Memorandum of Understanding

The Healthcare Safety Investigation Branch 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 Healthcare Safety Investigation Branch (HSIB) 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 HSIB and the HFEA will work together, and to ensure that effective channels of communication are maintained.

2. The working relationship between the HSIB 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. HSIB is a safety investigation body established under the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 and the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. The HSIB was set up to discharge the Secretary of State duties in relation to the promotion of a comprehensive health service and securing continuous improvement in the quality of services.

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

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

6. This MoU does not override the statutory responsibilities and functions of the HSIB and the HFEA and is not enforceable in law. However, the HSIB and the HFEA are committed to working in ways that are consistent with the principles of this MoU.

Principles of Co-operation

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.

7. The HSIB and the HFEA intend that their working relationship be characterised by the following principles:

    a. The need to make decisions which promote people's safety and high-quality health and social care.
    b. Respect for each organisation's independent status.
    c. The need to maintain public and professional confidence in the two organisations and the regulatory process.
    d. Openness and transparency between the two organisations as to when co-operation is and is not considered necessary and/or appropriate.
    e. Addressing gaps in the regulatory framework via safety recommendations.

Areas of Co-operation

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

    a. 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.
    b. Where the HSIB 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.
    c. Acknowledging the responsibilities and functions of each other and taking account of these when undertaking investigations (HSIB) or inspections (HFEA).

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

    a. Sharing information on how each organisation works to promote better co-operation
    b. Sharing information by the HFEA on the safety performance of healthcare providers that are relevant to HSIB investigations

c. Sharing information regarding serious, continuing risk to patient safety whilst respecting the safe space principle
d. Sharing evidence of emerging themes which may be indicative of a wider safety issues across embryo and fertility treatment within NHS funded care.
e. Co-operation between the HSIB and the HFEA on national, thematic and other reviews that relate to safety.
f. Sharing pre-published HSIB 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.
g. To share data that has been agreed on a regular, timely and ongoing basis

10. The HSIB and the HFEA recognise their responsibilities under the Freedom of Information Act 2000. Where the HSIB and the HFEA receives a request under the Act for information received from the other organisation the HSIB and the HFEA agrees to take reasonable steps to consult on the proposed disclosure and the application of exemptions but recognise that the responsibility for disclosure lies with the organisation that received the request.

11. The HSIB 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 GDPR (whichever is in force at the time).

    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

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

HSIB	HFEA
Whistle-blowing event or a concern as defined by HSIB policy.	Whistle-blowing event as defined by HFEA

A patient safety concern that the HSIB identify either via referral to the HSIB 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 HSIB 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 or the HCPC
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

Resolution of Disagreement

13. 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 HSIB and the Executive of the HFEA will then be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and Review

14. 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.

15. 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:

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

Signatures

[redacted]

Peter Thompson
Chief Executive
Human Fertilisation and Embryology Authority
Date: 06/03/2020

[redacted]

Keith Conradi
Chief Investigator
HSIB
Date: 06/03/2020

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.

Healthcare Safety Investigation Branch (HSIB)

The HSIB'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

HSIB approach

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

HSIB staff are investigators not regulators, so don’t enforce regulations but do publish the response to recommendations. When it’s necessary HSIB 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 HSIB and the HFEA are as follows:

Relationship Leads: (First points of contact for any specific matters relating to this MoU)		
	HFEA	**HSIB**
Name:	Sharon Fensome-Rimmer	Kirsty Benn-Harris
Position:	Chief Inspector	Associate Director of Information Governance
Email:	[redacted]	[redacted]
Tel:	[redacted]	[redacted]

Chief Executive	
Peter Thompson Chief Executive	**Keith Conradi** Chief Investigator [redacted]

Review history and approval

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