

## 26.0 IVF Unit (Fertilization Centers)

### 26.1 Introduction

#### 26.1.1 Description

The IVF Unit will provide facilities for In vitro fertilization (IVF) procedures. IVF is one of several Assisted Reproductive Techniques (ART) used to help infertile couples to conceive a child. The procedure involves removal of eggs (mature Oocyte or Ovum) from the woman's ovary. Ova are then fertilized with sperm in a laboratory procedure (in vitro). If fertilization occurs, a fertilized ovum, after undergoing several cell divisions, is transferred to the mother for normal development in the uterus, or frozen for later implantation.

The IVF laboratory may use Intracytoplasmic Sperm Injection (ICSI) in the process of IVF.

Services provided by the IVF Unit include:

- Patient consultation and interview on an outpatient basis
- Pretreatment assessment
- Blood collection
- Semen collection
- Artificial insemination
- Ovarian stimulation therapy
- Ultrasound examination
- Oocyte (egg) collection
- Embryo culture
- In vitro/ICSI fertilization
- Cryopreservation
- Embryo transfer
- Recovery.

#### 26.1.2 Licensing of Unit

IVF Units (Fertilization Centers) in the UAE require licensing according to the Cabinet Decision No 36 of 2009 Issuing the Implementing Regulation of Federal Law No (11) of 2008 Concerning the Licensing of Fertilization in the State. All IVF Units are to comply with the requirements stated in the Cabinet Decision document.

### 26.2 Planning

#### 26.2.1 Planning Models

The IVF Unit may be developed as:

- A stand-alone unit
- A dedicated Unit within a general hospital.

### 26.2.2 Functional Areas

The IVF Unit may consist of a number of Functional Zones:

#### Entry/Consult Zone

- Entry/Reception and waiting areas
- Administration/Records
- Interview Room/s
- Consult/Examination/Treatment Room/s
- Ultrasound room/s
- Collection Room/s with Ensuite shower and Toilet
- Public Toilets.

#### Patient Procedural Zone

- Operating Room/s for oocyte (egg) collection and re-implantation
- Recovery areas
- Change areas and toilets for staff and patients.

#### Laboratory Zone

- Laboratories (Embryology, IVF, ICSI, Andrology, Genetics)
- Cryopreservation facilities
- Gas Bottle Store.

#### Staff and Support Zone

- Clean-up and Disposal room
- Store rooms and Sterile store
- Offices, meeting rooms, staff room
- Sterilizing area: if the IVF unit is a stand-alone building, dedicated sterilizing facilities will be required.

#### Entry/Reception

The Entry and Reception provides the first point of contact for clients. Waiting areas should be calm, comforting and relaxing. They should be divided for gender separation.

#### Collection Rooms

Collection room/s should be discreet and private, enclosed rooms for collection of sperm samples.

#### Operating Rooms

Operating room/s will include equipment and facilities for egg collection and embryo transfer, under local anesthetic. Operating rooms will require adjacent Patient and Staff Change Rooms, scrub sink and patient toilet facilities.

#### Laboratories

Strict protocols for handling and labelling patient specimens in all laboratory areas are required. Laboratory areas should be zoned in a restricted staff access only area.

### Embryology/IVF/ICSI Laboratory

The embryology laboratory provides facilities for the handling, preparation, culture and storage of human gametes (sperm and oocytes). Due to the sensitive nature of its functions, the embryology laboratory should be located in a secure and sterile area away from the outpatient/clinic facilities but in close proximity to the procedure room where the oocytes (eggs) are collected. The laboratory is responsible for identifying oocytes in ovarian fluid, culturing these eggs with the partner's sperm, and embryo examination prior to embryo implantation into the patient.

The ICSI (Intracytoplasmic Sperm Injection) laboratory involves the process of injecting a single sperm into the nucleus of the egg using a microscopic needle without affecting the viability of the egg. The zygote (fertilized egg) is then monitored until it starts to divide forming a small cluster of cells known as the blastocyst (in approximately 5 days in the lab) which is then reimplanted to form an embryo.

### Andrology Laboratory

The Andrology laboratory performs the evaluation, testing, preparation and storage of sperm specimens. Diagnostic procedures include:

- Semen analysis determine sperm count, motility, viability and morphology,
- Preparation of sperm for fertilization and Intrauterine Insemination (IUI) and thawing of frozen specimens.

### Genetics Laboratory

The Genetics Laboratory undertakes cytogenetics studies of the embryo cells, particularly the nucleus which contains the chromosomes that carry genes and their DNA to determine the status of the embryo after IVF and before re-implantation, also referred to as Pre-implantation Genetic Diagnosis (PGD).

This process can also identify and diagnose abnormalities and genetic diseases that may accompany the pregnancy by the use of sophisticated techniques such as Fluorescence In-Situ Hybridization (FISH) or Polymerase Chain Reaction (PCR).

### Cryopreservation Facilities

Facilities for cryopreservation will include a separate room for storage of reproductive cells (gametes, zygotes and embryos) in liquid nitrogen storage tanks. Strict protocols on the method of storage and specimen labelling are required for this process (refer to regulations on the licensing of Fertilization Centers in UAE).

## 26.2.3 *Functional Relationships*

### External

The IVF Unit may have a close working relationship with

- Pathology Laboratories
- Pharmacy
- Medical Imaging.

The IVF Unit should be ideally located on the Ground floor. If located on an upper floor, there must be a stretcher carrying lift available.

### Internal

Within the IVF Unit the following relationships are significant:

- Laboratory areas should be located with a direct adjacent relationship to the Operating rooms for egg collection and re-implantation
- Laboratories should be located in a separate zone away from the outpatient/consult area and secured.

- Sperm Collection rooms have a close functional relationship with the Andrology Laboratory; specimens require rapid transfer to the laboratory to avoid deterioration.
- Office areas should be separate from the treatment and laboratory zone.

## 26.3 Design

### 26.3.1 General

The design of the unit should create a pleasant, reassuring atmosphere for patients whilst retaining the necessary functional requirements associated with clinical spaces and laboratories. Ideally, waiting areas should be divided into several small 'Family Waiting' zones or 'nooks' to allow partners or close relatives to wait in relative privacy. In addition to the above, in the UAE, separate zones for male and female patients should be provided.

Consideration may be given to a private and discreet entry area for patients, away from general public view.

### 26.3.2 Environmental Considerations

#### Natural Light

Natural light is highly desirable where achievable, particularly for laboratory areas where staff will spend a majority of their time.

#### Privacy

Privacy is essential for confidential conversations and interviews and will minimize stress and discomfort for patients.

Patient privacy and confidentiality can be enhanced by provision of private interview rooms for personal discussions between staff and patients.

#### Acoustics

Confidential patient information is exchanged between patients and staff, therefore the Interview, Consult, Collection and Treatment rooms should be acoustically treated to maximize privacy.

In acoustically treated rooms, return air grilles should be acoustically treated to avoid transfer of conversations to adjacent areas. Door grilles and undercuts to these areas should be avoided.

### 26.3.3 Space Standards and Components

Laboratories and storage areas shall be sized to suit the design requirements of the equipment to be used, to provide a safe working environment and to allow the effective movement of staff.

#### Ergonomics

Laboratories should be designed with consideration to ergonomics to ensure an optimal working environment. Aspects for consideration will include height of benches and chairs, height of equipment in constant use such as microscopes and bio-safety cabinets. Refer also to Part C of these Guidelines.

### 26.3.4 Safety and Security

Zones within the Unit will require access control to prevent unauthorized access, particularly laboratory areas, cryopreservation areas and staff office areas.

A separate room or a fume hood should be available for procedures requiring use of fixatives.

### 26.3.5 *Finishes*

Floor finishes should be appropriate to the function of the space. Consideration must be given to the appearance and quality of environment required e.g. non-institutional, acoustic performance, slip resistance, infection control, movement of trolleys and maintenance.

Laboratory, Storage and Procedural areas should have vinyl or similar impervious floors; patient recovery areas and staff offices may be carpeted.

Ceiling and wall finishes, laboratory cabinetry and bench tops must be easily cleaned.

Refer also to Part C and D of these Guidelines.

### 26.3.6 *Fixtures and Fittings*

Critical items of equipment including incubators and liquid nitrogen storage should be temperature alarmed and monitored. Consideration should also be given to emergency and uninterruptible (UPS) power supplies to critical equipment.

### 26.3.7 *Building Service Requirements*

Laboratories will require air-conditioning with controlled humidity and temperature to provide an environment that minimizes staff distraction and fatigue.

Procedure rooms will require temperature regulation to assist in maintaining patient temperature at 37 degrees C and prevent deterioration of oocytes.

Power supplies to critical equipment such as incubators, refrigerators, biosafety cabinets should be on emergency supply with generator back-up.

### 26.3.8 *Infection Control*

All assisted reproductive techniques involve handling of biological material and therefore pose a potential infection control risk to staff and to other patients' reproductive cells (gametes, zygotes, embryos).

Strict infection control measures are required within the unit to protect laboratory staff from potentially contaminated body fluids (follicular fluid etc. ) and to ensure aseptic environment for reproductive cells, preventing cross infection. Measures will include:

- Handbasins for staff hand washing in all patient areas and laboratories
- Use of laboratory clothing in laboratories
- Use of theatre clothing in procedure rooms
- Use of laminar flow biosafety cabinets in laboratories (a Class II cabinet should be available for handling of contaminated samples)
- Sharps containers and clinical waste collection and removal.

## 26.4 Components of the Unit

The IVF Unit will contain a combination of Standard Components and Non-Standard Components. Provide Standard Components to comply with details in the Standard Components described in these Guidelines. Refer also to Standard Components Room Data Sheets and Room Layout Sheets.

### 26.4.1 *Non-Standard Components*

#### Collection Room

##### Description and Function

The Collection Rooms are private and enclosed rooms used for collection of sperm specimens from patients.

##### Location and Relationships

The Collection rooms have a close functional relationship with the Andrology laboratory; rapid delivery of specimens is required to prevent cell deterioration. The Collection rooms will require an Ensuite shower/toilet.

##### Considerations

The rooms should include

- Comfortable seating
- Handbasin and fittings including soap and paper towel dispenser
- TV, DVD player
- Acoustic treatment
- A pass-through hatch for specimens.

#### IVF/ICSI Laboratory

##### Description and Function

Refer to Functional Areas for a description and functions of the IVF/ICSI laboratory. The space will be enclosed for specialty laboratory functions.

##### Location and Relationships

The IVF/ICSI Laboratory should be located with a direct relationship to the Operating Room/s for oocyte collection and reimplantation. A pass-through hatch from the Laboratory to each Operating Room is recommended.

Staff change and hand wash areas should be located at the laboratory entry.

##### Considerations

Fittings and Equipment to be located in this laboratory will include:

- Laboratory benches and storage units
- Laminar flow IVF workstation cabinets
- Bench top microscopes, inverted microscope, stereomicroscope
- CO2 Incubators
- Electrical pipettes
- Variable pipettes
- Fyrite analyzer (CO2 and O2 gas analyzer)
- Laboratory refrigerator
- Hand basin and staff change area at entry.

Laboratory equipment will require emergency power, temperature monitoring and alarms.

The construction of the lab should ensure aseptic and optimal handling of reproductive tissue during all stages of the process. Air-conditioning for the Laboratory will include HEPA filters, controlled humidity (20%) and controlled temperature (22 – 24 degrees C). Access to the laboratory should be limited.

## Andrology Laboratory

### Description and Function

Refer to Functional Areas for a description and functions of the Andrology laboratory.

The laboratory will include benches and storage units for examination of specimens. The space will be enclosed for specialty laboratory functions.

### Location and Relationships

The Andrology Laboratory has a close working relationship with the IVF/ICSI Laboratories. The Collection Room/s should be located in close proximity.

### Considerations

Fittings and Equipment to be located in this laboratory will include:

- Laboratory benches and storage units
- Laminar flow IVF workstation cabinets
- Bench top microscopes
- Automatic sperm analyzing units
- CO2 Incubators
- Electrical pipettes
- Variable pipettes
- Mackler cell
- Fyrite analyzer (CO2 and O2 gas analyzer)
- Laboratory refrigerator
- Hand basin and staff change area at entry.

Laboratory equipment will require emergency power, temperature monitoring and alarms.

The construction of the lab should ensure aseptic and optimal handling of reproductive tissue during all stages of the process. Air-conditioning for the Laboratory will include HEPA filters, controlled humidity (20%) and controlled temperature (22–24 degrees C). Access to the laboratory should be limited.

## Genetics Laboratory

### Description and Function

Refer to Functional Areas for a description and functions of the Genetics laboratory. The functions may be included in the IVF/ICSI Laboratory.

### Location and Relationships

The Genetics Laboratory has a close working relationship with the IVF/ICSI Laboratory.

### Considerations

Fittings and Equipment to be located in this laboratory will include:

- Laboratory benches and storage units
- Laminar flow IVF workstation cabinets
- Bench top microscopes
- Laboratory refrigerator
- Hand basin and staff change area at entry

Laboratory equipment will require emergency power, temperature monitoring and alarms.

The construction of the lab should ensure aseptic and optimal handling of reproductive tissue during all stages of the process.

Air-conditioning for the Laboratory will include HEPA filters, controlled humidity (20%) and controlled temperature (22–24 degrees C).

Access to the laboratory should be limited.

### Cryopreservation Store

#### Description and Function

Storage room for liquid nitrogen tanks containing frozen gametes. Nitrogen tanks should be stored in an enclosed space in case of nitrogen leakage.

#### Location and Relationships

The Cryopreservation storage area should be located in close proximity to the Laboratory areas, in an area with controlled access.

#### Considerations

A monitoring system is required for low levels of liquid nitrogen in the storage tanks and for high levels of nitrogen in the air.

Strict Cryopreservation protocols are required and will include:

- Infection control (minimizing the risk of cross contamination of frozen gametes, zygotes and embryos
- Labelling, packaging and documentation of tissue frozen.

Provide controlled access to the room.

### Sterilizing/Packaging

#### Description and Function

An area where cleaned and dried instruments are sorted, assembled into sets, packaged, and then sterilized in an autoclave.

#### Location and Relationships

The Sterilizing/Packing Room will be located adjacent to the Clean-up Room where the instruments are cleaned and decontaminated.

#### Considerations

Fittings and Equipment located in this room will include:

- Hand basin
- Benches and cupboards
- Instrument packing table
- Heat sealing device
- Autoclave
- Cooling trolleys.

The room requires a defined unidirectional workflow for instruments from clean to sterile and then to sterile store. Sterile stock should not be stored in this room to avoid the potential for mixing unsterilized instrument sets with sterile sets.



## 26.5 Schedule of Accommodation

### Typical IVF Unit (Fertilization Centers) at Levels 3 to 6

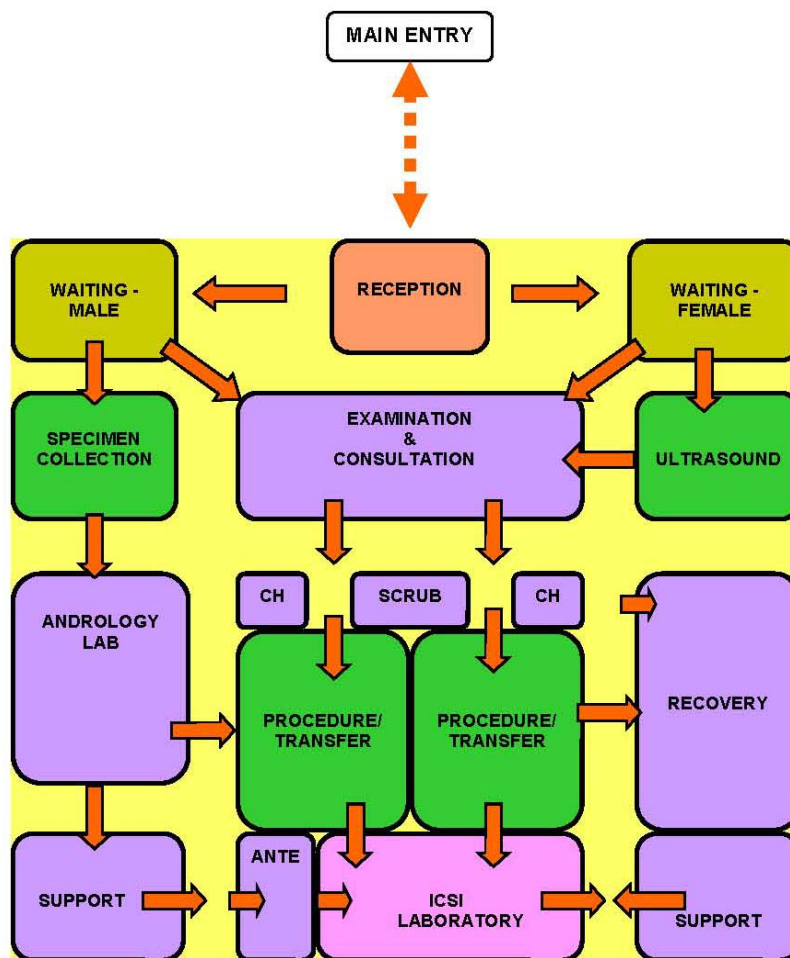
ROOM/SPACE	Standard Component				Level 3/4 Qty x m <sup>2</sup>			Level 5/6 Qty x m <sup>2</sup>			Remarks
<b>Entry/Consulting Area</b>											
Reception/Clerical	RECL-15-SJ				1	x	15	1	x	15	
Store – Photocopy/Stationery	STPS-8-SJ				1	x	8	1	x	8	
Store – Files	STFS-10-SJ				1	x	8	1	x	8	
Waiting – Male/Female	WAIT-10-SJ				2	x	10	2	x	15	Separate Female Waiting
Waiting – Family	WAIT-30-SJ				1	x	25	1	x	30	
Interview Room – Family	INTF-SJ				1	x	12	2	x	12	
Consult/Examination Room	CONS-SJ				3	x	14	4	x	14	
Collection Room					2	x	6	2	x	6	Semen samples
Ensuite – Shower/WC	ENS-ST-SJ				2	x	5	2	x	5	Adjacent to Semen Collection Rooms
Blood Collection Bay	BLDC-5-SJ				1	x	5	1	x	5	
Ultrasound	ULTR-SJ				1	x	14	2	x	14	
Toilet – Accessible	WCAC-SJ				1	x	6	1	x	6	May share general public amenities
Toilet – Public	WCPU-3-SJ				1	x	3	1	x	3	May share general public amenities
<b>Patient Procedural Area</b>					<b>2 Proc. Rooms</b>			<b>4 Proc. Rooms</b>			
Operating Room – General	ORGN-SJ				1	x	42	2	x	42	
Procedure Room	PROC-20-SJ				1	x	20	2	x	20	
Change Cubicle – Accessible Patient	CHPT-D-SJ				1	x	4	1	x	4	One adjacent to each Procedure Room
Toilet – Patient	WCPT-SJ				2	x	4	3	x	4	One adjacent to each Procedure Room; One adjacent to Recovery
Change – Staff (Male/Female)	CHST-12-SJ				2	x	12	2	x	14	
Scrub Up/Gowning	SCRB-6-SJ				2	x	6	4	x	6	One for each Operating/Procedure Room
Patient Bay – Holding/Recovery	PBTR-H-10-SJ				4	x	9	8	x	9	Two per Operating/Procedure room
Bay – Handwashing, Type B	BHWS-B-SJ				1	x	1	2	x	1	Refer to Part D
Bay – Beverage	BBEV-OP-SJ				1	x	5	1	x	5	
Bay – Linen	BLIN-SJ				1	x	2	1	x	2	
Bay – Resuscitation Trolley	BRES-SJ				1	x	1.5	1	x	1.5	
Clean Utility	CLUR-8-SJ CLUR-12-SJ				1	x	8	1	x	12	
Dirty Utility	DTUR-S-SJ DTUR-12-SJ				1	x	8	1	x	12	
Staff Station	SSTN-5-SJ SSTN-14-SJ				1	x	5	1	x	10	
Store – General	STGN-8-SJ				1	x	8	1	x	8	
<b>Laboratory Area</b>											
IVF/ICSI Laboratory					1	x	40	1	x	50	Size will be dependent on Service Plan
Andrology Laboratory					1	x	30	1	x	40	Size will be dependent on Service Plan
Genetics Laboratory					1	x	15	1	x	20	PGD functions
Cryopreservation Store					1	x	30	1	x	40	
Store – Gas Bottle					1	x	10	1	x	15	
Change – Staff (Male/Female)	CHST-12-SJ				2	x	10	2	x	10	Includes toilets and change facilities
<b>Support Areas</b>											
Clean-Up Room	CLUP-7-SJ				1	x	7	2	x	10	1 shared between 2 OR/Procedure rooms
Cleaner's Room	CLRM-5-SJ				1	x	5	1	x	5	
Disposal Room	DISP-8-SJ				1	x	5	1	x	8	

ROOM/SPACE	Standard Component				Level 3/4 Qty x m <sup>2</sup>			Level 5/6 Qty x m <sup>2</sup>			Remarks
Sterilising/Packing					1	x	15	1	x	20	Locate adjacent to Clean-up; Optional, may use SSU
Store – Sterile Stock	STSS-12-SJ				1	x	12	2	x	12	
<b>Staff Areas</b>											
Meeting Room – Medium/Large	MEET-L-30-SJ				1	x	20	1	x	30	
Office – Single Person, 12m <sup>2</sup>	OFF-S9-SJ Similar				1	x	12	1	x	12	Manager
Office – Single Person, 9m <sup>2</sup>	OFF-S9-SJ							1	x	9	Physician
Office – Single Person, 9m <sup>2</sup>	OFF-S9-SJ				1	x	9	1	x	9	Nursing
Office – Workstation	OFF-WS-SJ				1	x	5.5	2	x	5.5	Clerical support as required
Staff Room	SRM-15-SJ				1	x	15	1	x	20	
Property Bay – Staff	PROP-3-SJ				2	x	3	2	x	3	
<b>Net Department Total</b>					<b>621.0</b>			<b>910.5</b>			
<b>Circulation %</b>					<b>35</b>			<b>35</b>			
<b>Grand Total</b>					<b>838.4</b>			<b>1229.2</b>			

**Notes:**

- Areas noted in Schedules of Accommodation take precedence over all other areas noted in the FPU
- Rooms indicated in the schedule reflect the typical arrangement according to the Role Delineation
- Exact requirements for room quantities and sizes will reflect Key Planning Units identified in the Service Plan and the Operational Policies of the Unit
- Room sizes indicated should be viewed as a minimum requirement; variations are acceptable to reflect the needs of individual Unit
- Office areas are to be provided according to the Unit role delineation and staffing establishment; Executives and Managers may be responsible for more than one area but should have only one office assigned within the campus
- Staff and support rooms may be shared between Functional Planning Units dependent on location and accessibility to each unit and may provide scope to reduce duplication of facilities.

26.6 Functional Relationship Diagram



26.7 Further Reading

- Clinical and Laboratory Standards Institute (CLSI) (US). 'Laboratory Design; Approved Guideline Second edition' 2007. Retrieved from website: [http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCsQFjAA&url=http%3A%2F%2Fshopping.netsuite.com%2Fc.1253739%2Fsite%2FSample\\_pdf%2FQMS04A2\\_sample.pdf&ei=WqkGU\\_fwEoG-kAXogoDoBg&usq=AFQjCNFWHbNliIWEDtBaP96YHvIHkFTaUA&bvm=bv.61725948,d.dGI](http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCsQFjAA&url=http%3A%2F%2Fshopping.netsuite.com%2Fc.1253739%2Fsite%2FSample_pdf%2FQMS04A2_sample.pdf&ei=WqkGU_fwEoG-kAXogoDoBg&usq=AFQjCNFWHbNliIWEDtBaP96YHvIHkFTaUA&bvm=bv.61725948,d.dGI) 2014
- Magli, MC. et al. 'Revised Guidelines for Good Practice in IVF Laboratories' European Society of Human Reproduction and Embryology 2008. Retrieved from website: <http://humrep.oxfordjournals.org/content/23/6/1253.long> 2014
- The Facility Guidelines Institute (US). 'Guidelines for Design and Construction of Health Care Facilities' 2010 Edition. Retrieved from website: [www.fgiguideines.org](http://www.fgiguideines.org) 2014
- UAE, The Cabinet: Cabinet Decision No 36 of 2009 'Issuing the Implementing Regulation of Federal Law No (11) of 2008 Concerning the Licensing of Fertilization Centers in the State'.