

Additional HTA audits

# 1. Purpose

This document should be read along the Standard Operating Procedure (SOP) HTA-A1019-UoL “Auditing HTA Licenced Areas”, which is stored on the Research Governance Ethics and Integrity (REGI) Website. This document does not replace nor supersede the SOP.

The purpose of the above SOP is to set out the procedure for conducting audits of HTA licenced areas within UoL. It explains that the main aim of audit is to ensure that all licensed activities related to human tissue, including consent, transportation, storage and disposal are conducted in accordance with the Human Tissue Act (2004) and that internal systems for compliance are effectively in place. The SOP describes the minimum audit standards expected of material held under the University’s HTA Research Licence. As defined in the “Audit Plan” (page 4), additional audits may be conducted. This document provides a template for those additional HTA Audits.

As this document falls outside of the scope of the formal HTA auditing processes, while this document has been version controlled, it may be modified and adapted as needed.

The data from these audits need to be submitted to the HTA Monitor and will be reviewed at the following HT Governance meeting. Follow up actions will be monitored HTA Monitor and logged in Section 6 below.

# 2. Conducting additional audits

Audits should be undertaken by someone from outside the group being audited. This removes the risk of any unconscious bias in project or sample selection. If you would like assistance in approaching a suitably trained member of staff to conduct the audit, please contact the HTA Committee.

# 3. Audit findings

While these additional audits are informal and do not form part of the audit process described in HTA-A1019-UoL, these audits should be documented, and the findings should be reviewed, categorised and acted upon using processes described in “Internal Audit” (page 5) of the SOP HTA-A1019-UoL.

# 4. Known limitations

As this is designed as an additional audit to supplement those conducted in HTA-A1019-UoL, it does not cover all aspects of a full HTA audit. This is known and is a feature, not a bug. The intention is that these additional audits are not prohibitive resource wise. This means that the auditor may be able to justify a simple “yes” response. These frequent light touch audits should complement the mandated audits described in HTA-A1019-UoL.

# 5. Data collection template

## 5.1 Audit details

|  |  |
| --- | --- |
| **Name of collection being audited** |  |
| **PI for the collection** |  |
| **Date the PI undertook suitable HTA training** |  |
| **PD for collection being audited** |  |
| **Date the PD last undertook suitable HTA training** |  |
| **Name of person conducting audit** |  |
| **Date the auditor last undertook suitable HTA training** |  |
| **Date of audit** |  |

## 5.2 Audit history

|  |  |
| --- | --- |
| **Date of last audit** |  |
| **Have the audits required in HTA-A1019-UoL been completed?** |  |
| **Have all the corrective actions recommended in the last audit been implemented?** |  |

## 5.3 Sample storage conditions

|  |  |
| --- | --- |
| **What are the storage conditions of the samples?** |  |
| **Are these conditions appropriate to the samples?** |  |
| **Does the place for sample storage (container) e.g., -80 freezer have appropriate service and cleaning records?** |  |
| **Does the container have appropriate hazard labels?** |  |
| **Does the container have appropriate contact details in place?** |  |
| **Does the container have appropriate temperature monitoring?** |  |
| **Does the monitoring company have the correct contact details?** |  |
| **When was the monitoring process last tested?** |  |
| **Is the container on a maintained electrical supply? And if not why? And what other alternative mitigations are in place e.g., CO2 backup** |  |
| **Are the samples stored in a secure facility? If not, what additional mitigations are in place e.g., locked freezer** |  |

## 5.4 Sample traceability

|  |  |
| --- | --- |
| **Are all samples listing on the sample log?** |  |
| **Is the sample log backed up against catastrophic loss?** |  |
| **Select 5 samples at random from across the container to confirm the data is correct.** |  |
| **Are the samples logged as part of the PDs HTAC submission** |  |

## 5.5 Sample consent

|  |  |
| --- | --- |
| **Do all samples have appropriate consent** |  |
| **Do all people taking consent have appropriate consent training?** |  |
| **Review the consent forms for the samples selected in 5.4 to confirm the data is correct and the consenter was trained.** |  |
| **Are the consent forms stored appropriately in accordance with** **GDPR?** |  |
| **Are the consent forms stored in such a way to protect against catastrophic loss?** |  |

## 5.6 Quality management

|  |  |
| --- | --- |
| **Is there a quality manual in place covering all aspects of sample handling?** |  |
| **Does this include an SOP for sample collection?** |  |
| **Does this include an SOP for sample storage?** |  |
| **Does this include an SOP for sample disposal?** |  |
| **Does this include an SOP for sample release?** |  |
| **Are all SOPs within their review date?** |  |
| **Is there a site file for the collection?** |  |
| **Is the site file current and up to date?** |  |

## 5.7 User training

|  |  |
| --- | --- |
| **Do all staff working in the facility have a training record?** |  |
| **Have all staff reviewed the required HTA SOPs produced by REGI?** |  |
| **Is this recorded in their training records?** |  |
| **Have all staff reviewed the local SOPs?** |  |
| **Is this recorded in their training records** |  |

# 6. Audit outcomes

Based on the criteria set out in HTA-A1019-UoL how many findings have been identified in this audit?

|  |  |
| --- | --- |
| **Number of critical shortfalls** |  |
| **Number of major shortfalls** |  |
| **Number of minor short falls** |  |
| **Number of other shortfalls** |  |

## 6.1 Follow up actions

Based on the audit findings, use this space to create a prioritised action plan to correct the findings

|  |  |  |
| --- | --- | --- |
| **Action** | **Description** | **To be completed by  (initials and date)** |
| **Action 1** |  |  |
| **Action 2** |  |  |
| **Action 3** |  |  |
| **Action 4** |  |  |
| **Action 5** |  |  |
| **Add more or delete as necessary** |  |  |

## 6.2 Timeline for the next audit

Based on the audit findings, when do you plan to audit next, and what time of audit will it be?

|  |  |
| --- | --- |
| **Timeline for the next audit** |  |
| **Will this be an informal internal audit, additional audit or an audit conducted by REGI staff?** |  |