Memorandum of Understanding between the United Kingdom Accreditation Service and the Human Tissue Authority in relation to regulatory and accreditation activities

Memorandum of Understanding between the United Kingdom Accreditation Service and the Human Tissue Authority

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 Tissue Authority (HTA) in relation to the regulatory and accreditation activities it undertakes.

2. UKAS is the sole national accreditation body for the United Kingdom. The HTA is a regulator of the removal, storage and use of human tissue for a wide range of purposes, including within healthcare. The responsibilities and functions of UKAS and the HTA are set out at Annex A.

3. Both parties share a concern for the quality and safety of health and care services and recognise, through this MoU, that close cooperation by sharing information relating to organisations regulated or accredited by both parties is beneficial in supporting this.

4. This MoU is a statement in principle which does not override the statutory responsibilities and functions of UKAS and the HTA and is not enforceable in law. However, UKAS and the HTA are committed to working in ways that are consistent with the principles of this MoU.

Principles of cooperation

5. UKAS is recognised by the UK government to assess and accredit organisations that provide certification, testing, inspection, calibration and biobanking services against internationally agreed standards. The HTA licenses establishments which remove, store and use human tissue for a range of purposes. It has a remit that covers England, Wales and Northern Ireland for all its sectors and undertakes some functions in Scotland in relation to the use of human tissue for human application and organ donation and transplantation.

6. There are some establishments which are accredited by UKAS and licensed by the HTA, or where UKAS accredited establishments work directly with HTA licensed establishments; it is mainly in relation to these services where UKAS and the HTA will work together, as appropriate. This includes:

    a. sharing information about issues likely or potentially to be of mutual concern about matters pertaining to the respective remits of the two parties; and
    b. establishing and maintaining effective mechanisms for mutual engagement on matters of common or shared interest.

Areas of cooperation

7. UKAS and the HTA intend that their working relationship will involve cooperation in the following areas:

    a. the need to make decisions which protect and promote people's safety and promote high quality healthcare;
    b. a focus on working together using information obtained or provided by a UKAS accredited organisation to both parties and from UKAS if a UKAS accredited organisation has not notified the HTA about relevant services regulated by the HTA and vice versa;
    c. respect for each party's independent status and right to make different decisions about compliance;
    d. the need to maintain public confidence in the two parties;
    e. openness and transparency between the two organisations as to when cooperation is and is not considered necessary or appropriate; and
    f. the need to use resources effectively and efficiently through appropriate coordination and information sharing.

Exchange of information

8. Cooperation between UKAS and the HTA will often require the exchange of information. Exchange of information will be expected where either UKAS or the HTA 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 (GDPR), the Data Protection Act (DPA), 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 Tissue Act 2004 (as amended), all other relevant UKAS and HTA legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

10. Both parties agree that personal data will not be shared unless there is a lawful reason for doing so. Any such requests will be considered on a case-by-case basis and carried out in a manner consistent with the Data Sharing Code of Practice published by the Information Commissioner's Office.

11. For the purposes of the 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 HTA 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.

12. For the purposes of 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 UKAS as part of any information disclosures. The HTA is responsible for meeting individuals' requests regarding the exercising of their rights under the Data Protection Law for the personal data it holds.

13. UKAS and the HTA 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.

14. Both parties recognise their responsibilities under the Freedom of Information Act 2000. Where either party receives a request under the Act for information received from the other, both parties agree to take reasonable steps to consult on the proposed disclosure and the application of exemptions. They recognise that the responsibility for disclosure lies with the party that received the request.

Resolution of disagreement

15. Any disagreement between UKAS and the HTA will typically be resolved at working level. If this is not possible, it must be brought to the attention of those responsible for the management of this MoU identified at Annex C. The parties should aim to resolve disagreements in a reasonable time.

Duration and review

16. This MoU commences on the date of the signatures below. It is not time-limited and will continue to have effect unless the principles described need to be altered and/or cease to be relevant.

17. As a minimum, this MoU will be formally reviewed every three years, but may be reviewed at any time at the request of either party. Any alterations will require the agreement of both parties.

18. Both organisations have identified an individual responsible for the management of this MoU (known as the 'Relationship Lead') and their contact details are set out in Annex C. These individuals will liaise at least once a year to:

    a. discuss the points listed under the joint management arrangements set out at Annex B;
    b. discuss how this MoU is working operationally and to agree whether a formal review is required earlier than 3 years;
    c. ensure this MoU is kept up-to-date and reviewed;

d. identify any emerging issues in the working relationship between the parties; and
e. resolve any questions that arise regarding the interpretation of this MoU.

Signatures

Matt Gantley
Chief Executive
United Kingdom Accreditation Service

Date 23rd December 2024

Dr Colin Sullivan
Chief Executive
Human Tissue Authority

Date 23rd December 2024

Annex A: Responsibilities and functions

The United Kingdom Accreditation Service (UKAS) and the Human Tissue Authority (HTA) acknowledge the responsibilities and functions of the other party and will take account of these when working together.

The United Kingdom Accreditation Service

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, calibration and biobanking services.

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.

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.

UKAS is licensed by the Department for Business and Trade to use and confer the national accreditation symbols which symbolise government recognition of the accreditation process.

The Human Tissue Authority

The Human Tissue Authority is an independent regulator of the removal, storage and use of human tissue for a wide range of purposes. The HTA aims to ensure that human tissue is used safely and with appropriate consent.

The HTA is an arm’s length body of the Department of Health and Social Care and has a remit that covers England, Wales and Northern Ireland for all its sectors. It also undertakes some functions in Scotland in relation to the use of human tissue for human application and organ donation and transplantation.

The responsibilities and functions of the HTA are set out in human tissue legislation. This primarily includes the Human Tissue (HT) Act 2004, 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, the responsibilities and functions of the HTA are to:

- issue licences under the HT Act 2004, Q&S Regulations and Q&S (Organs) Regulations;
- inspect establishments licensed under the HT Act 2004, 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 2004;
- promote compliance with the HT Act 2004, Q&S Regulations, Q&S (Organs) Regulations 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 2004, Q&S Regulations and Q&S (Organs) Regulations.

In addition, under the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, relevant clinicians in England, Wales and Northern Ireland who work closely with patients that need, or have received, an organ transplant are required to report the following to the HTA:

- if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed under the Human Tissue Act or Modern Slavery legislation; and
- if they are made aware that a patient has received an organ transplant outside the UK.

Annex B: Joint working protocol

The United Kingdom Accreditation Service (UKAS) and Human Tissue Authority (HTA) have identified possible ways in which they can ensure information is shared about UKAS accredited organisations and HTA licensed establishments.

This joint working protocol sets out the working arrangements between UKAS and the HTA in two parts: **Operational protocols** which will be carried out by UKAS Assessment Managers and HTA Regulation Managers, and **Joint management arrangements** which will be carried out by members of senior staff and the Executive listed at Annex C.

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

Operational protocols

Joint working

This MoU sets out that information will generally be shared at an operational level and relate to an organisation which is licensed by the HTA and accredited by UKAS. Through the Relationship Leads, both parties may also seek to explore the future sharing of information on other matters relevant to the other party's remit or areas of common or shared interest.

UKAS and the HTA will endeavour to work together, wherever possible, with regards to the activities of UKAS accredited laboratories and biobanks that conduct activities within the scope of this MoU. Both organisations will work towards improving accreditation and regulatory efficiencies, respectively.

Where relevant accreditation of an organisation is suspended (either full or partial) or withdrawn due to concerns around patient safety, UKAS will notify the HTA. On occasion it may be necessary for UKAS and the HTA to work together, in line with the relevant governing policies, regarding certain incidents that may affect patient safety.

Sharing information

Who will share information?

Information will generally be shared at an operational level, between UKAS Assessment Managers and HTA Regulation Managers. The information shared will relate to an establishment that is accredited and/or licensed by either party (in accordance with the table below).

Circumstances where information will be shared

UKAS and the HTA will aim to establish a robust information-sharing process, in which Assessment Managers and Regulation Managers are empowered to contact their counterpart to discuss an establishment that is causing them concern. When doing so, UKAS Assessment Managers and HTA Regulation Managers will also include the single point of contact for each organisation. These are:

- UKAS: Alyson Bryant, Accreditation Specialist
- HTA: Anjeli Kara, Head of Policy and Development

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 licensed by both organisations and with due regard to relevant confidentiality agreements, , or where UKAS accredited establishments work directly with HTA licensed establishments.

Under certain circumstances, information held by UKAS or the HTA may be shared with the other. These circumstances are set out in the table below (Table 1)..

Table 1

UKAS	**HTA**
Whistleblowing event as defined by UKAS	Whistleblowing event as defined by the HTA
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	HTA Reportable Incident (HTARI) or Serious Adverse Event or Serious Adverse Reaction (SAEAR) reported in the post-mortem, human application or organ donation and transplantation sectors, which has the potential to cause serious harm or a reputational risk to the establishment
A non-routine assessment scheduled due to concerns raised by either party, and the outcomes of that assessment	A non-routine inspection is being undertaken in response to serious concerns or allegations, and the outcomes of that assessment
Accreditation is suspended or revoked, or steps are taken to restrict accredited activities	The HTA suspends or revokes a licence, or takes steps to restrict licensable activities
Significant sanctions are imposed relating to laboratory functions or tests have been deemed out of scope	Significant regulatory action is taken related to laboratory functions

A referral is made to another agency	Referral is made to another agency (e.g., the Health and Safety Executive (HSE), the Medicines and Healthcare products Regulatory Agency (MHRA))
[Intentionally left blank]	Police referral is made following suspicions of a criminal offence under the Human Tissue Act 2004 or other relevant legislation
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 establishment relating to patient safety or service quality, which may give rise to concerns which need further consideration

In the circumstances listed above, the UKAS single point of contact or HTA Regulation Manager will be expected to contact their counterpart in the other organisation to:

- pass on the information; and
- ascertain whether there is any additional information held by the other organisation 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 UKAS and the HTA may occur in other circumstances where it is considered to be appropriate and proportionate.

UKAS and the HTA 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 the individual party to determine.

What information will be shared?

Subject to UKAS confidentiality requirements as laid out in the UKAS agreement, the information to be shared in the situations listed in Table 1 above will include:

- information concerning the circumstance(s) outlined in Table 1, so the matter is properly understood in its entirety within context;
- 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(s) or enforcement action(s);
- assessment report(s) relating to mortuary services and other UKAS-accredited, HTA-licensed activities; and

- concerns that are identified in a situation where the laboratory has informed UKAS but not the HTA, or vice versa.

Only non-identifiable patient information will be shared with UKAS or the HTA under this protocol. The Data Protection Act (and other relevant legislation) will be considered when information is shared about accredited or licensed individuals and people who work for establishments.

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

Freedom of Information (FOI) requests

As a government arm's length body, the HTA is subject to FOI requests from members of the public. Any request under the FOI Act 2000 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, where a UKAS assessor has informed a HTA Regulation Manager about allegations made by a whistleblower and an FOI request is subsequently received, the HTA will not release information relating to the incident without prior discussion with UKAS about sharing the information.

Legal responsibility for responding to a request pursuant to the FOI Act 2000 – 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 (DPA)

Personal data has the meaning given to it under the UK GDPR. It 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 Information Commissioner's Office (ICO). Information that is requested from UKAS about the HTA and vice versa, shall be communicated to the relevant person specified in Annex C.

For the purposes of the 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 HTA 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.

For the purposes of 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 UKAS as part of any information disclosures. The HTA is responsible for meeting individuals' requests regarding the exercising of their rights under the Data Protection Law for the personal data it holds.

UKAS and the HTA 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 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 HTA 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.

For further information see also UKAS' data protection and security schedule set out within their UKAS Standard Terms of Business and the HTAs Privacy notice.

Press enquires

Where UKAS and the HTA share information about concerns within an establishment and that establishment becomes the subject of press interest, UKAS and the HTA will endeavour to cooperate to ensure that the judgement or position of each is accurately reflected in any and all press responses.

Joint management arrangements

This joint working protocol will have effect from the date both parties sign this MoU . The joint working protocol may be reviewed at any time at the request of either party.

The formal review will take place every three years, but can take place sooner at the request of the parties.

The joint working protocol may be reviewed at any time in the interim at the written request of either party.

Annex C: Contact details

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane Staines-upon-Thames TW18 3HR 01784 429000	**Human Tissue Authority** 2nd floor 2 Redman Place London E20 1JQ 020 7269 1900

Relationship leads: MoU Management (including strategic issues)
NOTE: These contacts should also be copied into all joint working correspondence.

Alyson Bryant Accreditation Specialist (Healthcare) alyson.bryant@ukas.com	Anjeli Kara Head of Policy and Development anjeli.kara@hta.gov.uk policy@hta.gov.uk

Operational contacts

Wendy Smith Head of Healthcare wendy.smith@ukas.com	Christopher Birkett Head of Regulation (for Research and Anatomy) christopher.birkett@hta.gov.uk
Sally Wood Senior Assessment Manager sally.wood@ukas.com	Jessica Porter Head of Regulation (for Organ Donation and Transplantation) jessica.porter@hta.gov.uk
	Robert Watson Head of Regulation (for Human Application) robert.watson@hta.gov.uk
	Mark Wrigley Head of Regulation (for Post Mortem and Public Display) mark.wrigley@hta.gov.uk

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

Lorraine Turner Accreditation Director lorraine.turner@ukas.com	Nicolette Harrison Director of Regulation nicolette.harrison@hta.gov.uk