

Name of Protocol:

Complexity Score:

Complexity Parameter
1. Hospital/Clinic Setting
2. Coordination and collaboration among Multidisciplinary Teams within one study
3. Study Design
4. Blinding Procedures
5. Number of Assessments Per Visit
6. Study Hours
7. Multiple Site Locations

8. Study-Specific Clinical Training/Certification

9. Study-Specific Applications Training (RDC, central lab, IVRS/IWRS, etc.)

10. Protocol Mapping, Logistics, Responsibilities, Accountabilities, Contacts

11. Prescreening Activities/Time

12. Time-Critical Randomization Parameters

13. Administrative Issues (Protocol Amendments, Contact/Budget Negotiation, ICF Template Issues, Regulatory Issues, Anticipated SAEs, Central IRB, Cooperative group, etc.)

14. Planned Enrollment agreed upon by PI and approved by IRB

15. Scientifically difficult protocol

TOTAL PROTOCOL COMPLEXITY SCORE
OVERALL PROTOCOL COMPLEXITY RATING

COMMENTS: Build in No. Visits

Date:

Overall Rating:

Complexity Qualifier	Score	Protocol Score
Inpatient	5	
Inpatient/Outpatient	3	
Outpatient	1	1
5 or more Departments/Offices	5	
3-4 Departments/Offices	3	
1-2 Departments/Offices	1	1
Multiple drug or procedure study with follow-up, intensive study	5	
Drug or device study or procedure that is completed over time (multiple cycles or visits) with follow-up	4	4
Study involves a one-time intervention or dose of drug with follow-up	3	
Minimal risk registry with follow-up, again simple data entry, but done over a period of follow-up visits	2	
Any study that is essentially once and done, generally is a registry collecting just data, no follow-up	1	
Blinded/Un-blinded Assessors	5	
Double-Blind	3	3
Single Blind or Open-Label	1	
Greater than 20	5	
16 to 20	4	
11 to 15	3	
6 to 10	2	
1 to 5	1	1
24/7 on-call	5	
Extended hours	3	
Routine office hours	1	1
Multiple locations (Off-campus)	5	
Multiple locations (On-campus)	4	
Hospital AND PI Office or other offices such as CAWR, Spring Ridge, etc.	3	
Hospital OR PI Office or other offices such as CAWR, Spring Ridge, etc.	2	
CTO	1	1

3 or more specialized clinical assessments involving certification and/or inter-rater reliability	5	
2 specialized clinical assessments involving certification and/or inter-rater reliability	3	
1 specialized clinical assessments involving certification and/or inter-rater reliability	1	1
3 or more data-entry applications/tools	5	
2 data-entry applications/tools	3	3
1 data-entry application/tool	1	
Difficult	5	
Moderately difficult	3	
Mildly difficult	1	1
Review potential patient charts/maintain screening logs (3 or more hours per day)	5	
Review potential patient charts/maintain screening logs (2 hours per day)	3	
Review potential patient charts/maintain screening logs (1 hour per day)	1	1
ICF and Randomization within 2 hours of identifying patient	5	
ICF and Randomization within 2 to 8 hours of identifying patient	4	
ICF and Randomization within 8-12 hours of identifying patient	3	
ICF and Randomization within 12 to 24 hours of identifying patient	2	
ICF and Randomization on next business day of identifying patient	1	1
Difficult	5	
Moderately difficult	3	3
Mildly difficult	1	
Greater than 20	5	
11 to 20	3	
1 to 10	1	1

Scientifically difficult protocol requiring educational sessions provided by the PI or other physician to explain the therapeutic area, disease state, pharmacology or test article, etc.)	5	
Protocol is scientifically difficult and will require active involvement of the PI to answer the questions of the lead CRC who will then be able to explain the protocol to the team	3	
CRC and study team is able to read and understand the protocol independently	1	1
SUM OF ALL 15 PROTOCOL COMPLEXITY PARAMETERS	75 Max; 13 Min	24
RATE 5 IF TOTAL SCORE IS 63 to 75	5	
RATE 4 IF TOTAL SCORE IS 50 to 62	4	
RATE 3 IF TOTAL SCORE IS 37 to 49	3	
RATE 2 IF TOTAL SCORE IS 25 to 36	2	
RATE 1 IF TOTAL SCORE IS 13 to 24	1	x