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Standards for Fertility Centers – Random

Name of the Facility:			
Date of Inspection:	/	/	

Ref.	Description	Final	Random	Remarks	
5.	STANDARD ONE: REGISTRATIONS AND LICENSURE PROCEDURES				
5.5.	As per the DHA policy for patient referral and interfacility transfer, all fertility centers must have a written agreement for patient referral and emergency transfer of critical cases to a nearby hospital setting. The transfer agreement shall detail the transfer plan/protocol of patients and meet the transfer timeframes for emergency patients with appropriate follow up plans for referred patients.				
5.5.1.	In the case of request for frozen specimen transfer by the patient, the fertility center should guide patients to abide by the internal policies and procedures of the fertility center. The fertility center must fill the "Request of Frozen Specimen Transfer" form and submit to DHA. Refer to Service Description (dha.gov.ae).				
5.6.	The fertility center shall have in place internal policies and procedures including but not limited to:				
5.6.10	There should be an allocated medical waste storage and collection area that is well ventilated, temperature controlled, monitored and secured from public and patient access.				
5.6.11	The medical waste storage and collection area shall be adequately labelled with a hazard sign to prevent unexpected entry from patients or the public.				
5.7.	All fertility centers shall have a business continuity plan to ensure the center's services are uninterrupted.				
6.	Standard Two: Fertility Center Requirements				

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6.1.	The fertility center must be accredited by a globally recognized accreditation body that is approved by DHA within a period of three years.		
6.3.	The Fertility center shall ensure the treatment environment is accessible and supports patient needs, safety, privacy and confidentiality for all patient groups.		
6.4.	Fertility centers shall abide by offering their services to all clients including people of determination.		
6.8.	The ART lab should be accredited by recognized accreditation body that has specific ART lab standards as per DHA's clinical lab accreditation policy.		
6.9.	HRS must be informed and approve changes to existing or new services or staffing levels.		
6.12.1	Monitoring medical, electrical and mechanical equipment, visual inspections for apparent defects and maintenance by the competent entity with valid testing certificates as per DHA Standards for Medical Equipment Management.		
6.12.2	Assure medical equipment and devices are in place for emergency scenarios.		
7.	Standard Three: Healthcare Professionals		
7.	Requirement		
7.2.2.	Minimum of one full time DHA licensed Specialist or Consultant obstetrics and gynecology specialized in Reproductive Medicine and Infertility or Reproductive Endocrinology and Infertility with minimum of 3 years of experience in fertility treatment.		
7.2.3.	Minimum of one DHA licensed consultant or specialist urologist with andrology subspecialty or at least 2 years of experience in male reproductive health services which can be available inhouse or outsourced.		
7.2.4.	Minimum of one full time DHA licensed consultant or specialist Anesthesiologist.		
7.2.5.	Laboratory director: full time DHA licensed Embryologist with minimum of 6 years of experience.		
7.2.6.	Minimum of two full time DHA licensed embryologist working under the supervision of the laboratory director.		
i.	The number of embryologists should reflect the number of cycles performed per year. As an approximate guide, clinics that perform up to 150 retrievals and/or cryopreservation cycles per year should always have a minimum of two qualified embryologists.		
7.2.8.	Minimum of one full time DHA licensed Anesthesia technologist or technician that corresponds to the		

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	minimum number of consultant or specialist		
	Anesthesiologist in the fertility center.		
	Minimum of two full time DHA licensed		
7.2.9.	Radiographer/Sonographer/Radiography technologist		
	or technician.		
7010	Minimum of five, DHA licensed registered nurses of		
7.2.10	which include those experienced in operation rooms.		
7.2	Inhouse or Outsourced healthcare professionals/		
7.3.	Services:		
7.3.1.	DHA licensed Genetic counsellor.		
7.3.2.	DHA licensed Psychologist.		
7.3.3.	DHA licensed Biomedical engineer		
7.3.4.	DHA licensed Central Sterile Services technician.		
	Only DHA licensed fertility specialists shall be		
7.5.	permitted to perform assisted medical reproductive		
	procedures.		
9.	Standard Five: Medical Equipment and Devices		
	Materials used in laboratory construction, painting,		
9.3.	flooring and furniture should be appropriate for clean		
9.5.	room standards, minimizing Volatile Organic		
	Compounds (VOC) release and embryo toxicity.		
9.4.5.	UPS Generator.		
	Incubator numbers should be calculated according to		
	incubator capacity and facility cycle numbers as		
9.5.	culture conditions fluctuate by frequent opening of		
	doors and can negatively impact gamete/embryo		
	development and viability.		
	Gametes and embryos should be conveniently		
9.5.1.	distributed across incubators to minimize door		
	openings.		
0.6	Equipment must be adequate for optimal laboratory		
9.6.	work, easy to disinfect and kept clean to avoid		
	contamination.		
9.7.	All equipment must be validated as fit for its purpose		
	and performance verified by calibrated instruments. Gas cylinders should be located outside the laboratory,		
	, ,		
9.9.	there should be an automatic change over system and sufficient cylinders stocked for immediate		
9.9.	replacement. High purity gas and inline HEPA and VOC		
	filters are highly recommended.		
	The fertility center shall maintain a copy of operator		
	and safety manuals of all medical equipment and		
	inventory list with equipment location. All Medical		
9.10.	Equipment should be registered and documented		
	properly in the inventory which will be updated every		
	the Standards for Medical Equipment Management.		
	time a new equipment arrives prior to use. To follow		

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	Equipment validation, calibration, maintenance and		
9.11.	repair must be documented and records retained.		
	Employ a biomedical engineer or maintain a service		
	contract with a certified maintenance company to		
9.12.	ensure safety, reliability, validity and efficiency of		
	medical devices and mechanical equipment.		
	Accepted ranges of use for all measured parameters		
0.40	should be determined and recorded. If measures are		
9.13.	out of range, correction should be made and their		
	effectiveness verified.		
0.44	For every item of equipment, the instruction manual		
9.14.	and the simplified instructions should be available.		
	Malfunctioning equipment and those under		
9.15.	maintenance should be labelled out of use to avoid its		
	usage and stored in a proper allocated area.		
	Critical equipment such as incubators, fridges, freezers		
0.16	and liquid nitrogen cryo- storage units should be		
9.16.	continuously monitored and equipped with alarm		
	systems.		
	An automatic emergency backup power system must		
9.17.	be in place for all critical equipment. e.g.: includes		
	incubator, fridge, and freezers.		
	Cryopreservation storage units should be continuously		
1	, ,		
0.18	monitored and equipped with alarm systems,		
9.18.	, ,		
9.18.	monitored and equipped with alarm systems, detecting any out of range temperature and/or levels of liquid nitrogen (LN2).		
	monitored and equipped with alarm systems, detecting any out of range temperature and/or levels of liquid nitrogen (LN2). Standard Six: Medical Assisted Reproduction		
9.18. 10.	monitored and equipped with alarm systems, detecting any out of range temperature and/or levels of liquid nitrogen (LN2). Standard Six: Medical Assisted Reproduction Procedures Terms and Conditions/ Pre-Requisistes		
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İ	Centers must hold the highest controls when handling		1	
	fertilized or unfertilized oocytes and frozen sperms,			
10.9.	and provide the upmost caution and precaution to			
10.5.	preserve them and prevent their use in unauthorized			
	ways, such as exploitation, replacement, or mixing.			
	Standard Seven: Approved Medical Assisted			
11.	Procedures			
	The number of times of oocytes (egg retrieval			
11.1.	procedures) for the purpose of fertilization should not			
	exceed six times per year per patient.			
	Patient health risks such as poor responder patients			
11.1.1	and physician assessment must be taken into			
	consideration.			
11.2.	Embryo transfer should not exceed two embryos at			
11.2.	one time.			
	High risks patients and/ or patients with chronic			
	disease that is associated with an increased risk of			
11.3.	complications to the mother or fetus require a medical			
11.5.	report from a specialized treating physician indicating			
	the safety of fertility treatment before commencing			
	the fertility treatment.			
	It is permissible to fertilize oocytes that are sufficient			
11.4.	for multiple implantations, according to the conditions			
	and controls determined by the executive decree.			
	The fertility center shall ensure the highest medical,			
	administrative, safety and other accuracy measures			
11.5.	when fertilizing a number of eggs for multiple			
11.5.	implantation in order to prevent eggs from mixing with			
	others or using them in ways beyond the permissible			
	procedures by providing the following:			
	A detailed process that will ensure the correct and			
11.5.2	approved steps taken to ensure traceability of the			
	gametes and ensuring the time and place of collection.			
	A confirmatory report detailing the number of			
11.5.3	preserved gametes/ embryos mentioning the duration			
	of time the gametes/ embryos will be preserved for.			
	A clear process for the separation of gametes/embryos			
11.5.4	of the viral positive parents from other			
	gametes/embryos originating from viral negative			
11.0	parents.			
11.8.	Preservation and disposal:			
	The fertility center shall have in place evidence of			
11 0 3	contacting the concerned parties or the spouses in the			
11.8.3	case of cryo-storage expiry with frequent reminders			
	decided by the fertility center as per internal policies			
	and procedures.	<u> </u>		

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a. b. c.	Fertilized eggs that were not implanted into the wife should be disposed (left without medical care until they naturally perish, unless concerned parties request otherwise) with clear documentation in the medical file in the following cases: The death of one of the spouses. Ending of the marital relationship. Spouses request. Expiry of the preservation period without a request for		
d.	extension (after five years) with evidence of contacting the concerned parties. Where there is no need for the rest of the fertilized		
e.	eggs, or in cases where a legal or a medical reason prevents their implantation.		
11.8.5	Unfertilized eggs and frozen sperms should be allowed to perish in the following cases:		
a.	The request of the concerned parties.		
b.	Expiry of the preservation period without a request for extension as per agreement and signed consent with evidence of contacting the concerned party.		
11.9.	It is prohibited to take samples of unfertilized or fertilized eggs or frozen sperms that were prepared inside the country and send them outside, or to bring these samples into the country if they were prepared outside, except in accordance with the controls and procedures determined by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.		
11.10.1	In the case of request for transfer, patients must abide by the internal policies and procedures of the fertility center. Facilities must fill the "Request of Frozen Specimen Transfer" form and submit to DHA. Refer to Service Description (dha.gov.ae).		
12.	Standard Eight: Patient Safety		
12.1.	To ensure patient safety, the fertility center shall ensure the availability of electronic medical records for patients is documented as per the DHA Policy for Health Data Quality with the following but not limited to:		
12.1.1	Patient Emirates I.D or Passport		
12.1.2	Medical history and family history	 	
12.1.3	Evidence of consultation, physical examination and confirmatory Laboratory diagnostics		
12.1.4	No emerging issues since the last pre-op assessment.		
12.1.5	Informed consent for the procedure.		

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12.2.	The fertility center shall ensure providing the following		
42.2.2	to guarantee patient safety in the fertility center:		
12.2.2	Emergency training and preparedness of employees.		
12.2.3	Up to date medical records.		
12.2.4	Confirmation of functioning equipment and a backup plan.		
12.2.5	Fully functional and maintained medical devices.		
12.2.6	Control of concentrated electrolyte solutions.		
12.2.7	Assuring medication availability, accuracy and safe		
12.2.0	dosing as per DHA pharmacy guidelines.		
12.2.8	Infection control program,		
12.2.9	Single use of injection devices and insert of the IV line.		
12.2.11.	Stopping the procedure in the event if the patient		
12.2.12	health deteriorates.		
12.2.12.	Patient recovery plan.		
12.2.13.	Falls management plan.		
12.2.14.	International patient safety goals.		
12.2.16.	Patient post-op instructions, discharge and follow up.		
13.	Standard Nine: Infection Control		
13.4. a.	The infection control program shall support safe practice and ensure a safe environment for patients, health workers and fertility center visitors. The infection control system shall address factors related to the spread of infections among professional/patient and prevention which includes: The clinical procedures for safe patient care and minimizing risks by/cleaning/disinfection/sterilization. The essential measures for infection control such as hand hygiene, the personal protective equipment, the safe use and disposal of sharps, the use of aseptic		
C.	"non-touch" technique for all invasive procedures, reprocessing of reusable instruments and equipment, routine environmental cleaning, waste management, respiratory hygiene and cough etiquette, appropriate handling of linen. Healthcare professional vaccination and		
d.	immunizations as per DHA's policy for health screening and Immunization of healthcare professional.		
e.	Frequent monitoring auditing of demonstrated or suspected spread of infection and of working practices within the fertility center.		
f.	Environmental cleaning, single use items and reprocessing of sterile instruments.		
h.	Sterilization may be outsourced and is subject to DHA approval.		

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i.	In case sterilization is not outsourced then there should be a sterilizing area, which can be located near the procedure room with an adequate high-speed autoclave machine. Cleaning and sterilizing medical tools should be done in a sterilizing area next to the cleaning room for the tools to be cleaned, sterilized and then received from the cleaning room, preferably through a window passage.		
i.	An active infection prevention surveillance program and ongoing educational competency evaluation of employees regarding activities pre- procedure, intraprocedure and post procedure phases that are necessary for employee and patient safety.		
14.	Standard Ten: Research and Medical Trials		
14.2.	All research concerning medical assisted reproductive procedures and other subjects relating to assisted reproduction require approval from DHA and Dubai Ethical Committee as per Clinicals Trials Policy.		
14.3.	Obtain a written consent of each of the spouses and concerned parties.		
14.4.	The consent to the spouses or the concerned parties should include the following information:		
14.4.1	Clarify to the spouses that refusal from agreeing to the research will not negatively impact their treatment at the fertility center.		
14.4.2	Clarify the purpose and impact of the scientific research.		
14.4.3	The expected period it will take to complete the research.		
14.10.	When using gametes or embryos in research, the following should be taken into consideration:		
14.10.1.	Refraining from using them for other than the specific purpose of the search.		
14.10.2.	The consent of the spouses or the concerned parties to conduct the research should not be a result of any financial or other compensation, nor the result of physical or moral persuasion, nor that the consent is based on fraud or deception.		
16.	Standard Twelve: Medical Records		
16.2.	Patients' identification in the medical records (Electronic or Physical), as per Ministerial decision No. (236) of 2022 Concerning Records of Operations in Assisted Reproduction Centers shall include, but not limited to the following:		
16.2.1	Fertility center name and logo.		

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ĺ	Name of the spouses or concerned parties with	ſ	1	1 1
16.2.2	pictures and copy of Emirates IDs or passports for both			
10.2.2	spouses or concerned parties.			
16.2.3	Nationality of spouses/concerned parties.			
16.2.4	Date of birth.			
16.2.5	Medical record number.			
16.2.6	Dates of visit.			
16.2.7	Name of treating physician.			
	Address, phone number and email address of spouses/			
16.2.8	concerned parties.			
16.2.9	Date of first registration of patient.			
	Confirmation of receiving a copy of the passport or			
	Emirates ID, recent pictures of each of the spouses or			
16.2.10.	concerned parties and a copy of attested marriage			
	certificate (for spouses).			
	Patient Medical record shall include all the patient			
16.3.	identification information in addition but not limited to			
	the following:			
16.3.1	Current health status of the spouses (or concerned			
16.3.1	parties).			
16.3.2	Medical history.			
16.3.3	Presence of chronic and/or genetic diseases.			
16.3.4	Clinical and physical examination results.			
16.3.5	Medical test results.			
16.3.6	Management plan and selected assisted reproduction			
10.3.0	technique.			
16.3.7	Sperm characteristics and status/fate of every sperm			
	sample unused.			
16.3.8	Number of eggs retrieved from the patient.			
16.3.9	Number of fertilized eggs.			
16.3.10.	Each embryo characteristics (number of cells and			
10.0.120.	types).			
16.3.11.	Fate/ status and use of each embryo (transfer,			
	freezing, disposal, use for research).			
16.3.12.	Treating physician's notes following each visit.			
16.3.13.	Results of ultrasound following each visit.			
16.3.14.	Medication information (number and type of			
	medications) for each treatment cycle.			
16.3.15.	Record of the name and signature of the embryologist			
	and treating physician handling the procedures.			
16.3.16.	Traceability records of media and consumables are			
	recorded in the ART Laboratory Records of the patient.			
	Coordination between the laboratory team and the			
16.3.17.	treating physicians' team for updates on the fate of			
	the embryos and recording the results in the medical			
	files.			

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ART Laboratory records, shall include all the information in the identification card, in addition to, but not limited to the following: 16.4.1 Place, date and time of specimen/sample collection. Record of identification code and specimen/sample reference. Evidence records of manual or electronic witnessing that has taken place during all critical steps in the ART Laboratory journey of the gametes (collection, processing, mixing of gametes, transferring from container to container, cryopreserving, thawing and transferring back to the patient). In case of pre-implantation genetic testing and biopsy these steps should be witnessed as well. Sperm characteristics or report of sperm examination and diagnosis. 16.4.5 Results of specimen/sample tests. 16.4.6 Number of eggs retrieved from the patient. 16.4.7 Rate/ status of all the retrieved eggs. 16.4.8 Number of fertilized eggs. 16.4.9 Records/Traceability of all ART consumables that come into contact with the gametes/embryos. 16.4.10 Each embryo characteristics (number of cells and grades). 16.4.11. Fate/status of each embryo (transfer, freezing, disposal, use for research). 16.4.12. Incubator details and location of specimen/samples in all the incubators. Records of media and plasticware as part of ART consumables. 16.4.13. All ART laboratory records shove shall be signed by the laboratory operator. 16.5.1 Laboratory records when receiving the seminal fluid shall include: 16.5.2 Method used to procure the sample. 16.5.3 Days of abstinence. 16.5.4 Room/incubator temperature. If sample not received as per standards i.e. uncapped, not labelled, leaking etc. to be rejected and patient to be requested to produce a second sample. 16.5.6 Presence of any viscosity and/ or gelatinous material in the semen sample.	16.3.18.	Copy of all required consents and approvals for each treatment cycle.		
but not limited to the following:		ART Laboratory records, shall include all the		
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:::: = m::: p::=:	16.5.6	the semen sample.		

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	Store record should include all the information about		
167	fertility center assets including but not limited to		
16.7.	furniture, machines, equipment, solutions,		
	medications and dates of productions and expiry.		
	Employees' record should include names of all		
	employees working in the fertility center, each		
	separately, with their identification, roles,		
16.8.	responsibilities, reporting manager and all related		
10.8.	human resource information including their		
	performance evaluation and employee's		
	immunizations as per DHA policy for Health Screening		
	and Immunization of Healthcare professionals.		
18.	Standard Fourteen: Laboratory Requirements and		
10.	Safety Controls		
	The laboratory director shall ensure the fertility		
18.2.	center's quality management system is implemented		
10.2.	and monitored in ART laboratories of which include		
	but not limited to:		
18.2.2	Having validated, written instructions for each process		
_	(SOP), including management of adverse events.		
	Ensuring full traceability of cells and tissues, materials,		
18.2.3	equipment and personnel involved in specific		
	laboratory activities, with records maintained accordingly.		
	Documentation system should be in place when		
	dealing with non- compliance, emergencies, errors,		
	adverse events and complaints. Corrective and		
18.2.4	preventive actions, implementation dates and		
	assessments of their effectiveness should be		
	documented.		
	Confirming that all media/reagents/disposables are		
10.2.5	tested for quality and have appropriate quality		
18.2.5	certificates as well as are from any form of bacterial		
	infection to produce valid and reliable results.		
	Ensuring proper and periodic equipment maintenance,	 	
18.2.6	service and calibration- verifying conformance to		
	specifications.		
	Quality Control records should be maintained and		
18.2.7	reviewed, including documentation of results and any		
	corrective action taken.		
18.3.	Every ART laboratory should have an up-to-date		
	disaster preparedness or emergency plan.		
10 2 1	Andrology and embryology laboratories need to have		
18.3.1	an exit strategy that includes a sensible way to salvage		
	the storage tanks with the cryopreserved specimens. To optimize environmental conditions, laboratory air		
a.	should be subjected to high-efficiency particulate air		
	should be subjected to high-efficiency particulate all		

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	(HEPA) and VOC control (Grade A environment with a		
	background of at least GMP Grade D) Laboratory access should be restricted to authorized		
18.8.	personnel.		
18.11.	Hand washing facilities should be placed outside and within the laboratory.		
	Mandatory Protective measures for laboratory		
18.15.	employees to ensure aseptic conditions for tissue,		
	gametes and embryos include:		
18.15.1.	Strict adherence to employees' hygiene regulations and aseptic techniques.		
18.15.2.	Use of protective laboratory clothing, preferably with low particle shedding.		
18.15.3.	Use of hairnets and nontoxic, non-powdered gloves and masks where appropriate.		
18.15.4.	Use of appropriate Biological Class II flow hood cabinet in order to protect sample and operator.		
18.15.5.	Use of mechanical pipetting devices.		
18.15.6.	Disposal of single-use consumables immediately into proper waste containers.		
18.15.7.	Potentially infectious materials must be disposed of in a manner that protects laboratory workers and other employees from exposure. Viral- positive waste segregated into a separate bin, labelled and disposed of according to biosafety policies).		
18.15.8.	Needles, glassware and other sharp objects should be handles with extreme caution and discarded into sharps containers.		
18.15.9.	Disinfectants with proven compatibility and efficacy for an ART laboratory should be used.		
18.15.10.	Food, gum, drinks and tobacco are strictly forbidden within the ART Laboratory.		
18.15.11.	Use of cosmetics and perfumes should be avoided within the ART Laboratory.		
18.15.12.	Employees should be appropriately attired to diminish possible sources of contamination.		
18.16.	Precautions that are encountered in ART laboratories related to samples/specimen that carry the risk of disease transmission include semen, blood and follicular fluid. Blood samples from patients with gametes/embryos destined to be cryopreserved should be tested for infectious diseases before cryopreservation.		
18.17.	Sanitation should occur when there is a spill and at the end of every shift.		
18.18.	Facilities should be available to cryopreserve and store biological material.		

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18.19.	During storage and handling of cryopreserved material, high care should be taken to maintain adequate and safe conditions, temperatures should never rise above -130 C.		
18.20.	The protocols should be present and clear for employees to avoid any form of exploitation, mixing or replacement of gametes with incorrect ones and they include:		
18.20.1.	Presence of approved infection control processes, sanitation and sterilization processes for equipment and fertility center, and separation of viral positive gametes/embryos from others in the ART laboratory.		
18.20.2.	Evaluate and record number of mature oocytes and have a clear policy and procedure on the fate of the non-mature oocyte collected.		
18.20.3.	Evaluate and document semen fluid parameters.		
18.21.	Cryopreservation documentation on biological materials include the following:		
18.21.1.	Labelling of devices.		
18.21.2.	Cryopreservation method.		
18.21.3.	Date and time of cryopreservation.		
18.21.4.	ART Laboratory Operator.		
18.21.5.	Embryo quality and stage of development.		
18.21.6.	Number of oocytes or embryos per device.		
18.21.7.	Number of devices stored per patient.		
18.21.8.	Location of stored samples.		
18.23.	Every ART laboratory should have in place an effective system to uniquely identify, trace and locate reproductive cells.		
18.23.1.	Before starting any procedure, the Laboratory must be given each patient's unique identification code which clearly identifies and refers to the patient's documentation. Each treatment cycle must be assigned a unique code.		
18.23.2.	Consent forms, clinical data and blood tests should be made available to the laboratory employees.		
18.23.3.	Rules concerning the correct identification and processing of reproductive cells must be established in the laboratory by a system of codes and checks including:		
C.	Direct verification of patient identity and correspondence with their assigned unique identification code is required at every critical step. Patients should be directly asked to give their own identifying information (full name and date of birth) before artificial insemination/embryo transfer.		

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d.	All devices containing biological material must be clearly and permanently labelled with the unique patient identification code and date of treatment.		
e.	Biological material from different patient must not be processed in the same working area at the same time.		
f.	Incubators and cryo- storage systems should be organized to ensure easy access and identification of the biological materials inside.		
g.	Products and material used with biological materials must be traceable.		
18.24.	Identity check before the oocyte retrieval is mandatory.		
18.25.	Timing of oocyte retrieval, number of collected oocytes and the operator should be documented.		
18.26.	Semen samples should be collected in non-spermicidal sterile, plastic containers with clear labelling and identification confirmed by the patient.		
18.27.	Records should be kept of the type of container used, the time and place of collection as well as the time between collection and analysis/preparation.		
18.28.	The following data on sperm preparation should be documented:		
18.28.1.	Sample origin (ejaculate, epididymal/testicular, fresh/frozen).		
18.28.2.	Preparation method.		
18.28.3.	Pre- and post-preparation sperm parameters and any dilution carried out.		
18.31.	Information to be provided to Laboratory personnel working with chemicals include:		
18.31.1.	The signs and symptoms associated with exposures to hazardous chemicals used in the laboratory.		
18.31.2.	The location and availability of known reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, the Material Safety Data Sheets received from the chemical supplier.		
18.31.3.	The circumstances under which a particular laboratory operation, procedure or activity requires prior approval from the employer or the employer's designee before being implemented.		
19.	Standard Fifteen: Genetic Screening and Testing		
19.1.	Genetic Screening of Gametes and Embryos may be performed at fertility centers based on the approval of a licensed Specialist Physician and after the consent of the person from whom the sperm and the unfertilized eggs are extracted from, provided that the screening is		

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	being conducted for the purpose of identifying and preventing hereditary diseases.		
19.2.	It is permissible to conduct genetic testing using Pre- implantation Genetic Testing (PGT) processes before implanting the embryo in the mother's uterus based on the following conditions:		
19.2.1	Defining need to conduct the genetic testing before implanting the embryo in the mother's uterus from the fertility center's genetic counsellor or an affiliated genetic Laboratory to the fertility center.		
19.2.2	Provision of multi-disciplinary team from the fertility center to conduct the genetic which includes:		
h.	Reproductive Medicine and Infertility Specialist or Reproductive Endocrinology and Infertility Specialist.		
i.	Embryologist.		
j.	Genetic counsellor.		
19.2.3	Approval and signed consent forms from married couple and non-married concerned parties who wish to conduct the genetic testing.		
19.2.4	Fertility centers should provide the couple with information detailing the genetic testing process with specific emphasis on the following points:		
k.	Presence of a medical genetic concern in the family or from either spouse that requires further testing to the embryo.		
I.	The process that will take place and its side effects.		
m.	The genetic test does not guarantee pregnancy success as well as does not prevent miscarriage from happening in the case of pregnancy.		
n.	The financial cost and the mental health strain that could occur in the case of unsuccessful pregnancy even though genetic testing was conducted preimplantation.		
0.	The average rate of false diagnosis in the genetic testing.		
19.3.	Conducting genetic testing to the embryos for the purpose of Human Leukocyte Antigen (HLA) matching the fertility center must acquire a medical report from the physician treating the patient asking for the necessity of this test.		
Appendix	Minimum Equipment in Art Laboratory and		
1:	Andrology Unit		
App1.1	2 TRI-GAS/CO2 incubator		
App1.2	BIOLOGICAL CLASS II HOOD Qt. 3 (2 in embryology Laboratory and 1 in Andrology Laboratory) - Backup 1		

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App1.3	Stereomicroscope - Qt. 3 (the number should match			
	the biological class II hood ratio 1:1) - Backup 1			
App1.4	1 Air filtration tower			
App1.5	1 Phase contrast microscope			
App1.6	1 Tube heater			
App1.7	1 Thermometer			
App1.8	1 ANTIVIBRATION TABLE			
App1.9	1 portable incubator			
App1.10	1 Continuous Monitoring System (24hrs)			
App1.11	2 O2 Sensor			
App1.12	2 Laboratory Oven			
App1.13	2 Gas Automatic Manifold			
App1.14	1 Laser System (if fertility center offers embryo genetic			
	testing) and 1 back up			
Appendix				
2:	Minimum Machinery Backup in Case of Emergency			
App 2.1	1 Inverted Microscope and 1 Backup			
App 2.2	1 Micromanipulator and 1 backup			
App 2.3	1 Centrifuge and 1 backup			
App 2.4	2 Freezing Tanks and 1 backup			
App 2.5	2 Electrical pipettes and 1 backup			
App 2.6	2 Variable pipettes and 1 backup			
App 2.7	1 O2/CO2 GAS ANALYZER (the machine name must be			
	the same name as stated) and 1 backup			
App 2.8	2Pharmaceutical fridge			
App 2.9	1 of each Camera and monitor			
App 2.10	1 Computer			
App 2.11	1 UPS BACKUP			
App 2.12	1 Backup warm plate and 1 backup			
App 2.13	1 Digital weighing media			
Appendix				
3	Minimum Operating Room Equipment			
App3.1	1 IVF Vacuum pump and 1 backup			
App3.2	1 Suction Unit			
App3.3	1 Laparoscopy Unit (optional for hysteroscopy)			
App3.4	1 Tele-cam			
App3.5	1 Endoflater (optional for hysteroscopy)			
App3.6	1 Light source XEN (optional for hysteroscopy)			
App3.7	1 Monitor			
App3.8	1 Anesthesia machine			
App3.9	1 OR table			
App3.10	2 cardiac monitor O2 monitor			
	1 Crash cart & defibrillator along with Intubation Kit			
App3.11	(laryngoscope with different sized blades, ETT Tubes			
''	different sizes, LMA different sizes) and AMBU Bag			
A 2 . 1 2	with different sizes Ambu masks.			
App3.12	1 ultrasound			

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App3.13	1 OR lamp and 1 portable standby			
App3.14	1 Examination table			
App3.15	1 Hormone immunoassay (optional)			
APPENDIX				
4	Minimum Additional Equipment in OT Room			
App 4.1	1 Water bath or bottle holder heater for flush			
App 4.2	2 Block heater for tubes			
App 4.3	1 Surgical light			
App 4.4	1 Anesthesia pen tents			
App 4.5	1 Anesthesia cart			
App 4.6	1 Patient shifting trolley			
App 4.7	1 nursing trolley			
App 4.8	1 Surgical chair			
App 4.9	1 Instrumental trolley			
App 4.10	1 IV pole			
App 4.11	1 Wormer			
APPENDIX	List Of Approved Main and Associated Art			
5	Procedures.			
1	Main ART procedures: Ovulation induction and ovarian stimulation.	+ +		
p.	Fertilization Conventional In Vitro (IVF).	+ +		
q. r.	Intra-cytoplasmic Selected Sperm Injection (ICSI).	+		
S.	Intra-Cytopiasinic Selected Sperin injection (icsi).			
2	ART Associated Procedures:	+		
t	Artificial Oocyte Activation.			
u	Embryo Biopsy.	+		
V	Embryo culture media analysis.			
w	Embryo transfer (ET).			
X	Frozen Embryo Transfer (FET).			
У	Frozen Oocytes Intracytoplasmic Sperm Injection.			
z	Gamete and embryo freezing.			
aa.	Gamete and embryo thawing.			
bb	Intracytoplasmic Morphologically Selected Sperm Injection (IMSI).			
СС	Microsurgical Testicular Sperm Extraction (Micro-TESE).			
dd	Oocyte In Vitro Maturation (IVM).			
ee	Ovarian and Testicular Tissue Cryo-preservation.			
ff	Percutaneous Epididymal Sperm Aspiration (PESA).			
gg	Polar Body Biopsy.			
hh	Preconception, preimplantation and prenatal genetic services			
ii	Surgical Correction for Obstructive Azoospermia.			
jj	Testicular Sperm Aspiration (TESA).			
kk	Testicular Sperm Extraction (TESE).			
II	Oocyte Retrieval (Ultrasound guided).			
	,			

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mm	Use of Hyaluronan based media.			
nn	Varicocele repair.			
00	Zone assisted hatching.			

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