Safety Audit

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Audit Date:

Created By:

Template Title: Compliance Audit for HTA (Research) University Licence (12196) against all HTA Standards

Internal Reference		School/Service/College/Institution	
Date Assessed		Faculty/Service Division	
Assessed by		Department	
		Sub Department	
		Sub Division	

Consent Standards (C)

C1 - Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice

Please Select From...			
Not Applicable	Relevant evidence provided	Partial evidence provided	
No evidence provided			

Guidance	Comments
• Consent is the fundamental principle of the Human Tissue Act 2004 and the HTA Codes of Practice A (Guiding principles and fundamental principles of consent) and E (Research) are the primary sources of guidance for compliance with this standard. For health-related research in general i.e. not limited to that involving human tissue, the HRA provides resources such as template consent forms and participant information sheets.	

Remedial Actions	Action To	Due Date

C1 a) - Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.

Please Select From...			
Not Applicable	Relevant evidence provided	Partial evidence provided	
No evidence provided			

Comments

Remedial Actions	Action To	Due Date

C1 b) - Consent forms are available to those using or releasing relevant material for a scheduled purpose.

Please Select From...			
Not Applicable	Relevant evidence provided	Partial evidence provided	
No evidence provided			

Guidance	Comments
• Legal requirements, such as the Data Protection Act 1998 and the common law duty of confidentiality, need to be considered in such circumstances.	

Remedial Actions	Action To	Due Date

C1 c) - Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C1 d) - Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C1 e) - Language translations are available when appropriate.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C1 f) - Information is available in formats appropriate to the situation.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C2 - Staff involved in seeking consent receive training and support in the essential requirements of taking consent

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• It is important that consent training is not considered a one-off event and that proficiency in seeking consent is upheld. There is no set requirement for the frequency of consent training. Consent-seekers are expected to maintain awareness of current standards through reference to published guidance and relevant policies. Training may need to be updated when legislation has changed, new policies or practices have been implemented, different research activities are to be undertaken or a significant period of time has elapsed since research activities have been conducted.	

Remedial Actions	Action To	Due Date

C2 a) - There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C2 b) - Records demonstrate up-to-date staff training.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

C2 c) - Competency is assessed and maintained.

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

Governance & Quality System Standards (G)

GQ1- All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement. The work of the staff at the establishment must be subject to a system of governance. This means that there should be clear reporting lines and accountability (particularly with regard to individual staff and the DI), documented roles and responsibilities. Establishments are encouraged to have an over-arching quality document which provides an overview of the establishment's main purpose, organisation and structure and approach to governance and quality. This document should be accessible to all staff involved in licensed activities. The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA's licensing standards.	

Remedial Actions	Action To	Due Date

GQ1 a) - Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities: • consent; • collection; • receipt; • labelling; • specimen preparation / preservation; • storage; • relevant transport arrangements; • cleaning and decontamination; • disposal. More complex establishments, especially those releasing material, may need to cover more areas in their suite of documents. A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained. People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs. If human tissue is to be transferred between establishments, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example, as part of a Material Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable. We do not specify or endorse any particular format for MTAs; a number of template agreements are publically available and can be adapted to suit individual circumstances. Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.	

Remedial Actions	Action To	Due Date

GQ1 b) - There is a document control system

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Governance documents should include: • Revision history and version number • 'Effective from' date • Review date (at least every three years) • Pagination • Author and reviewer names	

Remedial Actions	Action To	Due Date

GQ1 c) - There are change control mechanisms for the implementation of new operational procedures

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Change control mechanisms should take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.	

Remedial Actions	Action To	Due Date

GQ1 d) - Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.	

Remedial Actions	Action To	Due Date

GQ1 e) - There is a system for managing complaints

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ2 - There is a documented system of audit

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Audits will demonstrate compliance with our standards and demonstrate whether establishments are meeting the requirements of their own systems. A documented schedule of audits should be in place at each establishment. Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work. Some establishments may be able to make use of existing in-house expertise or services.	

Remedial Actions	Action To	Due Date

GQ2 a) - There is a documented schedule of audits covering licensable activities

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ2 b) - Audit findings include who is responsible for follow-up actions and the timeframes for completing these

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ3 - Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Training and induction packages help to ensure that staff are fully trained on all policies and procedures relevant to their work. Establishments should ensure that training and development plans are in place and that these are reviewed periodically. Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.	

Remedial Actions	Action To	Due Date

GQ3 a) - Qualifications of staff and all training are recorded, records showing attendance at training

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ3 b) - There are documented induction training programmes for new staff

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ3 c) - Training provisions include those for visiting staff

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ3 d) - Staff have appraisals and personal development plans

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

G4 - There is a systematic and planned approach to the management of records

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ4 a) - There are suitable systems for the creation, review, amendment, retention and destruction of records

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Documented records are used by establishments to evidence traceability and ensure a robust audit trail. In this context, traceability refers to the completeness of auditable information about every step in the pathway for the use of relevant material, from consent through to disposal, or the material has been used up entirely. Documented procedures for the creation, review, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. SOPS should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary.	

Remedial Actions	Action To	Due Date

GQ4 b) - There are provisions for back-up/recovery in the event of loss of records

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Records may be in various formats, including paper based, electronic, or stored on recordable media. A centralised system for the storage of records can help to ensure that records are regularly backed-up.	

Remedial Actions	Action To	Due Date

GQ4 c) - Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Consideration must be given to other relevant legislation, including compliance with the Data Protection Act 1998 where tissue has been taken from the living, and compliance with professional guidelines where applicable.	

Remedial Actions	Action To	Due Date

GQ5 - There are systems to ensure that all adverse events are investigated promptly

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis. Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored. Although there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice. Relevant examples of adverse events include: • specimen loss; • missing or incorrect documentation; • security breach; • abnormalities in storage temperature readings; • inappropriate disposal.	

Remedial Actions	Action To	Due Date

GQ5 a) - Staff are instructed in how to use incident reporting systems

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ5 b) - Effective corrective and preventive actions are taken where necessary and improvements in practice are made

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ6 - Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

GQ6 a) - There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our standards. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining. Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • storage failure or other damage affecting human tissue quality for useful research; • loss of human tissue; • sample mix-up or loss of traceability; • transport of specimens to and from the establishment ; • security arrangements; • incorrect disposal.	

Remedial Actions	Action To	Due Date

GQ6 b) - Risk assessments are reviewed regularly

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary.	

Remedial Actions	Action To	Due Date

GQ6 c) - Staff can access risk assessments and are made aware of risks during training

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.	

Remedial Actions	Action To	Due Date

Traceability (T)

T1 - A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Where relevant, through their coding and records systems, HTA-licensed establishments should be able to demonstrate their awareness and ability to track ethical approval expiry dates and any relevant conditional agreements, such as consent opt-outs.	

Remedial Actions	Action To	Due Date

T1 a) - There is an identification system which assigns a unique code to each donation and to each of the products associated with it

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 b) - A register of donated material, and the associated products where relevant, is maintained

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 c) - An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 d) - A system is in place to ensure that traceability of relevant material is maintained during transport

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 e) - Records of transportation and delivery are kept

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 f) - Records of any agreements with courier or transport companies are kept

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T1 g) - Records of any agreements with recipients of relevant material are kept

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T2 - Bodies and human tissue are disposed of in an appropriate manner

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, reason and method. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.	

Remedial Actions	Action To	Due Date

T2 a) - Disposal is carried out in accordance with the HTA's Codes of Practice

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

T2 b) - The date, reason for disposal and the method used are documented

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

Premises, Facilities and Equipment Standards (PFE)

PFE1 - The premises are secure and fit for purpose

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

PFE1 a) - An assessment of the premises has been carried out to ensure that they are appropriate for the purpose

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• The establishment must be clean, well maintained and subject to a programme of planned preventative maintenance. Suitable environmental controls should be in place to avoid potential contamination. Establishments should periodically review risk assessments of premises, facilities and equipment. This should ideally include an audit of the premises and equipment in order to identify areas requiring rolling maintenance, refurbishment or upgrade. This will help to ensure that remedial actions are implemented in a timely manner so that the premises, facilities and equipment remain fit for purpose.	

Remedial Actions	Action To	Due Date

PFE1 b) - Arrangements are in place to ensure that the premises are secure and confidentiality is maintained

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Security measures include the use of locks, alarm systems and protections against unauthorised access. Establishments are expected to have policies in place to review and maintain the safety of staff, visitors and other relevant people e.g. students or donors.	

Remedial Actions	Action To	Due Date

PFE1 c) - There are documented cleaning and decontamination procedures

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Documented cleaning and decontamination procedures should be supported by schedules.	

Remedial Actions	Action To	Due Date

PFE2 - There are appropriate facilities for the storage of bodies and human tissue

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Areas used for storage of human tissue for use in research must provide an environment that is safe for those working under the licence and preserves the integrity of the tissue. Refrigerators, freezers and other vessels which contain human tissue should be appropriately labelled so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with other tissues. Human tissue must be stored in such a way that it minimises the risk of contamination to those working under the licence. If necessary, the DI should work with health and safety personnel to implement environmental controls and appropriate equipment to reduce the risk of contamination.	

Remedial Actions	Action To	Due Date

PFE2 a) - There is sufficient storage capacity

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

PFE2 b) - Where relevant, storage arrangements ensure the dignity of the deceased

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

PFE2 c) - Storage conditions are monitored, recorded and acted on when required

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Documented temperature monitoring allows establishments to easily visualise and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regulary tested and manually challenged periodically to ensure that they are operating as expected. Signs should be added to freezers to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum temperatures. Where storage is critical, an appropriate remote temperature monitoring alarm and callout system may be required. Checks and filling of liquid nitrogen dewars should be documented. Where material can be stored at ambient/room temperature, this does not mean that storage conditions do not need to be monitored.	

Remedial Actions	Action To	Due Date

PFE2 d) - There are documented contingency plans in place in case of failure in storage area

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• The establishment must have contingency arrangements in place should there be an emergency situation that renders the premises unusable for the storage of human tissue; this may need to be through a formalised arrangement with another HTA-licensed establishment for transfer of material.	

Remedial Actions	Action To	Due Date

PFE3 - Equipment is appropriate for use, maintained, validated and where appropriate monitored

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Comments

Remedial Actions	Action To	Due Date

PFE3 a) - Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Equipment must be regularly maintained to ensure that it is suitable for use. Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.	

Remedial Actions	Action To	Due Date

PFE3 b) - Users have access to instructions for equipment and are aware of how to report an equipment problem

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• There should be a system for renewing items that are no longer suitable through wear and tear.	

Remedial Actions	Action To	Due Date

PFE3 c) - Staff are provided with suitable personal protective equipment

Please Select From...		
Not Applicable	Relevant evidence provided	Partial evidence provided
No evidence provided		

Guidance	Comments
• Staff must have access to the protective clothing, materials and equipment they need.	

Remedial Actions	Action To	Due Date