Autologous Haematopoietic Stem Cell Transplantation Inspection Checklist- Final

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
4	**STANDARD ONE: HEALTH FACILITY REQUIREMENTS**				
a.	Ensure designated inpatient unit with adequate space that minimises airborne microbial contamination (isolated-positive pressure room).				
i.	A high-efficiency HEPA filter is required for procedures involving immune-compromised patients.				
b.	There is a written plan for monitoring electrical and mechanical equipment for safety, with monthly visual inspections for apparent defects.				
c.	The lighting and utilities are adequate, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets, and communications.				
4.1.5.	The health facility design should provide assurance of patient and staff health and safety.				
4.2.	Scope of Services				
4.2.1.	Written AHSCT scope of services shall be in place, including but not limited to:				
a.	Donor identification, evaluation, selection, eligibility determination and management;				
b.	Stem Cell Collection and Apheresis;				
c.	Stem Cell Mobilisation;				
d.	Administration of the preparative regimen;				
e.	Administration of blood products;				
f.	Central venous access insertion and device care;				

g.	Administration of HPC as well as other cellular therapy products, such as products under exceptional release;				
h.	Management of cytokine release syndrome and toxicities of the central nervous system;				
i.	Transfusion blood products and monitoring of blood counts;				
j.	Infection Control and Sterilisation for AHSCT;				
k.	Communicable disease testing and management;				
l.	Monitoring infections and use of antimicrobials;				
m.	Disposal of medical and biohazard waste;				
n.	Cellular Therapy Product Storage;				
o.	Safe administration of cellular therapy products				
p.	Monitoring organ dysfunction or failure and institution of treatment;				
q.	Monitoring graft failure and institution of treatment;				
r.	Management of side effects such as vomiting, nausea, pain, and other discomforts;				
s.	Post-Transplant clinic follow-ups;				
t.	Patient Education (pre-and post-op procedure and graft failure);				
u.	Medication Management;				
v.	Clinical laboratory services;				
w.	Nutrition Management;				
x.	Medical equipment management and maintenance;				
y.	Patient Safety for Radiology and Chemotherapy;				
z.	Long-term follow-up, treatment, and plans of care;				
aa.	Palliative Care;				
bb.	Rehabilitation;				
cc.	Patient Transportation and Emergency management; and				
dd.	Morbidity and Mortality Management.				
4.4.	Accreditation				

4.4.1.	The hospital must be accredited as per DHA Policy for Hospital accreditation before the commencement of the service.				
4.4.2.	The hospital lab must be accredited as per DHA Policy for Clinical Lab before the commencement of service.				
4.4.3.	The health facility should have a Quality Management System (QMS) as 'an organization's comprehensive quality assessment, assurance, control, and improvement system'.				
4.4.4.	The service shall achieve and comply with FACT-JACIE International Standards for Cellular Therapy, Product Collection, Processing and Administration, Storage and Collection accreditation 24 months from licensure activation.				
4.5.	In house Lab Setup and Diagnostics				
4.5.1.	Equipment and supplies for a stem cell processing lab are set out in **Appendices 1 and 2.**				
c.	All essential equipment shall be connected with an uninterruptible emergency power supply.				
4.6.	There should be a mechanical freezer capable of storing a liquid nitrogen tank equipped with an audible alarm.				
4.6.1.	Self-pressurising dewars should be in place for a regular supply of liquid nitrogen from the main storage tank.				
4.6.2.	The space containing the liquid nitrogen storage tanks and supply dewars should be separate from the processing laboratory needs.				
4.6.3.	The tanks should have sufficient air handling capacity to maintain safe oxygen levels when the Liquid Nitrogen2 tanks are filled.				
4.6.4.	An oxygen sensor alarm to indicate when oxygen levels are dangerously low.				
4.6.5.	A temperature sensor should be fitted to track and temperature at least twice a day.				
4.6.6.	Adequate backup liquid (or vapour) nitrogen storage capacity should be in place.				

5	STANDARD TWO: HEALTHCARE PROFESSIONAL REQUIREMENTS				
5.9.	There shall be written Standard Operating Nursing Procedure procedures, including but not limited to:				
5.9.1.	Care of immunocompromised recipients;				
5.9.2.	Age-specific considerations;				
5.9.3.	Administration of preparative regimens;				
5.9.4.	Administration of cellular therapy products;				
5.9.5.	Administration of blood products;				
5.9.6.	Central venous access device care; and				
5.9.7.	Detection and management of immune effect or cellular therapy complications.				
5.9.8.	Trained to operate the apheresis Machine and collection of stem cells and storage.				
7	**STANDARD FOUR: AUTOLOGOUS HSCT SERVICE REQUIREMENTS**				
7.3.	The service should have policy and procedures supported by documentation for the following:				
7.3.1.	Patient acceptance criteria;				
7.3.2.	Investigational treatment protocols;				
7.3.3.	Patient assessment and admission;				
7.3.4.	Pregnancy testing;				
7.3.5.	Patient education and informed consent (Appendix 4);				
7.3.6.	Patient health record;				
7.3.7.	Pre and Post collection care;				
7.3.8.	Cell collection, processing storage, transportation and banking.				
7.3.9.	Conditions and duration of cellular therapy product storage as well as the indications for disposal;				
7.3.10.	Good Tissue Manufacturing Practice and Cell Processing;				
7.3.11.	Use of Equipment, Supplies and Reagents;				

7.3.12.	Coding, Labelling, Verification and Tracing of Cellular Therapy Products;				
7.3.13.	Available therapies and treatment protocols;				
7.3.14.	Medication management;				
7.3.15.	Incident reporting;				
7.3.16.	Patient privacy;				
7.3.17.	Post-transplant vaccination schedules and indications				
7.3.18.	Emergency action plan;				
7.3.19.	Patient discharge/Post Op Care/transfer;				
7.3.20.	Transfer of critical/complicated cases when required.				
7.3.21.	Quality Improvement and Control (including outcome at 100 days, one year and five years);				
7.3.22.	Cellular therapy emergency and disaster plan, and the Clinical Program response;				
7.3.23.	Patient Complaint Management;				
7.3.24.	Sentinel, adverse events, and adverse reaction reporting; and				
7.3.25.	Disposal of biological and medical waste as per Dubai Municipality (DM) requirements;				
7.4.	Infection control program for monitoring and managing infectious processes, including immune-deficiencies and opportunistic infections, central venous catheter infection and potential patient infections. The program shall assure:				
7.4.1.	Monitoring of infections and use of antimicrobials.				
7.4.2.	Blood samples for testing for evidence of clinically relevant infection shall be drawn, tested and reported within timeframes required by local and federal regulations.				
7.4.3.	Implement Post-procedure infection control measures.				
7.4.4.	Document infection control measures and hazardous waste management;				

7.4.5.	Compliance with hygiene and use of attire for personal protective equipment.				
7.5.	The service should maintain the Charter of Patient Rights and Responsibilities at the facility entrances in two languages (Arabic and English).				
8	**STANDARD FIVE: STEM CELL COLLECTION, PROCESSING, STORAGE, TRANSPORTATION AND BANKING**				
8.5.	Cells that require transportation shall:				
8.5.1.	Have an agreement and clear process between the sender and receiver.				
8.5.2.	Have in place a courier tracking mechanism to determine the status of the cells being transported.				
8.5.3.	Ensure cells are placed in a credo-box that is prepared to 4 °C.				
e.	The credo box shall include labels identifying the product being transported.				
8.6.1.	The cell banking system should have written documentation for:				
a.	Cell banking procedures to include reagents, temperature controls and maintenance of medical equipment and devices.				
b.	Cell types and sizes are being managed.				
c.	Containers, vessels and closure system used.				
d.	Methods of cell preparation, cryopreservation technique.				
e.	Safe use of reagents and protectants.				
f.	Cell storage and thawing technique.				
g.	Transportation and disposal of medical waste.				
h.	Procedures used to prevent microbiological contamination and cross-contamination and tracing.				
i.	Documentation and labelling procedures.				
j.	Back up and business continuity and recovery from catastrophic events.				
k.	Cell testing technique.				
l.	Testing for mycoplasma and sterility before the transfer of cells into the				

	facility.				
i.	Bacteriostasis and fungistasis testing should be performed before sterility testing to assess the sample matrix for inhibition.				
m.	Testing program and the schedule should include but not be limited to testing for:				
i.	Species-specific virus (2 weeks).				
ii.	Sterility (2.5 weeks).				
iii.	Mycoplasma testing (3.5 weeks).				
iv.	Retroviruses and animal viruses (5 weeks).				
v.	Adventitious virus (6 weeks).				
vi.	Antibody production (7 weeks).				
9	**STANDARD SIX: SAFETY AND QUALITY REQUIREMENTS**				
9.5.	Written agreements with suppliers, blood banks and tertiary hospitals to ensure patient safety and quality of care are not compromised.				
9.5.1.	Twenty-four-hour availability of appropriate and irradiated blood products needed to care for cellular therapy recipients.				
APPENDIX 1	**Equipment Needed to Start A Cell-Processing Lab**				
A	**Required equipment:**				
1	Biosafety cabinet (or equivalent)				
2	Water bath				
3	Plasma extractor				
4	Cryo-transporter (-80 °C) or liquid nitrogen dry shipper				
5	Pipette aid				
6	Refrigerator				
7	Centrifuge (with carriers to hold 600 mL blood bags)				
8	Tubing sealer				
9	Micropipettes (100 µL and 1000 µL)				
10	Hemostats				

11	Balance (Scale)				
12	Freezer (<-70 °C)				
13	Tubing stripper				
14	Reference thermometer				
B	**Desired equipment:**				
1	Sterile connecting device				
2	Label printer				
3	Microscope				
4	Controlled rate freezer				
5	CO2 incubator				
6	Personal computer				
7	LN2 (Liquid nitrogen) storage freezer				
8	Hemocytometer				
C	**Shared equipment:**				
1	Flow cytometer				
2	Hematology analyzer				
3	Automated instrument for cell processing				
4	Microbiology lab for bacterial and fungal couture				
APPENDIX 2	**Essential requirements for setting up a stem cell processing laboratory**				
A.	**Miscellaneous laboratory supplies**				
1	Cryobags (for example: 50; 250; 500 mL)				
2	Transfer packs (300; 600 mL)				
3	Syringes (1, 3, 10, 30, 60 mL)				
4	Safety needles; couplers				
5	Spike to needle, spike to spike adapters; stopcocks				
6	Alcohol swabs, iodine swabs, syringe caps, sterile swabs				
7	Labels, laminating tags; zip ties				

8	15, 50, 175 mL conical tubes				
9	Pipettes (1-50 mL)				
10	Biohazard sample bags				
11	Tube racks				
12	Pipette tips				
13	Cryovials, microtubes				
14	Biohazard bags; sharp containers; garbage bags; trash can				
15	Dry ice				
16	Sterile overwrap bags				
B.	**Sample reagent list (will vary depending on products and services offered)**				
1	DMSO (dimethyl sulfoxide)				
2	Plasmalyte (or equivalent)				
3	ACD-A (acid citrate dextrose solution)				
4	Human serum albumin				
5	Hetastarch				
6	Heparin				
7	70% IPA (isopropyl alcohol); bleach; bactericidal and fungicidal detergent				
8	Flow cytometry reagents				
9	Trypan blue				