Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

PRELIMINARY REPORT OF AUDIT FINDINGS

Revise ☐ Complete & Save

Credited Group: ECOG-ACRIN **Auditing Group:** ECOG-ACRIN **Category:** Treatment

Membership Study Type: Treatment **Audit Type:** Routine audit **Components:** REG ☒ P ☒ PTC ☒

Audit Date: 10/13/2017 **Date of Prior Audit:** 07/11/2016 **Audit Team Leader:**

Institution CTEP Code / Name: CHRISTIANA Delaware/Christiana Care NCI Community Oncology Research Program, 200 Hygeia Drive, Suite 2400, Newark, Delaware-19713, USA

Institution CTEP Code / Name Tier1: CHRISTIANA **Institution CTEP Code / Name Tier2:**
Delaware/Christiana Care NCI Community Oncology Research Program

CRITICAL AND/OR MAJOR DEFICIENCIES FOR REG: IRB, ICC and/or DTL ☐ YES ☐ NO ☐ Not Reviewed
If YES, briefly describe:

DRUG ACCOUNTABILITY /PHARMACY CRITICAL/NON-COMPLIANCE ☐ YES ☐ NO ☐ Not Reviewed
If YES or Not Reviewed, briefly describe

PATIENT CASE REVIEW SUMMARY

Category	# of PTC Reviewed	# of CRITICAL Deficiencies	# of Major Deficiencies	Briefly describe CRITICAL and/or Major Deficiencies
Informed Consent				
Eligibility				
Treatment				
Disease Outcome/Response				
Adverse Events				
General Data Management Quality				

UPLOAD THIS REPORT TO THE CLINICAL TRIALS MONITORING BRANCH (CTMB) AT NCI/CTEP INTO THE CTMB-AIS DATABASE WITHIN ONE WORKING DAY OF COMPLETING THE AUDIT .

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. 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 component (regulatory documentation, pharmacy and patient case review) 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 Network Group or NCORP Research Base 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 that the irregularity/misrepresentation of data does not need to be proven, a reasonable level of suspicion suffices for CTMB notification. It is also essential that involved individual(s) and/or institutions follow their own institutional scientific misconduct procedures in these matters.

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Additional Comments:

N/A

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