



Private human reproductive technology practice and storage licence application

Instructions

The following forms are for the application for a licence under the *Human Reproductive Technology Act 1991*. Please review and complete each section applicable.

Please note: It takes approximately 90 days to process an application.

There are 8 sections:

- A** Facility and key management
- B** Scope of clinical service
- C** Functional brief
- D** Assessment of the licensee
- E** Assessment of premises – adequate and appropriate management, staffing, equipment and support services
- F** Adequate and appropriate
- G** Accreditation RTAC/NATA
- H** Declaration

The following documents will assist you with your application.

- [Human Reproduction Technology Act 1991](#)
- [Human Reproduction Technology Regulations 1993](#)
- [Human Reproduction Technology Directions 2021](#)
- [National Construction Code \(NCC\) 2023](#)

A non-refundable fee for either the practice and/or storage licence must be paid when submitting your application. Contact LARULicensing@health.wa.gov.au for information regarding scheduled fees.

Once you have completed the application, please notify the Licensing and Accreditation Regulatory Unit (LARU) via LARULicensing@health.gov.wa.au. A set of instructions will be provided to assist you with the uploading and downloading of documents electronically along with an invite to access MyFT folder (document transfer platform).

Licence type

Please tick the licence/s you are applying for: practice storage

Section A: key people – senior management

Medical director

Title: Mr Mrs Ms Miss Dr Prof Other

Name:

Mobile:

Email:

Scientific director (however titled)

Title: Mr Mrs Ms Miss Dr Prof Other

Name:

Mobile:

Email:

Nurse manager (however titled)

Title: Mr Mrs Ms Miss Dr Prof Other

Name:

Mobile:

Email:

Laboratory manager

Title: Mr Mrs Ms Miss Dr Prof Other

Name:

Mobile:

Email:

IVF counsellor

Title: Mr Mrs Ms Miss Dr Prof Other

Name:

Mobile:

Email:



Section B: Scope of human reproductive services offered

Please tick if applicable, this will be listed on your licence

artificial insemination (AI)/IUI	artificial insemination (AI)	cryopreservation of embryos
cryopreservation of sperm	donor programme	gamete intrafallopian transfer (GIFT)
extended embryo culture (past 3 days) blastocyte culture		invitro fertilization (IVF)
intracytoplasmic sperm injection (ICSI)		invitro fertilization maturation (IVM)
thawed /frozen embryo transfer		intrauterine insemination (IUI)
preimplantation genetic testing		ovulation induction (IO)
surrogacy programme		
surgical sperm aspiration:	MESA PESA TESA	testicular biopsy (under local anaesthetic only)
Other clinical procedures:		

I confirm these ART services are provided at this facility.

Name: _____ Position: _____

Signature: _____ Date: _____

Please note: All items ticked will be reflected on your Licence. For any additional services to be added or removed from the licence, please complete the '**Changes to services request**' form located on the LARU [website](#) and submit to LARULicensing@health.wa.gov.au



Section C: Proposed function of the practice/storage facilities

In assessing an application for a private Human Reproductive Technology (ART) clinic practice and storage licence documents, the Director General of the WA Department of Health has a duty to approve the licensee, the premises to which the licence relates and the arrangements for management, staffing and equipment. This section on proposed functions provides vital information that is utilised by the Director General when determining whether to grant an applicant a licence/s.

The responses to this section should be no more than a few pages long and it should include the functions of the business as well as key management, staffing and the buildings in which the licenses pertain to. The intention is not to duplicate matters that are submitted in this licence application but to provide a snapshot business functions that will be carried out within the premises to be approved.

Please attach your proposed functionals of the practice and storage facility which shall briefly outline the following points:

General information

- name of Licensee/owner/company/firm/partnership/statutory body
- name of practice and storage facility
- location – if two addresses are used, please include both addresses
- primary function of the facilities – the normal or intended activities of the facilities
- the reason/rationale for the service
- service philosophy/scope of the service/proposed level of service
- model of care provision
- days and hours of operation

Clinical services

- clinical services to be offered- scope of clinical practice – please complete relevant section
- patient referral mechanisms

Building

- existing buildings: confirm classifications for practice (Class 5) and laboratory (Class 8 or 9a) and age of building/s
- anticipated life of building/s
- provide electronic copies of as constructed floor plans that are appropriately labelled
- advise if there will be phased building works, planned time frames, how services will be maintained (if required), how patient flows will be managed during building works (if applicable).

Staffing

- intended staff mix and qualifications
 - clinical
 - medical
 - scientific
 - administration
 - allied

Support services

- specific equipment and infrastructure, equipment and facility maintenance, infection prevention and control, fire safety and security, consumables, all waste management, information technology

External service agreements (provide list of external service agreements)

- ethics committee
- liquid nitrogen supply
- dewars and back up storage agreement
- equipment maintenance
- fire safety
- air conditioning/HVAC System
- facility maintenance
- consumables
- pharmacy supplies if applicable



Section D: Accessment of licensee

Part of the assessment of an application for a licence involves a determination that the licence applicant satisfies the requirements of the *Human Reproductive Technology Act 1991 and Human Reproductive Technology Determination 2021*.

The licensee is required to provide the following: (please tick if submitted)

birth certificate/s if applicable

- if the name has changed since birth certification, legal documentation of change to be provided (For example, certified deed poll or marriage certificate)

copies of:

- the certificate of statutory body number (if applicable)
- the specific legislation of incorporation
- any change of identity

character references: for every person who has management responsibility under the relevant legislation

current (dated within 6 months of application date) national policy certificate for each person charged with management responsibility under the relevant legislation

licensee's character and reputation declaration

licensee's financial declaration

copies of certificates of currency for the following classes of risk, including the amount of insurance cover:

- professional Indemnity
- cyber security
- medical malpractice
- building or industrial special risks
- public liability
- workers compensation, or if a self-insurer.

details on the operational management team, that being:

- positions that include medical director, scientific director, nurse manager and laboratory manager, IVF counsellor
- current curriculum vitae

written information on any outstanding criminal charges, convictions (other than spent convictions) made against them, or anyone involved in the management of the facility.

written documentation (details and outcome) of any breaches of the *Corporations Act 2001* (or any other Act administered by the Australian Securities Investments Commission) or the *Trade Practices Act*.

written documentation (details and outcome) of any referrals or complaints by any professional registration board or association.

written information (details and outcome) on any person involved in the management or ownership of the facility being declared bankrupt.

Section D: Assessment of licensee

(trustee/company/individual/firm/partnership/corporation/statutory body)

Name of registered business:

ACN:

ABN:

Business address:

Postal address:

Phone:

Mobile:

Email:

Licence Supervisor (if different to the licensee)

Title: Mr Mrs Ms Miss Dr Prof

Name:

Position:

Mobile:

Email:

Address:

Suburb:

Post code:

Nominated authorised delegate to act on the licence supervisor's behalf (if applicable)

For the licence supervisor to appoint an authorised delegate to act on their behalf, an authorised delegate form must be completed.

Title: Mr Mrs Ms Miss Dr Prof

Name:

Position:

Mobile:

Email:

Address:

Suburb:

Post code:

Section D: assessment of licensee

Names of board members/company directors/other (if applicable)

Name	Date started	Term in office

Section D: assessment of licensee

Licensee financial declaration

Explanatory Note: the person signing this declaration must be either the licence applicant or a person authorised by the licence applicant.

I declare that:

name of company/individual/firm/partnership/statutory body

1. Has sufficient material and financial resources available to comply with the requirements of the *Human Reproductive Technology Act 1991 (WA)*.
2. I am duly authorised to make this declaration.
3. The information contained in this application is true and correct. I understand that if it is subsequently established that any information provided is not true and correct, any licence issued may be suspended or revoked.

Name:

Position:

Signature:

Date:

Section D: assessment of licensee

Document checklist

Once you have completed the application, please notify the LARU via LARULicensing@health.gov.wa.au

A set of instructions will be provided to assist you with the uploading and downloading of documents electronically along with an invite to join the MyFT (document transfer platform).

Please tick if submitted:

functional brief

birth certificate (if applicable)

character references

curriculum vitae's (Medical Director and senior management)

national police clearances

financial declarations

insurances

additional information



Section E: Adequate and appropriate premises

Part of the assessment of an application for a human reproductive technology practice and/or storage licence involves a determination that the premises are approved. Refer to the *Australian National Construction Codes (NCC) 2023*.

You are required to advise on the following:

The licensee is the owner of the premises. If yes, sign declaration of ownership

The licensee is purchasing the premises. If yes, sign declaration from an existing licensee

The licensee is leasing the premises. If yes, sign declaration for lease of premises

Ownership of premises declaration

The person signing this declaration must be either the licensee or a person authorised by the licensee.

I,

name

of

address

declare that:

1. the licensee has ownership of the premises of the licensed private health facility
2. the information contained in this declaration is true and correct – I understand that if it is subsequently established that any information provided is not true and correct, any licence issued may be suspended or revoked
3. I am duly authorised to make this declaration.

Name:

Position:

Signature:

Date:

Section E: adequate and appropriate premises

Purchasing premises from an existing licence holder

The person signing this declaration must be either the licensee or a person authorised by the licensee.

I,

name

of

address

In the position of

declare that:

- I have discussed the proposed date of transfer with the current licence holder
- The current licensee and I have agreed the premises will be sold and the business handover will occur on or about (insert date)
- I am aware, and have advised the current licensee that the Licensing and Accreditation Regulatory Unit may require this date to change due to assessment of the licence application
- The information contained in this declaration is true and correct. I understand that if it is subsequently established that any information provided is not true and correct, any licence issued may be suspended or I am duly authorised to make this declaration.

Name:

Position:

Signature:

Date:

Section E: adequate and appropriate premises

Leasehold of premises declaration

The person signing this declaration must be either the licensee or a person authorised by the licensee.

I,

insert name

of

insert address

in the position of

insert position

declare that the owner of the building

insert name

of

insert address

Mobile:

Email:

- Where the licensee has entered into, or plans to enter into, a leasing arrangement for both the building and the land or either the building or the land, the terms of the leasing arrangement must comply with all the provisions of the *Human Reproductive Technology Act 1991*, including the possession of a lease that allows all necessary building works to be undertaken in compliance with the associated regulations, codes and standards, as amended from time to time.
- If the terms of the lease conflict with the requirements of the *Human Reproductive Technology Act 1991*, the *Human Reproductive Technology Act 1991* will prevail.
- The information contained in this declaration is true and correct. I understand that if it is subsequently established that any information provided is not true and correct, any licence issued may be suspended or revoked.
- I am duly authorised to make this declaration.

Name:

Position:

Signature:

Date:

Section E: adequate and appropriate premises

Assessment of premises

What is your proposed date for occupation:

The proposed date for occupation, is the date when full services can begin. Therefore, the date you require the licence for the practice and or storage facility to be issued.

Status of your building:

1. currently occupied
2. ready for occupation
3. requiring renovation prior to occupation
4. green field site
5. currently being built for occupation

If you have ticked 1 or 2, the following is required:

- a) plans of the facility
- b) a schematic fire and emergency evacuation plan

If you have ticked 3, 4 or 5, the following is required:

The licensee is required to contact the LARU on (08) 6373 2347 to arrange a meeting with the LARU building team to discuss the approval process and arrange a concept meeting.

Once your licence application is completed, please notify the Licensing Team via email LARULicensing@health.wa.gov.au
A link to a MyFT folder will then be sent to you along with instructions on how to upload your application documents electronically. Please tick if submitted.

Please tick if submitted:

- current floor plans
- fire evacuation plans



Section F: Adequate and appropriate staffing, equipment, and support services

Part of the assessment of an application for a licence involves determining if adequate and appropriate arrangements for management, equipment, staffing and support services have been made.

You are required to provide the following:

Organisational charts

a copy of the corporate organisational chart showing the relationship between the company (licence holder) and the facility, and/or

a copy of the facility organisational chart

Facility committee structure

Provide a diagrammatic committee structure – this must include:

medical advisory committee

The information requested is the minimum requirement to enable an assessment of adequacy and appropriateness to take place. The risk remains with the licensee if the information provided is in any way deficient.

A set of instructions will be provided to assist you with the uploading and downloading of documents electronically along with an invite to join the MyFT (document transfer platform).

Please upload completed documents and checklists into the Licensing MyFT folder.

Please tick if submitted

corporate organisation chart

facility organisation chart

facility committee chart



Section G: accreditation

It is a condition of each licence that the licensee is accredited to carry out reproduction technology by the Reproductive Technology Accreditation Council (RTAC) to the Fertility Society of Australia and New Zealand Code of Practice and maintains such accreditation – section 33 (2) (ea) of the Act.

In addition to maintaining RTAC accreditation, Part 4 of the *Human Reproduction Technology Act 1991*, requires the licensees to maintain NATA accreditation for the laboratory.

RTAC accreditation information

Accreditation agency name:

Certificate expiry date:

Date accreditation due:

A copy of the RTAC accreditation report and certificate has been provided to the LARU.
Please email to LARULicensing@health.wa.gov.au or upload into the MyFT folder.

NATA Accreditation Information (if applicable)

Accreditation agency name:

Certificate expiry date:

Date accreditation due:

A copy of the NATA Accreditation Report and certificate has been provided to the LARU.
Please email to LARULicensing@health.wa.gov.au or upload into the MyFT folder



Section H: declaration

Due diligence associated with compliance is the responsibility of the licensee.

I declare as the licensee licence supervisor authorised delegate

Note: The authorised delegate must have been previously appointed as the delegate and which has been approved by the regulator.

I am compliant with the:

1. terms and conditions placed on the licence/s
2. mandatory requirements of the Human Reproductive Technology Act 1991
3. data monitoring and reporting
4. adverse events management.

I am duly authorised to make this declaration

Name:

Position:

Signature:

Date:

This document can be made available
in alternative formats.

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