Attachment_D02_Prelim_Audit_Find

OMB# 0925-0753, Expiration Date: 07/31/2021

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency many not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB #0925-0753). Do not return the completed form to this address.

	Revise	PF	RELIMIN		PORT OF	AUDIT FIND	INGS	N: N:	ublic Health Service ational Institutes of Health ational Cancer Institute athesda, Maryland 20892
Credited Group:	E	COG-ACR	IN	Aud	iting Grou	p: ECOG-ACRI	N	Category:	Treatment
Membership Stu	dy Type: '	Treatment		Aud	it Type:	Routine audit	:	Components: Audit Team	REG P PTC
Audit Date:	10/13/20)17	Date	of Prior A	udit: 0)7/11/2016		Leader:	
Institution CTE	Code / N	ame: CH	RISTIANA	L		are/Christiana Care geia Drive, Suite (y Research Program, 9713, USA
Institution CTE Delaware/Christia					ch Program	Institution CT	EP Code	/ Name Tier2:	
CRITICAL ANI If YES, briefly describe:	OR MA	JOR DEFI	CIENCIES	FOR RE	G: IRB, IC	C and/or DTL	∏ ¥	ES NO	Not Reviewed
DRUG ACCOU	TABILI	TY /PHAR	MACY CR	TICAL	NON-COM	PLIANCE		ES NO	Not Reviewed
If YES or Not Reviewed, briefly describe									
PATIENT CASE									
Category		# of PTC Reviewed	# of CRITICAL Deficiencies	# of Major Deficiencies	Briefly de	scribe CRITICA	L and/or l	Major Deficienc	ies
Informed Conser	ıt								
Eligibility									
Treatment									
Disease Outcome/Respor	se								
Adverse Events									
General Data Management Qu	ality								
UPLOAD THIS DATABASE WI							(CTMB)	AT NCI/CTEP	NTO THE CTMB-AIS
Any data irregul misrepresentatio 6545] of any find any component (through other qu reported to CTM of any significant research program	arities ide n of data a ings suspi regulatory ality cont B. It is th irregular n. It shoul ces for C1	ntified thro must be im cious and/o y documen rol procedu e responsit ities or allo d be emph	ough qualit imediately : or suggestiv tation, pha ures suspic bility of the egations rel asized that	y control y reported to re of inten rmacy and ious and/o Network lated to so the irregu- also essen	procedures o CTMB. I tional misr l patient ca or suggestiv Group or I ientific mis ilarity/misu	or through the a The CTMB must l epresentation of es review) of an a re of intentional n WCORP Research conduct by a staf representation of	be notified data and/o nudit. Sim nisrepreso Base to i f member data does	l immediately b or disregard for ilarly, any data entation of data mmediately not or institution p not need to be p	ny suspicion of intentional y telephone [(240) 276- regulatory safeguards for irregularities identified must be immediately ify CTMB when they learn articipating in their proven, a reasonable level low their own institutional

July 2018

Addit	tional Comments:	PRELIMINARY REPORT	OF AUDIT FINDINGS e & Save	Public Health Service National Institutes of Health National Cancer Institute Bethesda, Maryland 20892
Auun	tional Comments:			
N/A				
DATA	ABASE WITHIN ONE WO	RKING DAY OF COMPLETIN	G THE AUDIT .	I NCI/CTEP INTO THE CTMB-AIS
misrep 6545] any co throug report of any resear of susp	presentation of data must b of any findings suspicious a omponent (regulatory docu gh other quality control pro- ted to CTMB. It is the resp y significant irregularities of rch program. It should be eff	e immediately reported to CTMI and/or suggestive of intentional m mentation, pharmacy and patien ocedures suspicious and/ or sugge onsibility of the Network Group or allegations related to scientific 1 mphasized that the irregularity/n otification. It is also essential tha	3. The CTMB must be notified in interpresentation of data and/or t case review) of an audit. Simili- sitive of intentional misrepresen or NCORP Research Base to im misconduct by a staff member on nisrepresentation of data does not a staff member of the staff memb	un that raise any suspicion of intentional immediately by telephone [(240) 276- disregard for regulatory safeguards for arly, any data irregularities identified itation of data must be immediately unediately notify CTMB when they learn or institution participating in their not need to be proven, a reasonable level institutions follow their own institutional