



**Memorandum of Understanding  
(MoU) between  
Healthcare Inspectorate Wales (HIW)  
and Human Fertilisation and  
Embryology Authority**

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Memorandum of understanding: HIW and HFEA

**Approval:**

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<b>Date created</b>	July 2024
<b>Authors</b>	HIW: Carole Smith HFEA: Sharon Fensome-Rimmer, Chief Inspector
<b>Date agreed</b>	December 2024
<b>Formally agreed by</b>	HIW: Alun Jones HFEA: Peter Thompson
<b>Date for review</b>	December 2027

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## 1. Introduction

- 1.1 This is a memorandum of understanding (MoU) between Healthcare Inspectorate Wales (HIW) and the Human Fertilisation and Embryology Authority (HFEA) Partner organisation.
- 1.2 The aim of the MoU is to support the working relationship between HIW and the HFEA and to facilitate the efficient, appropriate, and secure sharing of information and intelligence about the safety and quality of healthcare services in Wales.
- 1.3 The working relationship between HIW and the HFEA is an arrangement whereby partners provide oversight and assurance for healthcare services.
- 1.4 The agreement is based on a mutual understanding that communicating effectively, in a timely manner, and the sharing of information can benefit people who are in receipt of health care services.
- 1.5 This MoU does not affect the existing statutory functions of the respective organisations or the exercise of those functions; neither does it amend any other policies or agreements relating to their activities. It does not imply any transfer of responsibility from one to the other, nor does it imply any sharing of statutory responsibilities except where this is permitted by statute.
- 1.6 This MoU is not legally binding. However, HIW and the HFEA agree to adhere to its principles, have proper regard for each other's activities and work together to support and promote improvement in healthcare services.
- 1.7 This agreement begins on the date this MoU is signed and will be subject to review every three years or sooner if partners require.

## 2. Roles and responsibilities

- 2.1 HIW is the independent inspectorate and regulator of healthcare in Wales. HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy.

HIW inspects NHS services, and regulates independent healthcare providers against a range of standards, policies, guidance and regulations to highlight areas requiring improvement. Further details of what we do can be accessed on our website [www.hiw.org.uk](http://www.hiw.org.uk) or [here](#).

The current HIW strategy can be accessed [www.hiw.org.uk](http://www.hiw.org.uk) or [here](#), which outlines the current aims and objectives.

HIW's main functions and responsibilities are drawn from the following legislation:

- [Health and Social Care \(Community Health and Standards\) Act 2003 \(legislation.gov.uk\)](#)
- [Care Standards Act 2000 \(legislation.gov.uk\)](#)
- [Mental Health Act 1983 \(legislation.gov.uk\)](#)
- [Mental Health \(Wales\) Measure 2010 \(legislation.gov.uk\)](#)
- [The Controlled Drugs \(Supervision of Management and Use\) \(Wales\) Regulations 2008 \(legislation.gov.uk\)](#)

For NHS healthcare services the following must be considered:

- [The Health and Care Quality Standards \(2023\)](#).
- [The NHS Duty of Candour \(2023\)<sup>1</sup>](#).
- [Quality Statements \(where available\)](#).
- Where ionising radiation is used, the [Ionising Radiation \(Medical Exposure\) Regulations 2017 \(Legislation.gov.uk\)](#).

For independent healthcare services the following must be considered:

- [The National Minimum Standards for Independent Health Care Services in Wales \(2011\)<sup>2</sup>](#).
- Applicable regulations such as the [Independent Health Care \(Wales\) Regulations 2011 \(Legislation.gov.uk\)](#) and the [Private Dentistry \(Wales\) Regulations 2017 \(Legislation.gov.uk\)](#).

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<sup>1</sup> The Health and Care Quality Standards and the NHS Duty of Candour were introduced under the Health and Social Care (Quality and Engagement) (Wales) Act 2020 ([Legislation.gov.uk](#)).

<sup>2</sup> [the-national-minimum-standards-for-independent-health-care-services-in-wales-2011-no-16.pdf \(gov.wales\)](#).

- Where ionising radiation is used, [the Ionising Radiation \(Medical Exposure\) Regulations 2017 \(Legislation.gov.uk\)](#).

For relevant services where applicable the following should be considered:

- Relevant guidance and standards produced by regulators of healthcare professionals, such as, the General Medical Council (GMC), General Dental Council (GDC), the Nursing and Midwifery Council (NMC) and other recognised organisations.

2.2 The responsibilities and functions of the HFEA are set out in the Human Fertilisation and Embryology Act 1990 (as amended). The HFEA is a non-departmental public body established under the 1990 Act. In summary, the HFEA must:

- issue licences under the Human Fertilisation and Embryology Act 1990 (as amended);
- inspect establishments licensed under the Human Fertilisation and Embryology Act 1990 (as amended);
- issue a Code of Practice setting out a statement of the general principles which it considers should be followed in the carrying-on of activities governed by the Human Fertilisation and Embryology Act 1990 (as amended);
- ensure compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and promote compliance with the Code of Practice;
- maintain information about embryos, the provision of treatment services and activities governed by the Human Fertilisation and Embryology Act 1990 (as amended), and advise the Secretary of State about those matters;
- provide advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by the Human Fertilisation and Embryology Act 1990 (as amended), or may wish to do so.

### 3. Joint priorities and areas of work

3.1 Where there is scope for joint and collaborative work, a lead organisation will be identified. Joint and collaborative working may include taking assurance from each other's actions.

#### **4. Sharing of information**

- 4.1 As stated in the introduction, this agreement covers the sharing of information and intelligence. Please refer to Annex B that provides guidance on the sharing of personal information. The purpose of this is to promote the sharing of knowledge on the risks, concerns and good practice that exist within healthcare services.
- 4.2 The working relationship between HIW and the HFEA will be characterised by regular contact, and appropriate open sharing of information within the parameters of their respective legal frameworks.
- 4.3 Key contacts will be available to facilitate the sharing of intelligence and information when required.
- 4.4 All arrangements for collaboration and sharing of information set out in this MoU and any supplementary agreements will comply with the relevant legislation and codes of practice. This includes frameworks or other policies relating to confidential information. Please refer to Annex B.

HIW and the HFEA are subject to the Freedom of Information Act 2000. If one organisation receives a request for information that originated from the other, the receiving organisation will discuss the request with the other before responding.

- 4.5 The arrangements for exchange of information set out in this MoU will take account of and comply with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Please refer to Annex B.

#### **5. Media and Publications**

- 5.1 HIW and the HFEA will seek to give each other adequate notification of, and sufficient information about, any planned announcements to the public on issues relevant to both organisations, including the sharing of draft proposals and publications.
- 5.2 HIW and the HFEA commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations and will take account of and comply with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

- 5.3 HIW and the HFEA respect the confidentiality of any documents shared in advance of publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

## **6. Governance**

- 6.1 The effectiveness of the working relationship between HIW and the HFEA will be supported by regular contact, either formally or informally.
- 6.2 Any disagreement between HIW and the HFEA will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at Annex A, who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution.

## **7. Duration and review of this MoU**

- 7.1 Both organisations have identified a person responsible for the management of this MoU in Annex A. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.
- 7.2 This MoU will be reviewed every three years by the MoU managers identified in Annex A. It may also be reviewed more frequently at any time should it need to be altered or cease to be relevant at the request of either organisation.



## 8. Annex A - Contact Details and Approval

Signed: Alun Jones



Chief Executive  
Healthcare Inspectorate Wales

Date: 17/10/2024

Signed



Chief Executive  
Human Fertilisation and Embryology  
Authority

Date: 19/12/2024

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Named contacts between HIW and the HFEA as follows:

#### Chief Executives

**Mr Alun Jones**  
*Chief Executive*  
*Healthcare Inspectorate Wales*  
[HIW.PIM@gov.wales](mailto:HIW.PIM@gov.wales)

**Peter Thompson**  
*Chief Executive*  
*Human Fertilisation and Embryology  
Authority*

#### MoU Managers

**Richard Hayward**  
*Head of Partnerships, Intelligence and  
Methodology*  
*Healthcare Inspectorate Wales*  
[HIW.PIM@gov.wales](mailto:HIW.PIM@gov.wales)

**Sharon Fensome-Rimmer**  
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Authority*

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## **9. Annex B - General Data Protection Regulations and Information Sharing**

All information shared between partners must be in accordance with the MoU and General Data Protection Regulations (GDPR) and Data Protection Act (2018).

If partners intend to share any personal information it must comply with GDPR.

The Welsh Government Information Rights Department require HIW to complete a Data Protection Impact Screening Tool, prior to the sharing of any personal information.

The Welsh Government Information Rights Department will then advise HIW if an information sharing agreement is required. This will require HIW to complete and submit a Data Privacy Impact Assessment and draft an information sharing agreement to support the sharing of any personal information.