Clinical Research Documentation ALCOA PLUS Checklist

"If it wasn't documented, it wasn't done."

ttributable	Legible	Contem	poraneous	Original		Accurat	e
should be	The rese	earch Data sh	ould be	Study re	cords	For data	a to be
bvious who	data sho	ould be recorde	ed as it is	should b	be	viable it	t should
reated a record	easy to I	read. observe	ed. All	originals	s, not	be erroi	r free.
k when. It		signatu	res/	photoco	pies.	Data qu	ality
hould be		initials	should			must be	2
bvious who		be date	ed.			maintai	ned.
nade changes,							
vhen & why.							
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				J	S		
Complet		Consistent	Enduring		Available		
Complet Data sho		Consistent Data should be			Available Data show		
	ould		Enduring	erial		uld be	
Data sho	ould a	Data should be	Enduring The mate	erial ecord	Data shou	uld be e in a	
Data sho feature a	ould a e audit	Data should be chronologically	Enduring The mate used to re	erial ecord uld last	Data shou accessible	uld be e in a format	
Data sho feature a trackable	ould a e audit rove	Data should be chronologically arranged, with	Enduring The mate used to re data shou	erial ecord uld last iration	Data shou accessible readable	uld be e in a format er	
Data sho feature a trackable trail to p	ould a e audit rove has	Data should be chronologically arranged, with time stamps	Enduring The mate used to re data shou a long du	erial ecord uld last ration osing	Data shou accessible readable wheneve	uld be e in a format er over	