

Figure 1: Examples of Complexity Tool Categories and the Scoring Matrix

Complexity Tool				
Study Element	No Effort	Minimal Effort (1 point)	Moderate Effort (2 points)	Maximum Effort (3 points)
Active Scoring Elements				
PI expertise and experience with clinical research	N/A	Physician has been lead P.I. on several trials and has a clear understanding of a P.I.'s responsibilities	Physician has been Sub-I on a study (ies) and has enrolled and followed patients on a clinical trial	Physician has minimal research experience and/or requires an increased level of engagement
Study Recruitment	N/A	Development of flyers or adding to LCD screens	Community outreach	Specialized recruitment efforts will be required
Target enrollment	0	<20	20 - 100	> 100
Inclusion/ Exclusion Criteria	N/A	1-10 Inclusion/ exclusion criteria	11-20 inclusion/ exclusion criteria	> 21 Inclusion/ exclusion criteria
Informed consent process (initial)	No informed consent	1-10 pages	11-19 pages	> 20 pages
Screening procedures for eligibility (post IFC)	0	1-5	6-10	<u>> 10</u>
Screening visit (length)	N/A	< 4 hours	4-8 hours	Over 8 hours
Randomization/ Baseline Cycle 1 Procedures	0	1-5	6-10	<u>> 10</u>
Baseline visit/ randomization (length)	N/A	< 4 hours	4-8 hours	Over 8 hours
Personnel required other than the research team, Feasibility of the study	N/A	Involves only the research team,	Involves moderate number of different medical disciplines and staff	Involves high number of different medical disciplines and staff, requires more effort and coordination
Procedures needed after Baseline/ Randomization to End of Treatment (outside of procedure/drug)	0	1-10	11-20	<u>> 21</u>

Figure 3: Step-Down Categories

Follow-up (Post End of Treatment) Scoring Elements				
Post-treatment visits in 1st year (follow-up visits after drug administration)	N/A	1-2	3-4	> 4
Post-treatment visits after 1st year	N/A	Once per year	Twice per year	Over twice per year
Frequency of required telephone and non-clinic visits	N/A	Once per year	Twice per year	Over twice per year
Complexity of the follow-up visits (Additional testing at follow-up)	N/A	Vitals, questionnaire or survivorship check	Standard of Care tests that may include labs, ECHO, EKG, ect.	Non-standard/ complex testing