# Attachment\_D07\_Final\_Report\_CAPA

### OMB #XXXX-XXXX Expiration Date: XX/XX/XXX

Public reporting burden for this collection of information is estimated to average 1,800 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#xxxx-xxxx). Do not return the completed form to this address.

Audit Scheduling Information	Audit Domain	CTMSP1P2	Audit Date	03/08/2017	Audit Type	Data Audit
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Auditor Information	Membership Study Type	Treatment	Audit Category	Treatment		
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	Sent History					
Send Final Report	Sent History	Cover Letter Template				
Send Follow-up		Pedictric Oncology Branch				
Acknowledgment Email		Email To*				
		CC				
Final Report Information		Attachment				
		Subject Pediatric Branch Report				
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		Please see the attached NCI Pediatric Branch Data Audit.				
Follow-up Information						
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Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan			
Institution Name Tierl: Children's Hospital of Al	abama Institution CTEP Code Tier1: AL013		
Institution Name Tier2:	Institution CTEP Code Tier2:		
Audit Domain: COGC	Audit Type: COGC audit		

Audit Category: Treatment

In order to improve the <u>efficiency</u> the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

### IRB Review

Audit Date: 07/11/2017

Protocol Number: ADVL1211 Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getAssessmentScreens.action#

Corrective and Preventive Action Plan: (enter comments below)

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Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan			
Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013		
Institution Name Tier2:	Institution CTEP Code Tier2:		
Audit Domain: COGC	Audit Type: COGC audit		
Audit Date: 07/11/2017	Audit Category: Treatment		

In order to improve the <u>efficiency</u> the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to *semail* address<sup>2</sup>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax *s*Fax number<sup>3</sup>

#### ICC Review

Protocol Number: ADVL1211 Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getAssessmentScreens.action#

Corrective and Preventive Action Plan: (enter comments below)

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Audit Date: 07/11/2	2017	Audit Category: Treat	ment
Follow-up Request			
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## Department of Health & Human Services

Follow-up/Corrective And Preventive Action Plan				
Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013			
Institution Name Tier2:	Institution CTEP Code Tier2:			
Audit Domain: COGC	Audit Type: COGC audit			
Audit Date: 07/11/2017	Audit Category: Treatment			

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#### <u>Patient Case Review</u> F. General Data Management Quality

Protocol Number	Patient Number	
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Corrective and Preventive Action Plan: (enter comments below)

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