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Human Tissue Act (2004)

Quick Reference for HTA Training

Dr Tony Madgwick

Designated Individual on HTA licence 12015

Email: T.Madgwick@westminster.ac.uk

Extension phone: 64157

Room C2.16

(Based on an original presentation by Dr Nadège Presneau)

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Overview

- **Human Tissue Act was implemented on 1st September 2006:**
- It provides the regulatory framework for:
  - the storage & use of human organs & tissue from the living
  - the removal, storage & use of tissue & organs from the deceased
- Does not include removal, storage or use of tissue from the living for diagnosis or treatment
- The Human Tissue Authority (HTA) regulates activities that fall under the Human Tissue Act (2004).

- Information and Guidance documentation can be accessed from here:
  - https://www.hta.gov.uk/guidance-professionals

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What does The Act do?

- Makes **consent** the most important principle for the lawful retention and use of human tissue.
- Under The Act, the following are illegal:
  - Removing, storing or using human tissue without consent
  - Taking and testing DNA without consent (DNA "theft“)
  - Storing tissue or organs for a purpose not designated as a Scheduled Purpose
  - Organ trafficking
- Penalties range from a fine to three years imprisonment, or both.

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What is relevant material under the Human Tissue Act?

This is an important element of the Act, defining what human materials need to be recorded and tracked. See the website "List of materials considered to be 'relevant material' under the Human Tissue Act 2004" for more details.

Material	'Relevant material' for the purposes of the Human Tissue Act 2004?
Antibodies	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast milk	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines	No
Cells that have divided in culture	No
CSF (cerebrospinal fluid)	Yes
Eggs (ova)*	No
Embryonic stem cells (cells derived from an embryo)	No
Embryos (outside the body)*	No
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non-blood, derived stem cells (i.e. derived from the body.)	Yes
Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material).	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Serum	No
Skin	Yes
Sperm cells (spermatozoa)*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Sweat	No
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

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HTA Codes of Practice and Standards

Our Codes of Practice and Standards provide practical guidance to professionals carrying out activities within the scope of the HTA's remit.

Code A: Guiding principles and the fundamental principle of consent, is the overarching Code and contains information that is applicable to all establishments and professionals operating under our governing legislation.

In combination, this Code and the sector-specific Codes aim to provide anyone undertaking activities relevant to each sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

Our suite of Codes were published in April 2017, which was the last major review of the documents since 2009.

We have published our Codes of Practice and associated Standards to ensure that:

- they reflect our current interpretation of the law and regulatory practice;
- the Standards are fit for purpose; and
- the Codes and Standards make our regulatory requirements clear, while minimising regulatory burden where possible.

Download and Read the Code A here

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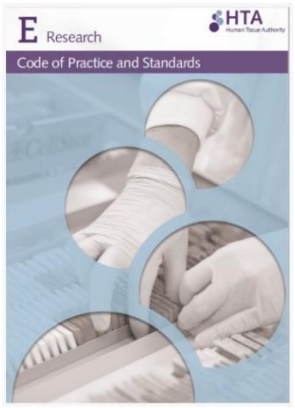
Sector specific codes

- In combination, Code A and the sector-specific Codes aim to provide anyone undertaking activities relevant to each sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.
- Code E is for Research and most relevant to activities within the University
- Two documents to be downloaded and read:
  - E Research: Code of Practice and Standards
  - E Research: Standards and guidance

Code E:
Research



Code E:
Research
Standards and guidance

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The Standards

- The Licensing Standards reinforce the HT Act's intention that:
  a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
  b) bodies of the deceased and organs and tissue removed from bodies are treated with respect;
  c) the dignity of the person, whether living or deceased, is maintained.
- There are 18 standards under four Standard headings:
  1. Consent (C)
  2. Governance and Quality Systems (GQ)
  3. Traceability (T)
  4. Premises, facilities and equipment (PFE)

Consent (C)

136. Establishments meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

137. Establishments meeting these standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

Traceability (T)

138. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and we expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

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Premises, facilities and equipment (PFE)

139. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for their licensed activities and are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

140. The HTA licensing Standards which will be applicable to the Research sector from April 2017 are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

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The Standards

This is why you are looking at his document

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities
b) There is a document control system.
c) There are change control mechanisms for the implementation of new operational procedures.
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.

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The Standards

GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

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Storage, tracking and disposal of relevant material

Traceability
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.

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Disposal of human tissue samples

- Material removed from the living can be treated as clinical waste and should be disposed of by incineration
- Acellular components (e.g. plasma or filtered urine) may be disposed of by autoclaving
- **If in doubt, consult the DI for disposal advice**
- The time, place and method of disposal should be recorded on the Tracking Form

Yellow sharps bin or bags should be labelled 'Waste Human Tissue for Incineration'.

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HTA eLearning

- You need to undertake training for a practical understanding of the Human Tissue Act if you
  - are intending to work with relevant material
  - need to recognise when human material might become “relevant”
- If your research involves the storage and use of relevant material (as defined under the Human Tissue Act), you must complete the MRC HTA eLearning programme
- This is required before applying to both College and University Research Ethics Committees for research ethics consideration if the project involves storage and use of relevant material.

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eLearning and the HTA

https://byglearning.co.uk/mrcrsc-lms/course/index.php?categoryid=1

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MRC Medical Research Council

Regulatory Support Centre

MRC Regulatory Support Centre Learning Management System

LMS Home ▶ Courses ▶ Regulatory Support Centre ▶ e-Learning

Course categories: Regulatory Support Centre / e-Learning

e-Learning

Our e-learning courses are free for all (once you have set up an account or used your Login). Each module aims to provide you with an understanding of the subject area and, where the course is assessed, there is the option to print a certificate when you pass. We try to ensure that all of our training conforms to the UKCRC Governance Training quality criteria.

Note: To allow the courses to run properly and track your score successfully please ensure your browser allows Javascript.

Good Research Practice (developed by MRC Head Office)

Applicable to everyone in the research community this section of the LMS provides access to e-learning and guidance materials that introduce the MRC's expectations for good research practice.

Research, GDPR and confidentiality Quiz

The quiz tests your knowledge against these learning outcomes.

You can take the quiz independently of the bite-sized modules.

It consists of 10 randomly generated questions; the pass mark is 70%. You may repeat the quiz as many times as you wish. A certificate can be printed when you pass.

Research, GDPR and confidentiality – what you really need to know

A series of 10 bite-sized e-learning modules accompanied by supplementary resources.

You will also find information on GDPR and confidentiality requirements for research on GDPR resources and Supporting research using health data.

Research and human tissue legislation

This module provides an overview of human tissue legislation in the UK; best practice and practical tips for compliance. It was developed by the MRC Regulatory Support Centre in consultation with the Human Tissue Authority, National Research Ethics Service, Scottish Government and others.

Research and human tissue legislation assessment - England, Wales & NI

This assessment consists of 10 randomly generated questions; the pass mark is 70%. You may repeat the assessment as many times as you wish. A certificate can be printed when you pass the assessment.

What you need to know

Test your knowledge and understanding and generate a certificate

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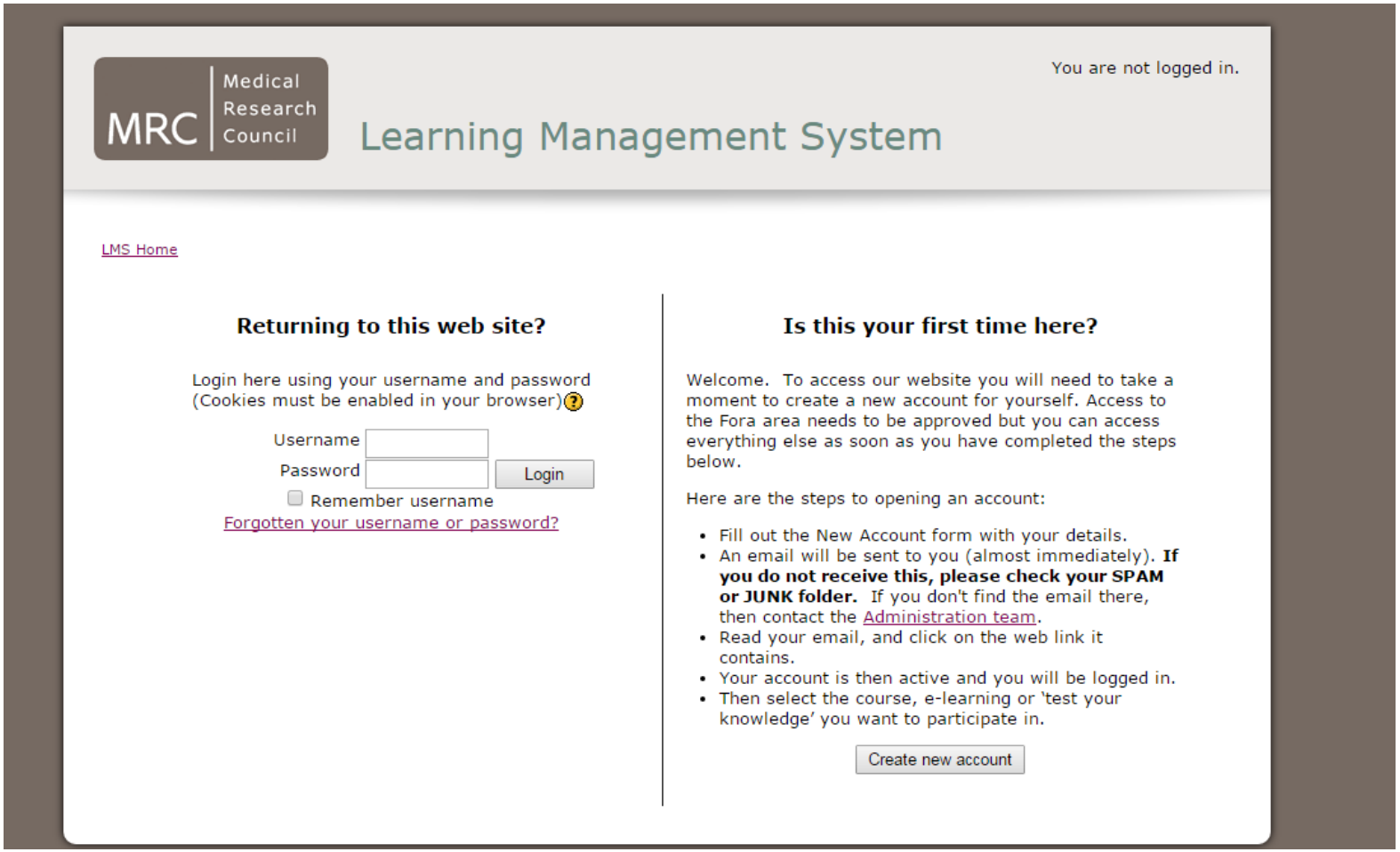
You will be asked create a new account



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Generate a certificate and submit a copy to the DI using the following filename format: surname_HTA_Cert_Year

MRC Medical Research Council

This is to certify that

[redacted]

completed the following e-learning with an assessment (England, Wales and Northern Ireland) score of

80%

Research and human tissue legislation

Overview of Human Tissue Act and Human Tissue (England, Wales and Northern Ireland) Act

When the Acts apply

What constitutes best practice

Top tips to support compliance

Where to find help

December 16, 2014

MRC Regulatory Support Centre

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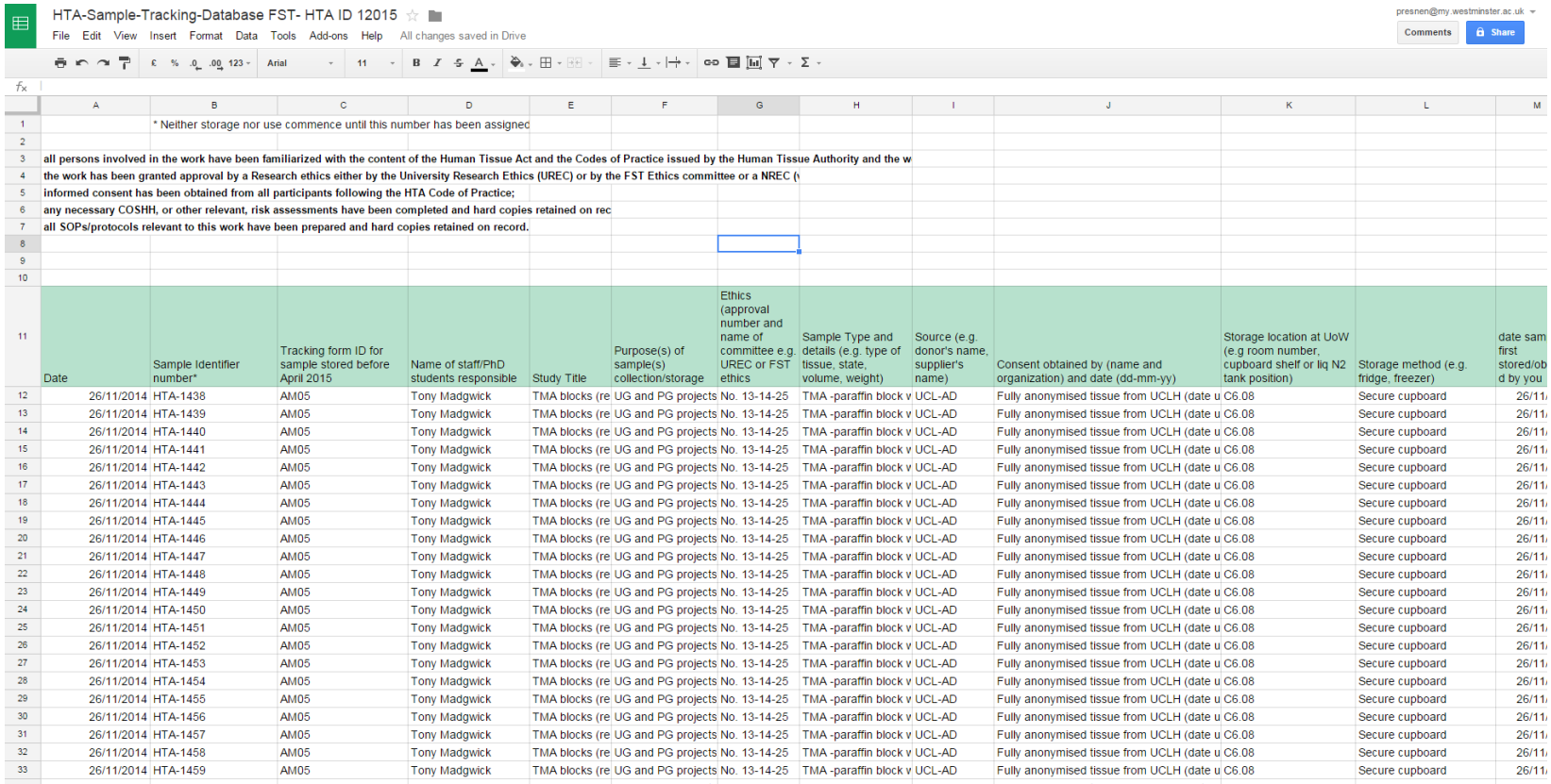
Sample Tracking Database

All relevant material will be tracked. BEFORE you begin collecting material, you must request a number series from the DI. You will then have access to the Sample Tracking Database where you will be responsible for recording the material's journey. Look at all of the headings and ensure that the relevant information is correct and up to date.



HTA-Sample-Tracking-Database FST- HTA ID 12015

File Edit View Insert Format Data Tools Add-ons Help All changes saved in Drive

presnen@my.westminster.ac.uk

Comments Share

* Neither storage nor use commence until this number has been assigned

all persons involved in the work have been familiarized with the content of the Human Tissue Act and the Codes of Practice issued by the Human Tissue Authority and the w

the work has been granted approval by a Research ethics either by the University Research Ethics (UREC) or by the FST Ethics committee or a NREC (

informed consent has been obtained from all participants following the HTA Code of Practice;

any necessary COSHH, or other relevant, risk assessments have been completed and hard copies retained on rec

all SOPs/protocols relevant to this work have been prepared and hard copies retained on record.

Date	Sample Identifier number*	Tracking form ID for sample stored before April 2015	Name of staff/PhD students responsible	Study Title	Purpose(s) of sample(s) collection/storage	Ethics (approval number and name of committee e.g. UREC or FST ethics	Sample Type and details (e.g. type of tissue, state, volume, weight)	Source (e.g. donor's name, supplier's name)	Consent obtained by (name and organization) and date (dd-mm-yy)	Storage location at UoW (e.g room number, cupboard shelf or liq N2 tank position)	Storage method (e.g. fridge, freezer)	date sam first stored/ob d by you
26/11/2014	HTA-1438	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1439	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1440	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1441	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1442	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1443	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1444	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1445	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1446	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1447	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1448	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1449	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1450	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1451	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1452	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1453	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1454	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1455	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1456	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1457	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1458	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/
26/11/2014	HTA-1459	AM05	Tony Madgwick	TMA blocks (re	UG and PG projects	No. 13-14-25	TMA -paraffin block v	UCL-AD	Fully anonymised tissue from UCLH (date u	C6.08	Secure cupboard	26/11/

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Risk Assessment

You are required to complete a risk assessment for the relevant material you are collecting and storing.

Name of person conducting this assessment:		**Title and Brief description of the human tissue related experimental procedures (i.e. DNA analysis, cortisol measurements etc):**	**HTA risk Assessment Number**	
Dept./Faculty:	Faculty of Science and technology FST		**Date risk assessment undertaken:**	
Location:	115 New Cavendish Street		**Proposed end date for this work (if known):**	Should be revised on a 2 year basis or when appropriate (big changes in the policies of the faculty for instance

1. Describe the procedures for sample handling in relation to:	***Ways in which the integrity of the samples can be compromised in relation to this activity***	***Control measures implemented to minimise these possibilities***	***Likelihood of occurrence (Improbable/Remote/Possible/Probable/Certainty)***	***severity (low - medium - high)***
Sample identification:				
Tracking samples:				
Obtaining consent and storing data:				
Donor confidentiality:				
Sample transport:				
Storage of relevant material				
Disposal				
Security of premises				

Review date:..... ▪ review the HTA risk assessment to make sure you are still improving

▪ If there is a significant change, or there has been an accident, check the assessment and where necessary, amend it.

Signed…….. Date……