Confidential HTA Audit Report

Dated:

|  |  |
| --- | --- |
| Audit title: |  |
| Study R&D P0 number: If applicable |  |
| REC reference number: If applicable |  |
| ISRCTN number: If applicable |  |
| Sponsor name: |  |
| CI/PI: If applicable |  |
| Auditor: |  |
| Date of audit: |  |
| Agreed date for action completion: |  |

|  |  |
| --- | --- |
| Audit report circulated to: |  |
| Date of circulation: |  |

## **Summary**

Date of audit, purpose, and name of auditor:

Brief overview of findings, key messages, recommendations:

*There are x findings arising from this audit. x have been classified as Critical, x have been classified as Major, x have been classified as Minor and x have been classified as Other*

*Critical findings were noted in the following areas:*

* *Finding summary*

*Major findings were noted in the following areas:*

*• Finding summary*

*Minor findings were noted in the following areas:*

*• Finding summary*

*Other findings were noted in the following areas:*

*• Finding summary*

Audit Scope

The audit included a detailed review of the following:

*Bullet points.*

Audit Standards

The audit was conducted with reference to the following documents:

*Bullet points.*

**Instructions For Responding to Findings**

Please respond in writing to the auditor within 10 working days of receipt of this report.

Please respond to all findings, in order to facilitate follow up of corrective actions where necessary. Responses already provided to the auditor have been included in the audit report for completeness.

In order to aid implementation of corrective actions and to reduce undesirable events such as non-compliances associated with audit findings, please identify details of any planned or completed corrective actions, person(s) accountable, and anticipated or actual date of completion. Please do not withhold responses because corrective actions have not been completed.

The completed report will be reviewed and approved by the appropriate team.

Audit Findings Categorisation

|  |  |
| --- | --- |
| Critical Shortfall | A critical shortfall is:  • A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions; or  • A combination 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 major shortfall is a non-critical shortfall that:  • Poses a risk to human safety and/or dignity  • Indicates a failure to carry out satisfactory procedures  • Indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines  • Has the potential to become a critical shortfall unless addressed; or  • Is a combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such. |
| Minor Shortfall | A minor shortfall is:  Something which cannot be classified as either critical or major, but which indicates a departure from expected standards. |
| 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. |

Audit Findings

|  |  |
| --- | --- |
| **Finding Number:** | 1 |
| **Finding categorisation:** |  |
| **Area:** |  |
| Finding: |  |
| Remedial action taken at the time if any: |  |
| Corrective action: |  |
| Preventive action: |  |
| Suggested Respondent(s): |  |
| Response: |  |
| Date for completion: |  |

|  |  |
| --- | --- |
| **Finding Number:** | 2 |
| **Finding categorisation:** |  |
| **Area:** |  |
| Finding: |  |
| Remedial action taken at the time if any: |  |
| Corrective action: |  |
| Preventive action: |  |
| Suggested Respondent(s): |  |
| Response: |  |
| Date for completion: |  |