Quality Manual		
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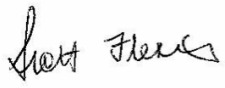
Approved by:	Professor Scott Fleming Designated Individual	

Revision Chronology	**Effective Date**	**Reason for Change**

NOTE: The Quality Manual is subject to frequent and/or annual review. Please ensure that the version of this document is the most up-to-date.

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Acknowledgements
This Quality Manual has been produced with reference to Quality Manuals and Standard Operating Procedures (SOPs) used at a number of other UK Universities, particularly the Universities of Warwick, Cardiff and York. Their permission was sought and granted.

The advice and input from colleagues has also been gratefully received.

Quality Manual

Contents

Abbreviations

CSHS	Cardiff School of Health Sciences
CSHTAMC	Combined School's Human Tissue Authority Management Committee
CSS	Cardiff School of Sport
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
MoSR	Member of Staff Responsible
NHS	National Health Service
QMS	Quality management System
PD	Person Designated
PI	Principal Investigator
REC	Research Ethics Committee
RNA	Ribonucleic Acid
RP	Responsible Person
SOP	Standard Operating Procedure
UEC	University Ethics Committee
UHSC	University Health and Safety Committee

Quality Manual

1. Purpose

The purpose of this Quality Manual is to document the University's Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples to ensure that all staff and students understand the necessary requirements and procedures covered by the Human Tissue Act (HT Act) 2004, the Human Tissue Authority's (HTA) Codes of Good Practice, the University's HTA licence for research and the University's Human Samples in Quality Manual.

2. Background

This Quality Manual forms part of the University's QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA and Cardiff Metropolitan University's Human Samples Quality Manual.

The key quality objectives are to establish an effective QMS that will:

- continue to evolve to demonstrate an enduring commitment to quality improvement;
- provide a robust but practical framework for compliance with the licensing obligations of the HT Act and to the standards required by the HTA;
- be an integral component of the University's research governance framework;
- have the confidence of and be fully embedded into practice by all workers;
- engender the highest levels of trust and confidence in our stakeholders and the broader public;
- enhance the University's reputation for the delivery of research of the highest quality and ethical standards.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

2.1 Human Tissue Act 2004

The purpose of the HT Act is to provide a consistent legislative framework for issues relating to collection, storage, use and disposal of human tissue (including organs and whole bodies). It applies to England, Wales and Northern Ireland. There is separate legislation in Scotland, the HT Act (Scotland) 2006.

The HT Act allowed for the establishment of the HTA in April 2005 as the regulatory and licensing authority and enabled licences to be issued to organisations storing tissue for human application (i.e. the use of human tissue to treat patients, for example, transplantation) from April 2006 and licences for all other activities (i.e. scheduled purposes, such as research) from September 2006.

The HT Act makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display (Scheduled Purposes). It also covers the removal of such material from the deceased

The HT Act regulates the removal, storage and use of human tissue – defined as material that has come from the human body and consists of, or includes, human cells (Relevant Material). Cell lines that have divided outside the human body are excluded, as is hair and nail from the living. Live gametes and embryos are also excluded as they are covered by regulation under the Human Fertilisation and Embryology Act 1990.

Offences under the HT Act, with penalties ranging from a fine to up to three years' imprisonment, or both, include:

- removing, storing or using human tissue for Scheduled Purposes without appropriate consent;
- storing or using human tissue donated for a Scheduled Purpose for another purpose;
- trafficking in human tissue for transplantation purposes;
- carrying out licensable activities without holding a licence from the HTA;
- having human tissue, including hair, nail and gametes (i.e. cells connected with sexual reproduction), with the intention of its deoxyribonucleic acid (DNA) being analysed, without the consent of the person from whom the tissue came or of those close to them if they have died. Medical diagnosis and treatment, criminal investigations are excluded.

For further information on the HT Act, see:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm

2.2 Human Tissue Authority

The HTA is an independent regulator, established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that store and use human tissue for the following activities (Scheduled Purposes under the HT Act, for which consent from the donor is required):

- teaching about or studying the human body;
- carrying out post-mortem examination;
- using human tissue to treat patients;
- carrying out research on human tissue;
- displaying human bodies or tissue in public (e.g. in a museum).

The HTA aims to:

- make sure that these laws are followed by setting clear and reasonable standards;
- provide codes of practice and other advice, guidance and support (including the provision of workshops and e-learning packages);
- give the public confidence that their wishes when donating tissue will be respected, that their donated tissue will be put to the best possible use, and in turn increase the willingness of the public to donate;
- give the professionals confidence that they are working within a clear and effective regulatory framework for the removal, retention, use and disposal of that donated tissue.

2.3 HTA Licensing

An HTA licence is granted to an organisation if it shows it will comply with certain essential standards set by the HTA. When an organisation applies for a licence it assesses itself against those HTA standards. The HTA then evaluates the information provided and where necessary asks for more information before it issues a licence (Phase 1 Inspection). The HTA also inspects organisations to check that they maintain good standards and follow appropriate procedures (Phase 2 Site Inspection). Organisations the HTA consider to be highest risk are amongst the first to be inspected.

Each licensed organisation has to nominate a person who will supervise the activities being carried out, the Designated Individual (DI). DIs have statutory duties as set out in the HT Act (Section 18).

A licence is granted for licensable activity or sector, such as, research, and specifies the premises where the activity is to be carried out (where there may be multiple places where the activity is undertaken, but within the same organisation, the licence will specify a hub site and other satellite sites, where these different premises have separate postcodes).

The HTA grants licences in six sectors:

- Anatomy
- Human application
- Post mortem
- Public display
- Research
- Organ donation and transplantation

A licence is granted under certain conditions:

- Statutory (e.g. licensed activities must only take place on the premises specified in the licence; licensed organisations must ensure activities carried out under the licence are supervised; information required by the HTA is recorded and access to it is given to HTA inspectors as required; licence fees are paid to the HTA);
- Standard;
- Additional (require compliance where a standard is not being met; to support the improvement of standards).

The HTA can revoke, vary or suspend a licence where, for example:

- information in the licence application is found to be false or misleading;
- DI has failed to discharge their duties;
- premises are no longer suitable.

A licence is required to store relevant material for use in research.

The licence will allow storage for the specified activity (in this case research) to take place at the specified premises under the supervision of the DI named on the licence. The licence requires particular records to be kept and to be made available to the HTA during inspection.

The DI carries out the main responsibilities under the licence. The DI needs to ensure that suitable people carry out the activity using suitable procedures (and SOPs need to be available for these) and that any conditions attached to the licence are met.

2.4 HTA's Codes of Practice

Nine Codes of Practice provide guidance and lay down expected standards for each of the six sectors regulated by the HTA. The Codes are designed to support professionals by giving advice and guidance based on real-life experience. They were approved by Parliament in July 2009. The Codes are:

1. Consent;
2. Donation of solid organs for transplantation;
3. Post-mortem examination;
4. Anatomical examination;
5. Disposal of human tissue;
6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation;
7. Public display;
8. Import and export of human bodies, body parts and tissue;
9. Research.

Codes 1, 5, 8 and 9 are the four key Codes for staff and students at Cardiff Metropolitan University.

To download the HTA's Codes of Practice:

https://www.hta.gov.uk/codes-practice

The HTA's Codes of Practice should be read in conjunction with the University's SOPs (see 8 below) and the University's Human Samples Quality Manual.

2.5 HTA Standards

In order to obtain an HTA licence, an organisation must demonstrate that it meets a number of core standards. These relate to consent provision of the HT Act and the regulatory requirements for governance and quality systems, suitable premises and appropriate arrangements for disposal. These four core standards can be summarised as follows:

- Consent – *must be obtained as set out in the HTA Code of Practice 1: Consent*
- Governance and Quality systems – *must have systems in place to ensure the provision of safe tissue of reliable quality*
- Premises, Facilities and Equipment – *must be suitable for the licensed activity undertaken*
- Disposal – *establishments should develop a clear and sensitive disposal policy*

These are generic, give goals to be achieved and provide a basis for the assessment of compliance with the HT Act and the HTA's Codes of Practice.

The HTA expects compliance with all its standards, irrespective of number and volume of samples stored and the duration of storage.

See HTA's Code of Practice 9: Research, paragraphs 97 – 130 for the HTA standards:

https://www.hta.gov.uk/code-practice-9-research

3. The University's HTA Licence

The University holds a licence from the HTA for research (Licence number 12408).

The University is licensed to store human tissue (Relevant Material) at the following sites (Licensed Premises):

Hub site:	Cardiff School of Health Sciences Cardiff Metropolitan University Llandaff Campus Western Avenue Cardiff CF5 2YB
Satellite site:	Cardiff School of Sport Cardiff Metropolitan University Cyncoed Campus Cyncoed Cardiff CF23 6XD

Licence Holder:	Mr. John Cappock, Chief Operating Officer
Designated Individual:	Professor Scott Fleming, Research & Enterprise Services
Person Designated (hub):	Mr Sean Duggan, Principal Technician
Person Designated (satellite):	Mr Mike Stembridge, Post-Doctoral Research Fellow

The licence authorises the storage of relevant material that has come from a human body for use for the following scheduled purposes:

- Determining the cause of death;
- Establishing after a person's death the efficacy of any drug or other treatment administered to him/her;
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);

- Public display;
- Research in connection with disorders, or the functioning, of the human body;
- Clinical audit;
- Education or training relating to human health;
- Performance assessment;
- Public health monitoring;
- Quality assurance.

The licensed activity should be carried on only at the licensed premises specified above, and under the supervision of the DI. A copy of the licence is displayed at each site i.e. at the licensed premises.

4. Quality Management System

The University's QMS relates to the governance of the acquisition, storage, use and disposal of human samples to ensure that all staff and students understand the necessary requirements and procedures covered by the HT Act, the HTA's Codes of Good Practice, the University's HTA licence for research and the University's Human Samples Quality Manual.

The successful implementation of the QMS framework of policies and procedures will ensure that all work at the University involving human samples is carried out in compliance with the licensing obligations of the HT Act, to the standards required by the HTA and the University's Human Samples Quality Manual.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

Specifically, under the HT Act, relevant material is defined as that which consists of, or contains, human cells. The fundamental principle is that if a sample is known to contain even a single cell that has come from a human body then the sample should be classified as relevant material.

There are four categories of relevant material:

Specifically identified relevant material

Bodily organs and tissues consisting largely or entirely of cells, and clearly identifiable and regarded as such.

Processed material

When processed material is generally agreed to leave it always either cellular or acellular (as a result of the process), then the presumption should be that all examples should be regarded as such.

Bodily waste products

Bodily waste is normally regarded as relevant material, this reflects the view that a single cell may be the subject to research. This includes excretions and secretions:

- Urine
- Saliva
- Sweat
- Stool
- Pus
- Washings (such as, nasopharyngeal or peritoneal)

Cell deposits and tissue sections on slides

Sections likely to contain whole cells or intended to be representative of whole cells are considered to constitute relevant material.

Relevant material under the HTA licence excludes:

- Gametes and embryos outside the human body (these are covered by legislation under the Human Embryology and Fertilisation Act, 2008);
- Hair and nail from a living person;
- Cell lines which have divided outside the human body (see note below);
- Extracted DNA and ribonucleic acid (RNA).
- Serum and plasma (provided they are prepared in a manner likely to render them acellular)

Note: If primary cells remain, then the cell line or cell culture could be considered relevant material. There is a judgement to be made in such instances depending on knowledge of the rate of cell division and culture conditions.

If doubt remains over whether or not a sample is acellular, it should be treated as though it is not.

Questions regarding relevant material should be directed to the DI. Further guidance on what does and does not constitute relevant material is available from the HTA at:

https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

All relevant material must be stored under an HTA licence unless one of the following licensing exceptions applies:

It is being held for a National Health Service (NHS) Research Ethics Committee (REC) approved study

The HTA's remit does not include ethical approval of research on human tissue, which must be applied for using the guidance provided by the Health Research Authority and the General Medical Council. Ethical approval can only be given by a recognised research ethics committee which is either:

1. A Research Ethics Committee established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments
2. An ethics committee recognised by United Kingdom Ethics Committee Authority, to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004

Material having ethical approval from an ethics committee that is not an NHS REC (e.g. an overseas ethical committee, or any of the University's Research Ethics Committees or Panels) must be stored under the HTA licence.

It is being held prior to transfer to another organisation

Samples must only be held for a matter of hours or days, and certainly for no more than a week.

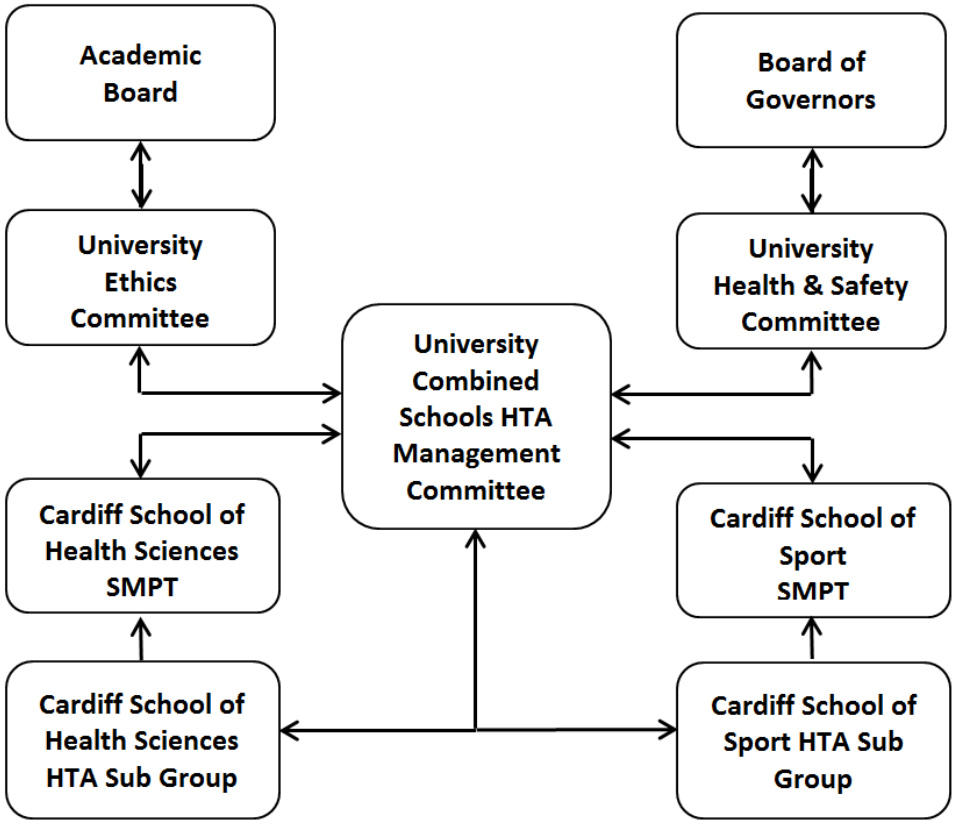
It is being held for processing to render it acellular

Samples must only be held for a matter of hours or days, and certainly for no more than a week.

It is very old

Samples must be from a donor who died more than 100 years ago.

5. Governance and management



6. Responsibilities

6.1 Licence Holder

The Licence is held by the University and the Licence Holder's Representative (the Chief Operating officer), is a named individual in a senior managerial role who should be senior to the DI and be able to substitute for the DI where necessary. Although the role of the Licence Holder does not impose duties that are expected of the DI, the Licence Holder has the right to apply to the HTA to vary the licence, which may include recommending a new DI where, for example, the DI is unable to continue in the role.

For further information on the role of the Licence Holder, see:

https://www.hta.gov.uk/policies/designated-individuals-and-licence-holders-under-human-tissue-act

6.2 Licence Holder's Representative

The Licence Holder's Representative will meet regularly with the DI to monitor the operation and compliance with the licence and will act as Chair to the University's Combined School's HTA Management Committee (CSHTAMC).

6.3 Designated Individual

Under the HT Act, it is the statutory responsibility of the DI to ensure that appropriate procedures and practices are in place and followed, that those involved in work using human samples are appropriately informed and trained, and that the conditions of the licence are complied with relating to the HT Act. The HTA expects compliance with all its standards and that the DI will be committed to improving quality, demonstrated by appropriate monitoring and an audit programme. The work conducted in the University involving human samples is under the supervision of the DI who is required to provide assurance to the senior management of the University that appropriate standards, legislative and regulatory requirements are met, and risks identified are managed effectively.

The DI must:

- be in a position within the licensed organisation to ensure that the activities are conducted properly by individuals who are suitable (and appropriately trained) to carry out those activities and that all necessary legislative and regulatory requirements are complied with;
- have knowledge and understanding of the HT Act and the relevant HTA's Codes of Practice;
- have time to carry out the role of DI in addition to their substantive role;
- ensure compliance with licence conditions;
- demonstrate managerial capability, ensuring quality and supervisory responsibility to effect change;
- have links to senior management/board level;
- know when to seek specialist advice to perform his/her role.

In addition, the DI will:

- act as the key point of contact for enquiries to the HTA;
- be responsible for investigating and reporting adverse events (including to the HTA, as appropriate);
- act as Chair to both the Cardiff School of Health Sciences (CSHS) and Cardiff School of Sport (CSS) HTA Sub Groups;
- meet regularly with the Licence Holder's Representative to provide briefings and updates as part of the monitoring of the operation and compliance with the licence;
- be informed of and authorise, as appropriate, all work and related activities in the University using human samples, in accordance with the SOPs.

For further information on the role of the DI, see:

https://www.hta.gov.uk/policies/designated-individuals-and-licence-holders-under-human-tissue-act

6.4 Persons Designated

Individuals can be nominated as Persons Designated (PDs) by the DI to work under the direction of the licence in support of the DI. PDs do not have the legal duties of the DI as set out in the HT Act (Section 18) but the role of the PD carries with it the ability to "direct" others in relation to the HT Act, e.g. to assist in developing and implementing the SOPs and offering advice and guidance to those working with human samples at a satellite site. This means other individuals working under the direction of the PD are advised about how and why they need to follow procedures and systems agreed by the DI to comply with the HT Act and the University's Human Samples Quality Manual. The PDs will normally be senior technical staff at each site, appropriately qualified to ensure that laboratory practice in relation to work using human samples is adopted.

PDs will assist the DI through the support and guidance they give staff and students and also in audits and monitoring activities and practices. PDs will also have regular dialogue with workers and technical staff, for example, to ensure they are confident in their work, SOPs are workable and that they support the highest quality work.

PDs and the DI together play an important role in the monitoring of activity and the effectiveness of the SOPs in the working environment, to give the University and external agencies, including the HTA, assurance of compliance with the licensing obligations under the HT Act and HTA standards. Ongoing dialogue, active engagement with and feedback from the workers, technical and support staff and students, is vital to underpin the development and successful implementation of the QMS.

6.5 Combined School's HTA Management Committee

The CSHTAMC supports the DI to ensure HTA compliance, monitors new legislative and regulatory requirements, reviews and recommends revisions to Cardiff Mets HTA Framework (Quality Manual and SOPs). The CSHTAMC will meet not less than three times per year.

Membership of CSHTAMC

- Licence Holder's Representative (or their nominated representative) [Chair]
- Designated Individual
- Pro Vice-Chancellor Research
- Person Designated (Hub site)
- Person Designated (Satellite site)

- CSHS Dean of School (or nominated representative)
- CSS Dean of School (or nominated representative)
- Representatives of staff working with human samples (two from each of the hub and satellite sites)

Terms of Reference of CSHTAMC

- Develop appropriate quality assurance procedures to support staff working with human samples.
- Establish HTA School Sub-Groups, including membership and terms of reference, to ensure quality assurance processes are in place at each site covered by the HTA licence.
- Establish an internal audit programme at each site and across sites.
- Identify the requirement for and facilitate the provision of staff development to ensure compliance with the requirements of the HTA Licence.
- Engage in an enduring programme of quality improvement.
- Receive and consider reports from sub-committees including audit and adverse incident reports.
- Review quality management systems on an annual basis and produce and monitor an action plan.
- Provide formal reports to the University's Ethics (UEC) and Health and Safety (UHSC) Committees.

6.6 School's HTA Sub Groups

The HTA School Sub Groups support CSHTAMC, to ensure that all activity involving human samples complies with the requirements of the Human Samples Quality Manual and further assurance processes as determined by the CSHTAMC.

Membership of the CSHS School's HTA Sub Groups

- Designated Individual [Chair]
- Person Designated (Hub site)
- CSHS Laboratory Manager(s)
- Representatives of staff working with human samples
- CSHS Research & Enterprise Support Manager

Membership of the CSS School's HTA Sub Groups

- Designated Individual [Chair]

- Person Designated (Satellite site)
- CSS Laboratory Manager
- Representatives of staff working with human samples
- CSS Research & Enterprise Support Administrator

6.7 Principal Investigator and Responsible Person

Principal Investigators (PIs) drive the work and have overall responsibility for their projects as well as the governance and management of the work and their team, including responsibility for the use of human samples. This may be delegated to a named, suitably trained colleague (Responsible Person) who will be the custodian of those samples.

The PI or Responsible Person will be responsible for conducting the work using human samples in accordance with the SOPs, related HTA standards and Codes of Practice and the University's Human Samples Quality Manual, and must maintain and make available for internal monitoring and audit by the DI and others (in addition to external audit and inspection requirements), all appropriate and required records and documentation.

6.8 Member of Staff Responsible

The Member of Staff Responsible (MoSR) is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

The MoSR will be responsible for conducting the work using human samples in accordance with the SOPs, related HTA standards and Codes of Practice and the University's Human Samples in Quality Manual, and must maintain and make available for internal monitoring and audit by the DI and others, in addition to external audit and inspection requirements, all appropriate and required records and documentation.

6.9 Individual Workers

The University maintains a register of all workers using with human samples. Registration requires the worker to undertake training appropriate to their immediate needs and to maintain a training programme that demonstrates they are competent to perform duties appropriate to their role in each project. The responsibility for ensuring the accuracy and completeness of ongoing personal development rests with the individual worker.

All workers using human samples must:

- register as an individual working with human samples;
- undertake the appropriate training;
- receive and maintain awareness of training support materials;

- have access to advice and guidance;
- understand and adhere to the University's QMS;
- comply with the requirements of the related policies and SOPs;
- maintain a Personal Training Portfolio to record relevant training and development activities.

6.10 Deans of School

Deans of School are accountable for human samples operational compliance within their school. They are responsible for ensuring, on the advice of the DI, that PIs and MoSR are complying with the Human Samples Quality Manual and SOPs.

7. Compliance

It is important in the pursuit of high quality work using human samples and for the reputation of the University and its workers that there is full compliance with the requirements of the HT Act and to the standards required by the HTA and Cardiff Metropolitan University's Human Samples Quality Manual.

8. Governance Framework

Key elements of the University research governance framework include:

The Research Governance Framework:

http://www.cardiffmet.ac.uk/research/Pages/Research-Governance.aspx

The Research Data Storage Policy:

http://www.cardiffmet.ac.uk/research/Pages/Research-Governance.aspx

University Health and Safety Committee

The UHSC receives reports from the University's CSHTAMC.

University Board of Governors

The Board of Governors receives reports from UHSC. Its function is to consider and approve Cardiff Metropolitan University's strategic plan in relation to learning and teaching, research, enterprise and internationalisation. It also sets the University's academic aims and objectives, and oversees the financial, physical and staffing strategies necessary to achieve them.

University Ethics Committee

UEC receives reports from the University's CSHTAMC.

UEC has responsibility for safeguarding the general principles laid down in Cardiff Metropolitan University's Ethics Framework. UEC reports to Academic Board, referring issues of policy.

Academic Board

Academic Board is a corporate academic committee.

It fulfils its responsibilities either directly or by virtue of its powers to establish such committees as it considers necessary to enable it to carry out its responsibilities

9. Standard Operating Procedures

As part of the QMS, the following SOPs have been developed, detailing polices and instructions on all the processes that affect the quality and safety of human samples used.

SOPs provide a uniform approach to the performance of specific functions to ensure continuity and consistency across the University. They have been produced in line with the relevant HTA's Codes of Practice and should be read in conjunction with them. These can be found at:

https://www.hta.gov.uk/codes-practice

and are:

HS01 Standard Operating Procedures

HS02 Consent

HS03 Acquisition and Transfer

HS04 Storage

HS05 Adverse Events

HS06 Disposal

HS07 Training

HS08 Audit

10. Training

All those involved in work involving human samples are required to read the Quality Manual and SOPs and to understand how their requirements relate to their work. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS7 Training.

11. Advice and guidance

Further advice on any aspect of the policies and procedures in this Quality Manual may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

12. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this Quality Manual will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, or the HTA, in accordance with SOP HS8 Audit.

13. Complaints

Any individual member of staff, student or member of the public wishing to raise a complaint in relation to the use of human samples should direct it to the DI in the first instance. If the complaint is not resolved to the satisfaction of the complainant, it may be referred to the Complaints Officer, in accordance with the University's Complaints Procedure:

http://www.cardiffmet.ac.uk/study/studentservices/Pages/Complaints.aspx

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

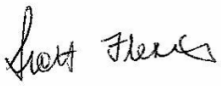
Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and

protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Standard Operating Procedures	
Version:	HS.01.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

Revision Chronology	Effective Date	Reason for Change

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

Please ensure that the version of this document is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

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The advice and input from colleagues has also been gratefully received.

Standard Operating Procedures

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
MoSR	Member of Staff Responsible
QMS	Quality Management System
PTP	Personal Training Portfolio
PI	Principal Investigator
RP	Responsible Person
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure

Cardiff Metropolitan University | Prifysgol Metropolitan Caerdydd

Standard Operating Procedures

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the production, review, approval, distribution and revision of SOPs relating to the acquisition, storage, use and disposal of human samples for research, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

SOPs are records of procedures reviewed by the School's HTA Sub Groups, authorised by the Designated Individual (DI) and approved by the Combined School's HTA Management Committee (CSHTAMC), for implementation across the University.

SOPs will be:

- produced when the need for a standard written procedure is identified;
- prepared, reviewed, revised, approved and issued according to this SOP;
- subject to regular reviews and to a system of document/version control;
- available for inspection by external agencies e.g. the HTA.

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the DI to ensure that appropriate procedures and practices are in place and followed, that those workers using human

samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR), as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Deans of School are responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The School's HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the University's CSHTAMC. The DI will sign each SOP following approval by CSHTAMC.

4. Policies

The University will introduce a series of SOPs to ensure that all staff and students understand the requirements and procedures relating to the acquisition, storage, use and disposal of human samples.

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to all human samples.

SOPs are working documents and will be subject to regular review.

5. Procedures

5.1 Format and content

5.1.1 Front Page

Each SOP produced will contain the following standard information:

- SOP Title
- Unique Version Number
- Effective Date
- Approved By
- Table of Revision Chronology
- Acknowledgements

This information will be displayed in the manner shown in Appendix 1. Each page of the SOP will contain a header showing Cardiff Metropolitan University's logo in the top right hand corner and the standard operating procedure number and title in the top left hand corner of the page. The footer of each page will display the page number, the effective date and the version number for reference.

5.1.2 Version Number

All SOPs will be issued with a version number to ensure individuals are referring to the current document. This unique number will be displayed on the front page of the document. Each page will also contain the version number in the footer on the bottom left hand side of the page. As documentation is reviewed, amended and approved, the version number will change e.g. HS.01 to HS.02 etc. The revision chronology table will be completed on the front page as a documented record of the date and reason for these changes.

5.1.3 Effective date

All SOPs will be issued with the date the document has been approved by the DI on behalf of the CSHTAMC. This information will be displayed on the front page and the footer of each page of the SOP.

5.1.4 Approval

The School's HTA Sub Groups will review all significant changes to SOPs before approval can be granted by the CSHTAMC.

5.1.5 Purpose

An explanation as to the purpose of the SOP i.e. to ensure all staff and students understand the requirements and procedures for the collection, storage, use and disposal of human samples, covered by the HT Act, the HTA's Codes of Good Practice, the University's HTA licence for research and the University's Human Samples QMS.

5.1.6 Background

Outlines clearly the reasons for and specific aims of the SOP. SOPs form part of the University's QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA and Cardiff Metropolitan University. The relevant HTA Code of Practice and the University's Human Samples QMS should be referred to within this section of the SOP.

5.1.7 Responsibilities

Describes the responsibilities of key individuals in terms of compliance with the SOP. It is the responsibility of the DI to ensure that the procedure is adhered to when developing and implementing a SOP. The PI, RP or MoSR is responsible for ensuring that SOPs are followed and adhered to. The relevant Dean of School is accountable for ensuring members of their School are operationally compliant with the processes and procedures for working with human samples. SOPs are reviewed by the School's HTA Sub Groups and approved by CSHTAMC.

5.1.8 Policies

Outlines the key principles behind the development of the SOP.

5.1.9 Procedures

Identifies how the aims are to be achieved by utilising a step-by-step description of the procedures.

5.1.10 Training

As a minimum, SOPs must be read by all relevant staff involved in work using human samples. This section will contain details of the training required.

5.1.11 Advice and guidance

Contains detailed information on whom to contact for further information or clarity.

5.1.12 Monitoring and audit

SOPs will be monitored for their effectiveness by the DI, with advice from the CSHTAMC. The DI will also undertake regular audits as required by the University or HTA inspectors.

5.1.13 Definitions

A list of terminology used and their explanations.

5.1.14 Appendices

Documentation which is to be completed in order to follow the step-by-step procedures of the SOP or to be used as a reference point.

5.2 Circulation and distribution

All staff and students working with human samples are required to register, undertake training and maintain a Personal Training Portfolio (PTP), in accordance with SOP HS.07 Training. The SOPs sign-off form is part of the PTP and all those registered must complete the form to confirm they have read the relevant SOP and understand how to apply it to their work.

SOPs will be subject to regular review and updating, when appropriate. CSHTAMC will consider and review each SOP at least every year. All staff and students registered for working with human samples will be alerted by email to any new version of a SOP that is produced and approved for implementation. SOPs will be made available for all those registered to download from the University's intranet.

Training and briefing sessions may be provided where there is a new SOP, major changes to the legislation, or HTA regulatory practice that impact significantly on an existing SOP. It is the responsibility of each individual working with human samples to ensure they are using the most up-to-date version of a SOP and all hard copies of out-of-date SOPs should be destroyed.

Hard copies of all the SOPs and other related documentation will be retained by the DI, for consultation by staff and students.

5.3 Review of content

SOPs are working documents and will be subject to regular review. They will be amended to respond to new legislation, updated regulatory guidance, new Codes of Practice issued by the HTA, advice and guidance from other related sources.

Members of staff or students who feel a particular SOP requires updating or revising to ensure that practices and procedures are effective and carried out in compliance with the licensing obligations of the HT Act, to the standards required by the HTA and the University's Human Samples QMS should notify the DI - highlighting their reasons for requesting the change. The School's Sub Groups will consider and review each SOP at least every year. The School's Sub Groups will review all significant changes to SOPs before approval can be granted by the CSHTAMC.

5.4 Archiving

Superseded versions of SOPs will be archived by the DI.

6. Training

All those involved in work involving human samples are required to read all SOPs and to understand how their requirements relate to their work. This should be recorded in the PTP on the Working with Human Samples sign-off form (see Appendix 2), in accordance with the SOP HS.07 Training.

7. Advice and guidance

Further advice on SOPs for the purposes of working on human samples and the provisions of this SOP may be sought from the DI, or the PDs. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's internal auditors or the HTA, in accordance with SOP HS.08 Audit.

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned

(the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and

the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

SOP Title	
Version:	
Effective date:	
Approved by:	

Revision Chronology	**Effective Date**	**Reason for Change**

NOTE: All SOP's are subject to frequent and/or annual review

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The advice and input from colleagues has also been gratefully received.

Appendix 2

Working with Human Samples

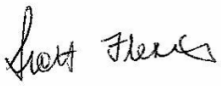
Standard Operating Procedures Sign-off

This form is to certify that you have:

- Read the Standard Operating Procedures (SOPs) relevant to your role;
- Understand how to apply the SOPs to your work;
- Know where to locate a copy of the current SOPs.

The original signed and dated form should be filed in the Personal Training Portfolio.

Name:			
SOP Number, and Title	**Version**	**Date read**	**Signature**

Consent	
Version:	**HS.02.01**
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

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Consent

Contents

Definitions

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
HIS	Inventory of Human Samples
MC Act	Mental Capacity Act
MoSR	Member of Staff Responsible
NHS	National Health Service
PD	Person Designated
PI	Principal Investigator
RP	Responsible Person
QMS	Quality Management System
SOP	Standard Operating Procedure

Consent

1. Purpose

The purpose of this SOP is to ensure that all staff and students understand the requirements and procedures for obtaining consent for the collection, storage and use of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence and the University's Quality Management System for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples Quality Management System (QMS) that covers the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which became law on 1 September 2006, and should be read in conjunction with the HTA's *Code of Practice 1: Consent* (September 2009):

https://www.hta.gov.uk/code-practice-1-consent

Consent is a central tenet of the HT Act and it specifies whose consent is needed in all relevant circumstances. The giving of consent is a positive act; the absence of refusal is not evidence of consent. The HTA's *Code of Practice 1: Consent* sets out guidance on the need for consent and addresses the closely related issues of communication and consultation with patients or other individuals and, where appropriate their families, which must support the consent process.

Consent for the collection and use of human samples is considered as part of the ethical approval application.

3. Responsibilities

Under the University's HTA licence for the storage of human samples, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using

human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the PI, RP or MoSR as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Dean is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The Schools HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Consent is the central tenet of the HT Act and it specifies whose consent is needed in all relevant circumstances. The HTA advises that it is best practice to obtain consent.

Appropriate consent must be in place to acquire, store and use relevant material, taken from the living or deceased. Appropriate consent is also required to hold material with the intention of analysing its deoxyribonucleic acid (DNA).

The HTA encourages the taking of informed and generic consent at the outset, as the default position. This allows human samples to be used for different projects over an unspecified period of time (with appropriate ethical approval).

Failure to comply with the requirements of this SOP will result in samples being secured and the work may be delayed.

For further information on consent, please refer to the HTA's Code of Practice 1: Consent (September 2009):

https://www.hta.gov.uk/code-practice-1-consent

5. Procedures

5.1 Appropriate consent

The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a 'qualifying relationship' with the donor.

5.2 The process of consent

Consent should be seen as part of a continuing process in which individuals, their relatives and friends, as appropriate, can discuss the issue fully, ask questions and make an informed choice.

5.3 Communication

Consent is only valid if proper communication has taken place. Particular consideration should be given to the needs of individuals and families whose first language is not English. Any difficulties in communication with the donor or other individual being interviewed e.g. because of language, literacy, or hearing difficulties and an explanation of how these were overcome (e.g. through an independent translator), should be recorded.

Attitudes towards the use of human samples may vary widely among different cultures and religions and should be respected. Workers must be sensitive to this. However, each case is an individual and personal one, and should be treated as such.

5.4 Information sheets and consent forms

Information sheets and consent forms are recommended by the HTA for human sample donation and are required by ethics committees approving projects.

Information sheets and consent forms should be based on the University's exemplars:

https://www.cardiffmet.ac.uk/research/Pages/Research-Ethics.aspx

The following additional information should be provided where appropriate:

- A central contact should an individual wish to withdraw consent for the storage and/or use of their samples. This contact is the relevant school's Research & Enterprise Support Administrator or Manager. An email address and telephone number should be provided.
- The duration of consent, including the length of time that all samples collected will be stored.
- The scope of consent. If the scope is specific, detailed information is required.
- If appropriate, whether the samples will or could be used for work involving the commercial sector.
- If appropriate, whether DNA analysis is involved and the potential risks of genetic testing.
- A statement explaining the practicalities of withdrawing consent and the implications of doing so.
- If appropriate, whether the samples will be or could be exported or transferred.

For further guidance on obtaining informed consent, participant information sheets and consent forms, see:

- the University's Research Ethics web pages at: https://www.cardiffmet.ac.uk/research/Pages/Research-Ethics.aspx
- the University's Research Governance web pages at: https://www.cardiffmet.ac.uk/research/Pages/Ethics-and-Research-Governance.aspx
- National Research Ethics Service Information Sheets & Consent Forms – Guidance for Researchers & Reviewers (March 2011): http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

5.5 Consent exemptions

There are circumstances where obtaining consent is not feasible and the HT Act provides a number of limited and specific exemptions:

- Old samples
- Imported samples
- Ethically approved and anonymised samples
- Samples to be used for DNA analysis

5.5.1 Old samples

Consent provisions do not apply retrospectively to tissue held before 1 September 2006. These are existing holdings. However, it is best practice to consider any ethical and legal issues before existing holdings are used without consent. Existing holdings are not exempt from requiring ethical approval for their use or from HTA licensing requirements for their storage.

5.5.2 Imported samples

Relevant material imported from outside England, Wales and Northern Ireland does not require consent for it to be used or stored for research. However, it is best practice to seek assurance that appropriate consent is available for imported samples. Imported samples are not exempt from requiring ethical approval for their use or from HTA licensing requirements for their storage.

5.2.3 Ethically approved and anonymised samples

Relevant material can be used, including the analysis of DNA, without consent only when ***all*** the following apply:

- The material came from a living person (when taken);
- It is anonymous to the researcher;
- Its use has ethical approval from a National Health Service (NHS) Research Ethics Committee or a Committee recognised by the UK Ethics Committee Authority.

NOTE: Review by any Cardiff Metropolitan University Research Ethics Committee is not sufficient.

Within the HT Act, anonymisation means that the worker is not able to identify the donor, and it is unlikely that they will be able to do so in the future. Robust coding of samples is an acceptable approach. For example, coded samples are assigned a unique identifier to protect the confidentiality of the individual during routine use of these samples. It may be possible to unlock the code and thus identify the individual from whom the samples were obtained. The key to the code should not be freely accessible but held under a strict duty of confidence. It is the responsibility of the PI, RP or MoSR to ensure the code is kept securely and under appropriate guardianship.

There are other reasons why samples may need to be anonymised that do not originate in human tissue legislation e.g. common law duty of confidence when sharing information or samples.

5.5.4 DNA analysis

If the results of the DNA analysis are to be used for research purposes, consent is required unless another exemption applies (e.g. DNA analysis on anonymised bodily material from the living and NHS ethics approval is in place or pending). If the results are to be used for other purposes (e.g. medical diagnosis) these may be exempt and consent may not legally be required. These are known as 'excepted' purposes.

For more detail on excepted purposes and DNA analysis, see the Medical Research Council's Regulatory Support Centre DNA Analysis Summary at:

https://www.mrc.ac.uk/documents/pdf/dna-analysis-summary/

Scheduled purposes other than research

Consent is not required to use or store human samples from the living for the following:

- Clinical audit;
- Education or training related to human health;
- Performance assessment;
- Public health monitoring;
- Quality assurance.

However, consent is required for the use of human samples from the deceased for these purposes.

5.6 Valid consent

The giving of consent is a positive act. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question, e.g. research. All consent must be valid in the context of the HT Act. For consent to be valid, the person should understand what the activity involves and, where appropriate, what the risks are. Persons seeking consent should ensure that it is appropriate for the intended purpose.

5.7 Scope of consent

Consent may be generic or specific. Generic consent typically only applies to research. If conducting research on human samples, it is good practice to request generic consent because this avoids the need to obtain further consent in the future.

5.8 Duration of consent

Consent may be enduring or time-limited. Enduring consent means that it remains in force unless consent is withdrawn. A person may, however, specify a time limit for how long they wish their consent to remain in force. In both cases, the decision should be clearly documented e.g. in the patient's records, the laboratory records or both.

5.9 Format of consent

Consent does not have to be in writing. The HT Act only specifies that consent must be in writing for the use of human samples in anatomical examination or public display. Written consent serves as evidence of consent, but a signature on a form will not of itself make the consent valid. When consent is obtained but not in writing, this should be clearly documented, for example, in the patient's records, the laboratory records or both.

5.10 Withdrawal or refusal of consent

Consent may be withdrawn at any time whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear. Withdrawal of consent cannot be effective where the samples have already been used.

Where consent is a legal requirement and is given but later withdrawn, then this must be respected. No further use may be made of the human sample and it must be disposed of or returned to the individual in accordance with their wishes.

Where consent is a legal requirement for the intended purpose and it is refused, then that human sample may not be used or stored for that purpose lawfully. Individuals should not be coerced into giving consent as that consent will not be valid.

5.10.1 Removal of Samples

Requests to withdraw consent from a study may be written or verbal.

If a Research & Enterprise Support Administrator or Manager receives a verbal request to withdraw consent from a study, s/he should keep a record the request.

The Research & Enterprise Support Administrator or Manager should record:

- for which purpose(s) the consent is being withdrawn.
- for which project the study is being withdrawn

Following a participant's request to withdraw from a study to which they have previously given consent, the following procedure must be followed:

1. The Research & Enterprise Support Administrator or Manager must inform the PI, RP or MoSR of the request in writing. This should include a copy of the written or recorded request.
2. The PI, RP or MoSR must identify all samples stored.
3. If appropriate, the PI, RP or MoSR must contact a Person Designated (PD) to arrange the disposal of the samples.
4. The samples must be disposed of in accordance with the University's QMS for human samples and SOP for disposal.
5. The PI, RP or MoSR must enter the reason for disposal on the Inventory of human samples (IHS).

   NB: The samples must not be deleted from the IHS.

This procedure should be completed as soon as is reasonably practicable and in the shortest timeframe achievable.

5.10.2 Removal of data

Following a participant's request to withdraw from a study to which they have previously given consent, the following procedure must be followed:

Any data relating to the participant already collected must be deleted from the study records and hard copies of such data destroyed.

The PI, RP or MoSR must record these actions in the project file giving dates of withdrawal, disposal and destruction of records.

Mechanical shredding or disposal as 'confidential waste' are the only methods permitted for the destruction of hard records.

No data relating to the withdrawn participant may be used for any aspect of the study and steps must be taken to remove such data from any analysis of the study. The wishes of the participant are paramount and must be respected in all instances regardless of any impact to the study.

5.11 Records of consent

It is likely that some consent records will not be held by or be available to the University. Regardless, it is the responsibility of the PI, RP or MoSR to ensure that informed consent has been obtained. This may be by means of documentation from a clinician, tissue bank or other organisation supplying the human samples that is responsible for obtaining consent.

If the consent records are held by the University, the appropriate requirements concerning data protection and security must be followed.

5.12 Who can give consent?

5.12.1 Human samples from the living

5.12.1.1 Competent adults

If an adult is competent i.e. has the capacity to make the decision, only they are permitted to give consent.

5.12.1.2 Adults lacking capacity

Under the Mental Capacity Act 2005 (MC Act), a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following:

- Understand the information given to them that is relevant to the decision
- Retain that information long enough to be able to make the decision;
- Use or weigh up the information as part of the decision-making process;
- Communicate their decision by any means.

Where there is any doubt about whether an adult has the capacity to consent, he/she should be supported to make their own decisions and be given all appropriate help before anyone concludes that they cannot make their own decisions. Any work involving adults who lack the capacity to give consent must be in the best interests of that individual. Generally, if work can be done equally well on those who do have the capacity to consent, the involvement of those who lack capacity to consent should be avoided. If lack of capacity is temporary, then full consent must be sought as soon as capacity is regained. Further guidance on the provisions of the MC Act is available from the Office of Public Guardian website:

https://www.gov.uk/government/collections/mental-capacity-act-making-decisions

5.12.1.3 Children

The HT Act defines children as being under 18 years old and they may consent to involvement in a study if they are competent to do so. Under the Children Act 1989 a person with parental responsibility for the child can consent on the child's behalf only if the child has not already made a decision either way and the child is not competent to do so, or is competent to do so but is unwilling to make that decision.

5.12.2 Human samples from the deceased

5.12.2.1 Adults

Where a person aged 18 or above has, whilst alive and competent, given valid consent for the removal, use or storage of their tissue to take place following their death, then that consent is sufficient for the activity to be lawful.

5.12.2.2 Nominated representatives

If a deceased adult has neither consented to nor specifically refused any particular donation or removal, use or storage of their tissue, then a nominated representative appointed by the individual may give consent. If a

nominated representative had not been appointed, then consent can be given by someone in a qualifying relationship. Qualifying relationships are defined in the HT Act in the following order and consent should be obtained from the person ranked highest:

1. Spouse or partner;
2. Parent or child;
3. Grandparent or grandchild;
4. Niece or nephew;
5. Stepfather or stepmother;
6. Half-brother or half-sister;
7. Friend of long-standing.

5.12.2.3 Children

In the case of deceased children, if while alive and competent consent was given for work to be undertaken after their death, this is sufficient to make lawful the removal, use and storage of their tissue for that purpose. However, if while alive the deceased child did not consent or was not competent to make a decision, the HT Act makes it clear that the appropriate consent will be that of a person with parental responsibility for the child. If there is no person with parental responsibility, then consent should be sought from someone in a qualifying relationship (as defined above).

5.13 Foetal tissue

In the case of foetal tissue, consent should be obtained from the mother for the examination, storage and use of foetal tissue and non-foetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is non-identifiable.

5.14 Research involving NHS patients

NHS patients have a fundamental legal and ethical right to determine what happens to their own bodies and to expect their personal information and any human samples are used primarily for their own benefit and treatment. Where their samples are being used for other purposes, for example, research, the patient must be fully informed and valid consent obtained. In addition, approval from an NHS Research Ethics Committee and NHS Research & Development approval must be obtained, as appropriate. All research involving NHS patients must also comply with the appropriate policies and Standard Operating Procedures of the specific NHS Trust providing care to the patient.

5.15 Work involving healthy volunteers

Human samples may also be obtained from healthy volunteers in a non-clinical setting. The provisions of the policies within this SOP still apply.

Obtaining consent should be by individuals with appropriate training and the donor must be fully informed of the purpose of the work and of any risks involved. The PI, RP or MoSR must ensure that valid consent is taken and recorded, either by use of a duly signed and dated consent form or by a written note of any non-verbal or oral consent.

5.16 Use of images

The making and displaying of images, including photographs films and electronic images, falls outside the scope of the HT Act. The HTA expects that appropriate practices are observed and procedures to prevent inappropriate use of images are in place. The HTA endorses the guidance on images provided by the General Medical Council in its publication *Making and using visual and audio recordings of patient. April 2011:*

http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp

This guidance should be followed in respect of work on human samples undertaken at the University and by University staff and students.

6. Training

Seeking and obtaining consent are sensitive issues. Those seeking consent should have a good understanding of the activities they are seeking consent for. They should also be in a position to answer questions that donors or their families may have. All those involved in seeking consent for the removal, storage and use of human samples must receive training in the implications and statutory requirements for consent under the HT Act. Training and support in the taking of consent, provided by the University's Research and Enterprise Services team should also be received. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS.07 Training. This will enable individuals to understand the requirements and procedures for seeking and obtaining consent for human samples.

7. Advice and guidance

Further advice on consent for the purposes of work on human samples and the provisions of this SOP may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Auditors or the HTA, in accordance with SOP HS.08 Audit.

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are

designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

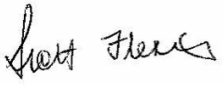
Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Acquisition and Transfer	
Version:	HS.03.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

Revision Chronology	Effective Date	Reason for Change

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

Please ensure that the version of this document is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

Acknowledgements
This Quality Manual has been produced with reference to Quality Manuals and Standard Operating Procedures (SOPs) used at a number of other UK Universities, particularly the Universities of Warwick, Cardiff and York. Their permission was sought and granted.

The advice and input from colleagues has also been gratefully received.

Acquisition and Transfer

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
IHS	Inventory of Human Samples
MTA	Materials Transfer Agreement
MoSR	Member of Staff Responsible
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
QMS	Quality Management System
REC	Research Ethics Committee
RP	Responsible Person
SOP	Standard Operating Procedure

Acquisition and Transfer

1. Purpose

The purpose of this SOP is to ensure that all staff and students understand the requirements and procedures for the acquisition and transfer of human samples for work, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's *Code of Practice 8: Import and export of human bodies, body parts and tissue* (May 2007):

https://www.hta.gov.uk/code-practice-8-import-and-export

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR) as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Deans of School are responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The School's HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the University's Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to the acquisition and transfer of all human samples for all uses.

Human samples may be acquired from, or transferred to another organisation, research institution, collaborator on a research project, tissue bank or commercial supplier of human samples for storage and use.

As under the HT Act, imported human samples are those which come from outside England, Wales and Northern Ireland.

The transfer, import or export of all human samples should be handled with respect, and caution as all samples have the potential to transmit disease. For example, brains, brain tissue, spinal cord and cerebrospinal fluid (fresh, fixed or frozen) carry the risk of spreading infectious diseases. Appropriate risk assessment must be undertaken and documented to ensure that all who come into contact with the samples are protected from the presence of any infectious agents.

All staff and students working with human samples are required to register and undertake appropriate training, in accordance with SOP HS.07 Training, before transferring or working with any human samples.

The storage and cataloguing of any transferred human samples must be in accordance with SOP HS.04 Storage.

Consent is a central tenet of the HT Act and it specifies whose consent is needed in all relevant circumstances. Appropriate consent must be in place to acquire, store and use relevant material, taken from the living or deceased, for research. Appropriate consent is also required to hold bodily material with the intention of analysing its deoxyribonucleic acid (DNA). For further information on consent, please refer to the SOP HS.02 Consent, which should be read in conjunction with the HTA's *Code of Practice 1: Consent* (September 2009):

https://www.hta.gov.uk/code-practice-1-consent

Failure to comply with the requirements of this SOP may result in samples being secured and the work being delayed.

5. Procedures

5.1 Import of human samples

5.1.1 Biological Risk Assessment

An appropriate Biological Risk Assessment form must be completed and approved by a School HTA Sub Group, to ensure the health and safety of those handling the samples has been taken into account.

5.1.2 Consent and Ethical Approval

Although the consent requirements of the HT Act do not apply to samples transferred into the University from countries outside England, Wales and Northern Ireland, the HTA advise that it is good practice for a mechanism to be in place that provides assurance that the human samples are imported with appropriate consent.

Samples transferred into the University from sources within England, Wales and Northern Ireland must have appropriate consent. As the receiving organisation, the University should ensure that any material is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. For samples sourced from National Health Service (NHS) patients, approval (i.e. a favourable ethical opinion) should be obtained from an NHS Research Ethics Committee (REC). It is good practice for the Principal Investigator and any proposed research to be undertaken on these samples at the University to be detailed in the REC approval document (possibly through an amendment to the original REC application).

As the importing organisation, the University should ensure that, with due assurance from collaborators overseas, that any material intended for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. It is good practice for approval (i.e. a favourable ethical opinion) to be obtained from a research ethics authority or local equivalent in the source country before the samples are transferred to the University. Many countries have research ethics arrangements which operate to agreed standards. The ethical review in the source country may, in some cases, be considered to provide appropriate assurances for the importing of human samples into this country.

Advice may be sought on the appropriateness of a country's ethical review arrangements by the DI or from the National Research Ethics Service (NRES) and with reference to the International Compilation of Human Research Protections, produced by the United States Department of Health and Human Services. If considered appropriate, with relevant risk assessments in place, approval for the importation will be agreed by the DI.

All available documentation relating to the application for ethical approval must be available prior to the arrival of the samples at the University. These will include:

- details of the process of obtaining consent and donor information supplied, or of the anonymisation of the samples;
- scope of the work and the role of the worker(s) at the University;

- confirmation of ethical approval being given in the source country and details of the application for the approval given.

Documentation must be presented in English, with the original papers in the language of the source country, accompanied by a certificate of translation or equivalent, to provide assurance that the translation was undertaken by an appropriately qualified, independent translator or translation service.

Where the University cannot be assured that the appropriate ethical review standards in the source country have been put in place, the risks of accepting such material will be reviewed by the DI. Advice may be sought from the NRES and the project may be submitted to a local NHS REC for approval.

Whilst it is outside the normal remit of NHS, an NHS REC may be approached to provide ethical review of a project using imported tissue. Where an application involves imported tissue the NHS REC will seek justification for importation in preference to sourcing material within the United Kingdom where practicable. The REC may also seek confirmation that consent for research has been or will be given by donors in the source country. However, RECs are not expected to undertake detailed review of the consent arrangements or other research activities undertaken by collaborators in the source country.

5.1.3 Materials Transfer Agreement

The acquisition and receipt of any human samples transferred into the University from another organisation must be under an appropriate legal agreement – usually a Materials Transfer Agreement (MTA).

In accordance with the University's Financial Regulations, all legal agreements and contracts at the University must be processed through and formally signed by the appropriate person in Procurement on behalf of the University (who have the appropriate delegated authority). It is common for the worker in receipt of the imported material to be named on and be a signatory to a MTA but only in addition to the official signatory on behalf of the University which is normally the DI.

No Dean, Head of Department, member of staff, or student can enter into an agreement on behalf of the University.

The CSHTAMC has approved a University standard MTA that can be used and negotiated with suppliers of human samples and will also advise on MTAs received from other organisations, and the terms and conditions of commercial suppliers. The PI, PR or MoSR is responsible for notifying the DI of every instance of human samples transferred into the University and the DI's signature is required on the MTA prior to receipt of human samples by the University.

A legal contract or MTA is not required for transfer of human samples between the University's schools. However, the reasons for transfer, the storage conditions and use of the samples should be documented on the

Authority to Import Human Samples Form (Appendix 1) and approved by the DI prior to the transfer.

5.1.4 Authority to Import Human Samples Form

An Authority to Import Human Samples Form (see Appendix 1) must be completed and submitted for approval to the DI, with appropriate supporting documentation and risk assessment(s), in advance of the date for receipt of any human samples to be transferred into the University. In cases where human samples are being imported from overseas (outside England, Wales and Northern Ireland), the PI, RP or MoSR, should attach a brief statement of justification for the importation to the Authority to Import Human Samples Form.

An Authority to Import Human Samples Form must be completed for human samples transferred between the University's academic schools (e.g. from the School of Sport to the School of Health Sciences).

The DI, by authorising the transfer of samples into the University, must be satisfied and have the appropriate auditable evidence that:

- an appropriate MTA or equivalent is in place (see 5.2);
- a minimum level of consent is in place before the tissue is transferred to the University (see 5.3);
- the premises, facilities and equipment are suitable for the work to be undertaken;
- workers involved in the storage or use of the samples transferred to the University are registered, suitably qualified and appropriately trained.

The DI will ensure a copy of the approved Authority to Import Samples Form is logged on the Human Samples Project File.

No human samples should be used in work at the University without prior approval. Risk Assessment forms are available at:

- University Health Safety and Wellbeing Unit Site: link
- Cardiff School of Health Sciences SharePoint Site: link

5.2 When the samples arrive

5.2.1 Checks on samples and documentation

Samples and their accompanying documentation must be checked and samples stored securely, under the appropriate conditions. All samples must be labelled in accordance with SOP HS.04 Storage. Any discrepancies with the Authority to Import Human Samples Form or related documentation must be highlighted to the DI. Any adverse event or incident involving the samples (e.g. damage to the packaging, damage to the samples) should be reported and investigated in accordance with SOP HS.05 Adverse Events.

5.2.2 Inventory of Human Samples

The PI, RP or MoSR for receiving the human samples is responsible for ensuring the Inventory of Human Samples (HIS) is updated with the details of

the samples transferred to the University and that a unique identifier is assigned to each sample and to each of the products associated with it. Numbering and labelling of samples (using labelling that is clear, robust and appropriate to the storage conditions) and the labelling of storage facilities must be in accordance with the SOP HS.04 Storage.

5.3 Export of human samples

5.3.1 Materials Transfer Agreement

All human samples transferred out of the University should be done under an MTA. Human samples should not be transferred from one organisation to another unless both organisations have ethical approval from a recognised research ethics committee or are subject to an appropriate HTA licence and operating in accordance with HTA standards and Codes of Practice.

A material transfer schedule should accompany the transfer.

No Dean, Head of Department, member of staff, or student can enter into an agreement on behalf of the University.

5.3.2 Authority to Export Human Samples Form

An Authority to Export Human Samples Form (see Appendix 2) must be completed and submitted for approval to the DI, with appropriate supporting documentation and risk assessment(s), in advance of the date for transportation of any human samples out of the University. The DI will ensure a copy of the approved Authority to Export Samples Form is logged on the Human Samples Project File.

5.3.3 Mechanisms of transport

Suitable routes and appropriate modes of transport will need to be considered with all parties involved when planning transportation. This needs to be arranged in advance and risk assessments for the handling and transportation undertaken. The University's preferred suppliers of transportation/courier services must be used. The PI, RP or MoSR should contact the transport operator and/or Customs (for air transport) prior to the transportation to establish any appropriate conditions for the transportation of the samples.

Samples must be contained in a secure, leak-proof and break-resistant container.

Suitable weather-proof labelling, including biohazard warnings where appropriate, should be placed on the containers and must be able to remain fully legible during transport.

Documentation should be attached to the container with the following information:

- Description and identification details of the sample
- Address of the source
- Address of the destination
- Details of hazardous contents

- Emergency procedures
- Contact numbers and addresses

This information may be in a sealed envelope that can be opened in an emergency.

The human samples should not be left unattended at any time unless secure storage is available.

5.3.4 Inventory of Human Samples

The PI, RP or MoSR for exporting the human samples is responsible for ensuring the IHS is updated with the details of the samples exported from the University.

6. Training

All those involved in work involving human samples are required to read this SOP and to understand how its requirements relate to their work. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS.07 Training. This will enable individuals to understand the requirements and procedures for the acquisition and transfer of human samples.

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Further advice on the acquisition and transfer of human samples for research and the provisions of this SOP may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

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Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

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Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

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Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

Authority to Import Human Samples

To be completed by the Principal Investigator, Responsible Person or Member of Staff Responsible for undertaking the import or transfer of human samples into the University and submitted to the Designated Individual

Name:	Title:
Contact Details Email: Telephone:	School: Department:
Project Title:	
Ethical Approval Number:	
Supplying organisation	
Address/country of supplying organisation	
Type of sample(s) (e.g. urine)	
Quantity of sample(s) (e.g. 100 x 1.5ml tubes)	
Proposed date of import	
Fate of samples following project completion: (Return, transfer to another organisation, retain, dispose, in accordance with the terms of the MTA)	

I confirm that the information above is accurate and complete and that the Inventory of Human Samples will be updated following the transfer/import of the human samples:

Signature of PI/RP/MoSR _____ Date _____

I authorise the transfer/import of these human samples:

Signature of DI _____ Date _____

A Biological Material Risk Assessment Form covering the use of the imported samples must have been approved by the School HTA Sub Group

Appendix 2

Authority to Export Human Samples

To be completed by the Principal Investigator, Responsible Person or Member of Staff Responsible for undertaking the export or transfer of human samples from the University and submitted to the Designated Individual

Name:	Title:
Contact Details Email: Telephone:	School: Department:
Project Title:	
Ethical Approval Number:	
Destination organisation	
Address/country of destination organisation	
Type of sample(s) (e.g. urine)	
Quantity of sample(s) (e.g. 100 x 1.5ml tubes)	
Under what conditions will the samples be transported? (e.g. refrigerated container)	
Proposed date of export	
Fate of samples following project completion: (Return, transfer to another organisation, retain, dispose, in accordance with the terms of the MTA)	

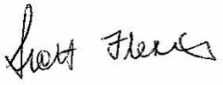
I confirm that the information above is accurate and complete and that the Inventory of Human Samples will be updated following the transfer/import of the human samples:

Signature of PI/RP/MoSR _____ Date _____

I authorise the transfer/import of these human samples:

Signature of DI _____ Date _____

A Biological Material Risk Assessment Form covering the use of the imported samples must have been approved by the School HTA Sub Group

Storage	
Version:	**HS.04.01**
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

Revision Chronology	Effective Date	Reason for Change

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

Please ensure that the version of this document is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

Acknowledgements
This Quality Manual has been produced with reference to Quality Manuals and Standard Operating Procedures (SOPs) used at a number of other UK Universities, particularly the Universities of Warwick, Cardiff and York. Their permission was sought and granted.

The advice and input from colleagues has also been gratefully received.

Cardiff Metropolitan University | Prifysgol Metropolitan Caerdydd

Storage

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
IHS	Inventory of Human Samples
L&T	Learning and Teaching
MoSR	Member of Staff Responsible
NHS	National Health Service
QMS	Quality Management System
PD	Person(s) Designated
PI	Principal Investigator
R&E	Research and Enterprise
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure
RP	Responsible Person

Storage

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the storage of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the Human Tissue Authority's *Code of Practice 9: Research* (September 2009):

https://www.hta.gov.uk/code-practice-9-research

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR) as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Dean is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The Schools HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to the acquisition and transfer of all human samples for all uses.

In line with HTA guidance, imported samples will be treated in the same way as samples originating from participants in England, Wales and Northern Ireland (and the same exceptions to licensing apply).

All human samples must be stored in such a way as to ensure the integrity, security and traceability of the sample, and to minimise the risk of contamination and protect the health and safety of individuals handling the sample.

All those involved in the acquisition, storage, use and disposal of human samples must be appropriately trained and demonstrate due care and respect for human samples at all times. Staff must use personal protective clothing and equipment at all times. Where practical, human samples should be stored separately from other biological samples. The research facilities and laboratories where human samples are being stored and used must be secure, clean and well maintained and subject to a programme of planned preventative maintenance.

5. Procedures

5.1 Risk assessments of stored material

Risk assessments must be undertaken on all human samples stored at Cardiff Metropolitan University and logged on a biological risk assessment form that has been assessed by a Schools HTA Sub Group to determine:

- Nature of the material;
- Significant biological hazards;
- Location of proposed work;
- Personnel at risk;
- Protocols employed;
- Handling requirements;
- Training requirements;
- Rendering material safe
- Disposal of material;
- Decontamination of equipment or personnel;

- Storage of material;
- Emergency provisions;
- Vaccination recommended.

5.2 Consent

Appropriate consent must be in place to acquire, store and use samples, taken from the living or deceased, for research. Appropriate consent is also required to hold samples with the intention of analysing its deoxyribonucleic acid (DNA). Failure to comply with the requirements of this SOP will result in samples being secured and the work may be delayed.

All human samples collected, transferred to the University from another organisation in England, Wales or Northern Ireland or imported from overseas for must be imported with the appropriate consent in place, unless one of the following specific exemptions applies:

- Old samples – existing holdings from before 1 September 2006;
- Imported samples – from outside England, Wales and Northern Ireland;
- Anonymised samples being used on a project with National Health Service (NHS) Research Ethics Committee approval.

For further information on consent, please refer to the SOP HS2 Consent, which should be read in conjunction with the HTA's *Code of Practice 1: Consent* (September 2009):

https://www.hta.gov.uk/code-practice-1-consent

5.3 Storage facilities

5.3.1 Management of the storage facilities

Management of the storage facilities at the hub site (Llandaff) will be the responsibility of the Laboratory Managers Research & Enterprise (R&E) and Learning & Teaching (L&T). Management of the storage facilities at the satellite site (Cyncoed) will be the responsibility of the Technician Demonstrator. Management of both facilities will be in accordance with the relevant school SOP "Work with Human Samples , Management of Storage Units".

5.3.2 Storage units

All human samples must be stored in appropriate storage units which must be lockable and labelled clearly. If a lock is not integral to the unit, a padlock must be used. Storage units containing human samples must remain locked at all times when samples are not being used. Storage units available include:

- Cupboard at room temperature for microscope slides
- Refrigerators at +4°C;
- Freezers at -20°C;
- Freezers at -40°C;
- Freezers at -80°C;
- Liquid nitrogen units at -196°C.

All storage units (including those that are used to store non-human materials) must be logged into the relevant school's spread-sheet which is maintained on the school's HTA SharePoint site.

The following information should be recorded:

- Unit Reference Number
- Asset Reference Number
- Building
- Floor
- Laboratory Number
- Storage Temperature

All storage units containing human samples should be monitored on a regular basis to ensure the appropriate storage conditions are maintained.

5.3.3 Storage unit labelling

All storage units used for human samples must be clearly labelled in accordance with the instructions given in Appendix 1.

There are two categories of storage units for human samples:

- Emergency units – for use in the event of another freezer malfunctioning.
- Units containing human samples, including:
  - material held under licence
  - material not held under licence
  - material not being used on an active project

5.3.4 Security of storage facilities

Storage units containing human samples must be lockable and located in rooms within buildings that are access-controlled and accessible only to University-authorised personnel. University card-controlled access must be in operation to enter the building and the storage of human samples held under licence must be held in locked storage units.

The emergency refrigerators and freezers will remain unlocked whilst on stand-by to be available to receive samples from another freezer due to a malfunction or other serious adverse event at any time. Once human samples have been transferred to an emergency freezer, it will be locked. For further information on the procedures in the event of a freezer malfunction or other incident, see SOP HS.05 Adverse Incidents.

Keys for storage units containing human samples will be held as follows:

At the Hub Site:

Storage, emergency and active projects	Laboratory Key Safe (T0.01, T2.06, D2 R&E Corridor)

At the Satellite Site:

Storage, emergency and active projects	Laboratory Key Safe (A1.22A)

All keys are held in digital or combination lock key safes. Access to the safe(s) is restricted to the DI, Persons Designated (PDs), Laboratory Managers, PIs, RPs, MoSR and trained workers.

5.3.5 Sample labelling

In line with HTA standards, all human samples (and their products) must be uniquely identifiable to ensure traceability. The identification coding must not contain patient or donor identification. Each coded label must be robustly secured to the sample container, be clearly readable, and appropriate to the storage conditions under which it will be held.

Please refer to the appropriate, School SOP for Storage of Human Samples.

5.3.6 Sample racks/boxes numbering and labelling

All individual, uniquely identifiable human samples must be stored in an orderly and consistent manner in all storage units and be easy to locate. Individual samples should be grouped in boxes to ensure they are not loose and could be damaged when removed from their storage unit. It is preferred that storage boxes are contained within racks. Racks and boxes must be assigned a number.

Please refer to the appropriate, School SOP for Storage of Human Samples.

5.3.7 Use of chemicals

Where chemicals are used for preservation of human samples, the area must be adequately ventilated to control exposure. This may include monitoring of levels and continuously operating extract ventilation.

5.3.8 Equipment maintenance, cleaning and decontamination

Calibration and maintenance of storage units must be in line with the manufacturer's guidance. Records of calibration, monitoring of storage conditions and maintenance will be kept at both the hub and satellite sites. The Laboratory Managers R&E and L&T and the Technician Demonstrator at the hub and satellite sites will be responsible for ensuring these records are accurate, complete and up-to-date, and available for inspection as required.

5.3.9 Equipment monitoring

Freezers at -80°C, -40°C and -20°C used for the storage of human samples have independent alarm systems separate from in-built alarms (provided by Testo Limited Instruments). These function by wireless transmitters to alert technical staff by text to establish a response.

The freezers at -80°C and -40°C are located in rooms with controlled and monitored air conditioning maintaining an average room temperature of 20°C.

The Testo Limited Instruments alarm system triggers emergency alert texts when:

- any -80°C freezer's temperature has risen to -65°C;
- any -40°C freezer's temperature has risen to -30°C;
- any -20°C freezers temperature has risen to -10°C;
- any +4°C refrigerator or cold-room's temperature has risen to +10°C;

The temperature in each freezer is monitored every 15 minutes and the emergency alarms have a delay. Alarms are triggered only if two consecutive readings are recorded above the set temperature limit.

5.3.10 Equipment failure

The laboratories at both the hub and satellite sites must have a management plan in place to cover the eventuality of equipment failure. Emergency freezers have been identified at both the hub site and are unlocked and labelled in line with the protocol for human sample storage unit labelling.

In the case of freezers used to store human samples, the freezers at -80°C, -40°C and at -20°C have independent alarm systems separate from in-built alarms (provided by Testo Limited Instruments). In the event of an alarm being triggered by the Testo Limited Instruments alarm system, a text detailing the site and which freezer or room alarm has been activated will be sent to two members of the technical team.

Upon receiving an emergency alert text, members of the technical team will attend the incident. On arrival at the site, the members of the technical team will assess the conditions, and a decision on the need to re-locate the samples to an emergency freezer will be taken. If appropriate, the samples will be moved to the emergency freezer and the emergency freezer will be re-labelled to indicate that it contains human samples. The member of the technical team attending the incident will inform the PD by telephone of the action taken.

In the event of loss of power to the building, the technical team will seek to resolve the problem as quickly as possible. Generators will be used when possible.

In the event of catastrophic failure, the DI will arrange the safe disposal of unusable samples (in line with SOP HS.06 Disposal).

Any adverse event or serious malfunction of equipment involving the storage of human samples should be investigated in accordance with the SOP HS.05 Adverse Incidents, and reported by the DI to the HTA as appropriate.

5.4 Inventory of Human Samples

It is the responsibility of the PI, RP or MoSR, to ensure that all human samples are logged on the Inventory of Human Samples (IHS) and that sample records remain accurate and up-to-date. During the course of a project, it is the responsibility of the PI, RP or MoSR to ensure appropriate laboratory records are kept of the use of and any processing of the samples

and that the IHS is updated when samples are disposed of, and that the records in the IHS are updated at the end of the project.

Samples and their records in the IHS will be subject to review and audit (as described in the SOP HS.08 Audit).

Recorded data held on the Sample Register should include:

- Sample unique identifier code;
- Sample location (freezer, shelf and/or rack number);
- Sample type;
- Amount of sample when acquired (wt/vol);
- Name of Lead Investigator;
- Supplying individual or organisation;
- Import reference number;
- MTA reference number;
- Ethical approval reference number;
- Date of import;
- Date of export/transfer or disposal.

Please refer to the appropriate, School SOP for Storage of Human Samples.

An electronic version of the IHS is held centrally and securely, under the overall management of the DI. It is the responsibility of the PI, RP or MoSR to ensure that the IHS is kept up-to-date to reflect the totality of the human sample collections held by the University and must be available, with all associated documentation, for inspection at any time.

Any material without appropriate ethical approval and legal agreements, etc. in place will be secured under the University's HTA licence, in the designated, secure storage facilities, and will be the responsibility of and managed by the DI. No other individual will be allowed to access or use the samples until all appropriate documentary evidence of ethical approval has been approved by the DI and there is a fully signed MTA, etc.

Records in the IHS must **not** contain any patient identifiable data including, for example, patient name, date of birth, date of death, address, NHS number, General Practitioner.

5.5 Storage period

Under the HT Act, where human tissue is in storage pending transfer elsewhere, providing it is held for a matter of hours or days and certainly no longer than a week, then storage is considered incidental to transportation and the samples do not need to be held under licence.

Where human tissue are held whilst being processed with the intention to extract DNA or ribonucleic acid (RNA), or other sub-cellular components that are not relevant material (i.e. rendering the tissue acellular), the HTA views this as analogous to the incidental transportation exception above. Such

samples do not need to be held under licence, providing they are stored for no longer than a week prior to processing.

5.6 Disposal

When a project is finished, human samples may only be kept if there is consent to do so, or the samples are existing holdings (collected before 1 September 2006). All other samples should be disposed of in accordance with the SOP HS.06 Disposal.

6. Training

All those involved in work involving human samples are required to read this SOP and to understand how its requirements relate to their work. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS.07 Training. This will enable individuals to understand the requirements and procedures for the storage of human samples.

7. Advice and guidance

Further advice on the storage of samples and the provisions of this SOP may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Auditors or the HTA, in accordance with SOP HS.08 Audit.

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

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Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

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Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

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Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

Storage unit labelling

All storage units used for human samples must be labelled clearly in accordance with the following instructions:

1 Labels for all storage units containing human samples will be typed on card, laminated and fixed to the outside front face of the storage unit with double sided tape.

2 All storage units will have an identifier number on the front in the top left hand corner, for example:

LLD2-M01

The PD at each site is responsible for implementing a storage unit identification numbering system.

3 Storage units containing human samples will have one of the following labels on laminated **pink** card, fixed below the unit identifier number:

3.1 Storage unit containing human samples

CONTAINS HUMAN SAMPLES
TO BE KEPT LOCKED

3.2 Emergency storage unit

EMERGENCY FREEZER
NOT FOR GENERAL USE

4 In addition, storage units containing human samples will also have the following label on laminated **white** card, fixed below the pink label:

In the event of a malfunction, please contact:

- **Laboratory Manager, *Name* (Extn:)**
- **Technician Demonstrator, *Name* (Extn:)**
- **Person Designated (Mobile:)**

5. If the handling of human samples requires the user to wear gloves for protection and to avoid contamination of the samples, the following sign must be affixed to the outside of the storage unit;

6. If the handling of human samples may cause a user to be at risk then the following warning sign should be placed on the front of the freezer. Each risk should be individually assessed and if necessary a gloves required sign also affixed.

7. It is the responsibility of the Laboratory Managers R&E and L&T and the Technician Demonstrator at the hub and satellite sites to ensure that the labelling on all storage units used for human samples is accurate and up-to-date (including any contact names and numbers in the event of an emergency or Serious Adverse Incident), and agrees with the details held on Storage Statement, as appropriate.

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Appendix 2

Example freezer door sign (human samples)

LLD2-M01

CONTAINS HUMAN SAMPLES
TO BE KEPT LOCKED

In the event of a malfunction, please contact:

Laboratory Manager, ** ***** (Extn: ****)**
Technician Demonstrator, ** ***** (Extn: ****)**
Person Designated (Mobile *********)**

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Appendix 3

Example freezer door sign (human samples)

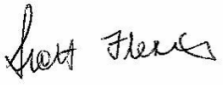
LLD2-M01

EMERGENCY FREEZER
NOT FOR GENERAL USE

In the event of a malfunction, please contact:

Laboratory Manager, ** ***** (Extn: ****)**
Technician Demonstrator, ** ***** (Extn: ****)**

- **Person Designated (Mobile ***********)**

Adverse Incidents	
Version:	HS.05.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

Revision Chronology	Effective Date	Reason for Change

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

Please ensure that the version of this document is the most up-to-date.

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Acknowledgements
This Quality Manual has been produced with reference to Quality Manuals and Standard Operating Procedures (SOPs) used at a number of other UK Universities, particularly the Universities of Warwick, Cardiff and York. Their permission was sought and granted.

The advice and input from colleagues has also been gratefully received.

Adverse Incidents

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
IHS	Inventory of Human Samples
MoSR	Member of Staff Responsible
PD	Person Designated
QMS	Quality Management System
PI	Principal Investigator
RP	Responsible Person
SOP	Standard Operating Procedure

Adverse Incidents

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for recognising, managing and reporting any adverse event or incident related to the storage and use of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Good Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the standards required by the HTA.

It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's *Code of Practice 9: Research* (September 2009):

https://www.hta.gov.uk/code-practice-9-research

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR), as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS under the supervision of the DI.

The relevant Dean is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The Schools HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the University's Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

4.1 As an establishment licensed by the HTA, the University is required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis. The focus may be on non-compliance with the HT Act and HTA's Codes of Practice or damage to the tissue integrity; for example, through inappropriate storage.

4.2 Staff working under the HTA licence and HTA's Codes of Practice must understand what is meant by an adverse event and the procedure to follow when such an event occurs.

4.3 The DI is responsible for ensuring that appropriate reports about adverse events are notified to the HTA.

5. Procedures

5.1 Identifying an adverse event

All staff and students working with human samples should be vigilant and alert to the actual, or potential for, theft, damage or loss of the material, as it occurs or once it has occurred, or where it could be predicted to occur. A number of adverse events are listed below as a guide to what might require a report but this is not an exhaustive list. All staff and students are encouraged to identify any event they believe may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of their work using human samples.

Further advice on the identification or handling of an adverse event may be sought from the DI, or Persons Designated (PDs). The DI will seek advice directly from the HTA as appropriate.

Examples of adverse events include:

Consent and ethical approval

- Human samples collected, stored or used without appropriate consent;
- Human samples collected, stored or used without appropriate ethical approval.

Governance and quality

- Wrong version of SOP in use;
- Breach of data protection/confidentiality;

- Samples transferred without appropriate authorisation (Materials Transfer Agreement).

Import of samples

- Samples received without relevant approval from the DI;
- Incorrect sample received;
- Unlabelled or unidentifiable sample received;
- Sample in inappropriate or unusable condition;
- Sample packaging damaged in transit and samples compromised.

Sample tracking

- Sample labelling error or missing label;
- Information about stored material not updated on Inventory of Human Samples (IHS);
- Discrepancy between storage location and record on IHS;
- Incomplete audit trail resulting in inability to trace a sample.

Premises, equipment and facilities

- Cold storage/freezer breakdown with alarm failure that is caught in time – near miss;
- Cold storage/freezer breakdown with alarm failure that is **not** caught in time - sample loss;
- Unauthorised access to storage facilities/breach of security;
- Human samples stored in inappropriate storage containers and/or inappropriate conditions.

Disposal

- Human samples disposed of with general clinical waste or general waste;
- Record of disposal of samples not updated on IHS;
- Incorrect or failure to label human sample waste.

Export of samples

- Samples transferred without appropriate authorisation (outgoing Materials Transfer Agreement);
- Samples lost during transportation;
- Sample quality compromised during transportation.

5.2 Storage equipment failure

The laboratories at both the hub and satellite sites must have a management plan in place to cover the eventuality of equipment failure. Emergency freezers have been identified at the hub (Llandaff) site and are unlocked and labelled in line with the protocol for human sample storage unit labelling (see SOP HS.04 Storage).

The refrigerators and freezers used to store human samples at -80°C, -40°C, -20°C and + 4°C have independent alarm systems separate from in-built

alarms (provided by Testo Limited Instruments). In the event of an alarm being triggered, a text detailing the site and which refrigerator or freezer has activated the alarm will be sent to two members of the technical team.

Upon receiving an emergency alert text, members of the technical team will attend the incident. On arrival at the site, the members of the technical team will assess the conditions, and a decision on the need to re-locate the samples to an emergency freezer will be taken. If appropriate, the samples will be moved to the emergency freezer which will be re-labelled to indicate that it contains human samples. A member of the technical team attending the incident will inform the PD by telephone of the action taken.

Should there be an emergency situation at the satellite site that renders the storage unit unusable then the human samples will be transferred to the hub site.

5.3 Power failure

In the event of a planned loss of power, all freezers will be connected to an emergency back-up generator.

In the event of an unplanned power outage, a call should be logged through to the Estates Helpdesk (Extension 6493). Estates will mobilise electricians as a matter of urgency. If the team is not able to reconnect the power supply (for example, in the event of a failure of the national grid) Estates will contact our service provider.

There have been very few unplanned power outage lasting more than an hour over the past 10 years, and none have lasted longer than 2 hours.

5.4 Disposal of samples following an adverse event

In the event of catastrophic failure, the DI will arrange the safe disposal of unusable samples (in line with SOP HS.06 Disposal).

At the earliest opportunity, and within 24 hours of the incident, the DI will inform the PI, RP or MoSR of the disposal of the samples. The PI, RP or MoSR is responsible for updating the record on the IHS, in accordance with SOP HS.04 Storage. Updating of the IHS must be completed at the earliest opportunity and within one week of the incident.

5.5 Reporting an adverse incident

All adverse incidents involving human samples stored or used must be reported to the DI immediately they occur or they are found to have occurred.

Any event or incident that has caused the loss of human samples or damage to human samples must be reported to the DI. “Near miss” events should also be reported where there was the potential for loss or damage.

An Adverse Incident Report (see Appendix 1) must be completed and submitted to the DI as soon as possible, and within 24 hours of the PI, RP or MoSR being informed. The PI, RP or MoSR is responsible for ensuring this

form is completed and submitted to the DI. The DI is responsible for maintaining a log of adverse events involving human samples.

5.6 Investigating an adverse event

All adverse events and incidents involving human samples reported will be investigated by the DI who will compile a report. For a checklist to support the investigation, see Appendix 2. The investigation will be reported by the DI to the School's HTA Sub Group. The DI will inform the relevant Dean of School. The investigation will be reported to the CSHTAMG and HTA, as appropriate.

6. Training

All those involved in research involving human samples are required to read this SOP and to understand how its requirements relate to their research. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS.07 Training. This will enable individuals to recognise an adverse event and understand the requirements of reporting the event.

7. Advice and guidance

Further advice on recognising and reporting adverse events and the provisions of this SOP may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Auditors or the HTA, in accordance with SOP HS.08 Audit.

Definitions

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Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

Adverse Incident Report

Section 1 of this form must be completed by a Principal Investigator, Responsible Person or Member of Staff Responsible (as soon as is reasonably practicable after the incident) and then submitted to:

Professor Scott Fleming
Designated Individual (DI) (Research Licence 12408)
Email: sfleming@cardiffmet.ac.uk
Telephone 02920417025
Room Number R1.02, Llandaff Campus

Section 2 of this form will be completed by the DI

Section 3 of this form will be completed by the DI's nominated person

Section 1 - Adverse Incident

Date, time and location of adverse incident _____

The person(s) completing this form:

Name: _____ Email: _____

Position: _____ Telephone: _____

Describe the circumstances of the adverse event

Witnesses

List witnesses, including contact information and position

Analysis of incident

What do you believe to be the apparent cause of this incident?

Corrective action

1. Describe any immediate action(s) taken

2. Recommendations to prevent a recurrence?

Name: _____ Date report completed: _____

Section 2 - DI's Decision on Action

Section 3 - Investigation and completion of corrective actions

I confirm that I have fully investigated this adverse incident.

Name: _____ Date report completed: _____

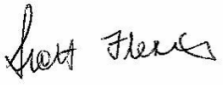
Position: _____ Telephone: _____

Email: _____

Appendix 2

Investigation checklist

SOP	Is there a SOP to cover the procedure? If yes:	Yes/No
	Is it adequate?	
	Does it need to be revised?	
	Did the individual know about and follow the SOP?	
Training	Was the individual appropriately trained? If not, why not?	Yes/No
	No training available	
	Training available but not advertised appropriately	
	Training available and advertised but individual did not attend	
	Other (please specify)	
Equipment/ facilities	Was the equipment/facilities/security fit for purpose? If not, why not?	Yes/No
Previous occurrence	Have similar incidents happened before? If yes, give details	Yes/No
Immediate Corrective Action	Was any immediate corrective action performed? If yes, give details	Yes/No
Review incident	Has the incident (including corrective/preventative actions) been reviewed at the a Schools HTS Sub Group? Specify date:	Yes/No
HTA Notification	Is HTA Notification required? If yes, state date completed:	Yes/No
Follow up	Is the action plan complete? Date of closure:	Yes/No

Disposal	
Version:	HS.06.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

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Cardiff Metropolitan University | Prifysgol Metropolitan Caerdydd

Disposal

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
IHS	Inventory of Human Samples
MoSR	Member of Staff Responsible
QMS	Quality Management System
PTP	Personal Training Portfolio
PI	Principal Investigator
RP	Responsible Person
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure

Disposal of Human Samples

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the disposal of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Good Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and the required standards set by the HTA. It is important the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the Human Tissue Authority's *Code of Practice 9: Research* (September 2009):

https://www.hta.gov.uk/code-practice-9-research

The HT Act includes the regulation of disposal of human tissue (excluding gametes and embryos), including imported tissue, following its use for a scheduled purpose.

The HT Act makes it lawful to treat as clinical waste any material that has come from a living person who was:

- in the course of receiving medical treatment,
- undergoing diagnostic testing, or
- participating in research.

The HT Act also states that material no longer used, or stored for use, for any scheduled purpose can be dealt with as waste.

This document should also be read in conjunction with the HTA's *Code of Practice 5: Disposal of human tissue* (September 2009, amended February 2010):

https://www.hta.gov.uk/code-practice-5-disposal

There may be additional requirements and considerations relating to the disposal of existing unidentifiable holdings, identifiable but unclaimed samples, organs and foetal material not specifically included in this SOP. Staff should consult with the DI in such cases, who will seek advice directly from the HTA, as appropriate.

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR) as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Dean is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The Schools HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS will require approval by the Combined Schools HTA management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to the disposal of all human samples.

Any member of staff or student disposing of human samples must be appropriately trained, see SOP HS.07 Training.

Dignified treatment and separate disposal are the minimum considerations for the disposal of stored human samples. This means disposal should be carried out separately from other clinical waste, but it is not necessary for each human sample to be disposed of separately.

Human samples must be disposed of observing due care and respect for the sample at all times, the consent given and the wishes of the donor and/or their family or other appropriate individual, in the case of samples from the deceased, where appropriate. Wishes of a deceased person or those close to them, regarding the method of disposal must be reasonable and lawful.

Some patients/donors may wish to retain tissue samples or make their own arrangements for disposal. Such arrangements should be considered on a case-by-case basis, and with advice from the DI where appropriate, assessing the risk to the patient/donor and others. Patients/donors should be given sufficient information at the point of consent to allow them to make an informed decision.

Any specific requirements relating to the disposal of human samples agreed at the time of their acquisition, e.g. in a Materials Transfer Agreement, must be observed.

Samples may need to be disposed where, for example, the consent does not permit its broad use for research beyond the end of the project for which it was collected, or where, more rarely, consent has been withdrawn. Such disposal must be in accordance with the guidance set out in the HTA's Code of Practice 5: Disposal of human tissue:

https://www.hta.gov.uk/code-practice-5-disposal

5. Procedures

5.1 Disposal of human samples

Personnel responsible for disposing of human samples must be appropriately trained and qualified, and demonstrate due care and respect for the material at all time.

It is the responsibility of the PI, RP or MoSR to complete the Human Samples Disposal Form (see Appendix 1) and to obtain the approval of the DI prior to disposal.

All human samples to be disposed of should be collected in the rigid yellow containers marked for the disposal of human samples.

Human samples will be disposed of by incineration. This includes surplus material from human samples, such as:

- tissue fragments trimmed from the tissue sample before it is processed for histology;
- issue in sections trimmed from a wax-embedded block before the usable sections are cut;
- unrecoverable bodily material that is washed out of the tissue during processing into a wax block.

It is the responsibility of the PI, RP or MoSR to update the Inventory of Human Samples (IHS) following the disposal of any material. For further information on sample tracking and the data requirements for the IHS, see SOP HS.04.

When samples require disposal and there is no regular collection of clinical waste (e.g. routine weekly collection), a clinical waste collection should be requested.

5.2 Disposal following an adverse event or catastrophic equipment failure

Following an adverse event or catastrophic equipment failure, where human samples have been severely damaged or destroyed, the PI, RP or MoSR must complete a Work with Human Sample Adverse Incident Report and submit it to the DI, in accordance with the SOP HS.05 Adverse Incidents. Where the samples have been rendered unfit for use and require disposal, the PI, RP or MoSR must ensure that the Human Samples Disposal Form (Appendix 1) is completed and submitted to the DI for authorisation to dispose of the damaged material.

6. Training

All those involved in work involving human samples are required to read this SOP and to understand how its requirements relate to their work. This should be recorded in the Personal Training Portfolio on the Working with Human Samples sign-off form, in accordance with the SOP HS.07 Training.

This will enable individuals to understand the requirements and procedures for the disposal of human samples.

7. Advice and guidance

Further advice on the disposal of human samples and the provisions of this SOP may be sought from the DI or the PDs. The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

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Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

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Human Samples Disposal Form

To be completed by the Principal Investigator, Responsible Person of the Member of Staff Responsible

Project Details	
Project Number	
Project Title	
Ethical Approval Number	
PI/PR/MoSR	
Disposal Details	
Proposed date of disposal	
Type of sample (e.g. urine; plasma)	
Quantity of samples	
Unique Sample Identification Numbers	
Reason for Disposal (include reference to consent, wishes of donor, or agreement on sample acquisition e.g. in MTA, as appropriate)	

I confirm that the information above is accurate and complete and that the Inventory of Human Samples will be updated following the transfer/import of the human samples:

Signature of PI/RP/MoSR ..... Date: .....

I authorise the disposal of these human samples:

Signature of DI ..... Date: .....

Training	
Version:	HS.07.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee

Revision Chronology	**Effective Date**	**Reason for Change**

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

Please ensure that the version of this document is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

Acknowledgements
This Quality Manual has been produced with reference to Quality Manuals and Standard Operating Procedures (SOPs) used at a number of other UK Universities, particularly the Universities of Warwick, Cardiff and York. Their permission was sought and granted.

The advice and input from colleagues has also been gratefully received.

Training

Contents

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
MRC	Medical Research Council
QMS	Quality Management System
PTP	Personal Training Portfolio
PD	Person(s) Designated
PI	Principal Investigator
SOP	Standard Operating Procedure

Training

1. Purpose

The purpose of this SOP is to ensure that all staff and students understand the requirements for training and the procedures for compiling and maintaining a Personal Training Portfolio (PTP) related to the storage and use of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the required standards set by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's *Code of Practice 9: Research* (September 2009):

https://www.hta.gov.uk/code-practice-9-research

3. Responsibilities

Under the University's HTA licence for the storage and use of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those researchers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person as delegated by the PI (and appropriately trained) or the Member of Staff Responsible as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Dean of School is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The School's HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the Quality Management System, will require approval by the Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to the acquisition, storage and use of all human samples.

The DI has a duty to ensure that all those working under the licence are suitably trained. This means they should:

- register as an individual working with human samples;
- undertake the appropriate training;
- receive and maintain awareness of training support materials;
- have access to advice and guidance;
- understand and adhere to the University's QMS;
- comply with the requirements of the related policies and SOPs;
- maintain a PTP to record related training and development activities undertaken (see Appendix 1).

The University will maintain a register of all persons working with human samples. Registration requires the worker to undertake training appropriate to their immediate needs and to maintain a training programme that demonstrates they are competent to perform duties appropriate to their role in each project. Workers are required to attend training every four years. The responsibility for ensuring the accuracy and completeness of ongoing personal development rests with the individual worker.

5. Procedures

5.1 Registration

Registration is a requirement irrespective of an individual's experience of working with human samples either at the University or elsewhere. It is an important means by which the DI can identify all those working with human samples and communicate effectively with them, to provide effective training, advice and guidance. Failure to register or attend the appropriate training and briefings may result in a project being delayed, or a worker being unable to work with human samples.

Training sessions are open to all staff and students, some of whom may not be actively working with human samples. They may be supporting or providing administrative or other services to those who do work with human samples and may find that more detailed knowledge and understanding of the issues, legislative and regulatory requirements would be beneficial to their role.

Staff and students will be notified of the University's programme of training sessions run by the DI and others. The training session: *Using Human Samples – Knowing your Responsibilities* will be repeated on a regular basis and must be attended prior to any work conducted using human samples.

All staff and students working with human samples are required to undertake the Medical Research Council (MRC) e-learning module: *Research and human tissue legislation* (April 2010), which is free to use and available at:

http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/

A copy of the MRC Certificate available on completion of the e-learning module must be sent to the DI and must also be kept in the PTP.

All staff and students working with human samples are required to complete their registration by submitting a *Working with Human Samples - Registration of Individual Workers* Form (see Appendix 2) which must be submitted to the DI for authorisation. A fully authorised copy of the form will be returned to the worker and should be filed in the PTP. A copy will be held by the DI, for the purposes of audit by the University and HTA.

Registration is complete only when the following have been completed:

1. The training session: *Using Human Samples – Knowing your Responsibilities*;
2. The MRC e-learning module: *Research and human tissue legislation; and*
3. The *Working with Human Samples - Registration of Individual Workers* Form has been authorised by the DI.

The date of registration is taken as the date the worker attends the training session with the DI (although registration is not complete until the DI has authorised the *Working with Human Samples - Registration of Individual Workers* Form.).

Workers are required to update their registration and training at least every 4 years. Retraining may be required earlier following a significant change to the HT Act, a significant change to the University's Human Samples QMS or it is deemed appropriate by the DI. The renewal process requires the worker to attend the training session: *Using Human Samples – Knowing your Responsibilities* and to submit a *Working with Human Samples - Registration of Individual Workers* Form to be authorised by the DI.

Additional training sessions and briefings will be notified to registered staff and students and advertised widely in the University as required. Additional information may also be made available through the University's intranet and

distributed to those registered users of human samples (e.g. if HTA guidance or legislation changes, existing SOPs are updated or new SOPs developed).

Individuals must also undertake training in laboratory techniques and health and safety policies and procedures, appropriate to their work with human samples.

It is an individual's responsibility to remain up-to-date with training and guidance available in the University and to maintain their competence in this field.

5.2 Personal Training Portfolio

All individuals working with human samples will receive a PTP folder, on completing the registration process described in 5.1 above. They are responsible for maintaining a complete and up-to-date PTP that should be available to their line manager, the DI, Internal Auditors or the HTA for inspection.

The PTP will contain a number of core documents:

- Cover sheet
- Training Portfolio Sign-off
- SOP Sign Off Form
- Internal Training Log
- External Training Log
- Relevant HTA Codes of Practice, for example
- Code of Practice 1: Consent
- Code of Practice 9: Research

The following documentation should be added to the PTP folder:

- Registration declaration – signed by the DI;
- Certificate of completion of the MRC e-learning module: Research and human tissue legislation;
- Certificate of attendance at the *Using Human Samples – Knowing your Responsibilities* training session.

The Training Logs should be updated with the details of the MRC e-learning module completed and the DI's introductory training session.

All additional training documentation and other related information, including, for example, a copy of the University's Quality Manual, SOPs and other HTA Codes of Practice may also be held in the PTP.

6. Training

All those involved in work involving human samples are required to read this SOP and to understand how its requirements relate to their research.

7. Advice and guidance

Further advice on training and registration for research with human samples and the provisions of this SOP may be sought from the DI, or the Persons Designated (PDs). The DI may seek advice directly from the HTA when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the PDs and the University's Auditors, in accordance with SOP HS.08 Audit.

Templates available

Appendix 1: Cover sheet – Personal Training Portfolio

Appendix 2: Registration of Individual Workers

Appendix 3: Training Portfolio Sign-off

Appendix 4: SOP Sign-off Form

Appendix 5: Training Log

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

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Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the

context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.

Appendix 1

Working with Human Samples

Personal Training Portfolio

All workers using human samples at Cardiff Metropolitan University must maintain a complete record of their ongoing personal development to demonstrate they are competent to perform duties appropriate to their role in each project.

The responsibility for ensuring the accuracy and completeness of each folder rests with the individual worker. Portfolios may be checked periodically for completeness and should be available for inspection by internal or external parties at all times.

Documents to be filed for personal development and training:

- Induction documentation
- HTA Code of Practice 1 – Consent
- HTA Code of Practice 9 – Research
- Certificate of attendance at Session 1 (Knowing your Responsibilities)
- Certificate of completion of MRC e-learning module
- Record of training at Cardiff Metropolitan University (as appropriate)
- Record of training of external courses (as appropriate)

Appendix 2

Working with Human Samples

Registration of Individual Workers

Cardiff Metropolitan University maintains a register of all workers using human samples. Registration requires the worker to undertake training appropriate to their needs and to maintain a training programme that demonstrates they are competent to perform duties appropriate to their role in each project. The responsibility for ongoing personal development rests with the individual worker.

The following section is taken from the Declaration of Registration document that is signed by each researcher following their training. It is countersigned by the Designated Individual.

Declaration of Registration

I believe that I have received adequate information, instruction and training to be able to carry out my work with human samples safely and in accordance with the Human Tissue Act (2004) and the University's Standard Operating Procedures. I will at all times follow the appropriate instructions I have been given and adopt safe working practices.

I have read/attended and understood the following documents/presentations:

- HTA Code of Practice 1 – Consent
- HTA Code of Practice 9 – Research
- Briefing Session 1 (Knowing your Responsibilities)
- MRC e-learning module:

In the event of any situation arising where I am not sure about the appropriate action to take I will seek advice before proceeding. Where appropriate, I will bring to the attention of my supervisor and/or Principal Investigator, Responsible Person or Member of Staff Responsible for the work any concerns that I have in relation to my work with human samples. If I still have concerns, or where I am the Principal Investigator, Responsible Person or Member of Staff Responsible, I will notify the Designated Individual.

Name: _____

Signed: _____ Date:_____

Principal Investigator, Responsible Person or Member of Staff Responsible

I confirm that I accept overall responsibility for the involvement of the above named worker on projects involving human samples that I am custodian for.

Name: _____

Signed: _____ Date: _____

Confirmation of Registration

I confirm that the above named worker is registered for working with human samples at Cardiff Metropolitan University.

Name: Scott Fleming (Designated Individual, HTA Licence #12408)

Signed: _____ Date: _____

All workers working with human samples are required to update their skills at least every 4 years.

This registration will be due for renewal on _____

Appendix 3

Working with Human Samples
Training Portfolio Sign-off

Personal Training Portfolios should be checked periodically for completeness. The portfolio should be 'signed-off' by the Designated Individual or the Person Designated.

Date Checked	Checked by	Comments

Appendix 4

Working with Human Samples

Standard Operating Procedures Sign-off

This form is to certify that you have:

- Read the Standard Operating Procedures (SOPs) relevant to your role;
- Understand how to apply the SOPs to your work;
- Know where to locate a copy of the current SOPs.

The original signed and dated form should be filed in the Personal Training Portfolio.

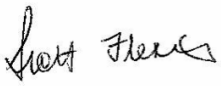
Name:			
SOP Number, and Title	**Version**	**Date read**	**Signature**

Appendix 5

Working with Human Samples
Training log

This form is to document all training courses attended. The form should be filed in your Personal Training Portfolio together with the course agenda and certificates where available. You are responsible for ensuring that your training record is kept up to date.

Name				
Training Event	**Organiser**	**Date**	**Duration**	**Key Learning Outcome**

Audit	
Version:	HS.08.01
Effective date:	25 November 2015
Author:	Sean Duggan and Scott Fleming
Approved by:	Professor Scott Fleming, Designated Individual and the Combined School's HTA Management Committee
	

Revision Chronology	Effective Date	Reason for Change

NOTE: All Standard Operating Procedures (SOP) are subject to frequent and/or annual review

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The advice and input from colleagues has also been gratefully received.

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Audit

Contents

Definitions

Abbreviations

CSHTAMC	Combined School's Human Tissue Authority Management Committee
DI	Designated Individual
DNA	Deoxyribonucleic Acid
HT Act	Human Tissue Act 2004
HTA	Human Tissue Authority
MoSR	Member of Staff Responsible
QMS	Quality Management System
PD	Person Designated
PI	Principal Investigator
RP	Responsible Person
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure

Audit

1. Purpose

The purpose of this SOP is to ensure that all staff and students understand the requirements and procedures for the audit and monitoring of processes and practices associated with the acquisition, storage, use and disposal of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Practice, the University's HTA licence for research and the University's Quality Management System (QMS) for the governance, storage, use and disposal of human samples.

2. Background

This SOP forms part of the University's Human Samples QMS for the governance of the acquisition, storage, use and disposal of human samples. Successful implementation of the QMS will ensure that all work involving human samples is carried out in compliance with the licensing obligations of the HT Act and to the required standards set by the HTA. It is important that the University, the research community and the public have confidence that all human samples are acquired lawfully and with appropriate consent, and are stored, handled, used and disposed of respectfully, sensitively and responsibly.

The University requires that all use of human samples, must meet the standards of quality management as set out in the University's Human Samples QMS. This exception-less principle includes material from the living and deceased, whether cellular or acellular and classified as relevant or not under the HT Act.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's Code of Practice 9: Research (September 2009):

https://www.hta.gov.uk/code-practice-9-research

3. Responsibilities

Under the University's HTA licence for the storage of human samples for research, it is the responsibility of the Chief Operating Officer (as the Licence Holder's Representative) and the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those workers using human samples are appropriately informed and trained and that the conditions of the HT Act are complied with.

It is the responsibility of the Principal Investigator (PI), the Responsible Person (RP) as delegated by the PI (and appropriately trained) or the Member of Staff Responsible (MoSR), as custodian of the samples, to understand and follow the appropriate procedures and practices in place, attend training and updating, and comply with the conditions of the University's Human Samples QMS, under the supervision of the DI.

The relevant Dean is responsible for ensuring that members of their school are operationally compliant with the processes and procedures for working with human samples.

The School's HTA Sub Groups have the responsibility of reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the QMS, will require approval by the University's Combined Schools HTA Management Committee (CSHTAMC). The DI will sign each SOP following approval by CSHTAMC.

4. Policies

Although the HT Act applies only to relevant material, Cardiff Metropolitan University applies the standards in its Human Samples QMS to all human samples.

5. Procedures

5.1 Routine monitoring

The DI, supported by the Person(s) Designated (PDs), will routinely tour the premises, and informally inspect the equipment and facilities at the hub and satellite sites, supported by the Laboratory Manager(s) and/or Technician Demonstrator(s) as appropriate. Monitoring tours provide important opportunities for informal discussions and dialogue with staff and students in the working environment, to obtain detailed feedback e.g. on deficiencies in any SOPs, changes in related local procedures and practices needed, additional training and resource requirements, and ensure that the QMS and the SOPs remain workable and supportive. From observation of the working environment, the DI and the PDs will give assurance that all remains fit for purpose or will highlight issues for adjustment or improvement in support of work involving human samples.

5.2 Regular reviews

The DI will schedule and implement a rolling programme of regular reviews covering both the hub and satellite sites to evidence compliance with the licensing obligations of the HT Act and to the required standards set by the HTA. The objectives of each review will be to test and verify:

- adherence to the SOPs;
- accuracy of sample records;
- completeness of data and documentation (including training records).

Records scrutinised during a review may include:

- project risk assessments;
- applications for ethical approval and confirmation of approval;
- consent forms and/or participant information sheets;
- materials transfer agreements;
- import records
- inventory of human samples;

- disposal records;
- export records
- personal training portfolios.

Sample-to-record and record-to-sample tests will be undertaken to investigate their traceability. Samples will be selected from a range of projects notified to the DI. Reviews will cover the full range of human samples held and used by the University. A range of sample types and samples stored under different storage conditions will also be tested.

The effectiveness of the implementation of a SOP and of the procedures themselves will be prioritised for review following a significant amendment/revision to an existing SOP or a new SOP being introduced. A review may be as a result of an adverse event or incident, or in an area where poor practice may be suspected.

The reviews will be conducted with the support of the PD at each site and include other academic and technical staff as appropriate and agreed by the DI. Reviews will be conducted at pre-arranged times of which staff will be notified.

A review report will be completed, highlighting good practice and including a plan of corrective action, and will be presented to the relevant School's HTA Sub Committee and made available to staff impacted, as appropriate. A report on completion of the corrective action will be brought back to the relevant School's HTA Sub Committee within an agreed timescale.

A composite report of findings and actions arising from the review programme will be collated by the DI to provide a statement of compliance (i.e. a self-assessment) with the HTA standards and licensing obligations under the HT Act, and reported to CSHTAMC, as appropriate.

5.3 External Audit and HTA Inspection

Occasionally, audits will be conducted by external agencies including site inspections by the HTA. Any internal reviews conducted by the DI will aim to mirror (at least, in part) the requirements of such external monitoring, with preparations for external inspections co-ordinated by the DI.

Reports from any such inspections and any actions arising will be considered by the Schools HTA Sub Groups with recommendations agreed by the DI for any significant changes in the QMS or SOPs, for example, made to CSHTAMG. Where there may be issues of significant risk, reports and recommendations may be made to the University Ethics and/or Health and Safety Committees.

5.4 Reports

The DI is integral to a number of SOPs and processes that monitor activities in work involving human samples, for example:

- training and registration of workers;
- authorisation of sample import, export and disposal;

- storage of human samples;
- logging and investigating adverse events and incidents.

Regular reports on these activities will be prepared by the DI for consideration at the Schools HTA Sub Groups, CSHTAMC and by the Licence Holder's Representative. The DI is also responsible for the preparation of reports and investigations relating to serious incidents or adverse events, as appropriate, in accordance with SOP HS.05 Adverse Incidents.

The DI is responsible for co-ordinating the response to the annual review to the HTA on behalf of the Licence Holder's Representative. The HTA report requests information on the nature and number of human tissue samples held by the University, and can include questions related to other aspects of the licence (for example, consent and/or ethical approval).

6. Training

All those involved in work involving human samples are required to read this SOP and to understand how its requirements in terms of monitoring and audit relate to their work. This should be recorded in the PTP and on the Working with Human Samples sign-off form, in accordance with SOP HS.07 Training. This will enable individuals to understand the requirements and procedures for the audit and monitoring of processes and practices associated with the acquisition, storage, use and disposal of human samples.

7. Advice and guidance

Further advice on audit procedures and requirements may be sought from the DI or the PDs. The DI may seek advice from the HTA directly when appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI or the HTA.

Definitions

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or have the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or the good governance and output of work using human samples.

Appropriate consent: The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor

(e.g., spouse or partner, parent, child, etc.). This must be in place to use and/or store any human sample, taken from the living or deceased, and to hold the sample with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness.

Clinical waste: Any material which has come from a living person who was in the course of receiving medical treatment, undergoing diagnostic testing or participating in research.

Designated Individual: The person who is authorised and, supervises the activities under a licence issued by the HTA.

Disposal: The permanent removal or destruction of human samples previously used and/or stored.

Existing Holdings: Human samples of relevant material held immediately prior to 1 September 2006.

Human Samples: All material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines.

Human Tissue Act 2004: Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority: The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice: Provide guidance and set out expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support those involved in work with human samples by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Standards: Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Inventory of Human Samples: The system for recording data on and tracking all human samples from acquisition to disposal.

Member of Staff Responsible: A person that is the custodian of and has responsibility for human samples that are used solely for education or training relating to human health.

Personal Training Portfolio: A record of documentation regarding the training received and receipt of training support materials relating to the acquisition, storage, use and disposal of human samples, which must be constantly maintained and updated.

Person Designated: Individual appointed by the DI to assist in supervising the licensable activities carried out within the organisation.

Principal Investigator: Appropriately qualified individual who has responsibility for the conduct of the work and the human samples being acquired, stored and used. The PI might delegate the responsibility for the human samples to a suitably trained Person Responsible.

Procurement: The collection of, the act of acquiring or the buying of human samples.

Quality Management System: Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.

Responsible Person: Suitably trained individual responsible for the human samples acquired, stored and used, as delegated to do so by the PI for the project.

Sample box: Container or rack holding human samples safely and in an orderly manner within the storage unit (e.g., freezer or cabinet).

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate for the storage conditions.

Sample tracking: Process by by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site from the main (hub) site that are under the same governance processes and QMS and supervised by the same DI.

Scheduled purposes: The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure: Detailed, written instructions to achieve uniformity of the performance of a specific function which form an integral part of a QMS. In the context of work using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g., acquisition, storage, transfer, disposal).

Storage: The holding of human samples securely in appropriate facilities and under appropriate conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. are held for the purposes of a REC-approved research project) must be held under an HTA Licence. For all purposes, storage means held from one calendar day to the next.