Research Compliance Activity Summary Report
Quality Improvement Office (QIO)
Fiscal Year 2016-2017 (7/1/2016 to 6/30/2017)

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	0	0	0	**0**
• Number of PI's Reviewed/Education Sessions	0	0	0	0	**0**
• Number of of Studies Reviewed	0	0	0	0	**0**
• Number of Dates of Service Reviewed	0	0	0	0	**0**

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

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 PI's Reviewed/Education Sessions	1	1	4	10	**16**
• Number of Studies Reviewed	3	1	4	10	**18**
• Number of Subjects Reviewed	22	6	29	102	**159**

Research QA - Directed Reviews	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
• Number of PI's Reviewed/Education Sessions	2	3	0	0	**5**
• Number of Studies Reviewed	2	8	0	0	**10**
• Number of Subjects Reviewed	70	82	0	0	**152**

Area Training Activities	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Presentations (# of events)	1	3	2	2	**8**
Targeted Researcher Education/Guidance Sessions*	2	3	3	2	**10**

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

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Clinical Trials (CT.gov)					
Area Activities - Registration, Monitoring and Auditing	**Q1 (Jul-Sep)**	**Q2 (Oct-Dec)**	**Q3 (Jan-Mar)**	**Q4 (Apr-Jun)**	**TOTALS**
Determinations and Registrations	-	31	39	17	**87**
• ACT and NIH Determinatins	-	30	32	12	**74**
• New Record Registrations	-	1	7	5	**13**
Results Reporting Monitoring	-	8	5	2	**15**
• Results Reporting for Departed Principal Investigator	-	6	1	0	**7**
• Results Reporting for IU Principal Investigator	-	2	4	2	**8**
Maintenance Monitoring	-	25	59	28	**112**
• Update Not Released/Never Released	-	10	30	2	**42**
• Not Recently Updated	-	2	10	4	**16**
• Other	-	13	19	22	**54**

Area Training Activities	**Q1 (Jul-Sep)**	**Q2 (Oct-Dec)**	**Q3 (Jan-Mar)**	**Q4 (Apr-Jun)**	**TOTALS**
Presentations (# of events)	-	8	3	0	**11**
• Interactive, Computer Lab Training	-	1	0	0	**1**
• Departmental Training	-	5	3	0	**8**
• Coordinator Training	-	2	0	0	**2**

Area Activities - PRS Overview	**Q1 (Jul-Sep)**	**Q2 (Oct-Dec)**	**Q3 (Jan-Mar)**	**Q4 (Apr-Jun)**	**TOTALS**
All Records Total	-	-	518	536	**1054**
• Record Status = Enrolling by Invitation, Recruiting	-	-	128	127	**255**
• Record Status = Active-Not Recruiting, Not Yet Recruiting	-	-	62	73	**135**
• Record Status = Completed, Terminated, Withdrawn	-	-	325	333	**658**
• Record Status = Suspended	-	-	3	3	**6**
Problem Records Total*	-	-	87	76	**163**
• Late Results - per FDAAA	-	-	12	8	**20**
• Update Not Released/Never Released	-	-	45	53	**98**
• Not Recently Updated	-	-	16	27	**43**
Probable ACTs/Identified ACTs	-	-	163	167	**330**
• Update Expected in Next 12 Months	-	-	58	56	**114**
• Results Expected in Next 12 Months**	-	-	19	22	**41**

*Single record may have more than one problem; bulleted breakdown not inclusive and identifies only those problems monitored and audited as part of the IU ClinicalTrials.gov Compliance Program.

**Not inclusive of those records with posted results reporting

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Clinical Trials (CT.gov)					
Area Activities - Results Reporting In-Progress	**Q1** (Jul-Sep)	**Q2** (Oct-Dec)	**Q3** (Jan-Mar)	**Q4** (Apr-Jun)	**TOTALS**
Results Reporting - Status	-	-	15	8	**23**
• Not Started	-	-	3	3	**6**
• Created	-	-	1	0	**1**
• In PRS Review	-	-	9	1	**10**
• PRS Review Comments Issued	-	-	2	4	**6**
Results Reporting - Department Total	-	-	15	8	**23**
Results Reporting - PI IU Status Total	-	-	15	8	**23**
• Departed IU	-	-	7	1	**8**
• Remaining at IU	-	-	8	7	**15**