Memorandum of Understanding (MoU) between the Human Tissue Authority and the Health Research 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 Health Research Authority (HRA).

2. Collaboration between the HTA and HRA will contribute to:

    - a clearer understanding of the role and remit of each organisation
    - consistent messages to stakeholders about respective roles and remits
    - ensuring that the systems for licensing and ethical review are clearly understood by researchers and other stakeholders
    - clear and effective communication between HTA and HRA
    - a consistency of approach to matters of interest to HTA and HRA
    - licensing, inspection and ethical review in accordance with the principles of Better Regulation

3. The HTA is the regulator for the safe removal, use and disposal of human tissue and organs in the UK. The HRA works to make the UK a great place in which to undertake research. The responsibilities and functions of the HTA and HRA are set out at Annex A.

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

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

Principles of cooperation

6. The HRA protects and promotes the interest of patients and the public in health and social care research, co-ordinate and standardise practices relating to regulation, recognise and establish Research Ethics Committees (RECs), promote transparency in research and provide approvals for the processing of confidential information relating to patients.The HTA licenses and inspects organisations that remove, store and use tissue for research, medical treatment, post-mortem examination and teaching; it has responsibilities across the UK. There are some services which are overseen by the HRA and the HTA; it is mainly in relation to these services where the HRA and the HTA will work together in cooperation, as appropriate.

7. The HTA and HRA 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 research;
    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 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.

8. The HTA and the HRA are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of Better Regulation).

Exchange of information

9. Cooperation between the HTA and the HRA will often require the exchange of information. Exchange of information will be expected where either the HRA 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.

10. 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 Care Act 2014, and all relevant HTA and HRA 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

11. Any disagreement between the HTA and the HRA 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 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.

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 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 the HRA 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.

16. The Joint Working Group will oversee the development of operational working arrangements that support the delivery of the principles outlined in this MoU.

Signed

Allan Marriott-Smith
Chief Executive
Human Tissue Authority

Date: 12 September 2017

Teresa Allen,
Interim Chief Executive,
Health Research Authority

Date: 12th September 2017

Annex A: Responsibilities and functions

1. The Human Tissue Authority (HTA) and the Health Research Authority (HRA) 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 responsibilities and functions of the HTA are set out primarily in the Human Tissue Act 2004 (HT Act) and associated regulations, 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.

3. Under the Act, the HTA has a statutory role in regulating human tissue research 'in connection with disorders, or the functioning, of the human body'. A further piece of legislation relevant to the research regulatory environment is the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

4. Although the HTA has a broad regulatory remit – for example, in relation to providing guidance – its licensing remit with regard to research is limited to licensing premises where the storage of research material (from the living and the deceased) and the removal of tissue from the deceased for research takes place. Licences are tied to named premises, and the HTA does not license the 'use' of tissue for research or approve individual research projects.

Responsibilities and functions of the HRA

5. The responsibilities and functions of the HRA are set out in the Care Act 2014. The HRA is a non-departmental public body established under the Care Act 2014. In summary, the main functions of the HRA are:

- The co-ordination and standardisation of practice relating to the regulation of health and social care research
- The functions relating to research ethics committees
- The functions relating to approvals for processing confidential information relating to patients.

6. The main objective of the HRA in exercising its functions is; To protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and; to promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research).

7. The HRA must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, seek to ensure that such regulation is proportionate

Annex B: Joint working protocol

Introduction

1. The Human Tissue Authority (HTA) and Health Research Authority (HRA) have a long-established working relationship, underpinned by previous MoUs between HTA and NRES. In practical terms, there is a history of frequent contact and communication; for example, for enquiries, licensing matters or suspected regulatory breaches. There have also been regular formal meetings, supported by agendas and minutes.

2. Interfaces between HTA and HRA may arise:
    - when a specific research project or research tissue bank (RTB) has been granted ethical approval by a Research Ethics Committee
    - when human tissue is stored at an RTB on HTA-licensed premises
    - where advice and guidance is sought by a stakeholder on requirements for ethical approval, licensing or best practice
    - as a result of specific matters the HTA wishes to draw to HRA's attention
    - as a result of specific matters that HRA wishes to draw to the HTA's attention

3. Interfaces between the HTA and HRA may be addressed:
    - through regular, structured communication on an ongoing basis to exchange information on matters concerning both parties
    - through ad hoc communication and requests for advice and information
    - through the coordination of activities; for example:
        - stakeholder events
        - responses to consultations

Operational and governance arrangements

1. Formal meetings

1.1 Objectives of the meetings

- To provide organisation updates and raise awareness of each other's work in areas of common interest
- To discuss matters of joint relevance
- To agree areas of joint development work
- To undertake horizon scanning, aiming to seek maximum benefit from future opportunities

1.2 Organisation and administrative support

- Meetings will be scheduled and held at least annually. More typically, the frequency of meetings should be 2-3 times per year.
- Responsibility for setting an agenda and producing minutes will be agreed in advance of each meeting
- The hosting of the meeting will be subject to agreement, depending on available space

and any associated resources.

2. Sharing information

2.1 Who will share information?

Information will generally be shared at an operational level, between HTA and HRA staff at Officer, Manager, Head or Director level. The information shared will relate to organisations or individuals which are or may be undertaking work within the remit of one or both bodies.

2.2 Situations in which information will be shared

We will continue to foster a culture of transparent information-sharing.

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

The exchange of information between the HTA and HRA will be based on the following principles:

- It is understood by the HTA and HRA that the working relationship between the two parties will vary and may involve face-to-face, email, telephone and other forms of communication as required
- Each organisation will respect and take appropriate steps to protect the confidential documents and information the other may provide. It is agreed that statutory and other constraints on the exchange of information will be fully respected including the requirements of the Data Protection Act 1998, Freedom of Information Act 2000 and the Human Rights Act 1998
- Each organisation will inform and consult with the other in areas of forthcoming work and / or responses to stakeholders where the other organisation has a potential interest
- Each organisation will signpost stakeholders to information the other party provides and / or provide contact details as appropriate
- Each organisation will assist each other by disseminating information where appropriate
- HRA will report any possible or actual serious breaches of the Human Tissue Act 2004 to a member of staff in the HTA's Regulation Directorate
- HRA will provide the HTA with a list of REC-approved tissue banks as required and maintain the currency of the list
- Where applicable and possible, each organisation will support each other's training programmes and other events which affect both organisations

3. What information will be shared?

The information to be shared may typically 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 under this protocol.

Account must also be taken of the Data Protection Act.

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 parties. 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 parties

Any request under the FOI Act relating to information which was all or in part provided by the other party 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 the HRA informs the HTA of 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 HRA 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 both bodies share information about regulatory non-compliance within an organisation, and that organisation becomes the subject of press interest, the parties will co-ordinate their press responses, while ensuring that the judgement or position of each is adequately reflected.

Annex C: Contact details

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www.hta.gov.uk
020 7269 1900

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