

# C T A O Decision Tree and Required Documents



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		New Contract	A	M	E	N	D	M	E	N	T	S	Coverage Analysis
		Original Contract formation ("the complete packet")	Budget Increase to Per Patient Costs	Budget Increase to Invoiceables	Budget Increase to: 1) Fixed Costs OR 2) Number of Patient Allotment	Budget Decrease to: 1) Per Patient OR 2) Invoiceables	Budget Decrease to Fixed Costs	Protocol Amendment that does not impact the budget in any way	Contract Amendment that does not impact the budget in any way	Change of PI	NCTE (amendment required if there is a firm fixed end date in the Agreement)		Coverage Analysis Only - as required by UCLA <a href="#">Policy 915</a>
MINIMUM DOCUMENTS	1) EPASS (intake form) [minimum document only requires PI signature]	<u>X</u>	<u>X</u>		<u>X</u>					<u>X</u>			
	2) Financial Disclosures -Sponsors	<u>X</u>	<u>X</u>		<u>X</u>					<u>X</u>			
	3) Financial Disclosures - CRO (if applicable - when CRO will sign CTA instead of sponsor)	<u>X</u>	<u>X</u>		<u>X</u>					<u>X</u>			
	4) Budget - Internal Itemized <sup>^</sup>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>			<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>
	5) Budget - Sponsor (if different from Internal Itemized)	X	X	X	X	X	X						X
	6) Draft ICF <sup>^</sup> (if currently approved ICF not available)	X	X	X	X	X	X	X*	X*	X*	X*	X*	X*
	7) Current Protocol <sup>^</sup>	X	X	X		X		X*	X*	X*	X*	X*	X*
	8) Completed QCT Form <sup>^</sup>	<u>X</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>	<u>X*</u>
	9) Draft Contract /Amendment (word document) or Sponsor/CRO contact info	X	X	X	X	X	X		X	X	X	X <sup>+</sup>	
FINAL DOCUMENTS	10) IRB Approval Notification	X	X	X	X	X	X	X	X	X	X	X	X
	11) Approved ICF <sup>^</sup> (for Coverage Analysis - if available)	X	X	X	X	X	X	X	X	X	X	X	X
	12) PI Exception Letter (if applicable)	X								X			
	13) DOM Other Support Form (Department of Medicine only)	<u>X</u>	<u>X</u>		<u>X</u>					<u>X</u>			
	14) DOM PI Responsibility Form (Department of Medicine only)	<u>X</u>	<u>X</u>		<u>X</u>					<u>X</u>			
	15) PI Signs Agreement/ Amendment (when applicable)	X	X	X	X	X	X	X	X	X	X	X	

\* For studies that originated prior to Policy 915 implementation (July 16, 2012) & have not had an amendment reviewed

<sup>^</sup> Required for coverage analysis certification.

\* If applicable - if unsure check with your contract analyst