

APPENDIX 5

Clinical Trials Monitoring Branch

**Preliminary Report of
Audit Findings**

PRELIMINARY REPORT OF AUDIT FINDINGS

Group : _____ NCI Code : _____ Category : _____
 Institution : _____
 Main Member/CCOP Name : _____ Main Member/CCOP NCI Code : _____
 Audit Date : _____ Date of Prior Audit : _____
 Audit Type : _____ Components : _____
 Audit Team Leader : _____ Telephone : _____
 Name of NCI Representative Present : _____

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 describe MAJOR Deficiencies
Informed Consent			
Eligibility			
Treatment			
Disease Outcome / Response			
Toxicity			
Data Quality			

**FAX THIS REPORT TO THE CLINICAL TRIALS MONITORING BRANCH, NCI
 (301) 480-2642 WITHIN ONE WORKING DAY OF COMPLETION OF AUDIT.**

**CALL CTMB IMMEDIATELY IF THERE IS ANY SUSPICION OF
 SCIENTIFIC MISCONDUCT: (301) 496-0510**