|  |  |
| --- | --- |
| HTA master file document: | Section 9 – audit report |
|  | Type b – consent audit (reverse) |
| Laboratory: |  |
| Person designate: |  |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Sample ID number | Date collected | Proof of consent  (Y/N/3rd party) | Non-conformance details |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |
| 7 |  |  |  |  |
| 8 |  |  |  |  |
| 9 |  |  |  |  |
| 10 |  |  |  |  |

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

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

Type b - consent audit (reverse)

Choose 10 samples from storage and record the following:

Sample ID number: identifier for the sample as stated on the tube/container

Date collected: date sample received into archive

Consent: Is signed consent form available? If consent is held by third party there must be ‘reasonable belief’ that informed consent was obtained.

Non-conformance: Record details of any non-conformance (e.g. no consent, details on consent form do not match sample details)

Corrective action: Decide on any corrective action to be implemented in light of any non-conformance found (e.g. new consenting procedure). 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 Research Governance Ethics and Integrity (REGI) Office.