

IRB									
New Study Rascal submission	Y	N	N	Y	Y	Y	N	N	N
Rascal Modifications	Y	N	N	Y	Y	Y	N	N	N
Rascal Renewals	Y	N	N	Y	Y	Y	N	N	N
Communication with IRB	Y	N	Y	Y	Y	Y	N	N	N
Report Protocol Deviations	Y	N	N	Y	Y	Y	N	N	N
Study Conduct									
Communication with sponsor	Y	N	Y	Y	Y	Y	S	N	N
Creation of source documents	Y	N	N	Y	Y	Y	S	S	S
Creation of study checklist	N	N	N	Y	Y	Y	S	S	S
Create worksheets	N	N	N	Y	Y	Y	S	S	S
Capturing source	Y	Y	Y	Y	Y	Y	S	N	N
Complete case report forms	N	N	N	Y	Y	Y	Y	Y	S
Answer queries	Y	N	N	Y	Y	Y	N	N	N
Maintain study manual	N	N	N	Y	Y	Y	Y	Y	Y
Collection of source from EMR	N	N	N	Y	Y	Y	S	S	S
Creation of Index Hospitalization File	N	N	N	Y	Y	Y	S	S	S
Complete and sign source sign off sheet	N	N	N	Y	Y	Y	N	N	N
Certify Source Documents	N	N	N	Y	Y	Y	N	N	N

N=NO

Y=YES

S=With close supervision

1. Research Assistants may obtain consent for registry studies or minimal risk studies only
2. After internal certification (trained and observed successfully inserting 3 IV lines).
3. After internal certification (trained and observed successfully drawing blood from IV line or saline lock 3 times).
4. After internal certification (trained and observed successfully collecting urine from catheter or drainage from drain 2 times).