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: