

NCI Trial Complexity Elements & Scoring Model

Study Title:			
Protocol Version being used _____			
Number	Element	Standard = 0 / Moderate = 1 / High = 2	Score (0-2)
1	Number of study arms		
2	Informed consent process		
3	Registration or randomization steps		
4	Complexity of investigational Treatment		
5	Length of Investigational Treatment		
6	Feasibility and personnel impact		
7	Data collection complexity		
8	Follow up requirements		
9	Ancillary studies		
10	Participant feasibility & Enrollment		
11	Anticipated recruitment levels		
		<b>Total Score</b>	

Additional Comments:

Complexity assessment completed by: \_\_\_\_\_ Date \_\_\_\_\_

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