Autologous Adipose-Tissue Derived Stem Cells/Stromal Vascular Fraction Cells (ADSCs/SVFCs) Therapy Inspection Checklist- Final

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
5.1.	The health facility shall have in place written documentation for the following:				
5.1.1.	Service description.				
5.1.2.	Scope of services.				
5.1.3	Staff job descriptions.				
5.1.4.	Policy and procedure for end to end provision of ADSCs services to include but limited to:				
a.	Staffing requirements and their roles and responsibilities				
b.	Clinical privileging, governance and reporting arrangements				
c.	Patient acceptance and referral criteria				
d.	Patient exclusion criteria				
e.	Patient assessment, admission, management, discharge and follow up				
f.	Patient education and informed consent (English and Arabic)				
5.1.5.	Standard Operating Procedures for cellular therapy for Autologous Minimal Manipulation (AMM) that are approved by a DHA recognised clinical lab accreditor (refer to DHA Policy for Clinical Lab Accreditation)				
5.1.6.	Harvesting				

a.	Marking site for tissue harvest				
b.	Sterilisation and numbing				
c.	Incision/puncture wound				
d.	Administration of sub-dermal or tumescent anesthetic fluid				
e.	Lipo-aspirate harvesting				
f.	Cleansing and suturing				
g.	Lipo-aspirate preparation/decanting				
5.1.7.	Current Good Tissue Practice				
a.	Clinical laboratory services				
b.	Equipment monitoring and maintenance services				
c.	Transfer of fat to sterile lab				
d.	Placement of tissues in isolator hood or equivalent				
e.	Ultrasonic sonication-mediated cavitation of specimen or methods of cell processing				
f.	Cell washing				
g.	Centrifugation				
h.	Cell harvesting				
i.	Cell filtration				
j.	Cell count testing and viability				
k.	Cell sample sterility testing				
l.	Tissue labelling and tracing				
m.	Cell insertion to patient (intravenous or site specific)				
5.1.8.	Infection control and prevention measures for communicable diseases (infection disease testing for laboratory processed cells).				
5.1.9.	Managing patient health records.				
5.1.10.	Incident reporting.				
5.1.11.	Patient privacy and confidentiality.				

5.1.12.	Medication management.				
5.1.13.	Emergency action plan.				
5.1.14.	Patient discharge/transfer/follow up.				
5.1.15.	Transfer of critical/complicated cases when required.				
5.1.16.	Complaints procedure.				
5.1.17.	Laundry services.				
5.1.18.	Housekeeping services.				
5.1.19.	Hazard waste management.				
5.1.20.	Medical waste management to meet Dubai Municipality (DM) requirements				
5.2.	The Health Facility shall:				
5.2.1.	Maintain a Charter of patients' Rights and Responsibilities posted at the entrance of the premise in two languages (Arabic and English).				
5.2.2.	Make available printed patient information leaflets (or online) of available therapies including risks and alternatives to support informed decision-making.				
5.2.3.	Ensure there is adequate lighting and utilities, including environmental and temperature, humidity, ventilation controls and air filtration, water taps, medical gases, sinks and drains, lighting, and electrical outlets.				
5.2.4.	Install and operate required equipment in accordance to the manufacturer's specifications/biomedical certification.				
5.2.7.	Clearly define consent for investigations and ADSCs therapies.				
5.2.8.	Fulfil DHA health facility and lab requirements for accreditation as per DHA Policy requirements.				
5.2.10.	Ensure there are written procedures for all surgical procedures in the facility involving adipose tissue aspiration.				

5.2.11.	Ensure there are written procedures for all non-surgical procedures in the facility involved in the process of the stem cell regenerative therapy.				
8	**STANDARD FIVE: SAFETY & QUALITY REQUIREMENTS FOR AUTOLOGOUS ADSCs**				
8.1.	A quality and safety program for Current Good Tissue Manufacturing and tracking of HCT/Ps must be in place and reviewed frequently to detect and prevent adverse or sentinel events and transmission of communicable diseases. The quality program must:				
8.1.1.	Include a nominated lead for Quality Assurance and Quality Control				
8.1.2.	Incorporate Current Good Tissue Practice into Standard Operating Procedures.				
a.	Ensure documented and appropriate action is taken when Good Tissue Practice requirements are not met				
8.1.3.	There must be in place a system for contact tracing of cells used				
8.1.4.	Assure infection control and sanitation is met to the highest standards				
8.1.5.	Ensure only licensed, trained and privileged staff are engaged in ADSCs therapies, reporting and investigation of complaints and adverse and sentinel events.				
a.	Staff training and education needs must be documented and up to date.				
b.	Changes in staffing must be documented and all clinical privileging requirements must be met confirmed by the Medical Director or the Privileging committee as per DHA Policy prior to issuance of privileges for service provision of ADSCs				
8.1.6.	Form part of the facility and lab accreditation program				
8.1.7.	Ensure clinical audits are conducted twice a year with a				

	documented improvement plan				
8.1.8.	Take corrective action when Standard Operating Procedure requirements are not met				
8.2.	The location/room for ADSCs therapy is specified to reduce the risk of infection, contamination, improper labelling and tracing.				
8.2.1.	Aseptic locations for assessment, extraction/recovery, preparation and harvesting and reinsertion or infusion of cells must be included as part of safety and the quality control program.				
8.2.2.	Isolation of ADSCs shall only be conducted in a sterile point of care setting or lab setting.				
8.4.	Ensure measures taken to assure sterility, infection control, and minimisation of microbiological contamination and/or transfer of communicable diseases during extraction/harvesting, manufacturing, handling, storage and administration of stem cells through strict lab policy and procedures/protocols and quality control and compliant with manufacturer recommendations.				
8.7.	Have clear written protocols to ensure the validation of labels, tests or results or procedures and their times are accurate as per pre-determined standards.				
9	**STANDARD SIX: PRE-OPERATIVE EVALUATION AND INFORMED CONSENT**				
9.8.1.	Informed consent shall include an explanation in Arabic or English with supporting written educational material and discussion with patient and documentation in the patient records as a separate form.				
9.8.2.	Informed consent shall include details of the procedure, possible risks/complications and alternative treatment options				
9.8.4.	Informed consent should cover the following:				
a.	Comprehensive and accessible information concerning the diagnosis and procedure/surgery alternatives to ADSCs Therapy				

b.	All usual and occasional side effects, risks and complications e.g. swelling, bruising, pain, seroma, haematoma, hyperpigmentation, infection.				
c.	Potentially life-threatening complications e.g. Fat Embolism Syndrome (FES), pulmonary oedema and necrotizing fasciitis sepsis, perforation of abdominal or thoracic viscera, cardia arrest, hypotension and haemorrhage.				
d.	Limitations of the procedure and if further procedures are needed for proper results				
e.	The possibility of a poort surgical or cosmetical outcome				
f.	The recovery duration and expected results				
g.	The full cost of the procedure				
10	**STANDARD SEVEN: INTRA-OPERATIVE MANAGEMENT**				
10.9.	Devices or drugs must be made immediately available and include a stethoscope, source of oxygen, self-inflating bag-valve-mask device and emergency crash cart.				
10.10.	DHA Health Facilities shall have a policy in place for management and transfer of patients in case of emergencies supported by a signed written transfer agreement with a nearby hospital to ensure timely transfer of complicated cases.				
12	**STANDARD NINE: DISCHARGE AND OUTPATIENT FOLLOW UP**				
12.2.	The health facility shall maintain written policies and procedures concerning the patient discharge, which reflect acceptable standards of practice and compliance with applicable regulations in the Emirate of Dubai.				