



SAMPLE AUDIT REPORT TEMPLATE¹

PROTOCOL TITLE: _____

PRINCIPAL INVESTIGATOR: _____

Name

Department, School

FUNDING SOURCE: _____

DATE OF REVIEW: _____

AUDITORS: _____

DATE OF REPORT: _____

DISTRIBUTION: _____

PI Name

CONFIDENTIAL

1. Howes, L. M., White, S. A., & Bierer, B. E. (2019). Quality Assurance and Quality Improvement Handbook for Human Research (1st ed.). Johns Hopkins University Press.

I. INTRODUCTION: *(include brief introduction; suggested details to include: purpose of site review, who was present, etc.)*

II. STUDY SUMMARY: *(include brief summary of the study being audited)*

III. SCOPE OF REVIEW: *(include all material reviewed including regulatory documentation, consent forms, subject files, etc.)*

THE FOLLOWING DOCUMENTS WERE REVIEWED DURING THE AUDIT:

- Enrollment log
- Delegation of responsibility
- Staff qualifications (CV, medical/clinical licensure)
- Laboratory certification and normal value ranges
- Sponsor correspondence
- IRB documentation (all significant correspondence submitted to or received from the IRB, including submissions, investigator responses, notification letters, and approved consent forms)
- Documentation of data and safety monitoring, including log of monitoring activities, meeting agendas, minutes and reports of the data monitoring committee
- Participant files for the following subjects: _____
 - Consent forms Eligibility Protocol Compliance Adverse Events
 - Events requiring IRB reporting Other: _____
- Other:

IV. REGULATORY REVIEW HISTORY:

OVERALL FINDINGS: *(include summary of observations in bulleted format with sufficient detail and outline any specific findings below)*

SPECIFIC AUDIT FINDINGS:

Regulatory Documentation:

Corrective Action: _____

Best Practice Recommendation: _____

Informed Consent:

Corrective Action: _____

Best Practice Recommendation: _____

Participant Files:

Corrective Action: _____

Best Practice Recommendation: _____

V. CONCLUSIONS: *(summarize the site review and provide contact for questions; if response from site is required, identify timeline for response)*