

Part B – Health Facility Briefing & Design
140 IVF Unit (Fertilisation Centres)



iHFG

International Health Facility Guidelines

Version 4 May 2014

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140 IVF Unit (Fertilisation Centres)

1 Introduction

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

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.

2 Planning

Planning Models

The IVF Unit may be developed as:

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

Functional Areas

The IVF Unit may consist of a number of Functional Areas or zones:

- Entry/ Consult Area
 - 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 Area
 - Operating Room/s for oocyte (egg) collection and re-implantation
 - Recovery areas
 - Change areas and toilets for staff and patients
- Laboratory Area
 - Laboratories (Embryology, IVF, ICSI, Andrology, Genetics)
 - Cryopreservation facilities
 - Gas Bottle Store
- Staff and Support Area
 - 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 and Waiting

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.

Procedural Areas

Collection Room/ s

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

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.

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.

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.

Laboratory Areas

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. The space will be enclosed for specialty laboratory functions.

The IVF/ICSI Laboratory should be located with a direct relationship to the Operating Room/s for oocyte collection and re-implantation. 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.

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 analyser (CO2 and O2 gas analyser)
- Laboratory refrigerator

Laboratory equipment will require emergency power, temperature monitoring and alarms. The construction of the laboratory 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

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

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

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

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

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 analysing units, e.g. Mackler chamber
- 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.

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). The functions performed in the Genetics Laboratory may be included in the IVF/ ICSI Laboratory.

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

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
- 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 Facilities

Facilities for cryopreservation will include a separate room for storage of frozen reproductive cells (gametes, zygotes and embryos) in liquid nitrogen storage tanks. Nitrogen tanks should be stored in an enclosed space in case of nitrogen leakage.

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

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 protocols on the method of storage and specimen labelling are required for this process (refer to local regulations and licensing laws) 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.

Staff and Support Areas

Sterilising/ Packing

The Sterilising/ Packing room is an area where cleaned and dried instruments are sorted, assembled into sets, packaged, and then sterilised in an autoclave.

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:

IVF Unit (Fertilisation Centres)

- 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.

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

3 Design

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.

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.

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.

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.

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.

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.

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.

Infection Control

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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.

4 Components of the Unit

The IVF Unit will contain Standard Components to comply with details described in these Guidelines. Refer to Standard Components Room Data Sheets and Room Layout Sheets.

Laboratories are to comply with applicable statutory requirements and international standards for clean rooms.

5 Schedule of Accommodation – IVF Unit

Entry/Consulting Areas

ROOM / SPACE	Standard Component				Level 5 Qty x m ²	Level 6 Qty x m ²	Remarks
RECEPTION / CLERICAL	RECL-15-I				1 x 15	1 x 15	
STORE - PHOTOCOPY / STATIONERY	STPS-8-I				1 x 8	1 x 8	
STORE - FILES	STFS-8-I				1 x 8	1 x 8	
WAITING MALE / FEMALE	WAIT-10-I WAIT-15-I				2 x 10	2 x 15	Separate Waiting areas for Male & Female
WAITING FAMILY	WAIT-25-I WAIT-30-I				1 x 25	1 x 30	
TOILET- VISITORS, ACCESSIBLE	WCAC-I				2 x 6	2 x 6	Located adjacent to Male & Female Waiting
MEETING/ INTERVIEW ROOM - FAMILY	MEET-12-I				2 x 12	3 x 12	
CONSULT / EXAMINATION /	CONS-I				3 x 14	4 x 14	
COLLECTION ROOM					2 x 6	2 x 6	Semen samples
ENSUITE SHOWER/ TOILET	ENS-ST-I				2 x 5	2 x 5	Adjacent to semen Collection Rooms
BLOOD COLLECTION BAY	BLDC-5-I				2 x 5	2 x 5	
ULTRASOUND ROOM	ULTR-I				1 x 14	1 x 14	

Patient Procedural Area

ROOM / SPACE	Standard Component				Level 5 Qty x m ²	Level 6 Qty x m ²	Remarks
OPERATING ROOM - GENERAL	ORGN-I				1 x 42	2 x 42	
CHANGE CUBICLE – ACCESSIBLE PATIENT	CHPT-D-I				1 x 4	2 x 4	1 adjacent to each Procedure Room
TOILET - PATIENT	WCPT-I				2 x 4	3 x 4	1 adjacent to each Procedure Room; 1 adjacent to Recovery
CHANGE - STAFF (MALE / FEMALE)	CHST-10-I CHST-14-I				2 x 10	2 x 14	
SCRUB UP / GOWNING	SCRB-6-I SCRBS-I				1 x 6	1 x 10	Maybe shared between 2 procedure room
PATIENT BAY – HOLDING/ RECOVERY	PBTR-H-10-I				2 x 10	4 x 10	
BAY - HANDWASHING , TYPE B	BHWS-B-I				1 x 1	2 x 1	
BAY - BEVERAGE	BBEV-ENC-I				1 x 5	1 x 5	
BAY - LINEN	BLIN-I				1 x 2	1 x 2	
BAY - RESUSCITATION TROLLEY	BRES-I				1 x 1.5	1 x 1.5	
CLEAN UTILITY	CLUR-8-I CLUR-12-I				1 x 8	1 x 12	
DIRTY UTILITY	DTUR-S-I DTUR-10-I				1 x 8	1 x 10	
STAFF STATION	SSTN-5-I SSTN-10-I				1 x 5	1 x 10	
STORE - GENERAL	STGN-8-I STGN-10U				1 x 8	1 x 10	
CIRCULATION ALLOWANCE %					35%	35%	

Laboratory Areas

ROOM / SPACE	Standard Component				Level 5 Qty x m ²	Level 6 Qty x m ²	Remarks
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	STGB-F-I similar				1 x 10	1 x 15	
CHANGE-STAFF (MALE /FEMALE)	CHST-10-I				2 x 10	2 x 10	Includes toilets and change facilities
CIRCULATION ALLOWANCE %					35%	35%	

Support Areas

ROOM / SPACE	Standard Component				Level 5 Qty x m ²	Level 6 Qty x m ²	Remarks
CLEAN-IP ROOM	CLUP-10-I CLUP-12-I				1 x 10	1 x 12	
CLEANERS ROOM	CLRM-5-I				1 x 5	1 x 5	
DISPOSAL ROOM	DISP-5-I DISP-8-I				1 x 5	1 x 8	
STERILISING / PACKING					1 x 15	1 x 20	Locate adjacent to Clean-up
STORE - STERILE STOCK	STSS-12-I similar				1 x 8	1 x 12	

Staff Areas

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

ROOM / SPACE	Standard Component				Level 5 Qty x m ²	Level 6 Qty x m ²	Remarks
MEETING ROOM – MEDIUM/ LARGE	MEET-L-20-I MEET-L-30-I				1 x 20	1 x 30	
OFFICE – SINGLE PERSON 12 m ²	OFF-S12-I				1 x 12	1 x 12	Manger
OFFICE - SINGLE PERSON 9 m ²	OFF-S9-I				1 x 9	1 x 9	Physician
OFFICE - SINGLE PERSON 9 m ²	OFF-S9-I				1 x 9	1 x 9	Nursing
OFFICE - 4 PERSON SHARED	OFF-4P-I					1 x 20	Multi-purpose
OFFICE - WORKSTATION	OFF-WS-I					1 x 5.5	Medical Records Clerk
SECURITY ROOM	SECR-10-I					1 x 10	Security guard; as required By Operational Policy
STAFF ROOM	SRM-15-I SRM-20-I				1 x 15	1 x 20	
PROPERTY BAY-STAFF	PROP-2-I				2 x 2	2 x 2	

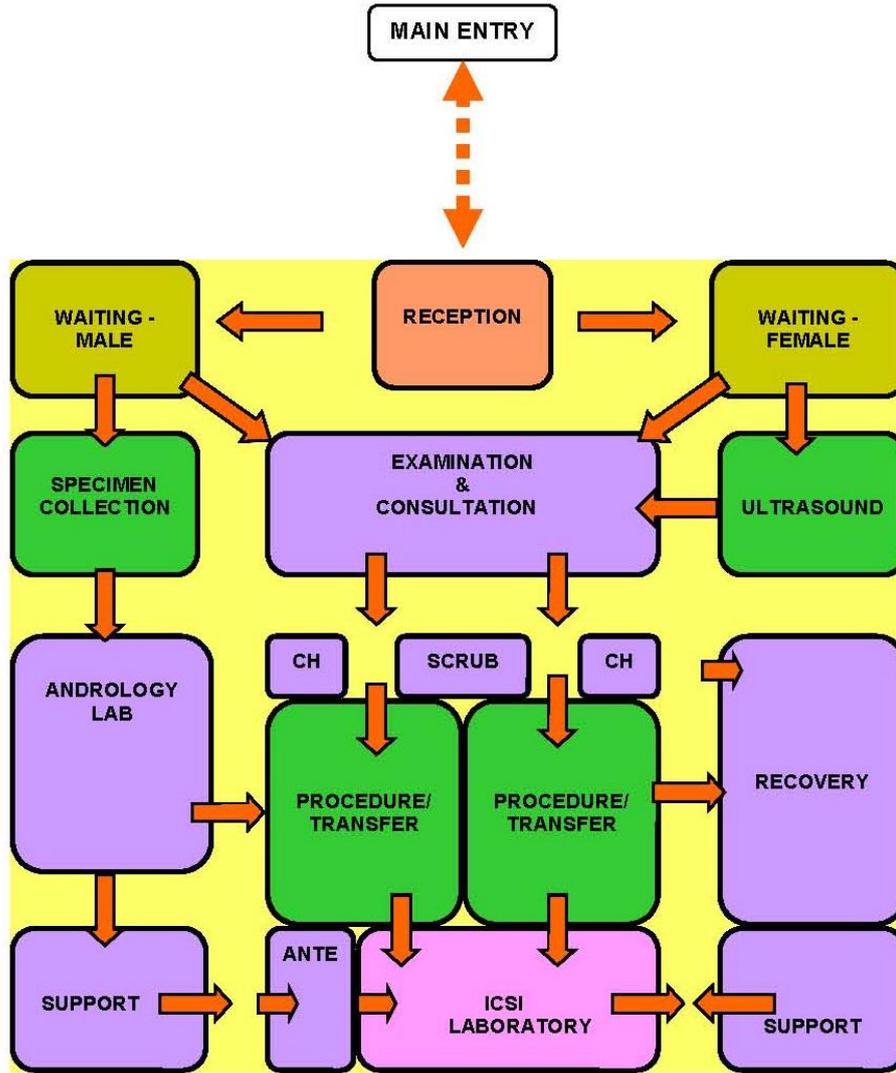
Please note the following:

- 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.

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- Office areas are to be provided according to the Unit role delineation and the number of endorsed full time positions in the Unit
- Room sizes indicated should be viewed as a minimum requirement; variations are acceptable to reflect the needs of individual Unit.
- 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.

6 Functional Relationship Diagram – IVF Unit



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 refer to website www.fgiguidelines.org .
- 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 International Health Facility Guidelines recommends the use of HFBS “Health Facility Briefing System” to edit all room data sheet information for your project.

HFBS provides edit access to all iHFG standard rooms, and departments, and more than 100 custom report templates.

HFBS Health Facility Briefing System



Briefing Module

The Health Facility Briefing System (HFBS) has numerous modules available via annual subscription. It suits healthcare Architects, Medical Planners, Equipment Planners Project Managers and Health Authorities.

Use the HFBS Briefing Module to quickly drag in health facility departments or pre-configured room templates from the iHFG standard, edit the room features such as finishes, furniture, fittings, fixtures, medical equipment, engineering services. The system can print or download as PDF more than 100 custom reports including room data sheets, schedules, and more...

To learn more about the HFBS web-based Healthcare Briefing and Design Software and to obtain editable versions of the “Standard Components” including Room Data Sheets (RDS) and Room Layout Sheets (RLS) offered on the iHFG website, signup for HFBS using the link below.

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