Memorandum of Understanding (MoU) between the Human Tissue Authority and the Human Fertilisation and Embryology Authority

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 is the regulator for the safe removal, use and disposal of human tissue and organs in the UK. The HFEA regulates the use of gametes and embryos in fertility treatment and research. The responsibilities and functions of the HTA and HFEA are set out at Annex A.

3. This MoU does not override the statutory responsibilities and functions of the HTA and HFEA and is not enforceable in law. However, the HTA and HFEA agree to adhere to the contents of this MoU.

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

Principles of cooperation

5. The HFEA licenses and monitors centres which undertake research and provide treatment for infertility: it has responsibilities across the UK. The HTA licenses and inspects organisations that remove, store and use tissue for medical treatment, post-mortem examination and teaching; it has responsibilities across the UK. There are some services which are licensed by the HFEA and the HTA; it is mainly in relation to these services where the HFEA and the HTA will work together in cooperation, as appropriate.

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

    a. the need to make decisions which protect and promote patient health, safety and welfare and promote high quality health care;
    b. a focus on working together by sharing information about relevant regulated services;
    c. respect for each organisation's independent status and right to make different decisions about compliance given that different regulations apply;
    d. the need to maintain public confidence in the two organisations
    e. openness and transparency between the two organisations as to when cooperation is and is not considered necessary or appropriate;
    f. the need to use resources effectively and efficiently through appropriate coordination and information sharing; and
    g. the aim of learning from each other about good practice in regulation and working together to collectively influence policy where relevant.

7. The HTA and the HFEA are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Exchange of information

8. Cooperation between the HTA and the HFEA will often require the exchange of information. Exchange of information will be expected where either the HFEA or the HTA 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.

9. All arrangements for cooperation and exchange of information set out in this MoU and the JWP will take account of and comply with the Data Protection Act 1998, the Human Tissue Act 2004 and other human tissue secondary legislation, the Human Fertilisation and Embryology Act 1990 (as amended), and all relevant HTA and HFEA legislation relating to these matters and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

Resolution of disagreement

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 12 months commencing on the date on which it was signed by the Chief Executives of the two organisations. 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.

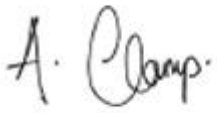
12. The review of the annexes will include:
    a. checking that relevant organisational, staff and contact details are current; and
    b. reviewing whether the objectives of the joint working protocol have been met and whether the processes for sharing information need to amended to improve effectiveness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

13. Both organisations have identified an MoU manager at 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 HFEA and the HTA are committed to exploring ways to develop increasingly more effective and efficient partnership working to promote quality and safety within their respective regulatory remits.

15. A Joint Working Group and Sub-group will oversee the development of operational working arrangements that support the delivery of the principles outlined in this MOU.

Signed



Alan Clamp
Chief Executive
Human Tissue Authority

Date: 4 January 2013

Peter Thompson
Chief Executive
Human Fertilisation and Embryology Authority

Date: 4 January 2013

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 CQC

2. 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 (Q&S Regulations) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q&S (Organs) Regulations). In summary they are to:

- issue licences under the HT Act, Q&S Regulations and Q&S (Organs) Regulations
- inspect establishments licensed under the HT Act, Q&S Regulations and Q&S (Organs) Regulations
- issue Codes of Practice setting out general principles which it considers should be followed in carrying out activities governed by the HT Act.
- promote compliance with the HT Act, Q&S Regulations, Q&S (Organs) Regulations and Codes of Practice
- 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

3. 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 maintain 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)

(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

(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 Care Quality Commission (CQC), Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) carried out some joint work in 2011/12 to look in detail at the three regulatory regimes. This was to identify possible ways in which we could reduce or improve regulatory overlaps for the benefit of registered or licensed organisations, and to develop mechanisms for sharing information about organisations where they are registered or licensed by more than one of the regulators. The work was carried out by a Sub-working group (SWG) which included representatives from each regulator, reporting to a Joint Working Group (JWG) of directors and senior managers from all three.

One output of this tripartite working group is the bilateral Joint Working Protocol between the HFEA and the HTA included in this annex. The JWP sets out the detail of the working arrangements between the HFEA and the HTA 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 SWG or JWG.

The HFEA and the HTA 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. Master list

1.1 What information is in the master list?

A 'master list' has been developed which identifies all the organisations that are registered or licensed by the CQC, the HTA and the HFEA. This list will enable each regulator's staff to check whether an organisation is also regulated by the other. The main purpose of this is to facilitate information sharing between the regulators' staff about organisations they 'share'.

CQC registers a significantly higher number of providers than either the HFEA or the HTA, therefore, CQC registered providers are only included on the master list if they are also licensed by the HTA or the HFEA. All HTA and HFEA licences are included on the list; for completeness the master list includes HTA-licensed organisations and HFEA-licensed organisations outside of England in other parts of the UK.

The name and email contact details of the CQC compliance inspector allocated to each CQC-registered provider on the list will be included to facilitate sharing of information relating to an organisation's compliance (see 2.2 below). There will be a

single point of contact in the HTA and HFEA for sharing this type of information whether an organisation is, or is not, registered by the CQC

1.2 Maintaining the list

It has been agreed that the Data Management team at CQC will maintain the list and keep it up-to-date. This will be done by the HTA and the HFEA, providing CQC with information whenever a new organisation is licensed, or an existing licence is revoked, suspended or changed. That information will be provided by the central contact person in the HTA.

The information supplied will include:

- For new providers: the name of the service, contact details and licence details.
- For revocations or suspensions of existing licences: details of the cancellation or suspension.
- For changes to licences: details of amendments to the services' licence including contact details, provider details or changes to the licence itself.

When new information is received, CQC's Data Management team will refresh the list and email an updated copy to the contact person in the HTA and the HFEA. Any changes that are made on the master list to CQC providers or to CQC compliance inspectors' allocations will be automatically updated by CQC's Data management team and included in their monthly refresh of the list.

A routine updating and emailing of the list will be carried out by CQC in the first week of every month, where new information has been provided by the HTA or HFEA, or in the preceding month, or changes to CQC information have been made, so the list is continually up-to-date.

The HTA and HFEA should send any updated information for the master list to the CQC Data Management Team and copied to the CQC MoU manager:

- CQC Data Management team: datamanagement@cqc.org.uk
- CQC MoU Manager: gemma.rafferty@cqc.org.uk

Updated versions of the master list will be sent to:

- CQC: gemma.rafferty@cqc.org.uk
- HTA: anthony.wright@hta.gov.uk
- HFEA: compliance@hfea.gov.uk

Any CQC compliance inspector who is affected by changes to the master list will also be notified.

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 in their portfolio which is causing them concern. HFEA and HTA inspectors will contact the single point of contact for the each organisation to speak to the relevant inspector. These contact details are:

- HTA: anthony.wright@hta.gov.uk
- HFEA: compliance@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. Information will only be shared where the organisation is regulated by, or carrying out activities which should be regulated or licensed by, both regulators.

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:

HFEA	HTA
• Whistle-blowing event as defined by HFEA	• Whistle-blowing event as defined by HTA
• Grade A incident reported	• Serious Untoward incident or SEAR reported that has the potential to cause a reputational risk to the establishment
• A responsive inspection is being undertaken	• A non-routine inspection is arranged
• Licence is suspended or revoked or varied to restrict the activities permitted.	• Licence is suspended or revoked or steps are taken to restrict licensable activities.
• Significant regulatory sanctions are imposed	• Significant regulatory sanctions are imposed
• Referral is made to another agency, for example the HSE or the 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, 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. Contact 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 it was shared with and when, 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
- 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 in both regulators. Account must also be taken of the Data Protection Act when information is shared about registered or licensed individuals and people who work for the provider.

Any proposed sharing of 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 FOI Act 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 a 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

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. 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 12 months commencing on the date on which the MoU was signed by the Chief Executives of the two organisations. The JWP may be reviewed at any time at the request of either party.

The formal review date will be: 2 January 2014

1. Review of master list

The efficacy of using the master list will be reviewed by the SWG of the JWG every six months. The SWG will canvas views and experiences of inspectors in each of the regulators and the CQC Data Management team to establish whether the list is working well, or improvements to the process need to be made.

The SWG will make recommendations to the JWG depending on the findings of the review.

2. Review of operational protocols and joint working arrangements

The efficacy of implementing the protocols for sharing information will be reviewed by the SWG every six months. The SWG will undertake an audit of when and under what circumstances information has been shared, the impact of that on regulatory responses, and whether any improvements to the process or changes to the scope of information sharing need to be implemented.

The SWG will make recommendations to the JWG depending on the findings of the review.

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

Annex C: Contact details

Human Tissue Authority 151 Buckingham Palace Road, Victoria, London SW1W 9SZ Telephone 020 7269 1900	**Human Fertilisation and Embryology Authority** Finsbury Tower 103-105 Bunhill Row London EC1Y 8HF Telephone: 020 7291 8200

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

Chief Executives (internal escalating policies should be followed before referral to Chief Executives)	
Alan Clamp Chief Executive Email: alan.clamp@hta.gov.uk	Peter Thompson Chief Executive Email: peter.thompson@hfea.gov.uk
MoU management (including strategic issues)	
Caroline Browne Head of Regulation Email: caroline.browne@hta.gov.uk Direct line: 020 7269 1927	Debra Bloor Head of Inspection Email: debra.bloor@hfea.gov.uk Telephone: 020 7291 8200