



The Department of Health Chief Executive Officer has a duty to approve the proprietor, the premises (entire site and building/s) and the arrangements for management, staffing and equipment when assessing an application for a Assisted Reproductive Technology (ART) practice and or storage facility. The building application is assessed for compliance with the *Australian National Construction Codes 2022 (NCC)*, the Licensing and Accreditation Regulatory Unit (LARU) Human Reproductive Technology Building Compliance Checklist and the *Human Reproductive Technology Directions 2021* for Management as amended from time to time. The LARU is the delegated authority which administers licensing and compliance components of the HRT Act.

In order to issue a licence/s, the Building Approval Process is a granted approval process which requires that all matters are addressed at each approval phase prior to progressing to the next approval phase. The four phases are Concept Approval, Approval in Principle, Approval to Construct and Approval to Occupy.

BUILDING APPROVAL PROCESS				
Process	Concept meeting		Documentation and Plans required by LARU	Timeframe
<b>Concept Approval</b>  	<p>The concept meeting introduces the licence applicant (or their authorised delegate), their agent/s and project director to the LARU team.</p> <p>The meeting provides the opportunity to assess high level plans for the proposed service provision, discuss the building design/redesign, outline any intended staging &amp; the timelines planned for each stage including consideration of impact on patient services. The requirement to comply with the National Construction Code for Class 5 (Practice) and Class 8 (independent building) or 9A (if attached to a hospital) for the Laboratory and Storage Buildings.</p> <p>For a new licence application, this meeting also introduces the licence applicant to the legislative requirements for operating an Assisted Reproductive Technology Practice/ Storage facility.</p>		<p>It is required that the licence applicant has undertaken their due diligence and consulted with an architect and engineer (depending on the project) prior to attending for concept meeting.</p> <p>High level drawings are required to be provided to <a href="#">LARU Building</a> <b>one week prior</b> to concept meeting.</p> <p>Email <a href="#">LARU Building</a> to organise a time for a concept meeting.</p> <p><b>Note 1:</b> The LARU requires confirmation that Development Approval with Local Council is underway or being considered (if applicable to the project).</p> <p><b>Note 2:</b> For building developments intended to provide care to mental health patients there is the requirement to ensure that the Office of the Chief Psychiatrist is formally notified in writing.</p>	<p>The LARU will provide formal correspondence advising if concept approval has been granted / not granted following the concept meeting.</p> <p>Verbal approval <b>may</b> be provided at the concept meeting; however, this will be at the discretion of the LARU and on a case-by-case basis.</p>
<b>Approval in Principle (AIP)</b>  	<p><b>Method of Submission</b></p> <p>Submit via My File Transfer <a href="#">MyFT</a> secure file transfer system.</p> <ul style="list-style-type: none"> <li>Contact <a href="#">LARU Building</a> to request access to <a href="#">MyFT</a>.</li> <li>A link will be sent via email to gain access to a folder within <a href="#">MyFT</a> to upload AIP 1 to 8 files.</li> <li>Access to upload files will be available for 2 weeks.</li> </ul> <p>Further information is provided in the LARU Building <a href="#">MyFT</a> Instruction Sheet.</p>	<p><b>Method of Assessment</b></p> <p>E-docs and plans are to be submitted via <a href="#">MyFT</a> for desktop audit.</p> <p>Consultants from various disciplines (architecture, clinical, engineering and fire) with experience in health facility design review the documentation and drawings. Compliance is assessed to the:</p> <ul style="list-style-type: none"> <li>Australian Standards</li> <li>National Construction Code</li> <li>Western Australian Health Facility Guidelines</li> <li>Legislation</li> </ul> <p>The consultants are procured by LARU.</p> <p>Correspondence which includes the audit report is sent to the applicant and states if AIP is recommended / not recommended or if resubmission is required.</p> <p>The report will identify mandatory items which will require a response to demonstrate intended compliance.</p> <p>Depending on the complexity and risk of the project there may be several response cycles between the LARU team and the project team until all mandatory items are satisfactorily addressed.</p>	<p><b>Documentation and Plans required by LARU</b></p> <p><b>AIP1 Functional Brief</b> - Refer to information contained at the end of this document.</p> <p><b>AIP2 Contact List</b> The Contact List is the consultants and contract persons being used in the project. This should include name, company name and contact phone number for the following areas:</p> <ul style="list-style-type: none"> <li>Project Co-ordinator</li> <li>Clinical/scientific contact person/s</li> <li>Architect</li> <li>Mechanical Engineer</li> <li>Electrical Engineer</li> <li>Hydraulic Services Engineer</li> <li>Structural Engineer</li> <li>Fire and Security Engineer</li> <li>Builder and associated contractor</li> </ul> <p><b>AIP3 Patient Management (AIP3 may not be applicable)</b> Patient management must include information on whether patient services will be impacted, and if so, how patient safety, privacy and infection control risks are mitigated during the building works. This section will advise of planned time frames, how services will be maintained and how patient and staff services will be managed.</p> <p><b>AIP4 Timelines</b> The proposed timelines for construction which clearly identifies any staging. For redevelopments – information on continuation and cessation of patient services.</p> <p><b>AIP5 Plans - Total Site (1:200)</b> For redevelopments - existing and proposed total site plan shall be provided.</p> <p><b>AIP6 Plans - Areas/Floors (1:100) – Architectural &amp; Fire</b> These plans shall include the architectural layout and fire engineering design. For redevelopments - architectural layouts of the specific areas/floors of the redevelopment shall be provided. Department boundaries (footprint) are required with an overlay on the existing floor plans. Areas of exclusion from the redevelopment shall be nominated and identified.</p> <p><b>AIP7 Plans - Traffic Flow Patterns (1:100)</b> On a separate architectural layout diagrammatically indicate the traffic flow patterns (using separate colours) for patients, clinical staff and support staff services (goods &amp; waste) in each area. This should include the required regulatory activities and all functional staff/patient relocations (temporary and permanent).</p> <p><b>AIP8 Conceptual Engineering Design</b> Outline the extent of engineering work and the concept for the area/floor.</p>	<ul style="list-style-type: none"> <li>LARU: Four to six weeks for assessment and review.</li> <li>Proprietor: Four weeks to respond.</li> <li>LARU: Four to six weeks to review responses.</li> <li>Process repeats until all AIP mandatory items are addressed and AIP is completed.</li> </ul>



<b>Approval to Construct (ATC)</b>  	<b>Method of Submission</b>	<b>Method of Assessment</b>	<b>Documentation and Plans required by LARU</b>	<b>Timeframe</b>
	Submit via <a href="#">MyFT</a> secure file transfer system. <ul style="list-style-type: none"> <li>Contact <a href="#">LARU Building</a> to request access to <a href="#">MyFT</a>.</li> <li>A link will be sent via email to gain access to a folder within <a href="#">MyFT</a> to upload ATC1 to 5 files.</li> <li>Access to upload files will be available for 2 weeks.</li> </ul> Further information is provided in the LARU Building MyFT Instruction Sheet.	Same as above.	<b>ATC</b> Full set of construction drawings and specifications (typically the tender documents) The construction drawings shall include: <b>ATC1</b> Architectural <b>ATC2</b> Electrical Engineering <b>ATC3</b> Hydraulic Engineering <b>ATC4</b> Mechanical Engineering <b>ATC5</b> Fire Engineering <b>ATC 6</b> Operational Commissioning Program	<b>Note 3:</b> <ul style="list-style-type: none"> <li>All high priority life safety mandatory items must be addressed prior to ATC being granted.</li> <li>All other mandatory items shall be addressed prior to progressing to an ATO inspection.</li> </ul>
<b>Approval to Occupy (ATO)</b>	<b>Documentation required at ATO</b>	<b>Method of Assessment</b>	<b>Required by LARU prior to ATO inspection</b>	<b>Timeframe</b>
	<ul style="list-style-type: none"> <li>One set of certification documents.</li> <li>'As Constructed' drawings – final floorplan.</li> <li>Workforce education records (fire evacuation and emergency training).</li> <li>Operational, Laboratory and Clinical policies.</li> <li>RTAC Accreditation Certification &amp; Report</li> <li>NATA Accreditation Certification &amp; Report if applicable</li> </ul> <u>Operational Commissioning</u> ready for occupation – <ul style="list-style-type: none"> <li>furnished (furniture and equipment),</li> <li>staffed and ready for occupation.</li> </ul>	<ul style="list-style-type: none"> <li>Verification at the site inspection of the 'As Constructed' drawings which reflects the final build and includes any changes/variations further to the construction drawings provided at ATC.</li> <li>Review of the documentation</li> <li>Documentation provided following the ATO inspection is to be sent as separate attachments and not embedded into the reports.</li> </ul>	<b>ATO Inspection can only occur when:-</b> <ul style="list-style-type: none"> <li>All building works have been completed.</li> <li>The building/area is furnished (furniture and equipment), staffed and ready for occupation.</li> <li>All consultant design and commissioning certifications and contractor installation and safety certifications shall be made available to the LARU Building Team and Consultants and include Certificate of Construction Compliance (BA17) for NCC Class 8 build.</li> <li>A certified dangerous goods consultant must have undertaken a hazardous goods risk assessment of laboratory and storage facility as per AS 1894:1997: <i>The storage and handling of non-flammable cryogenic and refrigerated liquids</i>. A copy of the report is to be kept on the premises.</li> </ul> <b>ATO - Step 1</b> <b>Four weeks prior to practical completion</b> , request in writing a tentative date for an Approval to Occupy inspection. <b>ATO - Step 2</b> ATO Inspection Declaration will be sent by LARU Building approximately two weeks prior to the ATO inspection and is to be completed and returned <b>5 working days</b> prior to the ATO inspection.	<ul style="list-style-type: none"> <li>Dependant on ATO scheduling and consultant availability.</li> <li>Proprietor to notify LARU four weeks in advance of practical completion.</li> <li>ATO inspection is to be scheduled at least one week prior to planned occupancy.</li> </ul>
<b>Additional Information</b>	<ol style="list-style-type: none"> <li>WA Health approval does not negate the need to comply with the requirements of the National Construction Code, Australian Standards and other statutory authorities, for example, the Water Corporation, Western Power, Local Council Authority, Economic Regulation Authority (ERA), Environmental Protection Authority (EPA) and the Department of Fire and Emergency Services (DFES).</li> <li>All approvals are valid for 12 months (Concept, AIP, ATC).</li> <li>Existing Dispensations/Conditions - if a facility has a dispensation and/or condition on the licence that will be impacted by the proposed works then the dispensation/condition will be reviewed in the context of the project.</li> <li>No AIP or ATC submissions will be accepted and no ATO inspections will be conducted between 10 December and 10 January (inclusive) each year due to the unavailability of LARU's external consultant panel.</li> </ol>			

## FUNCTIONAL BRIEF

The Functional Brief shall give an overview of the functions that will be provided within the area/premises that are to be approved. It is used to guide the appropriate facility classification and granting of occupancy at the approval of premises inspection. For a new licence application, following the approval of premises, the Functional Brief is finalised and becomes the validated Statement of Function (SoF). The SoF will be used to capture any changes to building history and as necessary, the title/date of site plans demonstrating the changes. For redevelopment projects the existing SoF is updated at the end of the project and following LARU approvals.

Ensure that the Functional Brief as per the License Application Form (AIP1 document) and which addresses the following points in the Approval in Principle submission.

General information	Clinical service	Building	Staffing	Support services
<ul style="list-style-type: none"> <li>Name of the Practice and Storage Facility</li> <li>Address of Facility</li> <li>ART services to be offered</li> <li>Donor / Surrogacy programme</li> <li>The reason/rationale for the service.</li> <li>Service Philosophy/Scope of the service/Proposed level of service.</li> <li>Hours of operation.</li> </ul>	<ul style="list-style-type: none"> <li>Clinical Services Plan               <ul style="list-style-type: none"> <li>Ethics Committee Agreement</li> <li>Day Hospital Agreement – if applicable</li> <li>External Service Provider Contracts ( new licence application )</li> <li>Staff Training</li> <li>Policies and Procedures</li> </ul> </li> <li>Referral mechanism.</li> <li>The intended age range of patients</li> <li>Infection Control.</li> <li>Management of Consumable and Sterile supply.</li> <li>Management of gases</li> </ul>	<ul style="list-style-type: none"> <li>Building Classification (BCA).</li> <li>Age of the facility.</li> <li>Anticipated life of the facility.</li> <li>Outline the layout of the spaces in the facility and their function</li> </ul>	<ul style="list-style-type: none"> <li>Licence Supervisor</li> <li>Medical Director</li> <li>Scientific Director</li> <li>Laboratory Manager</li> <li>Nurse Manager</li> <li>IVF Counsellor</li> <li>Administration</li> <li>Other support staff</li> </ul>	<ul style="list-style-type: none"> <li>Equipment and Infrastructure</li> <li>HVAC System</li> <li>Management of liquid nitrogen</li> <li>Information Technology/Communications.</li> <li>Fire &amp; Security</li> <li>Security.</li> <li>Waste management.</li> <li>Ambulance access.</li> <li>Asset management</li> <li>Facility Maintenance.</li> <li>Pharmacy</li> </ul>