

Board of the Assisted Human Reproduction Regulatory Authority

Assisted Human Reproduction (AHR) Licensing Committee

Terms of Reference

Version Control

Version Number	Purpose of Revision	Amended	Approved
0.1	Initial Draft		
0.2	Revisions prior to Board consideration	01/07/2026	
1.0			

1. Background and Purpose

The Assisted Human Reproduction (AHR) Licensing Committee (“the Committee”) is established to support the Authority in fulfilling its statutory functions under the **Health (Assisted Human Reproduction) Act 2024**, specifically:

- Overseeing the **licensing, monitoring, and compliance** of AHR treatment providers and AHR researchers.
- Ensuring that all AHR activities in the State are carried out **safely, ethically, and in accordance with the Act**, associated regulations, and licence conditions.
- Providing assurance to the Board that AHRRA’s regulatory decisions are **lawful, consistent, transparent, and aligned with the Authority’s statutory mandate** to protect the health and wellbeing of children born through AHR, persons undergoing treatment, and intending parents.

2. Authority

The Committee is an advisory committee of the AHRRA Board. It is authorised to:

- Review and recommend decisions on licence applications, renewals, variations, suspensions, and revocations.
- Oversee compliance monitoring, inspections, investigations, and enforcement actions.
- Request information, reports, and analysis from AHRRA staff.
- Commission expert advice where necessary to support regulatory decision-making.
- Make recommendations to the Board on regulatory policy, codes of practice, and statutory instruments relating to licensing and compliance.

The Committee does not have executive powers or decision-making authority beyond those explicitly delegated by the Board.

3. Functions and Responsibilities

3.1 Licensing

The Committee will:

- Review the AHR Licensing Process and Requirements for approval by the Board.
- Oversee the design, operation, and continuous improvement of the AHR licensing system.
- Review assessments of licence applications for AHR treatment providers and AHR researchers.
- Consider whether applicants satisfy statutory and regulatory requirements, including governance, clinical, operational, quality and safety requirements.
- Recommend to the Board the granting, renewal, variation, suspension, or revocation of licences and any related enforcement or compliance matters within its remit.
- Review proposed licence conditions and recommend proportionate conditions where appropriate.
- Promote consistency and fairness in licensing decision-making through the use of standard criteria, procedures and documented reasons.
- Oversee the maintenance and publication of the **Register of AHR Providers**.
- Oversee the maintenance and publication of the **Register of Genetic Diseases**.

3.2 Compliance and Monitoring

The Committee will:

- Oversee the development and implementation of inspection and monitoring programmes.
- Review inspection findings, compliance reports, and incident notifications.
- Ensure that licence holders comply with statutory obligations, licence conditions, and AHRRA codes of practice.
- Oversee the management of non-compliance, including corrective actions, improvement notices, and enforcement measures.
- Ensure that compliance activities are risk-based, proportionate, and aligned with best regulatory practice.

3.3 Enforcement

The Committee will:

- Review recommendations for enforcement actions, including suspensions, revocations, and prosecutions.
- Ensure enforcement decisions are evidence-based, legally robust, and procedurally fair.
- Recommend enforcement actions to the Board where required under the Act.

3.4 Regulatory Policy and Standards

The Committee will:

- Consider drafts of the Codes of Practice for AHR Activities and ESC Research for approval by the Board.
- Advise the Board on regulatory standards, codes of practice, and statutory instruments relating to licensing and compliance.
- Oversee the development of AHR information documents (required under sections 13 and 83 of the Act) for Board approval.
- Monitor emerging scientific, ethical, and clinical developments relevant to AHR regulation.

3.5 Assurance to the Board

The Committee will:

- Provide assurance that AHRRA's licensing and compliance functions are operating effectively.
- Review risk registers relating to licensing and compliance.
- Identify emerging issues relevant to the licensing framework and advise the Board on policy, procedural or resource implications.
- Report to the Board on trends, risks, and systemic issues in the AHR sector.

4. Membership

4.1 Composition

Membership will include:

- **At least one Board member**, who will act as Chair.
- Members with expertise in:

- Assisted human reproduction
- Clinical governance
- Regulatory compliance
- Ethics
- Law
- Public administration or health regulation

4.2 Appointment

- Members are appointed by the Board for a defined term (typically 3 years).
- The Board may appoint external experts as non-voting advisors.
- The CEO, Director of AHR Licensing & Compliance, and relevant AHRRA staff will attend meetings **in attendance**, not as members.

4.3 Conflicts of Interest

- Members must declare any actual, potential, or perceived conflicts.
- Members with a conflict will recuse themselves from relevant discussions or decisions.

5. Meetings

- The Committee will meet **at least four times per year**, with additional meetings as required.
- A quorum will consist of **the Chair plus at least two other members**.
- Papers will be circulated at least **five working days** in advance.
- Minutes will be recorded, approved, and submitted to the Board.

6. Reporting

- The Committee will report to each Board meeting through:
 - A written report of decisions, recommendations, and issues requiring Board attention.
 - Escalation of significant risks, compliance failures, or enforcement matters.
- An annual report will be prepared summarising:
 - Licensing activity
 - Compliance and inspection outcomes
 - Enforcement actions
 - Sectoral trends and risks

- Recommendations for regulatory improvement

7. Review of Terms of Reference

- The Committee will review these Terms of Reference **annually**.
- Amendments require approval by the Board.

8. Secretariat

- Secretariat support will be provided by AHRRA staff.
- The Secretariat will ensure:
 - Timely circulation of agendas and papers
 - Accurate minute-taking
 - Maintenance of records
 - Tracking of actions and decisions

9. Data Protection and Confidentiality

- Members must comply with all applicable data protection legislation.
- Committee papers and discussions are confidential unless otherwise agreed by the Board.
- Sensitive clinical, personal, or commercial information must be handled in accordance with AHRRA policies.

Date Approved by AHRRA Board:

DD/MM/YYYY

Date Approved by Assisted Human Reproduction Committee:

DD/MM/YYYY