Research Compliance Activity Summary Report
Quality Improvement Office (QIO)
Fiscal Year 2015-2016 (7/1/2015 to 6/30/2016)

Clinical Research Billing Compliance				
Area Activities				
Research Billing - Scheduled Reviews	**Q1*** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
• Number of Departments Reviewed	0	2	3	4	9
• Number of PI's Reviewed/Education Sessions	0	5	9	17	31
• Number of of Studies Reviewed	0	5	9	16	30
• Number of Dates of Service Reviewed	0	151	236	191	578

Note: Advisory Committee did not meet until end of August, 2015.

Area Training Activities	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
Presentations (# of events)	3	1	1	0	5

Human Subjects Research Quality Assurance (QA)/Quality Improvement (QI)				
Area Activities				
Research QA - Scheduled Reviews	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
• Number of Studies Reviewed*	7	3	5	3	18
• Number of PI's Reviewed/Education Sessions*	5	3	4	3	15
• Number of Subjects Reviewed	30	14	92	144	280

Note: Includes Breir, "Minnesota Report".

Research QA - Directed Reviews	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
• Number of PI's Reviewed/Education Sessions	1	2	1	3	7
• Number of Studies Reviewed	1	4	1	12	18
• Number of Subjects Reviewed	24	42	9	171	246

Area Training Activities	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
Presentations (# of events)	4	0	4	3	11
Targeted Researcher Education/Guidance Sessions* **	0	3	6	0	9

Note: Includes PI held IND/IDE Education.
**Includes FDA Audit Assistance/Liaison activities.

Clinical Trials (CT.gov)				
Area Activities - Registration	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
ACT Determinations	23	22	33	52	130
New Record Registrations	5	4	9	2	20
Results Reporting Monitoring	9	11	14	13	47
Maintenance Monitoring	38	31	41	36	146

Area Training Activities	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
Presentations (# of events)	1	5	5	1	12