PI:

Sponsor:                                                                                                          
Protocol#                                                                                                     Site #:  
IRB#:

Audit / Monitoring Visit Review Sheet

Type of Review \_\_\_\_\_\_\_\_\_\_ Reviewer \_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Review \_\_\_/\_\_\_/\_\_\_

**Audit / Monitoring Letter Received \_\_\_/\_\_\_/\_\_\_**

**Notify all appropriate personnel of visit and forward audit / monitoring letter**

PI

Supervisor

Senior Research Patient Coordinator

Regulatory Coordinator

Pharmacy

**Schedule audit preparation meeting (preferably week prior to audit/visit)**

Date \_\_\_/\_\_\_/\_\_\_

Supervisor or Senior RPC\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Regulatory Coordinator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Study Coordinator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pharmacy (if applicable)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please indicate that all have been verified:**

**Regulatory binder**

1572 complete with all appropriate treating physicians listed

Current CVs are available for review

CLIA, CAPs, & Lab Normals are available and current for all laboratories utilized

Current IRB approval for protocol \_\_\_/\_\_\_/\_\_\_

Amendment v. \_\_\_\_

All SAEs reported to IRB and sponsor (if applicable)

All Protocol Deviations reported to IRB and sponsor (if applicable)

**Informed Consent Forms (ICF)**

Verify all ICFs were at the correct version level for time frame and completeness (signed all sections, MD signature, boxes check marked, etc.)

# Eligibility

Verify eligibility

Verify all exceptions/waivers have been documented and are available

# Case Report Forms (CRFs)

Verify source documents are available for each form

Verify all disease responses/ tumor measurements are complete and consistent

Comments: