Memorandum of Understanding between the United Kingdom Accreditation Service 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 United Kingdom Accreditation Service (UKAS) and the Human Fertilisation and Embryology Authority (HFEA).

2. UKAS is the sole national accreditation body for the United Kingdom. The HFEA regulates the use of gametes and embryos in fertility treatment and research. The responsibilities and functions of the UKAS and HFEA are set out at Annex A.

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

4. More detail about the working relationship between UKAS and the HFEA is set out in the joint working protocol, included at Annex B of this MoU.

Principles of cooperation

5. UKAS is recognised by the UK government, to assess against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services. The HFEA licenses and monitors centres which undertake research and provide treatment for infertility: it has responsibilities across the UK. There are some establishments which are accredited by UKAS and licensed by the HFEA, or where UKAS accredited establishments work directly with HFEA licensed establishments; it is mainly in relation to these services where UKAS and the HFEA will work together in cooperation, as appropriate This includes the sharing of information from UKAS assessments and HFEA inspection reports such as diagnostic andrology, genetic testing in addition to any other diagnostic laboratory test that may impact on IVF treatments or its outcomes and in addition to incidents.

6. UKAS 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 using information obtained or provided by the laboratory to both parties and from UKAS if the laboratory has not notified the HFEA about relevant services regulated by the HFEA;
   c) respect for each organisation’s independent status and right to make different decisions about compliance given that different regulations and requirements 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 HFEA is committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Exchange of information

8. Cooperation between UKAS and the HFEA will often require the exchange of information. Exchange of information will be expected where either UKAS or the HFEA identifies concerns about an establishment and those concerns are considered to be relevant to the other party's functions. The Joint Working Protocol at 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 joint working protocol will take account of and comply with the General Data Protection Regulation, the Accreditation Regulations 2009, Schedule 33 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), the Human Fertilisation and Embryology Act 1990 (as amended), and all relevant UKAS and HFEA legislation relating to these matters and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

10. All exchange of information will pay due regard to the confidentiality requirements as set out in the UKAS Agreement and the confidentiality requirements set out in the Human Fertilisation and Embryology Act 1990 (as amended) as is subject to legal restrictions.

Resolution of disagreement

11. Any disagreement between UKAS 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

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

13. 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.

14. 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.

15. Both UKAS and the HFEA are committed to exploring ways to develop increasingly more effective and efficient partnership working to promote quality and safety within their respective remits.

Signatures

Matt Gantley **CEO** **United Kingdom Accreditation Service**	**Peter Thompson** **Chief Executive** **Human Fertilisation and Embryology Authority**
Date 14/04/2025	**Date 19/12/2024**

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Annex A: Responsibilities and functions

1. The United Kingdom Accreditation Service (UKAS) 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 UKAS

2. UKAS is the sole national accreditation body for the United Kingdom. UKAS is recognised by government, to assess against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services.

3. Accreditation by UKAS demonstrates the competence, impartiality and performance capability of these evaluators. UKAS is a non-profit-distributing private company, limited by guarantee. UKAS is independent of Government.

4. UKAS is appointed as the national accreditation body by Accreditation Regulations 2009 (SI No 3155/2009) and Schedule 33 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696). UKAS operates under a Memorandum of Understanding with the Government, through the Secretary of State for Business and Trade (DBT)

5. UKAS is licensed by DBT to use and confer the national accreditation symbols which symbolise Government recognition of the accreditation process.

Responsibilities and functions of the HFEA

6. 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 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, 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

The United Kingdom Accreditation Service (UKAS) and the Human Fertilisation and Embryology Authority (HFEA) have identified possible ways in which they can ensure that information is shared about establishments where they are accredited by the UKAS and licensed by the HFEA, or where UKAS accredited establishments work directly with HFEA licensed establishments.

This Annex sets out the working arrangements between UKAS and the HFEA in two parts – **Operational protocols** which will be carried out by UKAS assessors and HFEA inspection staff, and **Joint management arrangements** which will be carried out by members of the Executive listed at Annex C.

UKAS and the HFEA necessarily use different terminology to describe some aspects of their work, according to its governing legislation. Where this document refers to establishments, it also means UKAS accredited or HFEA licensed providers.

Operational protocols

Joint working

UKAS and the HFEA will endeavour to work together, wherever possible, to streamline the process of reporting serious untoward incidents and with regard to the activities of medical laboratories that conduct activities within the scope of this MoU. Both organisations will work towards improving accreditation and regulatory efficiencies, respectively.

Where relevant accreditation of a medical laboratory is suspended (either full or partial) or withdrawn due to concerns around patient safety, UKAS will work with the HFEA to risk assess the situation and ensure that the impact on patient safety regarding samples is considered. This is of particular importance to preimplantation genetic testing for monogenic or single-gene disorders (PGT-M) and preimplantation genetic aneuploidy screening (PGT-A) laboratories.

On occasion it may be necessary for UKAS and the HFEA to work together regarding certain incidents that may affect patient safety.

Sharing information

<u>Who will share information?</u>

Information will generally be shared at an operational level, between UKAS assessors and HFEA inspectors. The information shared will relate to an establishment that is accredited and/or licensed by either organisation.

Situations in which information will be shared

UKAS assessors and HFEA inspectors will contact the single point of contact for each organisation. These contact details are:

- UKAS: Sally Wood, Senior Assessment Manager (sally.wood@ukas.com)
- HFEA: Sharon Fensome-Rimmer, Chief Inspector (sharon.fensome-rimmer@hfea.gov.uk)

There will be a two-way sharing of information, which may be volunteered by one organisation to the other or provided in response to a particular request. Information will only be shared where the establishment is accredited or regulated by both organisations and with due regard to confidentiality agreements between UKAS and its customers and the confidentiality requirements set out in the Human Fertilisation and Embryology Act 1990 (as amended) as is subject to legal restrictions.

Under certain circumstances, information held by UKAS or HFEA may be shared with the other. These circumstances are as follows:

UKAS The below are in reference to HFEA licensed establishments (or establishments which work with HFEA licensed establishments).	**HFEA**
Whistle-blowing event as defined by UKAS.	Whistle-blowing event as defined by HFEA.
Serious untoward incident or significant nonconforming work reported that has the potential to cause serious harm to patients or a reputational risk to the establishment.	Grade A incident reported and trends in grade B and C incidents
	Concerns relating to staff members which may require a fitness to practice to either GMC, HCPC or NMC.
A non-routine assessment scheduled due to concerns raised by either party, and the outcomes of that assessment.	A responsive inspection is being undertaken, and the outcomes of that assessment.
Accreditation is suspended or revoked, or steps are taken to restrict accredited activities.	Licence is suspended or revoked, or varied to restrict the activities permitted.

Significant sanctions are imposed relating to laboratory functions or tests have been deemed out of scope.	Significant regulatory sanctions are imposed related to laboratory functions.
A referral is made to another agency.	Referral is made to another agency (eg, the Health and Safety Executive (HSE), the Medicines and Healthcare products Regulatory Agency (MHRA), or the Human Tissue Authority (HTA)).
Media interest in an organisation, which may give rise to concerns which need further consideration relating to patient safety or service quality.	Media interest in an organisation, which may give rise to concerns which need further consideration relating to patient safety or service quality.

In the circumstances listed above, the inspector or assessment manager 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 organisation which should be taken into account. The counterpart should ensure colleagues within their organisation, who may be relevant, are aware that the information sharing has taken place.

Contact between UKAS and the HFEA may occur in other circumstances where it is considered to be appropriate and proportionate, and if necessary agreed with a relevant manager.

UKAS and the HFEA 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 organisations to determine.

What information will be shared?

Subject to the accredited body waiving confidentiality as laid out in the UKAS Agreement, the information to be shared in the situations listed above will include:

- background information about the establishment 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
- assessment reports relating to diagnostic andrology, genetic testing, or any other diagnostic laboratory test that may impact on IVF treatments or its outcomes and in addition to incidents.

UKAS will ensure that the HFEA is appropriately informed of any concerns that are identified in a situation where the laboratory has not already informed the HFEA. Similarly, if the HFEA learn of any concerns they will ensure that UKAS are notified.

Where accreditation is withdrawn UKAS will where appropriate work with the HFEA to risk assess/risk benefit patient safety relating to lab samples that may still be in the process of being analysed, which may impact on licensed fertility treatments.

Only non-identifiable patient information will be shared with UKAS under this protocol. Sharing patient identifiable information is a criminal offence under the Human Fertilisation and Embryology Act 1990 (as amended) and is subject to legal restrictions. Account must also be taken of the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018 when information is shared about accredited or licensed individuals and people who work for the provider.

Where needed, case management meetings (using non-identifiable patient information) will be arranged between UKAS and the HFEA. This would be in exceptional circumstances only and subject to the agreement of the relevant senior managers.

Freedom of Information (FOI) requests for information shared

As an arm's length body of Central Government, the HFEA is subject to FOI requests from members of the public. Any request under the FOI Act relating to information which was all or in part provided 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 UKAS assessor informs a HFEA inspector about allegations made by a whistle-blower, following which an FOI request is received by the HFEA for information held about the organisation concerned, no information relating to the incident would be released without discussion with UKAS about whether the information which had been shared is subject to any exemptions under the FOI Act or Data Protection Act. Where these occur, all requests will be forwarded to UKAS. The HFEA at all times will respect the relationship UKAS has with its customers.

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.

UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018 for information shared between 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. From 28 June 2021, a transfer between public authorities from EEA to the UK may rely on the European Commission's adequacy decision that is expected to last until 27 June 2025, otherwise 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 GDPR 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 UKAS, 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, UKAS is the data controller for all personal data it holds in order to fulfil its own functions. UKAS will become the data controller for the personal data it receives from the HFEA as part of any information disclosure.

UKAS is responsible for meeting individuals’ requests regarding the exercising of their rights under the 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 UKAS as part of any information disclosures.

UKAS 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 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 UKAS or the HFEA may be lawfully shared by the other with law enforcement agencies and the Information Commissioner’s Office (ICO) without the need for prior consent from the originating party.

<u>Press enquires</u>

Where UKAS assessors and HFEA inspectors share information about medical laboratory concerns within an establishment, and that establishment becomes the subject of press interest, UKAS and the HFEA will co-ordinate their press responses to ensure cohesiveness, while ensuring that the judgement or position of each is adequately reflected.

Joint management arrangements

This joint working protocol will have effect for a period of 24 months commencing on the date on which the MoU was signed by both parties. The joint working protocol may be reviewed at any time at the request of either party.

The formal review date will be: May 2027

Review of operational protocols and joint working arrangements

The efficacy of implementing the protocols for sharing information will be informally reviewed by the UKAS and HFEA on an annual basis, to:

a) ensure that relevant organisational, staff and contact details are current
b) review joint instances where information has been shared, the subsequent impact, and whether joint working processes needed to be amended to improve effectiveness or efficiency.

Any changes made to the joint working protocol should be confirmed by relevant governance structures at UKAS and the HFEA; they do not require approval from the Chief Executive/Executive Director unless it is specifically deemed necessary.

Annex C: Contact details

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane Staines-upon-Thames TW18 3HR 01784 429000	**Human Fertilisation and Embryology Authority** 2nd floor, 2 Redman Place London E20 1JQ 020 7291 8200

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

Executive Directors (internal escalating policies should be followed before referral to Executive)

Lorraine Turner Accreditation Director Lorraine.turner@ukas.com	Peter Thompson Chief Executive peter.thompson@hfea.gov.uk

Information sharing

Sally Wood Senior Assessment Manager Sally.wood@ukas.com	Sharon Fensome-Rimmer Chief Inspector sharon.fensome-rimmer@hfea.gov.uk

MoU management (including strategic issues)

Alyson Bryant Accreditation Specialist (Healthcare) alyson.bryant@ukas.com	Sharon Fensome-Rimmer Chief Inspector Sharon.fensome-rimmer@hfea.gov.uk Annabel Salisbury Regulatory Policy Manager Annabel.salisbury@hfea.gov.uk

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

UKAS: alyson.bryant@ukas.com HFEA: compliance@hfea.gov.uk