



CAMC/WVU-CHARLESTON DIVISION IRB – AUDIT GUIDE FORM

BASIC STUDY INFORMATION (to be completed prior to audit)

Study Number _____ Date of Audit _____

Current Review Level of Study ___ Exempt ___ Expedited ___ Full Board

Most Recent Continuing Renewal _____

SUBJECT INFORMATION (partially completed prior to audit, partially completed during audit)

Total Subjects Reported Enrolled _____ Total Subjects Reported Consented _____

Total Subjects Found Enrolled at Audit _____ Total Subjects Found Consented at Audit _____

CONSENT (to be completed during the audit)

Are all consent forms accounted for? _____

Are all consent forms signed and dated by the subject or LAR? _____

Are all consent forms on the valid approved stamped consent for the time period? _____

Did the person obtaining consent sign and date at the same time as the subject on all consent forms? _____

DATA COLLECTION (to be completed during the audit)

Are all data collection instruments labeled appropriately per the protocol and HIPAA forms? _____

Is all hard data being kept in a secure location as per the protocol and HIPAA forms? _____

Is all electronic data being stored securely as per the protocol and HIPAA forms? _____

IRB APPROVALS (to be completed during the audit)

Are all IRB documents (letters, correspondence, approvals, etc.) accounted for? _____

Were recruitment methods used per the approval protocol? _____

Are only approved individuals being used for consenting, data collection and other research activities? _____

AUDIT INFORMATION (to be completed at beginning/end of audit)

Time Audit Began: _____ Time Audit Ended: _____

Auditors: IRB Member: _____ IRB Staff Member: _____