# HTA Internal Audit Checklist and Report

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| Department Name : |
| Auditor: |
| Department Manager: |
| PD/HTA Department Contact: |
| Location of audit:  |
| Date of Visit: |
| Date of Report: |
| Date Responses Due Back:  |

Findings from the audit will be categorised as Critical, Major or Minor as detailed in HTA-A1019-UoL. Response to all findings will be required in the format of a CAPA Corrective Action Preventative Action plan. A summary of all findings will be entered into a plan and submitted to the Departmental Manager and Persons Designated (PD)/HTA Department Contact for action. The CAPA must be returned to the Research Governance Ethics and Integrity (REGI) Office within twenty (20) working days of issue. This requires the PD/HTA Department Contact to explain what action they will take, not necessarily take the action at that point in time. The CAPA will be followed up by the REGI Office until completion/closure.

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| Critical shortfall | A shortfall which poses a significant risk to human safety and/or dignity or is in breach of the Human Tissue Act 2004 or associated directionsOr -A contribution of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such. |
| Major shortfall | A non-critical shortfall that poses a risk to human safety and/or dignity, or indicates a failure to carry out satisfactory procedures, or indicates a breach of the relevant codes of practice, the Human Tissue Act, and other professional and statutory guidelines, or has the potential to become a critical shortfall unless addressedOr - A combination of a number of minor shortfalls, none of which is major in its own right, but which together could constitute a major shortfall and should be explained and reported as such. |
| Minor shortfall | A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards/good practice. |
| Other | Where a shortfall has not been identified, but areas for improvement have been identified, leading to the auditor providing advice to the auditee on improvements. |

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| Summary/Purpose of Visit |
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| Outstanding Actions from Last Audit (if applicable) |
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List of Locations and Personnel in Attendance

|  |  |  |
| --- | --- | --- |
| Name | Position/Role | Department Location (Lab/Building) |
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The internal audit will follow the Human Tissue Authority group of standards:

• Consent
• Governance and Quality System
• Traceability
• Premises Facilities and Equipment

Audit Checklists

The audit checklists found in the Appendices of SOP HTA-A1019-UoL can be utilised to facilitate the internal audit, however the non-conformances and corrective actions can be collated in the CAPA at the end of the internal audit checklist for ease of response.

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| Consent Forward  | Appendix 1 to SOP HTA-A1019-UoL Audit Report Type A |
| Consent Reverse | Appendix 2 to SOP HTA-A1019-UoL Audit Report Type B |
| Traceability Forward | Appendix 3 to SOP HTA-A1019-UoL Audit Report Type C |
| Traceability Reverse | Appendix 4 to SOP HTA-A1019-UoL Audit Report Type D |
| Use/Disposal | Appendix 5 to SOP HTA-A1019-UoL Audit Report Type E |
| Training | Appendix 6 to SOP HTA-A1019-UoL Audit Report Type F |
| Document Control | Appendix 7 to SOP HTA-A1019-UoL Audit Report Type G |

Departmental Compliance Check with HTA Standards

| Consent Standards |  |  |  |
| --- | --- | --- | --- |
| C1 | Consent is obtained in accordance with the requirements of the Human Tissue Act (2004) and as set out in the HTA’s Codes of Practice | Yes | No | Comments |
|  | * Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA’s Codes of Practice
 |  |  |  |
| * Consent forms are available to those using or releasing relevant material for a scheduled purpose
 |  |  |  |
| * Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act and the HTA’s Codes of Practice
 |  |  |  |
|  | * 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.
 |  |  |  |
|  | * Language translations are available when appropriate.
 |  |  |  |
|  | * Information is available in formats appropriate to the situation.
 |  |  |  |
| C2 | Staff involved in seeking consent receive training and support in the essential requirement of taking consent | Yes | No | Comments |
|  | * There is suitable training and support of staff involved in seeking consent, which addresses the requirement of the HTA Act and the HTA’s Codes of Practice.
 |  |  |  |
|  | * Records demonstrate up-to-date staff training
 |  |  |  |
|  | * Competency is assessed and maintained
 |  |  |  |
| Governance and Quality Systems Standards |  |  |  |
| GQ1 | All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process | Yes | No | Comments |
|  | * Ratified, documented and up to date policies and procedures are in place covering all licensable activities
 |  |  |  |
| * There is a document control system.
 |  |  |  |
| * There are change control mechanisms for the implementation of new operational procedures.
 |  |  |  |
| * Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
 |  |  |  |
| * There is a system for managing complaints.
 |  |  |  |
| GQ2 | There is a documented system of audit | Yes | No | Comments |
|  | * There is a documented schedule of audits covering licensable activities.
 |  |  |  |
| * Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
 |  |  |  |

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| GQ3 | Staff are appropriately trained in techniques relevant to their work and are continuously updating their skills | Yes | No | Comments |
|  | * Qualifications of staff and training are recorded, including records showing attendance at training
 |  |  |  |
| * There are documented induction training programmes for new staff.
 |  |  |  |
| * Training provisions include those for visiting staff.
 |  |  |  |
| * Staff have appraisals and personal development plans.
 |  |  |  |
| GQ4 | There is a systematic and planned approach to the management of records | Yes | No | Comments |
|  | * There are suitable systems for the creation, review, amendment, retention and destruction of records.
 |  |  |  |
| * There are provisions for back-up/recovery in the event of loss of records.
 |  |  |  |
| * Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).
 |  |  |  |
| GQ5 | There are systems to ensure that all adverse events are investigated promptly | Yes | No | Comments |
|  | * Staff are instructed in how to use incident reporting system.
 |  |  |  |
| * Effective corrective and preventative actions are taken where necessary and improvements in practice are made.
 |  |  |  |
| GQ6 | Risk assessments of the establishments practices and processes are completed regularly and are recorded and monitored  | Yes | No | Comments |
|  | * There are documented risk assessments for all practices and processes requiring compliance with the HT Act and HTA’s Codes of Practice.
 |  |  |  |
| * Risk assessments are reviewed regularly.
 |  |  |  |
| * Staff can access risk assessments and are made aware of risks during training.
 |  |  |  |

| Traceability |  |  |  |
| --- | --- | --- | --- |
| T1 | A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.  | Yes | No | Comments |
|  | * There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
 |  |  | * *Check HTA Licence on display*
* *Check Freezers and Cryovessels labelled (including emergency contact)*
* *Ensure animal tissue and human tissue separated and labelled appropriately.*
 |
| * A register of donated material, and the associated products where relevant, is maintained.
 |  |  |  |
| * 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.
 |  |  |  |
|  | * A system is in place to ensure that traceability of relevant material is maintained during transport.
 |  |  |  |
|  | * Records of transportation and delivery are kept.
 |  |  |  |
|  | * Records of any agreements with courier or transport companies are kept.
 |  |  |  |
|  | * Records of any agreements with recipients of relevant material are kept.
 |  |  |  |
| T2 | Bodies and human tissue are disposed of in an appropriate manner | Yes | No | Comments |
|  | * Disposal is carried out in accordance with the HTA’s Codes of Practice.
 |  |  |  |
|  | * The date, reason for disposal and method used are documented.
 |  |  |  |

| Premises, Facilities and Equipment Standards |  |  |  |
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| PFE1 | The premises are secure and fit for purpose | Yes | No | Comments |
|  | * An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
 |  |  |  |
| * Arrangement are in place to ensure that the premises are secure and confidentiality is maintained.
 |  |  |  |
| * There are documented cleaning and decontamination procedures.
 |  |  |  |
| PFE2 | There are appropriate facilities for the storage of bodies and human tissue | Yes | No | Comments |
|  | * There is sufficient storage capacity.
 |  |  |  |
| * Where relevant, storage arrangements ensure the dignity of the deceased.
 |  |  |  |
| * Storage conditions are monitored, recorded and acted on when required.
 |  |  |  |
| * There are documents contingency plans in place in case of failure in storage area.
 |  |  |  |
| PFE3 | Equipment is appropriate for use, maintained, validated and where appropriate monitored.  | Yes | No | Comments |
|  | * Equipment is subject to recommended calibration, validation, maintenance, monitoring and records are kept.
 |  |  |  |
| * Users have access to instructions for equipment and are aware of how to report an equipment problem.
 |  |  |  |
| * Staff are provided with suitable personal protective equipment.
 |  |  |  |

Report written by:

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| Printed name: |
| Signature: |
| Date: |

CAPA Report – HTA Audit Response Document

Audit Date: CAPA report date: Date response required:

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| --- | --- | --- | --- | --- | --- |
| No | Category | Non-Conformance/Finding | Immediate/ Corrective Action(Please state owner of action) | Preventative Action (Please state owner of action) | Completed by - Initials & Date Completed |
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CAPA Report to be completed by:

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| PD/HTA contact/Departmental Head :  |
| Telephone  |
| e-mail:  |
| Signature:  |
| Date:  |

Completed CAPA Report Approved by:

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| --- |
| Designated Individual :  |
| Signature:  |
| Date Audit Closed:  |