Co-Site Visitor Preliminary Report of Audit Findings

Group : _____ **NCI Code :** _____ **Category :** _____

Institution : _____

Institution Name Tier1 : _____ **Institution NCI Code Tier1 :** _____

Institution Name Tier2 : _____ **Institution NCI Code Tier2 :** _____

Audit Date : _____

Audit Type : _____ **Components :** _____

Audit Team Leader : _____ **Telephone :** _____

Name of Co-site Visitor: _____ **Affiliation :** ☐ NCI ☐ CTMS

(check one)

MAJOR DEFICIENCIES WITH IRB OR INFORMED CONSENT CONTENT : NO / YES
If YES, briefly describe :

DRUG ACCOUNTABILITY/PHARMACY NON-COMPLIANCE : NO / YES
If YES, briefly describe :

PATIENT CASE REVIEW SUMMARY :

Category	No. of Patient Cases Reviewed	No. of MAJOR Deficiencies	Briefly decribe MAJOR Deficiencies
Informed Consent			
Eligibility			
Treatment			
Disease Outcome/ Response			
Adverse Events			
General Data Management Quality			

FAX OR EMAIL THIS REPORT TO THE CLINICAL TRIALS MONITORING BRANCH (CTMB), NCI WITHIN ONE WORKING DAY OF COMPLETING THE AUDIT.

FAX: (240) 276-7891

EMAIL: NCICTMBPrelimForms@mail.nih.gov

Any data irregularities identified through quality control procedures or through the audit program that raise any suspicion of intentional misrepresentation of data must be immediately reported to CTMB, CTEP, NCI. The CTMB must be notified immediately by telephone [(240) 276-6545] of any findings suspicious and/or suggestive of intentional misrepresentation of data and/or disregard for regulatory safeguards for any of the three (regulatory, pharmacy and patient case) components of an audit. Similarly, any data irregularities identified through other quality control procedures suspicious and/ or suggestive of intentional misrepresentation of data must be immediately reported to CTMB. It is the responsibility of the Cooperative Group, CCOP Research Base or CTSU to immediately notify CTMB when they learn of any significant irregularities or allegations related to scientific misconduct by a staff member or institution participating in their research program. It should be emphasized the irregularity/misrepresentation does not need to be proven, a reasonable level of suspicion suffices for CTMB/CTEP notification. It is also essential that involved individual(s) and/or institutions follow their own institutional scientific misconduct procedures in these matters.