Quality Manual	
Version	HSQ.04
Effective date:	25 February 2015
Author:	Professor John Davey, Designated Individual
Approved by:	Professor John Davey, Designated Individual and the Genetic Manipulation and Biosafety Committee

Revision Chronology	Effective Date	Reason for change
HSQ. 02	13 December 2011	Clarification of University policy – QMS applies to all human samples. Creation of the role of Administrative Officer, Deputy DI and changes to the role of PD. Reorganisation of Biological Sciences to form the School of Life Sciences.
HSQ.03	10 January 2012	Changes in staff, room numbers and external links.
HSQ.04	25 February 2015	Changes to University governance and assurance structures relating to human samples.

NOTE: All SOPs are subject to regular review.

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

Out of date documents must not be used and hard copies must be destroyed.

Acknowledgements
This SOP has been produced with valuable advice and input from colleagues and with reference to SOPs used at a number of other UK universities and NHS Trusts, particularly, the Paterson Institute, the Universities of Liverpool and Cardiff, Imperial College, and University Hospitals of Coventry and Warwickshire NHS Trust. Their input was gratefully received. We also acknowledge the contributions of Kate Hughes and Gemma Wild to the original versions of the University's SOPs

Quality Manual

Contents

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 for research to ensure that all staff and students understand the necessary requirements and procedures 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 Human Samples in Research Quality Manual.

2. Background

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

The University requires that research using material of human origin, from the living or deceased, cellular or acellular, or whether the material is classed as relevant or not under the HT Act, should meet the standards of quality management as set out in the Human Samples in Research 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 researchers;
- 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.

2.1 Human Tissue Act 2004 (HT Act)

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 (Human Tissue 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 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, etc. are excluded.

For further information on the HT Act, see:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm

2.2 Human Tissue Authority (HTA)

The Human Tissue Authority (HTA) is an independent regulator, established by the Human Tissue Act 2004 (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 undergo specific training provided by the HTA to undertake this role and have statutory duties as set out in the HT Act (Section 18).

A licence is granted for a principle activity or 'scheduled purpose', 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 five key areas of activity (sectors):

- Human Application;
- Post Mortem;
- Anatomy;
- Research;
- Public Display.

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. There is an exception where tissue is being stored for use in a specified REC-approved project and is not retained after that project for unspecified future use. 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 Standard Operating Procedures 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 five sectors regulated by the HTA. The Codes are designed to support professionals by giving advice and guidance based on real-life experience, and were approved by Parliament in July 2009:

*****Consent;
Donation of solid organs for transplantation;
Post-mortem examination;
Anatomical examination;
*****Disposal of human tissue;
Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation;
Public display;
*****Import and export of human bodies, body parts and tissue;
*Research.

*The four key Codes for staff and students undertaking research are asterisked above.

To download the HTA's Codes of Practice:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

The HTA's Codes of Practice should be read in conjunction with the University's Standard Operating Procedures (SOPs) (see 8 below) and the University's Human Samples in Research 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, even if human tissue is to be held only for a short period of time or if only a few samples are held under the authority of a licence.

See HTA's Code of Practice 9: Research, paragraphs 82 – 115 for the HTA standards:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm?FaArea1=customwidgets.content_view_1&cit_id=766&cit_parent_cit_id=757

3. The University's HTA Licence

The University holds a licence from the HTA for research (Licence number 12297).

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

Hub site:	Clinical Sciences Research Laboratory Warwick Medical School University of Warwick University Hospitals Coventry and Warwickshire NHS Trust Clifford Bridge Road Coventry, CV2 2DX
Satellite site:	School of Life Sciences University of Warwick Gibbet Hill Road Coventry, CV4 7AL

Licence Holder's Representative:	Ken Sloan, University Registrar and Chief Operating Officer
Designated Individual:	Professor John Davey, Warwick Medical School
Deputy Designated Individual	TBC
Person Designated (hub):	Dr Mei Gu, Technical Manager
Person Designated (satellite):	Dr Rob Eason, Technical Manager

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 (QMS)

The University's Quality Management System (QMS) relates to the governance of the acquisition, storage, use and disposal of human samples for research 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 in Research Quality Manual.

The successful implementation of the QMS framework of policies and procedures will ensure that all research 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 in Research Quality Manual.

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

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

- continue to evolve to demonstrate an enduring commitment to quality improvement;
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- enhance the University's reputation for the delivery of research of the highest quality and ethical standards.

The University requires that all human samples, from the living or deceased, cellular or acellular, or whether the material is classed as relevant or not under the HT Act, should meet the standards of quality management as set out in this Quality Manual.

The following section is provided as additional information about the definition of Relevant Material in the HT Act.

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;
- Processed material;
- Bodily waste products;
- Cell deposits and tissue sections on slides.

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. For example:

- Plastinated body parts are relevant material (the plastination process is designed to preserve cellular structure);
- Plasma and serum are not relevant materials.

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 RNA.

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.

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:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

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

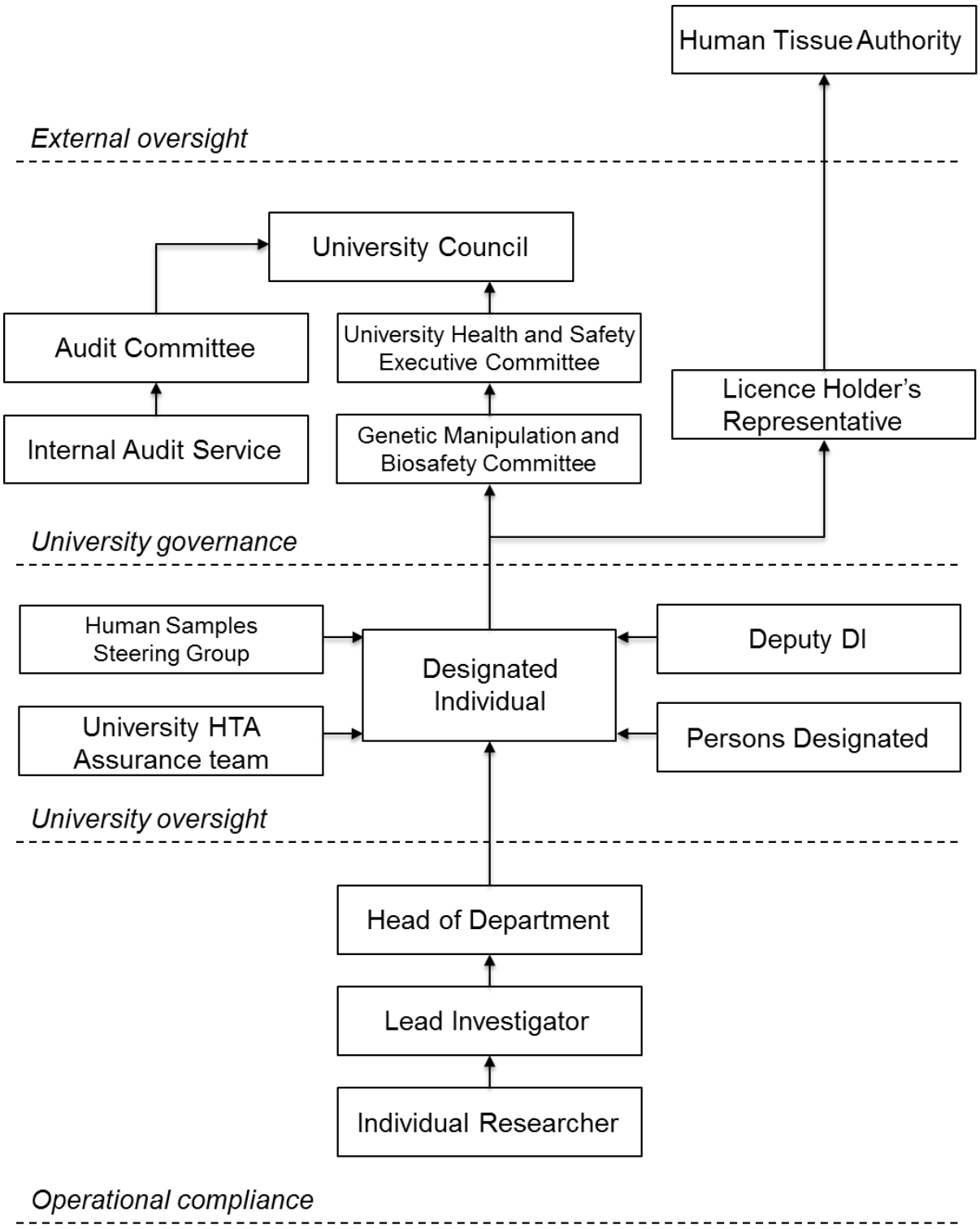
It is being held for an NHS REC approved study
Ethical approval must be from an NHS Research Ethics Committee (REC), or be pending approval. An application for REC approval is pending from the point it has been submitted until the decision of the committee has been communicated to the applicant. Material having ethical approval from an ethics committee that is not an NHS REC (e.g. an overseas ethical committee, or the University's Biomedical Research Ethics Committee) 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 structure



6. Responsibilities

6.1 Licence Holder

The Licence is held by the University and the Licence Holder's Representative 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 their 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, will have a named nominee as a member of the Human Samples Steering Group (HSSG) and receive the minutes and reports from the Group.

6.3 Designated Individual (DI)

Under the HT Act, it is the statutory responsibility of the Designated Individual (DI) to ensure that appropriate procedures and practices are in place and followed, that those involved in research 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 research 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 and 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 a 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 the Human Samples Steering Group (HSSG);

- 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 research and related activities in the University using human tissue, in accordance with the Standard Operating Procedures (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 Deputy Designated Individual (Deputy DI)

An individual can be nominated by the DI to act as Deputy DI. The Deputy DI will be a member of academic staff and have knowledge and understanding of the HT Act, the relevant HTA's Codes of Practice and compliance with licence conditions. The Deputy DI supports the DI, providing advice and guidance to staff and students and also supporting the conduct of audits and monitoring activities and practices. The role ensures that there is continuity of support for researchers, specifically at times when the DI may be unavailable, for example, on leave or during other short periods of absence.

The Deputy DI will not automatically replace the DI should the DI no longer be able to continue the role, as a formal application to undertake the role of DI must be made by the Licence Holder's Representative to the HTA for HTA Approval.

6.5 Persons Designated (PDs)

Individuals can be nominated as Persons Designated (PD) 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 in Research Quality Manual. The PDs will be senior technical staff at each site, appropriately qualified to ensure that laboratory practice in relation to research 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 researchers and technical staff, for example, to ensure they are confident in their work, SOPs are workable and support the highest quality output in research.

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 researchers, technical and support staff and students, is vital to underpin the development and successful implementation of the QMS.

6.6 Human Sample Steering Group (HSSG)

The HSSG Supports the DI to ensure HTA compliance, monitors new legislative and regulatory requirements, reviews and recommends revisions to Warwick HTA Framework (QM and SOPs). The HSSG will meet quarterly.

Membership of HSSG

- Designated Individual [Chair]
- Licence Holder's Representative (or their nominated representative)
- Deputy Designated Individual
- Person Designated (Hub site)
- Person Designated (Satellite site)
- Representatives of staff working with material of human origin
- UHCW NHS Trust R&D Manager
- Designated Individual (Anatomy & Pathology, UHCW NHS Trust)
- Person Designated (Pathology, UHCW NHS Trust)

Terms of Reference of HSSG

- To support the DI in their role as defined by the HT Act and the University's Human Tissue Authority (HTA) licence;
- To monitor new legislative and regulatory requirements relating to research activity using human material, including specific requirements under the HT Act;
- To recommend revisions to existing policies and SOPs, training and guidance available to staff and students, where appropriate, in consultation with UHCW;
- To monitor and review the effectiveness of the implementation of the QMS at the hub and satellite sites to ensure adherence to policies and SOPs to ensure consistency across the University, and with UHCW, where appropriate;
- To receive reports of adverse events and their investigation, reviewing and recommending revisions to policies, SOPs, training and guidance available to staff and students, if appropriate and monitor the implementation of corrective action;
- To approve reports on the University's research involving material for submission to GMBSC and the Licence Holder's Representative.

6.7 Delivery Assurance and Resolution Service

The Delivery Assurance and Resolution Service is responsible for ensuring that arrangements are in place to capture and report on performance across the University. The Service reports to the Registrar (Licence Holder's Representative).

6.8 Lead Investigator and Person Responsible

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

The Lead Investigator or Person Responsible will be responsible for conducting the research using human samples in accordance with the SOPs, related HTA standards and Codes of Practice and the University's Human Samples in Research 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 Researchers

All researchers, and those working in research, 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 Quality Management System;
- comply with the requirements of the related policies and Standard Operating Procedures (SOPs);
- maintain a Personal Training Portfolio to record relevant training and development activities.

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

6.10 Head of Department

Each Head of Department is accountable for human tissue operational compliance within their department (including ensuring appropriate storage appliances and accommodation exist and embedding into performance management processes). They are responsible for monitoring research activity within their department involving human tissues and for ensuring, on the advice of the DI, that PIs are complying with the human tissue QM and SOPs.

7. Compliance

It is important for the continuation of research, the reputation of its researchers and that of the University more broadly, that the University adheres to its HTA licence and adopts best practice, including robust and effective quality management, to its activities involving human tissue. If any staff or students knowingly breach the HT Act, the provisions of the HTA licence, the HTA Directions or Codes of Practice, or the University's related policies and Standard Operating Procedures, detailed in the Quality Manual, they may be subject to the University's Code of Practice for the Investigation of Research Misconduct: http://www2.warwick.ac.uk/services/rss/researchgovernance_ethics/research_code_of_practice

8. Governance Framework

Key elements of the University research governance framework include:

Code of Conduct for Research
http://www2.warwick.ac.uk/services/rss/resources/policies/code_of_conduct.pdf

Ethical Scrutiny Framework:
http://www2.warwick.ac.uk/services/rss/researchgovernance/research_code_of_practice/humanparticipants_material_data/

Guidelines on Ethical Conduct
http://www2.warwick.ac.uk/services/rss/researchgovernance/research_code_of_practice/

In partnership with the UHCW NHS Trust, a number of agreements have been developed including a Memorandum of Understanding on Joint Working for Effective Research Governance and a Joint Human Tissue Policy, to bring about greater continuity for the management and conduct of research across the two organisations. Both organisations remain committed to further development of compatible quality management and governance systems and the existing joint agreements will be subject to regular review.

See also:
http://www2.warwick.ac.uk/services/gov/committees/diagram/diagrammatic_rep_of_cttee_structure_2013-14.pdf

8.1 Genetic Manipulation and Biosafety Committee (GMBSC)

The GMBSC is responsible for subjecting projects, facilities, biological materials (including material of human origin) and genetic modification across the University to the necessary level of oversight, authorisation and risk management, and for keeping the Registrar informed. GMBSC will receive and consider periodic reports from the DI on the university's research involving human samples (to include, for example, reports on training & registration, information on catalogue and storage devices, adverse events etc.). GMBSC is a sub-committee of the University Health and Safety Executive Committee (UHSEC).

8.2 University Health and Safety Executive Committee (UHSEC)

The UHSEC receives reports from GMBSC and reports to the Council of the University on the legal obligations of the University in respect of health and safety.

8.3 University Research Ethics and Governance Committee (UREGC)

UREGC is a committee of Council and Senate which oversees the operation of the University's research governance framework and will recommend policies on issues of ethics and conduct in relation to research. Application for the ethical approval of research projects involving human samples and not requiring NHS REC approval would be considered by the UREGC sub-committee, the Biomedical and Scientific Research Ethics Committee (BSREC).

8.4 Audit Committee

The Audit Committee is a committee of Council, and comprises lay members. It plays a key role in considering issues relating to risk management and internal control.

8.5 Council

The Council is the executive governing body of the University with particular managerial responsibilities for finance and the University estate, and also a more general remit to oversee the conduct of the University in concert with the Senate.

9. Standard Operating Procedures (SOPs)

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 in research:

HS1 Standard Operating Procedures
HS2 Consent
HS3 Acquisition and Transfer
HS4 Storage
HS5 Adverse Events
HS6 Disposal
HS7 Training
HS8 Audit

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.

10. Training

All those involved in research involving human samples are required to read the Quality Manual and SOPs and to understand how their 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 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, Deputy 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 Deputy DI, the PDs and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Audit Service 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 in research 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 Director of Delivery Assurance, on behalf of the Registrar, in accordance with the University's Complaints and Feedback Procedure.

See: http://www2.warwick.ac.uk/services/gov/complaintsandfeedback/

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 research 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 store relevant material, taken from the living or deceased, for research and to hold bodily material with the intention of analysing its DNA.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

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.

Deputy Designated Individual (Deputy DI): The person who deputises for the DI during short-term absences by the DI.

Designated Individual (DI): The person who is authorised and, supervises the activities under a licence issued by the Human Tissue Authority (HTA).

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

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

Human Samples Project Log: A database (stored on a secure drive) containing information on each and every project involving human samples at the University of Warwick.

Human samples, tissue and material: All material derived from a human (cellular and acellular) that may be acquired, stored and used in research.

Human Tissue Act 2004 (HT Act): 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 Human Tissue Act lists the purposes for which consent is required (Scheduled Purposes).

Human Tissue Authority (HTA): 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 lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals 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.

Lead Investigator: Appropriately qualified individual who has responsibility for the conduct of the research and the human samples being acquired, stored and used on the research project. Usually the chief or Principal Investigator but who might delegate responsibility for the human samples to a suitably trained Person Responsible.

Material of human origin: All material derived from a human (cellular and acellular) that may be acquired, stored and used in research.

Quality Management System (QMS): 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.

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

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

Personal Training Portfolio (PTP): A record of documentation regarding the training received and training support materials relating to the acquisition, storage, use and disposal of human samples in research, which is required to be constantly maintained and updated.

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. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate to the storage conditions. Sample labels must not contain patient identifiable information.

Sample Register: The system for recording data on and tracking all human samples from acquisition to disposal.

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

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

Satellite site: Premises within the same organisation on a different site to the main (hub) site that are under the same governance processes and quality management system, and supervised by the same Designated Individual.

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 (SOP): Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research 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.