Memorandum of Understanding

The Health Services Safety Investigations Body and the Human Fertilisation and Embryology Authority

Introduction

1. This Memorandum of Understanding (MoU) sets out the framework to support the working relationship between the Health Services Safety Investigations Body (HSSIB) and the Human Fertilisation and Embryology Authority (HFEA), to promote the safety and wellbeing of the public receiving NHS funded health and social care in England. It is intended to inform members of staff about how the HSSIB and the HFEA will work together, and to ensure that effective channels of communication are maintained.

2. The working relationship between the HSSIB and the HFEA supports the maintenance of a regulatory and safety improvement system for health and adult social care in England that promotes patient safety and high-quality care.

3. The HSSIB investigates patient safety concerns across the NHS in England and in independent healthcare settings where safety learning could also help to improve NHS care. HSSIB came into operation on 1 October 2023 and are a fully independent arm's length body of the Department of Health and Social Care. The detailed responsibilities and the functions of HSSIB are set out on the HSSIB website: Health Services Safety Investigations Body (HSSIB)

4. The legal landscape for the functions of HSSIB has been established by the Health and Care Act 2022 (the "HCA 2022"). The HCA 2022 establishes a prohibition on the disclosure of "protected material" which is held as part of an investigation. Protected materials are defined under Section 122 of the HCA 2022 as any information, document, equipment or other item which is held by HSSIB for the purpose of its investigation function and which relate to an incident occurring in England during the provision of health services which has, or may have implications for the safety of patients. It is an offence for a person to disclose protected material except when limited exemptions apply. HSSIB will not disclose protected material unless there is an appropriate authority to make a disclosure.

5. In exceptional, limited circumstances, HSSIB may be allowed to disclose 'protected material.' The process at HSSIB is that any disclosure of these types of materials must be authorised, on a case-by-case basis, by the Chief Executive Officer (CEO).

6. The HFEA regulates the use of gametes and embryos in fertility treatment and research across the UK.

7. The HSSIB and the HFEA have determined that they do not exchange sufficient quantities of personal data to warrant entering into a separate data sharing agreement, but this will be kept under review.

8. The responsibilities and functions of the HSSIB and the HFEA are set out in Annex 1. Both organisations seek to encourage and promote patient safety and quality within healthcare settings.

9. This MoU does not override the responsibilities and functions of HSSIB and the HFE and is not enforceable in law. However, both HSSIB and the HFEA are committed to working in ways that are consistent with the content of this MoU.

Purpose of information sharing

10. The broad purpose of the MoU is to enable HSSIB and HFEA to share relevant information which is required to enable the other to fulfil their respective functions.

11. This MoU should not be interpreted as imposing a requirement on either party to disclose information in circumstances where doing so would breach their statutory responsibilities. In particular, both HSSIB and HFEA must ensure that any disclosure of personal data pursuant to these arrangements fully complies with both the UK General Data Protection Regulations (UK GDPR), Data Protection Act (DPA) 2018, the Health and Care Act 2022 (HCA 2022), the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) and the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004. The MoU refers to legal basis for information sharing, but it is for both HSSIB and HFEA to determine for themselves that any proposed disclosure is compliant with the law.

Principles of Co-operation

12. This MoU is a statement of principle which supports our focus on promoting patient and public safety and wellbeing. More detailed operational protocols and guidance can be developed as required.

    The HSSIB and the HFEA intend that their working relationship will be characterised by the following principles:

    - The need to make decisions which promote people's safety and high-quality health and social care.
    - Respect for each organisation's independent status.
    - The need to maintain public and professional confidence in the two organisations and their respective functions.
    - Openness and transparency between the two organisations as to when co- operation is and is not considered necessary or appropriate.
    - The need to use resources effectively and efficiently.

13. All arrangements for exchange of information set out in this MoU and any supplementary agreements will take account of and comply with: DPA; UK GDPR; HCA 2022; Freedom of Information Act 2000; The Human Rights Act 1998; HFE Act 1990 (as amended); the HFEA (Disclosure of Donor Information) Regulations 2004; Common Law Duty of Confidentiality; The European Convention of Human Rights specifically Article 8; any HSSIB and HFEA codes of practice, frameworks or other policies relating to personal information.

Areas of Co-operation

14. The working relationship between the HSSIB and the HFEA involves co-operation in the following areas:

    - To act in the public interest by sharing data and information of concern relating to patient safety and any other information it considers relevant (having regard to the list below) relating to the safety and quality of services to inform the regulatory functions of the HFEA and it is fair and lawful to do so to achieve the objectives of this MOU.
    - Where the HSSIB or the HFEA encounters concerns which, it believes may fall into the remit of the other, they will raise these concerns at the earliest opportunity. This must not go against requirements set out for each organisation in either legislation or Secretary of State Directions.
    - Acknowledging the responsibilities and functions of each other and taking account of these when undertaking investigations (HSSIB) or inspections (HFEA).

15. Consideration of information should include but is not exclusive to:

- Sharing information on how each organisation works to promote better co-operation.
- Sharing information by the HFEA on the safety performance of healthcare providers that are relevant to HSSIB investigations.
- Sharing information regarding serious, continuing risk to patient safety whilst respecting the safe space principle.
- Sharing evidence of emerging themes which may be indicative of wider safety issues across embryo and fertility treatment within NHS funded care.
- Co-operation between the HSSIB and the HFEA on national, thematic and other reviews that relate to safety.
- Sharing pre-published HSSIB investigation reports and recommendations that may be relevant to the HFEA. To be open and transparent when in receipt of information regarding the safety of services that are registered with the HFEA and funded by the NHS in England. The information is shared with the HFEA in a timely way through the named contact or by a representative delegated by them.
- To share data that has been agreed on a regular, timely and ongoing basis.

Access requests for data

16. Where a request for information is received by either party under data protection laws or FOIA, the recipient of the request will seek the views of the other party as described in the FOIA section 45 Code of Practice, where the information being sought under the request includes information obtained from, or shared by, the other party. However, the decision to disclose or withhold the information (and therefore any liability arising out of that decision) remains with the party in receipt of the request as Data Controller in respect of the data.

17. The HSSIB and the HFEA will ensure that the personal data held by them and shared with each other will only be processed (including internally) in accordance with the DPA or the UK GDPR (whichever is in force at the time). See Annex 3 for details of joint working protocol and UK GDPR responsibilities.

18. It is important that any information received by the other is not disseminated to any other third party without the prior written permission of the originating party. Information passed between the parties is to be used only for the purposes that it was shared. If the originating party gives written permission for the information to be disclosed to a third party, the origin of the information should be made clear to the third party, in order that they can take appropriate action on flagging the origin of the information on their own internal systems.

Situations in which information will be shared

19. Under certain circumstances, there will be an **expectation** that information held by one will be shared with the other. These circumstances are as follows:

HSSIB	HFEA
Whistle-blowing event or a concern as defined by HSSIB policy.	Whistle-blowing event as defined by HFEA
A patient safety concern that the HSSIB identify either via referral to the HSSIB or during a live investigation that it deems the HFEA would need to be notified of.	Grade A incident reported An increase or a noticeable trend of increase in grade B or C incidents Any incident investigations in an NHS hospital whereby issues have been identified that are not related to the fertility clinic and may benefit from HSSIB investigation.
An investigation is being undertaken and any issues raised need to be raised with the other organisation.	A responsive inspection is being undertaken and any issues raised need to be raised with the other organisation.
To liaise with the HFEA in formulating recommendations which are relevant to the HFEA.	License is suspended or revoked or varied to restrict the activities permitted
Enforcement powers are currently not enforceable. Recommendations are made.	Significant regulatory sanctions are imposed
Referral is made to another agency or professional body, for example the HSE, HTA, GMC, MHRA, CQC or the HCPC, PHSO.	Referral is made to another agency, for example the HSE, HTA, GMC, or the MHRA, CQC, HCPC or the PHSO.
Media interest in an organisation, which may give rise to concerns which need further consideration.	Media interest in an organisation, which may give rise to concerns which need further consideration

The above table relates only to centres falling into the remit of both the HFEA and HSSIB.

Resolution of Disagreement

20. Where there is disagreement between the parties, this should be resolved in the first instance at working level. If this is not possible, it may be referred through those responsible for the management of this MoU, up to and including Chief Investigator of the HSSIB and the Chief Executive of the HFEA will then be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and Review

21. This MoU commences on the date of the signatures below. The MOU will be reviewed every two years or when changes to either party's legislation or Directions. It will also be reviewed if the principles described above need to be altered and/or cease to be relevant for any other reason. Any alterations to the MoU will require both parties to agree.

22. Both organisations have identified a person responsible for the management of this MoU (known as 'Relationship Leads') and their contact details are set out in Annex 2. Relationship Leads will liaise as required to ensure that:

    - This MoU is kept up to date;
    - They identify any emerging issues in the working relationship between the organisations;
    - They resolve any questions that arise regarding the interpretation of this MoU.

Signatures

Peter Thompson
Chief Executive
Human Fertilisation and Embryology Authority
Date: 19 December 2024

Rosie Benneyworth
Interim Chief Investigator
HSSIB
Date: 2 January 2025

Annex 1: Responsibilities and functions

The Human Fertilisation and Embryology Authority

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.

Health Services Safety Investigations Body

The HSSIB's purpose is to:

- conduct thorough, independent, impartial and timely investigations into clinical incidents
- engage patients and relatives, NHS staff, and medical organisations throughout the investigation process
- help the patients and relatives understand 'what happened?' and what's being done to prevent similar events in the future
- produce clearly written, thorough and concise reports with well-founded analysis and conclusions that explain the circumstances and causes of clinical incidents without attributing blame
- make safety recommendations to improve patient safety
- improve patient safety by sharing the lessons learned from investigations as widely as possible
- raise the standard of local investigations of healthcare safety incidents by establishing common standards and skills development

HSSIB approach

The HSSIB use a range of approaches in our investigations focusing on identifying risk and the causes of incidents.

Safety issues for potential investigations can be shared by individuals, groups or organisations. The decision to start an investigation could relate to a single event, a series of events or an issue discovered through current, ongoing investigations.

All HSSIB cases are logged and stored on a database and become part of a process of review to help identify themes and patterns of safety issues over time.

Learning not blaming

The HSSIB act independently and do not investigate on behalf of the families, staff, organisations or regulators. HSSIB can make public safety recommendations to the healthcare sector.

HSSIB staff are investigators not regulators, so don't enforce regulations but do publish the response to recommendations. When it's necessary HSSIB ask the Care Quality Commission and other regulatory bodies to act via safety recommendations.

Annex 2: Contact details for all parties

Named contacts between the HSSIB and the HFEA are as follows:

Relationship Leads: (First points of contact for any specific matters relating to this MoU)		
	HFEA	**HSSIB**
Name:	Sharon Fensome-Rimmer	Sarah Graham
Position:	Chief Inspector	Board, Governance and Records Manager
Email:	Sharon.fensome-rimmer@hfea.gov.uk	sarah.graham@hssib.org.uk
Tel:	0207 291 8263	07708 345904

Chief Executive	
Peter Thompson Chief Executive	**Rosie Benneyworth** Interim Chief Investigator rosie.benneyworth@hssib.org.uk

Annex 3: Joint working protocol

UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018 for information shared between the regulators

From 1st January 2021 the EU General Data Protection Regulation (GDPR) was brought into UK law as UK General Data Protection Regulation (UK GDPR), the principles remain the same and continue to apply to all organisations processing personal data in the UK. The transfer of personal data from UK to EU/EEA is allowed to continue as is, however, the UK is awaiting an adequacy decision, any transfer between public authorities from EEA to the UK will require compliance with Article 49 of the UK GDPR. The Information Commissioner Office (ICO) will provide further guidance and should be referred to if you are processing personal data from the EU/EEA.

Personal data includes any information related to a natural person or 'Data Subject', that can be used to directly or indirectly identify the person. It can be anything from a name, a photo, an email address, bank details, posts on social networking websites, medical information, or a computer IP address.

Compliance with the UK GPDR is essential to ensure that data shared is processed in a manner compliant with UK GDPR regulations. Any organisation not compliant with UK GDPR is subject to a number of enforcement actions from the ICO including potentially heavy fines. Information that is requested from the HFEA about the HSSIB, and vice versa, shall be communicated to the relevant person specified in Annex 2 of this MOU.

For the purposes of the Data Protection Act 2018 (DPA) and the UK GDPR, collectively Data Protection Law, the HSSIB is the data controller for all personal data it holds in order to fulfil its own functions. The HSSIB will become the data controller for the personal data it receives from the HFEA as part of any information disclosure.

The HSSIB is responsible for meeting individuals' requests regarding the exercising of their rights under Data Protection Law for the personal data it holds. This also applies to the HFEA.

For the purposes of the Data protection Law, the HFEA is the data controller for all personal data it holds in order to fulfil its own functions. The HFEA will become the data controller for the personal data it receives from the HSSIB as part of any information disclosures.

The HSSIB and the HFEA will ensure that the personal data held by them and shared with each other will only be processed (including internally) in accordance with Data Protection Law.

It is important that any information received by the other is not disseminated to any other third party without the prior written permission of the originating party. Information passed between the parties is to be used only for the purposes that it was shared. If the originating party gives written permission for the information to be

disclosed to a third party, the origin of the information should be made clear to the third party, in order that they can take appropriate action on flagging the origin of the information on their own internal systems.

It is recognised that personal data provided to the HSSIB or the HFEA may be lawfully shared by the other with law enforcement agencies and the ICO without the need for prior consent from the originating party.

Review history and approval

Version	1.0
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