

**MEMORANDUM OF UNDERSTANDING MADE BETWEEN
THE HUMAN TISSUE AUTHORITY AND
THE NATIONAL RESEARCH ETHICS SERVICE**

PREAMBLE	
1.	The objective of this Memorandum is to set out the framework that the Human Tissue Authority (HTA) and the National Research Ethics Service (NRES) have agreed for cooperation and collaboration.
2.	<p>Collaboration between the HTA and NRES will contribute to:</p> <ul style="list-style-type: none"> a) a clearer understanding of the role and remit of each organisation b) a consistent message to stakeholders about the role and remit of each organisation c) ensuring that the systems for licensing and ethical review are clearly understood by researchers and other stakeholders d) clear and effective communication between both organisations e) a consistency of approach to matters of interest to both organisations f) licensing, inspection and ethical review in accordance with the principles of Better Regulation
3.	This Memorandum does not affect existing statutory functions or amend any other policies or agreements relating to the activities of the HTA and NRES. It is not intended that this Memorandum should create any legally binding obligations on the signatories.
FUNCTIONS OF THE HTA AND NRES	
4.	<p>The Human Tissue Authority</p> <p>The Human Tissue Authority (HTA) is a regulatory authority that protects public confidence by licensing and inspecting organisations that store and use tissue for purposes such as research, human application, post-mortem examination, teaching, and public exhibitions.</p>

	<p>The HTA also gives approval for organ and bone marrow donations from living people through an independent assessment process.</p> <p>The HTA provides advice and guidance about matters within its remit as defined in the Human Tissue Act 2004 (the Act). As well as the Act, there are two further pieces of legislation that could apply to the research community; the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, which set out exceptions from the licensing requirement, and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. This latter piece legislation provides the framework within which the HTA regulates the removal storage and use of human tissue</p> <p>The HTA aims to set standards that are clear and reasonable, and in which both the public and professionals can have confidence.</p>
5.	<p>National Research Ethics Service</p> <p>The National Research Ethics Service (NRES) is a division of the National Patient Safety Agency. It comprises the former Central Office for Research Ethics Committees (COREC) and Research Ethics Committees (RECs) in England.</p> <p>NRES provides a system of ethical review that protects the safety, dignity and well being of research participants, whilst facilitating and promoting ethical research. It does this by:</p> <ul style="list-style-type: none"> • providing ethical guidance and management support to Research Ethics Committees in England • delivering a quality assurance framework for the Research Ethics Service • working with colleagues in the UK to maintain a UK-wide framework • working with colleagues in the wider regulatory environment to streamline the processes. <p>Research ethics committees review research projects requiring ethical review under the law or the policies of the UK Health Departments. This includes projects involving the collection, storage and use of human tissue. RECs also review voluntary applications for ethical review of research tissue banks. All research ethics committees within the Research Ethics Services of the UK are recognised as research ethics authorities for the purposes of the Human Tissue Act.</p>

SCOPE OF THIS MEMORANDUM	
6.	<p>This Memorandum relates to the areas of interface between the HTA and NRES. It does not place additional responsibilities on either organisation or imply any transfer of responsibility from one to the other or sharing of statutory responsibilities or functions.</p>
7.	<p>Primary principles</p> <p>The primary principles underlying this Memorandum are:</p> <ul style="list-style-type: none"> • a commitment to working together to ensure research involving human tissue and storage of tissue for research are undertaken in accordance with the relevant legislation and recognised ethical and governance standards • an understanding of each organisation's role and remit and a recognition of areas of common interest whilst seeking to avoid unnecessary duplication of work between: <ul style="list-style-type: none"> ○ the HTA and NRES; and ○ stakeholders and the HTA and/or NRES
8.	<p>Interfaces</p> <p>Interfaces may arise:</p> <ol style="list-style-type: none"> a) when a specific research project or research tissue bank (RTB) has been granted ethical approval by a Research Ethics Committee b) when human tissue is stored at an RTB on HTA licensed premises c) where advice and guidance is sought by a stakeholder on requirements for ethical approval, licensing or best practice d) as a result of specific matters the HTA wishes to draw to NRES's attention e) as a result of specific matters that NRES wishes to draw to the HTA's attention

	<p>Interfaces between the HTA and NRES may be addressed:</p> <ul style="list-style-type: none"> f) through regular, structured communication on an ongoing basis to exchange information on matters concerning both parties g) through ad hoc communication and requests for advice and information h) through the coordination of activity, for example: <ul style="list-style-type: none"> o stakeholder events o responses to consultations
<p>9.</p>	<p>Exchange of information</p> <p>The exchange of information between the HTA and NRES will be based on the following principles:</p> <ul style="list-style-type: none"> a) It is understood by the HTA and NRES 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 b) 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 c) 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 d) Each organisation will signpost stakeholders to information the other party provides and / or provide contact details as appropriate e) Each organisation will assist each other by disseminating information where appropriate f) NRES will report any possible or actual serious breaches of the Human Tissue Act 2004 to someone in the HTA's Regulation Directorate

	<p>g) NRES will provide the HTA with a list of REC-approved tissue banks as required and maintain the currency of the list</p> <p>h) Where applicable and possible, each organisation will support each other's training programmes and other events which affect both organisations</p>
10.	<p>Review of this Memorandum of Understanding</p> <p>This Memorandum will be reviewed in one year by the Director of Regulation of the HTA and the Director of NRES.</p>

Signed: _____ Dated: _____

Dr Sandy Mather
Director of Regulation
Human Tissue Authority

Signed: _____ Dated: _____

Dr Janet Wisely
Director
National Research Ethics Service

Annex A – Contact Details

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National Research Ethics Service

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Contact details for RECs are available at <http://www.nres.npsa.nhs.uk/contacts/>