirements of technical facilities:

##### The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology Department, Digestive System Diseases Department, (Endoscopy is available), Chest Diseases Department (with endoscopy available), Medical Imaging Department, Hematology Department, Pathological Anatomy Department, Chemical and Biological Analysis Laboratory, Kidney and Hemodialysis Unit, (germs, parasites,

viruses and fungi) and Intensive Care Unit. At least two operations rooms must be available.

- c. At least two rooms for management of post-transplant patients.

### **3. Requirements of Departments of Support services:**

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. Laboratory: All routine investigations necessary for the patients either before or after the transplantation must be available. Facilities to perform tissue typing, cytotoxic antibodies, and blood levels of drugs including cyclosporine or similar drugs should be available.
- b. Radiology: whether conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography.

### **4. Drugs Requirements:**

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

## **Second: Heart Transplantation**

### **1. Requirements of the Technical Staff:**

The technical staff shall consist of:

- a. Consultant cardiac transplant surgeons: They must have a good experience in performing open heart surgeries and are fully certified and experienced from one of

the recognized heart centers internationally, and have performed an adequate number of pump cases (more than 200).

- b. ICU specialists: They should have an adequate experience in follow-up of patients after open heart surgery and preferably having adequate experience in follow-up of cardiac transplant recipients.
- c. Consultants in cardiology: They should have an adequate experience to perform all relevant cardiac investigations, whether through conventional or advanced means, including endomyocardial biopsy and to follow-up pre-and post-heart transplant patients.
- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after heart transplantation.
- e. Organs transplant coordinator.
- f. A social worker.
- g. A dietitian.

## **2. Requirements of technical facilities:**

The hospital must have the following departments:

- a. The following technical departments:
- b. Departments of Gastroenterology, Radiology, Hematology, Pathology laboratory, Biochemical laboratory, Nephrology with hemodialysis unit, and Immunology. At least two fully equipped open-heart surgical theatres must be available.
- c. Circulatory support systems, such as intra-aortic balloon pump, by-pass support systems (CPR), or mechanical assist devices with the availability of technicians necessary to handle them.
- d. A fully equipped ICU should be available for management of patients after open-heart surgery with facilities to isolate patients as well as installation of pacemakers, both temporary and permanent.
- e. The following specialists shall be available:
  - 1. Fully certified nephrologist experienced in the follow-up of organ transplant

recipients.

2. Immunologists experienced in the follow-up of heart transplant recipients.
3. Pulmonologist.
4. Certified respiratory therapist.
5. Infectious disease specialist.
6. Medical team for infection control at the hospital.
7. Certified pathologists with sufficient experience in interpreting myocardial biopsies.
8. Certified psychiatrist.

### **3. Requirements of Departments of Support services:**

Departments of support service at the hospital shall fulfil its technical requirements as follows:

- a. The laboratory: It shall have all regular test equipment required to assess patients before and after transplanting in addition tissue culture devices, calibration of Cytotoxic antibodies, level calibration of difference medicines, including Cyclosporine or alike and different immunity tests.
- b. Radiology: Conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography. There should be availability of bimodal echocardiography.

### **4. Drugs Requirements:**

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

### **Third: Lung Transplantation**

#### **1. Requirements of the Technical Staff:**

The technical staff shall consist of:

- a. Consultant lung transplant surgeons: They must have a good experience in performing open lung surgeries and are fully certified and experienced from one of the recognized lung centers internationally, and have performed an adequate number of lung transplantation.
- b. ICU specialists: They should have an adequate experience in follow-up of patients after open lung surgery and preferably having adequate experience in follow-up of lung transplant recipients.
- c. Consultants in chest medicine: They should have an adequate experience to perform all lung investigations, whether through conventional or advanced means, including lung biopsy and to follow-up pre-and post-lung transplant patients.
- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after lung transplantation.
- e. Organs transplant coordinator.
- f. A social worker.
- g. A dietitian.

#### **2. Requirements of technical facilities:**

The hospital must have the following departments:

- a. The following technical departments:
- b. Departments of Gastroenterology, Radiology, Hematology, Pathology laboratory, Biochemical laboratory, Nephrology with hemodialysis unit, Immunology, Cardiology and Cardiac surgery. A fully-equipped lung transplantation theatre.
- c. ICU with isolation possibilities if the patient condition requires this.
- d. The following specialists shall be available:
  1. Fully certified nephrologist experienced in the follow-up of organ transplant recipients.
  2. An immunologist.

3. A cardiologist.
4. Certified respiratory therapist.
5. Medical team for infection control at the hospital.
6. A pathologist with sufficient experience in interpreting lung biopsies.
7. A psychiatrist to evaluate patients before and after transplantation.

### **3. Requirements of Departments of Support services:**

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. The laboratory: It shall have all regular test equipment required to assess patients before and after transplanting in addition tissue culture devices, calibration of Cytotoxic antibodies, level calibration of difference medicines, including Cyclosporine or alike and different immunity tests.
- b. Radiology: X-ray facilities for conventional and advanced lung investigations (e.g., CT scan, radioisotope scanning...etc.).

### **4. Drugs Requirements:**

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

## **Fourth: Liver Transplantation**

### **1. Requirements of the Technical Staff:**

The technical staff shall consist of:

- a. Consultants in liver transplantation: They should have at least one year of experience in hepatobiliary surgery from a recognized liver transplant center internationally.
- b. Hepatologist: A hepatologist with a minimum of one year's experience from a recognized liver transplant center internationally.
- c. Pediatric gastroenterologist: with a minimum of one year's experience from a recognized liver transplant center internationally.
- d. Anesthesia consultant: an anesthesia consultant with a minimum of one year's experience from a recognized liver transplant center internationally.
- e. Intensive Care Consultant.
- f. A dietitian.
- g. An infectious disease consultant.
- h. Liver transplant coordinator.
- i. Nursing staff: They should be well trained with high experience in taking care of patients during and after liver transplantation.

## **2. Requirements of technical facilities:**

The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology, Endoscopy, Radiology, Hematology and blood bank, Pathology, Biochemistry laboratory, Nephrology with hemodialysis unit, ICU facility, Immunology, Chest diseases, Psychiatry, Physio-therapy, Microbiology laboratory (germs, parasites, viruses and fungi).  
At least two fully-equipped operating theatres containing all the necessary equipment for liver transplantation, specifically the following:

Thromboelastogram, Cell saver machine, Rapid infusion system, Venovenous by-pass machine, Infra-red coagulator or equivalent, Blood warmer, Technicians needed to operate these machines should be available.

## **3. Requirements of Departments of Support services:**

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. The laboratory: It shall have all routine laboratory services, including pre- and post-

transplant work-up in addition to HLA typing, cytotoxic antibodies, drug levels of cyclosporine and similar drugs.

- b. Radiology: whether conventional X-ray facility, ultrasound (with the availability of a portable machine), Doppler ultrasonography, isotope scan, CT scan, and percutaneous transhepatic cholangiography.
- c. Endoscopy department: This department should have all diagnostic and therapeutic facilities, including Endoscopic Retrograde Cholangio Pancreatography (ERCP).

#### **4. Drugs Requirements:**

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, fungal, or parasitic infections.

### **Fifth: Pancreas Transplantation**

#### **1. Requirements of the Technical Staff:**

The technical staff shall consist of:

- a. A consultant pancreas transplant surgeon: A consultant in the field of pancreas transplantation, with at least one year experience in an internationally recognized center for pancreas transplantation.
- b. Consultant nephrologist: with at least one year's experience from an internationally recognized kidney transplant center.
- c. A diabetologist: There should be at least one diabetologist consultant with at least one year experience in an international recognized center for treating complicated diabetic cases.



- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after transplantation.
- e. Pancreas transplant coordinator: This individual must have an adequate experience in order to perform coordination duties. The coordinator can also be appointed from the above-mentioned staff.
- f. A dietitian.
- g. A social worker.

## **2. Requirements of technical facilities:**

The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology and Angioplasty Department, Digestive System Diseases Department, (Endoscopy is available), Chest Diseases Department (with endoscopy available), Medical Imaging Department, Hematology Department, Tissues Department, Chemical and Biological Analysis Laboratory, Kidney and Hemodialysis Unit, (germs, parasites, viruses and fungi) and Intensive Care Unit. At least two surgical operations rooms must be available.
- c. At least two rooms for management of post-transplant patients.

## **3. Requirements of Departments of Support services:**

Departments of support service at the hospital shall fulfil its technical requirements as follows:

- a. The laboratory: It shall have all routine laboratory test equipment required to assess patients before and after transplant, including bacterial, viral and fungal infections, in addition to HLA typing, cytotoxic antibodies, drug levels of cyclosporine and similar drugs.
- b. Radiology: whether conventional X-ray, ultrasound, radioisotope scanning, computerized axial tomography and interventional radiology.

#### **4. Drugs Requirements:**

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

#### **Sixth: Corneal Transplantation**

##### **1. Requirements of the Technical Staff:**

The technical staff shall consist of:

- a. Consultant corneal transplant surgeon: There should one consultant in corneal transplantation with good experience in performing corneal transplant and treating external eye diseases for at least one year from a recognized international corneal transplant center, provided that he has done such kind of operations himself within this period, with a certificate confirming that experience. Alternatively, he should have a certificate of experience of at least five years in corneal transplantation from a recognized hospital provided that he provides this certificate from the same hospital he worked for.
- b. A consultant anesthesiologist with a previous experience in anesthesia for eye surgery.
- c. A full-time microbiologist working for the hospital, with Microbiology laboratory Department (germs, parasites, viruses and fungi).
- d. An eye-bank technician with experience in preservation of corneas and evaluation of suitability of corneas for transplantation. Alternatively, the consultant corneal transplant surgeon can perform this duty.
- e. A corneal transplant coordinator with experience in coordination of corneal transplantation and preservation of corneas until the time of transplant.

- f. Nursing staff: They should be well trained with high experience in taking care of patients during and after corneal transplantation.

## **2. Requirements of technical facilities:**

The hospital must have the following departments:

- a. Ophthalmology department fully equipped with necessary medical equipment, specifically:
  - 1. Bio-microscopes (slit lamp)
  - 2. Ophthalmoscopes.
  - 3. Visual acuity charts.
  - 4. Refractometer.
  - 5. Retinoscopes.
  - 6. Tonometers.
  - 7. Fully equipped operating rooms for corneal transplant operations such as a surgical microscope and vitrectomy equipment.
- a. Outpatient clinics shall be fully equipped for examination of patients who have already undergone corneal transplantation as well as evaluating those who are potential candidates (such as have special forceps, blades, eyelid retractor, etc.).