

WI 027 - Appendix B

Description and detail of how-to score each element in the NCI trial complexity elements and scoring model

Number	Element	Description and detail of scoring	Score
1	Number of study arms	standard: 1-2 study arms moderate: 3-4 study arms high: >4 study arms	0 1 2
2	Informed consent process	standard: - Straightforward - 1-step randomization - Standard of Care vs. Investigational moderate: - Simple trial with placebo arm - Observation only arms - 2-step rando/registration - Requires assent process high: - Highly complex to explain to pts (predictive markers, crossover, extra mandated consents/tests forms) - Multiple steps / randomizations - Intra-operative randomization	0 1 2
3	Registration or randomization steps	standard: - 1-step registration / randomization moderate: - Separate registration / randomization - Central pathology review high: - Multiple steps / randomizations - Intra-operative randomization - Complex central path review prior to randomization (ie. tumor genotyping)	0 1 2
4	Complexity of investigational Treatment	standard: - outpatient, single modality - similar to standard of care moderate: - combined modality	0 1

		<ul style="list-style-type: none"> - conventional chemo + biologics - simple inpatient treatments high: - therapy with high risk of toxicity (eg. gene transfer, stem cell tx) - special credentialing required 	2
5	Length of Investigational Treatment	<p>standard:</p> <ul style="list-style-type: none"> - regimens with defined # of cycles - routine/standard hormonal therapy <p>moderate:</p> <ul style="list-style-type: none"> - lengthy regimens (until progression) - long hormone &/or maintenance rx (in addition to investigational agent) <p>high:</p> <ul style="list-style-type: none"> - extended investigational treatment (eg. >6 mos, or q21 days x 22 cycles) 	0 1 2
6	Feasibility and personnel impact	<p>standard:</p> <ul style="list-style-type: none"> - 1 typical research team - one discipline <p>moderate:</p> <ul style="list-style-type: none"> - moderate number of med disciplines <p>high:</p> <ul style="list-style-type: none"> - high number of disciplines needed - > 2 disciplines with significant need for complex coordination of activities 	0 1 2
7	Data collection complexity	<p>standard:</p> <ul style="list-style-type: none"> - standard AE reporting - prospective, standard regulatory data - adjuvant study with standard CRFs <p>moderate:</p> <ul style="list-style-type: none"> - specific AE reported expedited means - retrospective additional regulatory data - prospective additional reg data (labs norm) - additional data (eg. concomitant meds) - RECIST criteria - multiple step study <p>high:</p> <ul style="list-style-type: none"> - real time reporting of AE - real time data reporting 	0 1 2

		<ul style="list-style-type: none"> - significant data under a SPA / registration trial - complex hematological - retro/prospect scan collection - central imaging review dictates rx decisions 	
8	Follow up requirements	<p>standard:</p> <ul style="list-style-type: none"> - up to 2 years follow-up <p>moderate:</p> <ul style="list-style-type: none"> - 2 to 5 years follow-up <p>high:</p> <ul style="list-style-type: none"> - greater than 5 years follow-up - requiring rx and toxicity data for pts off study / post disease progression 	<p>0</p> <p>1</p> <p>2</p>
9	Ancillary studies	<p>standard:</p> <ul style="list-style-type: none"> - no ancillary studies <p>moderate:</p> <ul style="list-style-type: none"> - 1-2 ancillary studies <p>high:</p> <ul style="list-style-type: none"> - 2 + Ancillary studies 	<p>0</p> <p>1</p> <p>2</p>
10	Participant feasibility & Enrollment	<p>standard:</p> <ul style="list-style-type: none"> - target population routinely seen <p>moderate:</p> <ul style="list-style-type: none"> - target population is uncommon cancer - target is common ca, but rare trials for - trial has highly selective eligibility (eg. molecular screening criteria) <p>high:</p> <ul style="list-style-type: none"> - target population includes groups often underrepresented (elderly, minorities) 	<p>0</p> <p>1</p> <p>2</p>
11	Anticipated recruitment levels	<p>standard:</p> <ul style="list-style-type: none"> - <5 <p>moderate:</p> <ul style="list-style-type: none"> - 5-20 <p>high:</p> <ul style="list-style-type: none"> - 20+ 	<p>0</p> <p>1</p> <p>2</p>