Memorandum of Understanding between the Human Tissue Authority and the Human Fertilisation and Embryology Authority

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1. The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between the Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA).

2. The HTA licenses and inspects organisations that remove, store and use tissue for medical treatment, post-mortem examination and teaching. The HFEA licenses and monitors centres which undertake research and provide treatment for infertility. Both Authorities have responsibilities across the UK.

3. There are some services which are licensed by both the HTA and the HFEA; it is mainly in relation to these services where the HTA and the HFEA will work together in cooperation, as appropriate.

4. This MoU only relates to regulatory activity within the United Kingdom (UK), and does not override the HTA or HFEA's statutory adherence to, responsibilities or functions in relation to any relevant legislation or governance standards and is not enforceable in law. Wherever appropriate however, the HTA and HFEA will adhere to the contents of this MoU.

5. More detail about the working relationship between the HFEA and the HTA is set out in the Joint Working Protocol, included as Annex B of this MoU.

Principles of cooperation

6. The relationship between HTA and HFEA will be characterised by the following principles:

   a) the need for clarity in the regulatory roles, remit, processes and mutual interests of both organisations and promotion of public confidence by making decisions which protect and promote patient health, safety and welfare and high quality health care;

   b) mutual support, clear and effective communication with a focus on working together and the relevant coordination and sharing of information, investigative knowledge and experience in the regulation of services;

   c) good decision making and minimisation of risks that respects each organisation's independent status and right to make different decisions about compliance given that different regulations apply;

   d) decisions about cooperation based on clear lines of accountability, consistency in approach and effective and efficient use of resources with a shared commitment to transparent, accountable, proportionate, and targeted regulation (the principles of better regulation);

e) the aim of learning from each other about good practice in regulation and working together to influence relevant policy and enable the partnership to continuously develop and improve; and

f) an open approach to the possibilities of responsible innovation in the sectors we regulate.

Exchange of information

7. Cooperation between the HTA and the HFEA will often require the exchange of information. Exchange of information will be expected where either the HTA or the HFEA identifies concerns about an organisation and those concerns are considered to be relevant to the other party's regulatory functions. The Joint Working Protocol (JWP) in Annex B sets out the detailed arrangements for sharing information between the parties.

8. Each organisation will respect and take appropriate steps to protect the confidential documents and information that the other may provide. All arrangements for cooperation and exchange of information set out in this MoU and the JWP will take account of, and comply with, data protection legislation, the Freedom of Information Act 2000 and the Human Rights Act 1998. This agreement will be administered in accordance with the primary and secondary HTA and HFEA legislation relating to these matters. This includes the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Fertilisation and Embryology Act 1990 (as amended). This agreement will also comply with the respective Codes of Practice, frameworks or other policies of both organisations, relating to the management and use of confidential information.

Resolution of disagreement

9. The effectiveness of the working relationship between the HTA and the HFEA will be ensured through regular contact, both formally and informally, at all levels up to and including the Chief Executives of the respective organisations.

10. Any disagreement between the HTA 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 C. The parties should aim to resolve disagreements in a reasonable time.

Duration and review of this MoU

11. This MoU is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. The Annexes of the MoU will be reviewed after a period of 24 months commencing on the date on which it was signed by the Chief Executives of the two regulators. Any

changes made to the Annexes should be confirmed by relevant governance structures in each organisation; they do not require sign-off by the Chief Executives unless it is specifically deemed necessary. The MoU may be reviewed at any time at the request of either party.

12. The review of the annexes will include:
    a) checking that relevant organisational, staff and contact details are current; and
    b) reviewing whether the objectives of the Joint Working Protocol have been met and whether the processes for sharing information need to be amended to improve effectiveness or efficiency.

13. Both organisations have identified a MoU Manager in Annex C and these will liaise as required to ensure this MoU is kept up to date and to identify any emerging issues in the working relationship between the two organisations.

14. Both the HTA and the HFEA are committed to exploring ways to develop an increasingly more effective and efficient partnership, working to promote quality and safety within their respective regulatory remits.

Signatures

Allan Marriott-Smith
Chief Executive
Human Tissue Authority

Date 7 February 2021

Peter Thompson
Chief Executive
Human Fertilisation and Embryology Authority

Date 26 January 2021

Annex A: Responsibilities and functions

1. The Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA) acknowledge the responsibilities and functions of each other and will take account of these when working together.

Responsibilities and functions of the HTA

2. The HTA is a Non-Departmental Public Body sponsored by the Department of Health and Social Care. The HTA was established under the Human Tissue Act (HT Act) 2004 – which covers England, Wales and Northern Ireland. The HTA is also a UK Competent Authority for the European Union (EU) Tissues and Cells Directives and the EU Organ Donation Directive.

3. The responsibilities and functions of the HTA are set out primarily in the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (Q&S Regulations) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (Q&S (Organs) Regulations). In summary they are to:

   - issue licences under the HT Act, Q&S Regulations and Q&S (Organs) Regulations (as amended);
   - inspect or audit establishments licensed under the HT Act, Q&S Regulations and Q&S (Organs) Regulations (as amended);
   - issue Codes of Practice and standards setting out the general principles which it considers should be followed in carrying out activities governed by the HT Act;
   - issue Directions setting out the requirements which should be followed in carrying out activities governed by the Q&S Regulations and the Q&S (Organs) Regulations (as amended);
   - promote compliance with the HT Act, Q&S Regulations, Q&S (Organs) Regulations (as amended) and Codes of Practice; and
   - provide advice and information for persons to whom licences apply or persons who may wish to undertake activities which are governed by the HT Act, Q&S Regulations and Q&S (Organs) Regulations.

Responsibilities and functions of the HFEA

4. 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:

   a) issue licences under the Human Fertilisation and Embryology Act 1990 (as amended);

   b) inspect establishments licensed under the Human Fertilisation and Embryology Act 1990 (as amended);

   c) issue a Code of Practice setting out 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);

   d) promote compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and with the Code of Practice;

   e) keep under review information about embryos and about 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; and

   f) 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.

Annex B: Joint working protocol

Introduction

The Human Tissue Authority (HTA) and Human Fertilisation and Embryology Authority (HFEA) carried out some joint work in 2011-12 to look at their regulatory regimes in detail. This was to identify possible ways in which both regulators could reduce regulatory burden for the benefit of registered or licensed organisations, and to develop mechanisms for sharing information about organisations where they are registered or licensed by both of the regulators.

One output was this bilateral Joint Working Protocol between the HTA and HFEA included in this Annex. This sets out the detail of the working arrangements between the HTA and HFEA in two parts – **Operational Protocols** which will be carried out by each regulator's registration and inspection staff, and **Joint Management Arrangements,** which will be carried out by members of the Executive listed at Annex C.

The HTA and HFEA necessarily use different terminology to describe some aspects of their work, according to its governing legislation. Where this document refers to organisations, it also means registered or licensed providers.

Operational protocols

1. Joint inspections

The HTA and HFEA will endeavour to carry out joint inspections of organisations that require a licence from both Regulators, where possible, to reduce regulatory burden.

Both organisations will work together to maintain an up to date list of organisations suitable for joint inspections to facilitate the inspection of these establishments where possible.

Joint inspections will require the HTA and HFEA to meet prior to and following an inspection, via teleconference or in person, to discuss:

Before a joint inspection takes place

- background information about the organisation concerned and its compliance history
- information about any regulatory action taken to date and the effect it has had
- any areas of concern
- the scope of the inspection
- which inspectors from the HTA and HFEA will lead on certain areas of the inspection to avoid duplication (e.g. quality management system, consent, etc.)

After a joint inspection takes place

- general observations and any areas of concern
- the need to monitor compliance, or follow up areas that require improvement or enforcement actions
- where there are areas of co-regulation, which inspection report will note the outcomes of inspection findings (including any non-conformities)
- where there are areas of co-regulation, whether the HTA or HFEA will lead on following up the areas that require improvement or enforcement actions (including liaising with the organisation and receiving assurance that actions have been, or are being, taken)

2. Sharing information

2.1 Who will share information?

Information will generally be shared at an operational level between HTA and HFEA inspectors. The information shared will relate to an organisation which is licensed or registered by both Regulators.

2.2 Situations in which information will be shared

We will aim to foster a culture of information sharing in which inspectors are empowered to pick up the phone to their counterpart to discuss an organisation that is causing them concern. In the first instance, HTA and HFEA inspectors will contact the single point of contact for each organisation to identify the relevant inspector. These contact details are:

- HTA: Robert.Watson@hta.gov.uk
- HFEA: sharon.fensome-rimmer@hfea.gov.uk

There will be a two-way sharing of information, which may be volunteered by one Regulator to the other, or provided in response to a particular request.

The HTA and HFEA will share findings from site inspections. The Regulators will then consider the use of such information to reduce the scope of forthcoming site inspections. This will streamline the inspection and post inspection process. For, example, the review of an organisation's quality management system by the HTA could be streamlined if it has already been assessed by the HFEA. A collaborative approach to the assessment of corrective and preventative action plans may also be used, where applicable.

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

HTA	HFEA
• Whistle-blowing event as defined by HTA	• Whistle-blowing event as defined by HFEA
• Serious Adverse Events and Reactions (SAEARs) reported that has the potential to cause a reputational risk to the establishment	• Grade A incident reported • Trends in grade B and C incidents
• A non-routine inspection is arranged	• A responsive inspection is being undertaken
• A licence is suspended or revoked or steps are taken to restrict licensable activities.	• A licence is suspended or revoked or varied to restrict the activities permitted.
• Significant regulatory sanctions are imposed	• Significant regulatory sanctions are imposed
• Referral is made to another agency, for example the Health and Safety Executive (HSE) or the Medicines and Healthcare products Regulatory Agency (MHRA)	• Referral is made to another agency, for example the HSE or the MHRA
• 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

In the circumstances listed above, the inspector will be expected to contact their counterpart in the other organisation using the details above, both to pass on the information and to ascertain whether there is any additional information held by the other regulator which should be taken into account. The counterpart should ensure relevant colleagues within their organisation are aware that the information sharing has taken place. Contact between the HTA and HFEA may occur in other circumstances where it is considered to be appropriate and proportionate, and if necessary agreed with a relevant manager.

Each Regulator should record the information shared, who and when it was shared with and any outcomes. The manner in which this is done is up to individual regulators to determine.

3. What information will be shared?

The information to be shared in the situations listed above will include:

- background information about the organisation concerned and its compliance history;
- information about regulatory action taken to date and the effect it has had and
- the steps in place for on-going monitoring of compliance or follow up of required improvement or enforcement actions.

Only non-patient identifying information will be shared between the regulators under this protocol. Sharing patient identifiable information is a criminal offence under the Human Fertilisation and Embryology Act 1990 (as amended) and also subject to legal restrictions on both Regulators. Account must also be taken of data protection legislation when information is shared about registered or licensed individuals and people who work for the provider.

Any proposed sharing of information, which may potentially include patient identifiable data, should follow the policies and guidance of the disclosing organisation, and must be lawful and proportionate.

Where needed, case management meetings will be arranged between the Regulators. This would be in exceptional circumstances only and subject to the agreement of the relevant senior managers.

4. FOI requests for information shared between the regulators

Any request under the Freedom of Information Act 2000 relating to information which was all or in part provided by the other Regulator will not be released without first seeking advice from the organisation that provided the information. This includes information or data relating to serious incidents, which may include information about individuals. For example, if an HFEA inspector informs an HTA inspector about allegations made by a whistle-blower, following which an FOI request is received by the HTA for information held about the organisation concerned, no information relating to the incident would be released without discussion with the HFEA about whether the information which had been shared is subject to any exemptions under the FOI Act or Data Protection Act 2018.

Legal responsibility for responding to an FOI Act request – including final responsibility for making any decision to withhold information under exemption – remains with the organisation receiving that request.

5. 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) will be 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 HTA, and vice versa, shall be communicated to the relevant person specified in Annex C of this MOU.

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

The HTA 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 HTA as part of any information disclosures.

The HTA 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.

Information that is requested from the HFEA about the HTA, and vice versa, shall be communicated to the relevant person specified in Annex C of this MoU.

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 HTA 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.

6. Communications and Press enquires

Where inspectors share information about regulatory non-compliance within an organisation, and that organisation becomes the subject of press interest, the

regulators will co-ordinate their press responses, while ensuring that the judgement or position of each is adequately reflected.

Joint Management Arrangements

This JWP will have effect for a period of 24 months commencing on the date on which the MoU was signed by the Chief Executives of the two regulators. The Joint Working Protocol may be reviewed at any time at the request of either party.

The formal review date will be: January 2023

Review of operational protocols and joint working arrangements

The efficacy of implementing the protocols for joint inspections and sharing information will be informally reviewed by the HTA and HFEA on a biennial basis:

a) to ensure that relevant organisational, staff and contact details are current; and
b) to review joint inspections and instances where information has been shared the impact of that on regulatory responses, and whether the processes need to be amended to improve effectiveness or efficiency.

Any changes made to the Joint Working Protocol should be confirmed by the relevant governance structures in the HTA and HFEA; they do not require approval from the Chief Executives unless it is specifically deemed necessary.

The Chief Executives of the HTA and HFEA will meet annually, where possible, and will include consideration of joint working arrangements. Additional meetings may be called at any time if required.

Joint Advice Arrangements

The HTA and HFEA collaborate with other agencies to provide joint regulatory through the Regulatory Advice Service for Regenerative Medicine (RASRM).

This advice service offers research and development professionals across academia, industry and the NHS (including clinicians) a single point of access to free, joined-up regulatory information, advice and guidance. This service is provided in partnership by the Health Research Authority (HRA), HFEA, HTA, MHRA (and the National Institute for Health and Care Excellence . Where necessary, the advice service can also link up to other specialist bodies such as HSEand Department for Environment, Food and Rural Affairs .

Annex C: Contact details

Human Tissue Authority 2nd floor, 2 Redman Place London E20 1JQ Telephone 020 7269 1900	Human Fertilisation and Embryology Authority 2nd floor, 2 Redman Place London E20 1JQ Telephone: 020 7291 8200

There will be named contacts between the HTA and HFEA as follows:

NOTE: The following generic email address should be copied into all joint working correspondence. This includes matters concerning joint inspections, information sharing and review of this MoU.

HTA: licensing.enquiries@hta.gov.uk
HFEA: compliance@hfea.gov.uk

Chief Executives (internal escalating policies should be followed before referral to Chief Executives)	
Allan Marriott-Smith Chief Executive Email: Allan.Marriott-Smith@hta.gov.uk	Peter Thompson Chief Executive Email: peter.thompson@hfea.gov.uk
Joint inspections and information sharing	
Robert Watson Head of Regulation Robert.Watson@hta.gov.uk	Sharon Fensome-Rimmer Chief Inspector sharon.fensome-rimmer@hfea.gov.uk
MoU management (including strategic issues)	
Nima Sharma Board Secretary Email: nima.sharma@hta.gov.uk	Niamh Marren Regulatory Policy Manager Email: niamh.marren@hfea.gov.uk Emily Tiemann Email: Emily.tiemann@hfea.gov.uk
Data Protection Officers	
Dan Howard Data Protection Officer Email: Dan.Howard@HFEA.gov.uk	David Thomson Data Protection Officer Email: David.Thomson@HTA.gov.uk