Memorandum of Understanding between the Care Quality Commission and the Human Tissue Authority

STATUS: FINAL - SIGNED

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Introduction

1. This Memorandum of Understanding (MoU) sets out the framework to support the working relationship between the Care Quality Commission (CQC) and the Human Tissue Authority (HTA), in order to safeguard the wellbeing of the public receiving health and social care in England.

2. The working relationship between the CQC and the HTA is part of the maintenance of a regulatory system for health and adult social care in England that promotes patient safety and high-quality care.

3. The CQC is the independent regulator of health and social care in England. 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 the CQC and the HTA are set out in Annex 1. 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 by both parties is beneficial in supporting this.

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

Principles of co-operation

5. This MoU is a statement of principle, which supports our focus on promoting patient and public safety and wellbeing and on delivering our respective roles and remits set out in legislation through our regulatory activities. More detailed operational protocols and guidance can be developed as required.

6. The CQC and HTA intend that their working relationship be characterised by the following principle of sharing information about issues likely or potentially to be of mutual concern about matters pertaining to the respective remits of the two parties

7. Some services registered with the CQC also hold one or more HTA licences for a range of different activities. This will be the focus for CQC and HTA engagement, sharing knowledge and information and working together collaboratively as appropriate. Any mutual engagement will be underpinned by a shared commitment to:

    - The need to make decisions that promote people's safety and high-quality health and social care;
    - Promote the rights of individuals;
    - Respect the independence of each party;
    - Maintain public and professional confidence in the two parties and the regulatory process;

- Openness and transparency between the two parties as to when cooperation is and is not considered necessary and/or appropriate;
- The need to use resources effectively and efficiently; and
- Address intersections in the regulatory framework, including gaps and overlaps.

Areas of co-operation

8. The working relationship between the CQC and HTA involves co-operation in the following areas:
    - Exchange of information will be expected where either the CQC or HTA identifies concerns about an organisation that are considered to be relevant to the other party's regulatory functions. The Joint Working Protocol in Annex 2 sets out the detailed arrangements for sharing information between the parties.
    - Sharing information when it is appropriate, necessary, fair and lawful to do so about media interest in an organisation, for which both the CQC and HTA have regulatory responsibilities and which may give rise to concerns that need further consideration by either the CQC or HTA.
    - Exchange of information about the CQC or HTA's functions and make sure that wherever possible regulatory intersections, including overlap, is identified and action is taken to minimise adverse or negative consequences as much as possible.
    - Ensuring that the CQC or HTA share information and concerns and jointly agree any actions that may be required to protect the rights of individuals.
9. Both parties recognise that they will be responsible for its own negligent acts or omissions.
10. Both parties recognise that personal data (including the sharing of personal data) will be processed in accordance with:
    - the General Data Protection Regulation (GDPR),
    - the Data Protection Act 2018 (DPA),
    - sections 76-79 of the Health and Social Care Act 2008,
    - the Human Rights Act 1998, and
    - other relevant legislation relating to these matters and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.
11. 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.
12. For the purposes of the DPA and the UK GDPR (collectively Data Protection Law), CQC is the data controller for all personal data it holds in order to fulfil its own

functions. CQC will become the data controller for the personal data it receives from the HTA as part of any information disclosure. CQC 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 HTA.

13. For the purposes of the 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 CQC as part of any information disclosures.

14. CQC and 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.

15. 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 but recognise that the responsibility for disclosure lies with the party that received the request.

Resolution of disagreement

16. Where there is disagreement between CQC and HTA, this should be resolved in the first instance at working level. If this is not possible, it may be referred through those responsible for the management of this MoU, up to and including the Chief Executives of the CQC and HTA, who will then be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and review

17. 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 above need to be altered and/or cease to be relevant.

18. 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.

19. Both parties have identified a person responsible for the management of this MoU (known as 'Relationship Leads') and their contact details are set out in Annex 3. Relationship Leads will meet at least annually to:

    - discuss how this MOU is working operationally and to agree whether a formal review is required earlier than 3 years,
    - ensure this MoU is kept up-to-date and reviewed,
    - identify any emerging issues in the working relationship between the parties, and
    - resolve any questions that arise regarding the interpretation of this MoU.

Signatures

Sir Julian Hartley
Chief Executive
Care Quality Commission

Date:16/04/2025

Dr Colin Sullivan
Chief Executive
Human Tissue Authority

Date: 25/04/2025

Annex 1: Responsibilities and functions of CQC and HTA

The Care Quality Commission

The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England. Its purpose is to make sure health and care services provide people with safe, effective, compassionate, high-quality care and to encourage them to improve.

The CQC does this by registering, monitoring, inspecting and regulating hospitals, adult social care services, dental and general practices and other care services in England, to make sure they meet fundamental standards of quality and safety. We set out what good and outstanding care looks like, and we make sure services meet these standards which care must never fall below.

The CQC aims to tackle inequalities and protect and promote people's rights to make sure everyone has good quality care, and equal access, experience and outcomes. This is in line with our strategy, our core purpose and legal responsibilities, including the Equality Act (2010) Public Sector Equality Duty, and the Human Rights Act (1998).

Since April 2023, the CQC has a responsibility to give a meaningful and independent assessment of care in a local area. This includes assessment of Local Authorities' performance against their duties under Part 1 of the Care Act 2014. The Health and Care Act 2022 also gives the CQC responsibilities to assess whether integrated care systems are meeting the needs of their local populations.

The CQC reports publicly on what it finds locally, including performance ratings for care providers, to help people choose care and encourage providers to improve. It also reports annually to Parliament on the overall state of health and adult social care in England.

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, 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; 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.

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 2: Joint Working Protocol

The Joint Working Protocol (JWP) sets out the detail of the working arrangements between the CQC and HTA.

This MOU does not preclude or prevent the lawful sharing of information for other purposes which may be agreed between the parties

The CQC and HTA necessarily use different terminology to describe aspects of their work, driven by their differing roles, remit and governing legislation. Where this document refers to organisations, it also means registered or licensed providers.

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 in addition registered with CQC**. However, both parties will also, through the relationship leads, explore the future sharing of information on other matters relevant to the other party's regulatory remit or other areas of common or shared interest. For example, sharing information on general themes and issues emerging across the organisations they both regulate.

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.

Types of HTA licensed activities that may be carried on by providers that are also registered with the CQC are broadly as follows:

- Hospitals with mortuaries where post-mortem examinations or related activities take place (such as storage of bodies for the purpose or undertaking a post-mortem examination, the storage of material taken at post-mortem examination or removal of tissue from the deceased other than for a post-mortem examination). Body stores – used for the storage of deceased people – which do not undertake post-mortems or other related activities are not required to be licensed by the HTA.
- Establishments that store human tissue for use under a scheduled purpose.[1]
- Establishments that carry out the procurement, processing, storage, distribution, import or export of human tissues and cells for human application, or which carry out associated donor testing.
- Establishments involved in the transplantation of solid organs.
- Establishments that are not necessarily licensed by the HTA but where activities are carried out under a licence held by another organisation (e.g. retrieval of tissue or organs for use in patient treatment).

[1] Consent is the fundamental principle of the Human Tissue Act 2004 ('the Act'). Schedule 1 of the Act lists the purposes for which consent is required. These are called scheduled purposes and include, for example, 'anatomical examination', 'research in connection with disorders, or the functioning, of the human body' or 'determining the cause of death'.

- The donation of bone marrow and peripheral blood stem cells from children and adults who lack the capacity to consent.[2]

CQC does not regulate activities or arrangements that are not being carried on for the purpose of providing a Regulated Activity. Regulated Activities are defined in Schedule 1 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This means as an example, that CQC does not inspect mortuaries or body stores.

CQC will take into account cold storage arrangements in cases when these are part of providing care for a person receiving a regulated activity. As an example, arrangements for providing a parent with cold cot facilities following a still birth.

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:

CQC	**HTA**
Whistleblowing that may impact or be connected with HTA interests	Whistleblowing
A notification is submitted by a provider which triggers a responsive assessment and concerns HTA responsibilities and functions	HTA Reportable Incident (HTARI) or Serious Adverse Event or Adverse Reaction (SAEAR) in human application or organ donation and transplantation reported that has potential to cause a reputational risk to the establishment
A responsive assessment is being undertaken (on or off site) and concerns management functions of areas that overlap with HTA functions	A non-routine inspection is arranged in response to serious concerns or allegations
Registration is suspended or cancelled, or conditions of registration are imposed by CQC to restrict the Regulated activities permitted that may be of interest to the HTA	Instances where the HTA suspends or revokes a licence, or takes steps to restrict licensable activities
Enforcement powers are used by CQC, including issuing a warning notice, simple caution or fixed penalty notice concerning the leadership of a provider that also holds an HTA licence or cold storage facilities.	Significant regulatory action is taken
Referral is made to another agency, for example the Health and Safety Executive (HSE) or the Medicines and	Referral is made to another agency, for example the HSE or the MHRA or a referral of suspicions of a criminal

[2] Donation of bone marrow and PBSC by adults with capacity and children who are competent to give consent is not classified as transplantable material for regulatory purposes and, subject to valid consent being obtained by the treating clinician, may proceed without HTA approval.

Healthcare products Regulatory Agency (MHRA)	offence under human tissue or related legislation
Media interest in an organisation, which may give rise to concerns which may need further consideration by the HTA.	Significant media interest in an organisation, which may give rise to concerns which need further consideration

Annex 3: Contact details

Care Quality Commission	**Human Tissue Authority**
Citygate Gallowgate Newcastle upon Tyne NE1 4PA 03000 616161	2nd floor 2 Redman Place London E20 1JQ 020 7269 1900

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

Relationship leads

Carolyn Jenkinson Deputy Director of Secondary and Specialist Healthcare Carolyn.Jenkinson@cqc.org.uk	Head of Policy and Development policy@hta.gov.uk

Operational contacts

First point of CQC contact: CQC National Contact Centre enquires@cqc.org.uk 03000616161 (Monday to Friday, 8.30am to 5.30pm excluding bank holidays)	Christopher Birkett Head of Regulation (for Research and Anatomy) christopher.birkett@hta.gov.uk
	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
	Nicolette Harrison Director of Regulation nicolette.harrison@hta.gov.uk

Chief Executives (internal escalating policies should be followed before referral to Chief Executives)

Sir Julian Hartley Chief Executive julian.hartley@cqc.org.uk	Dr Colin Sullivan Chief Executive colin.sullivan@hta.gov.uk