|  |  |
| --- | --- |
| HTA master file document: | Section 9 – audit report |
|  | Type g – document control audit |
| Laboratory: |  |
| Person designate: |  |

|  |  |
| --- | --- |
| Lead auditor: |  |
| Audit date: |  |

|  |  |  |
| --- | --- | --- |
| HTA-specific documents | Current version in HTA Master File (Y /N)\* | Non-conformance details |
|  |  |  |
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| --- |
| All local SOPs/Policies have: |
| Document title | Yes/No |
| Document control number | Yes/No |
| Version number | Yes/No |
| Page numbers | Yes/No |
| Author | Yes/No |
| Issue date | Yes/No |
| Review date | Yes/No |

|  |
| --- |
| Details of non-conformance |
|  |

|  |
| --- |
| Corrective action |
| Target date: |  | Owner: |  |
| Details: |  |

|  |
| --- |
| Follow up |
| Details: |  |
| Audit Closed Date: |  | Audit Closed by: |  |

Type g – document control audit

HTA-specific documents: Are the latest versions in the folder? Check against list on the University intranet or contact the Research Governance Ethics and Integrity (REGI) Office.

Local SOPs/Policies: Must have title, unique document number, version number, issue date, review date, author and page number.

Corrective action: Decide on any corrective action to be implemented in light of any non-conformance found (e.g. new document control procedure or document revision). Assign a date and person responsible for this action.

Follow-up: Enter details of follow up on audit (e.g. corrective actions completed). When all corrective actions have been completed the audit is closed.

Note: Corrective action and follow up must not be done by the same person.

Audits, corrective actions and follow-up will be checked on a random basis by the REGI Office.