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

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
4	**STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES**				
4.3.	ADSCs Therapy services shall only be performed in a Hospital or Day Surgical Centre or Clinic setting that fulfils the requirements set out in the Standard.				
4.3.1.	Extraction of ADSC is only permitted in a Hospital, Specialty Hospital or Day Surgical Centre setting.				
5	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
5.1.17.	Laundry services.				
5.1.18.	Housekeeping services.				
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).				
5.2.3.	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.				
6	**STANDARD THREE: HEALTHCARE PROFESSIONALS REQUIREMENTS**				
6.1.	Autologous Adipose-Tissue Derived Stem Cell Stem Cell/SVFCS therapy shall only be provided by:				
6.1.1.	A DHA licensed physician working under the supervision of a consultant in related field.				
o.	Hold an Advanced Cardiac Life Support (ACLS) or Advanced Life Support (ALS) certification				
6.3.	Regenerative Physicians shall:				
6.3.1.	Be supported by a minimum of one (1) perioperative Registered Nurses (RNs) for each ADSCs Therapy procedure and one (1) lab technician.				
8	**STANDARD FIVE: SAFETY & QUALITY REQUIREMENTS FOR AUTOLOGOUS ADSCs**				
8.3.	Ensure documentation of environmental monitoring of temperature, filtration, humidity and equipment is maintained on a regular basis.				
8.5.	Maintain up to date records of all equipment cleaning, sanitisation, calibration, use and disposal.				
8.6.	Equipment must be calibrated on a regulation basis with supporting documentation.				
8.8.	Validation testing and study must be conducted and documented on a regular basis to include but not be limited to:				
8.8.1.	Testing for microorganisms				
8.8.2.	Preparation				
8.8.3.	Sterilization				
8.8.4.	Cleansing				
8.8.5.	Temporary storage and removal of cells for insertion				
8.10.	Maintain up to date records of all supplies and reagents used for ADSCs therapy.				

8.11.	Supplies and reagents must be registered by the Ministry of Health and Prevention and authorised by the health facility for use.				
8.12.	Use of growth factors, hormones or enzymes (excluding GMP collagenase for human adipose cell isolation approved for use in the UAE) to enhance or expand the number and/or efficacy of ADSCs from SVFCS or use of embryonic or amniotic or placenta or cord blood stem cells or any other form of stem cells in silo or combination with ADSCs is NOT permitted.				
8.13.	Sale, storage or use of ADSCs for any other person(s) who is not the 'same patient/individual' is NOT permitted.				
8.15.	Pooling of ADSCs from one or more donors or for one of more procedures is NOT permitted.				
8.16.	Storage and cryopreservation of ADSCs beyond the same day same procedure is permitted upon patient written consent for up to 1 year only to maximise the efficacy and survival of ADSCs.				
8.16.1.	ADSCs prepared in the lab should be delivered in an accepted transport medium (hypothermic 2 - 8°C preservation medium) and transferred in a cool environment ready for syringe for deployment.				
8.16.2.	ADSCs should be used within a 2 hour period after preparation from surgery and no more than 4 hours at a controlled temperature				
9	**STANDARD SIX: PRE-OPERATIVE EVALUATION AND INFORMED CONSENT**				
9.1.	A detailed medical history to account for any previous disease, drug intake and prior surgical procedures and screening of communicable diseases shall be undertaken for patients indicated for ADSCs Therapy.				
9.1.1.	Communicable Disease Screening shall include:				
a.	HCV Ab				
b.	HBs Ag				
c.	HIV Ag/Ab				

9.2.10	General anesthesia for children under the age of five years.				
a.	The Legal Guardian must provide informed consent				
b.	A Paediatric Consultant, Paediatric Anaesthetist and a RN must be present during the procedure.				
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				
9.8.5.	Informed consent shall be obtained from the patients their legal guardian if the patient is under 18 years or lack the full capacity to make a decision before the procedure/surgery is performed.				
10	**STANDARD SEVEN: INTRA-OPERATIVE MANAGEMENT**				
10.1.	ADSCs Therapy should be limited between 60-120cc of total aspirant volume per procedure.				

10.2.	Larger volumes up to a maximum of 240cc of ADSCs may be undertaken with other procedures subject to additional necessary preoperative assessments under the direction of the treating physician.				
10.4.	Each ADSCs Therapy procedure must be conducted by a physician trained in regenerative medicine and supported by minimum of one (1) perioperative registered nurses who are trained and knowledgeable in the ADSCs Therapy procedure, safe tumescent drug concentrations or subdermal block, fluid management and appropriate patient monitoring by an RN and a lab technician for tissue processing.				
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.				
11	**STANDARD EIGHT: POST-OPERATIVE CARE**				
11.1.	There should be a dedicated RN in the recovery area who is trained (knowledgeable and skilled) to monitor vital signs, fluid and electrolyte balance and manage potential complications of tumescent anesthesia. The RN's sole responsibility shouldt be to monitor the patient post-operatively and follow emergency procedures until the patient is deemed well enought for discharge by the treating physician or the medical team.				