

Research Compliance Activity and Turn-Around-Time (TAT) Summary Report
Quality Improvement Office (QIO)
 Fiscal Year 2014-2015 (7/1/2014 to 6/30/2015)

| Clinical Research Billing Compliance | | | | | |
|--|-----------------|-----------------|-----------------|-----------------|--------|
| Area Activities | | | | | |
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| Research Billing - Scheduled Reviews | | | | | |
| • Number of Departments Reviewed | 0 | 4 | 3 | 3 | 10 |
| • Number of PI's Reviewed/Education Sessions | 0 | 9 | 5 | 3 | 17 |
| • Number of Studies Reviewed | 0 | 9 | 5 | 4 | 18 |
| • Number of Dates of Service Reviewed | 0 | 286 | 117 | 130 | 533 |

| Area Training Activities | | | | | |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|--------|
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| Presentations (# of events) | 1 | 2 | 0 | 1 | 4 |

| Human Subjects Research Quality Assurance (QA)/Quality Improvement (QI) | | | | | |
|--|-----------------|-----------------|-----------------|-----------------|--------|
| Area Activities | | | | | |
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| Research QA - Scheduled Reviews | | | | | |
| • Number of PI's Reviewed/Education Sessions | 1 | 4 | 6 | 4 | 15 |
| • Number of Studies Reviewed | 1 | 8 | 10 | 4 | 23 |
| • Number of Subjects Reviewed | 3 | 17 | 53 | 34 | 107 |
| | | | | | |
| Research QA - Directed Reviews | | | | | |
| • Number of PI's Reviewed/Education Sessions | 0 | 1 | 0 | 2 | 3 |
| • Number of Studies Reviewed | 0 | 1 | 0 | 2 | 3 |
| • Number of Subjects Reviewed | 0 | 10 | 0 | 23 | 33 |
| • IRB Meeting/Documentation Review | 12 | 12 | 12 | 10 | 46 |

| Area Training Activities | | | | | |
|--|-----------------|-----------------|-----------------|-----------------|--------|
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| Presentations (# of events) | 2 | 1 | 2 | 5 | 10 |
| Targeted Researcher Education/Guidance Sessions* | 2 | 2 | 3 | 0 | 7 |

*Includes PI held IND/IDE Education.

| Reportable Events/Activities | | | | | |
|-------------------------------------|-----------------|-----------------|-----------------|-----------------|--------|
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| OHRP Notifications | 3 | 6 | 4 | 5 | 18 |
| FDA Notifications | 17 | 13 | 7 | 8 | 45 |
| VA Notifications | 0 | 0 | 0 | 1 | 1 |

| Clinical Trials (CT.gov) | | | | | |
|---------------------------------------|-----------------|-----------------|-----------------|-----------------|--------|
| Area Activities - Registration | | | | | |
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| ACT Determinations | n/a | 0 | 45 | 59 | 104 |
| New Record Registrations | n/a | 0 | 12 | 12 | 24 |
| Results Reporting Monitoring | n/a | 0 | 1 | 8 | 9 |
| Maintenance Monitoring | n/a | 0 | 67 | 48 | 115 |

| Area Training Activities | | | | | |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|--------|
| | Q1 (Jul-Sep) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-Jun) | TOTALS |
| Presentations (# of events) | n/a | 16 | 3 | 2 | 21 |