

21.0 IVF Unit (Fertilisation Centres)

21.1 Introduction

21.1.1 Description

The IVF Unit will provide facilities for In vitro fertilisation (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 fertilised with sperm in a laboratory procedure (in vitro). If fertilisation occurs, a fertilised 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
- Pre treatment assessment
- Blood collection
- Semen collection
- Artificial insemination
- Ovarian stimulation therapy
- Ultrasound examination
- Oocyte (egg) collection
- Embryo culture
- In vitro / ICSI fertilisation
- Cryopreservation
- Embryo transfer
- Recovery
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21.1.2 Licensing Of Unit

IVF Units (Fertilisation Centres) in the region may require licensing according to the requirements of pertaining laws of the land. Please refer to local licensing laws for additional information on the licensing process for IVF Units.

21.2 Planning

21.2.1 Planning Models

The IVF Unit may be developed as:

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

21.2.2 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
- Sterilising area: if the IVF unit is a stand-alone building, dedicated sterilising 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 ROOM(S)

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

OPERATING ROOM(S)

Operating room(s) will include equipment and facilities for egg collection and embryo transfer, under local anaesthetic. 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 (fertilised 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 local regulations and licensing laws).

21.2.3 *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

21.3 Design

21.3.1 *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.

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

21.3.2 *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 minimise 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 maximise 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. Please refer to Part C, 9.2 "Acoustic Solutions for Healthcare Facilities"

21.3.3 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.

21.3.4 Safety and Security

Zones within the Unit will require access control to prevent unauthorised 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.

21.3.5 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.

21.3.6 Fixtures and Fittings

Critical items of equipment including incubators and liquid nitrogen storage should be temperature alarmed and monitored.

21.3.7 Building Service Requirements



Laboratories will require air conditioning with controlled humidity and temperature to provide an environment that minimises 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.

21.3.8 *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 handwashing 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.

21.4 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.

21.4.1 *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 handwash 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
- Benchtop microscopes, inverted microscope, stereomicroscope
- CO2 Incubators
- Electrical pipettes
- Variable pipettes
- Fyrite analyser (CO2 and O2 gas analyser)
- Laboratory refrigerator
- Handbasin 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
- Benchtop microscopes
- Automatic sperm analysing units
- CO2 Incubators
- Electrical pipettes
- Variable pipettes
- Mackler cell
- Fyrite analyser (CO2 and O2 gas analyser)
- Laboratory refrigerator
- Handbasin 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
- Benchtop microscopes
- Laboratory refrigerator
- Handbasin 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 (minimising the risk of cross contamination of frozen gametes, zygotes and embryos)
- Labelling, packaging and documentation of tissue frozen

Provide controlled access to the room.

STERILISING/ PACKING

Description and Function

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

Location and Relationships

The Sterilising/ 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:

- Handbasin
- 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.



21.5 Schedule of Accommodation

21.5.1 IVF Unit (Fertilisation Centres) Generic Schedule of Accommodation Schedule of Accommodation for an IVF Unit in a Hospital at Levels 5 and 6.

ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks
ENTRY / CONSULTING AREA:							
RECEPTION / CLERICAL	yes				1 x 15	1 x 15	
PHOTOCOPY / STATIONERY	yes				1 x 8	1 x 8	
STORE - FILES	yes				1 x 8	1 x 8	
WAITING	yes				1 x 20	1 x 30	
WAITING FAMILY	yes				1 x 25	1 x 30	
TOILET- VISITORS, ACCESSIBLE	yes				2 x 5	2 x 5	Located adjacent to Waiting
INTERVIEW ROOM - FAMILY	yes				2 x 12	3 x 12	
CONSULT / EXAMINATION / TREATMENT ROOM	yes				3 x 15	4 x 15	
COLLECTION ROOM					2 x 6	2 x 6	Semen samples
ENSUITE	yes				2 x 5	2 x 5	Adjacent to semen Collection Rooms
BLOOD COLLECTION BAY	yes				2 x 5	2 x 5	
ULTRASOUND ROOM	yes				1 x 14	1 x 14	
PATIENT PROCEDURAL AREA:							
OPERATING ROOM - GENERAL	yes				1 x 42	2 x 42	
PATIENT CHANGE CUBICLE	yes				1 x 4	2 x 4	1 adjacent to each Procedure Room
PATIENT TOILET	yes				2 x 3	3 x 3	1 adjacent to each Procedure Room; 1 adjacent to Recovery
CHANGE - STAFF (MALE / FEMALE)	yes				2 x 10	2 x 14	
SCRUB UP	yes				1 x 6	1 x 10	Maybe shared between 2 procedure room
PATIENT BAY - RECOVERY	yes				2 x 10	4 x 10	
BAY - HANDWASHING , TYPE B	yes				1 x 1	2 x 1	
BAY - BEVERAGE	yes				1 x 5	1 x 5	
BAY - LINEN	yes				1 x 2	1 x 2	
BAY - RESUSUSCITATION TROLLEY	yes				1 x 2	1 x 2	
CLEAN UTILITY	yes				1 x 8	1 x 10	
DIRTY UTILITY	yes				1 x 8	1 x 10	
STAFF STATION	yes				1 x 5	1 x 10	



ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks
STORE - GENERAL	yes				1 x 8	1 x 10	
DISCOUNTED CIRCULATION					35%	35%	

LABORATORY AREAS

ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks Size will be dependant on equipment to be located and function
IVF/ ICSI LABORATORY					1 x 40	1 x 50	
ANDROLOGY LABORATORY					1 x 30	1 x 40	
GENETICS LABORATORY					1 x 15	1 x 20	PGD functions
CRYOPRESERVATION STORE					1 x 30	1 x 40	
STORE - GAS BOTTLE	yes				1 x 10	1 x 15	
CHANGE-STAFF (MALE /FEMALE)	yes				2 x 6	1 x 6	Includes toilets and change facilities
DISCOUNTED CIRCULATION					35%	35%	

SUPPORT AREAS

ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks
CLEAN-UP ROOM	yes				1 x 10	1 x 12	
CLEANERS ROOM	yes				1 x 5	1 x 5	
DISPOSAL ROOM	yes				1 x 5	1 x 8	
STERILISING / PACKING					1 x 15	1 x 20	Locate adjacent to Clean-up
STORE - STERILE STOCK	yes				1 x 8	1 x 12	

STAFF AREAS

Provision of Offices, Workstations and staff areas will be dependant on the Operational Policy and staffing establishment.

ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks
MEETING ROOM - MEDIUM	yes				1 x 20	1 x 30	
OFFICE - MANAGER	yes				1 x 12	1 x 12	
OFFICE - SINGLE PERSON	yes				1 x 9	1 x 9	Physician
OFFICE - SINGLE PERSON	yes				1 x 9	1 x 9	Nursing
OFFICE - 4 PERSON SHARED	yes					1 x 20	Multi-purpose
OFFICE - WORKSTATION	yes					1 x 6	Medical Records Clerk
SECURITY ROOM	yes					1 x 10	Security guard
STAFF ROOM	yes				1 x 15	1 x 20	



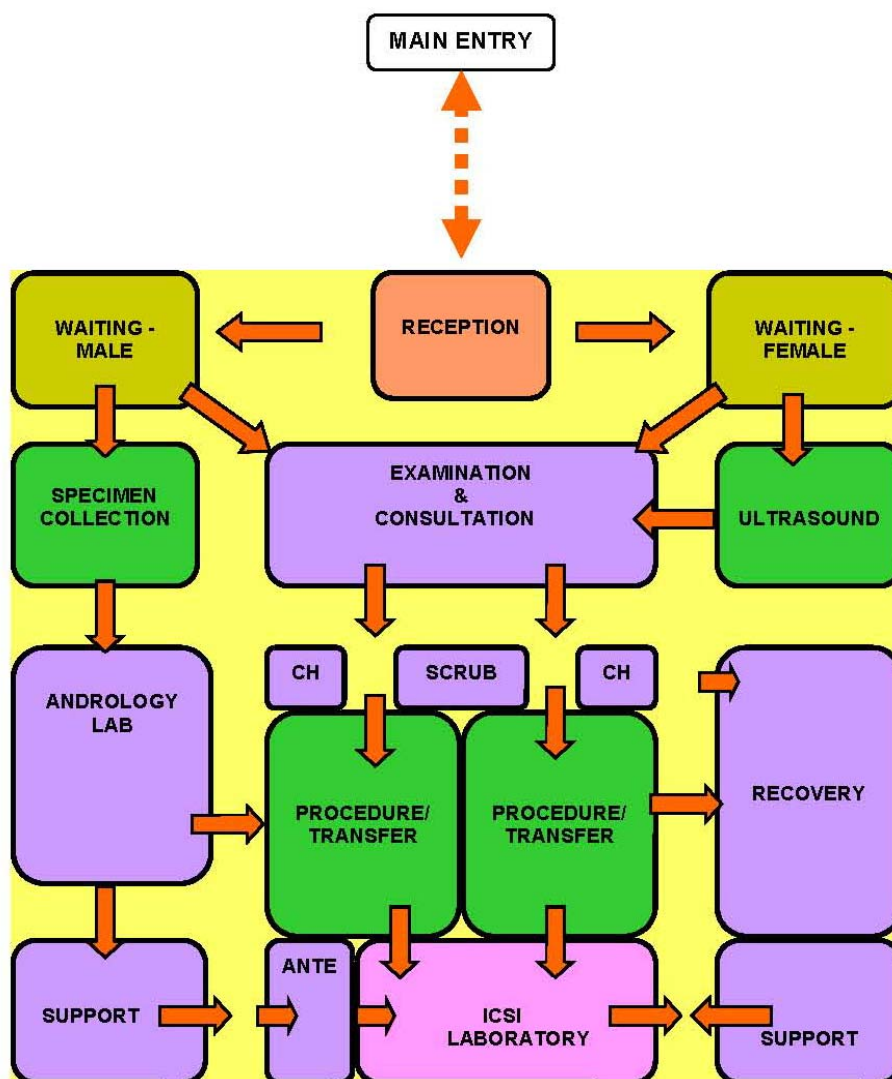
ROOM / SPACE	Standard Component				Level 5 Qty x m2	Level 6 Qty x m2	Remarks
PROPERTY BAY-STAFF	yes				1 x 4	1 x 4	

Please note the following:

- 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 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.
- Staff and support rooms may be shared between Functional Planning Units dependant on location and accessibility to each unit and may provide scope to reduce duplication of facilities.

21.6 Functional Relationship Diagram

21.6.1 IVF Unit (Fertilisation Centres) Functional Relationship Diagram



21.7 References and Further Reading

- Revised Guidelines for good practice in IVF laboratories; Magli, M.C. et al, Human Reproduction Vol 23, No 6, 1253-1262, 2008
- Guidelines for Design and Construction of Health Care Facilities; The Facility Guidelines Institute, 2010 Edition.
- Clinical and Laboratory Standards Institute (CLSI) (www.clsi.org) "Laboratory Design; Approved Guideline," 2nd edition. GP18-A2. Vol 27, No.7. Wayne, PA:CLSI, 2007.



The Indian Health Facility Guidelines recommends the use of **HFBS** “**Health Facility Briefing System**” to edit all room data sheet information for your project.

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