

FY24 Q2 OCR Scorecard

****Confidential--Internal Emory Use Only****

As of March 1, 2024, there were total active clinical research studies conducted by Emory faculty with participants on-study. There were studies with no enrollment.

Education & QI Team:

educational seminars/courses with attendees (attendees on-line & attendees in-person) awarded total CMEs/CEUs

clinical research personnel received CPR certification for Emory Healthcare credentialing.

clinical research personnel (RNs and Non-RNs) were credentialed for Emory Healthcare hospital facilities at applications pending approval

newly trained clinical research personnel received OnCore user access for subject enrollment and visit tracking for study activities

of active investigators conducting FDA-regulated clinical trials completed the GCP course (% compliant)

of active study coordinators coordinating FDA-regulated clinical trials completed the CRC course, including GCP (% compliant)

Customer inquiries processed: ; Internal QA/EHC Quality Process Improvement Projects completed:

Pre-award Team: (Inclusive of both OCR & WISC (Woodruff Sponsored Clinical Trials) pre-award teams which became separate teams on February 1, 2024): (Turnaround metrics based on completion date)

New studies submitted to OCR for review:

Pre-award review completed (budget, PRA, OCR review needed &/or LOI): studies

PRAs completed: Business days from receipt to submission for externally funded studies (all effort): mean; median

Business days from receipt to submission for all studies¹ (all effort): mean; median

Total \$ and % difference between OCR negotiated sponsor budget & sponsor initial offer for studies: ; % mean; % median

¹All studies include externally funded, non-negotiable studies, no OCR review needed, & LOIs (letters of intent for industry studies)

Data Integrity & Integration Team

Clinical Research New Studies: activated in Oncore & EPIC

IRB Initial Approval pushed to EPIC New Process started 1/19/2023 (for Beacon Team)

MRNs Generated through Red Cap:

Signed Informed Consent Documents (ICD): Reviewed/Uploaded from OnCore to EPIC

Clinical Research Key Points: uploaded to Emory Share Point and linked to EPIC; IDS Drug Data Sheets: uploaded to Emory Share Point and linked to EPIC **2/7/2024 Discontinued CRKP and IDS**

Calendars released in OnCore New and Amended/Revised and then released in EPIC:

Billing Grids release in OnCore new and Amended/Revised and then released to EPIC: (Some studies have more than one billing grid)

*Special Project (Migrated Studies PRA's uploaded to OnCore) – Over 1,000 documents, *Special Project (Migrated studies CRKPs and IDS uploaded to Share point) Over 600 documents. *CRKP AND IDS # 815 Q1

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ClinicalTrials.gov Team

Total eIRB Studies Reviewed: 72 ; Total ad Hoc Studies Reviewed: 43 ; Total eIRB studies reviewed: 115

EHC Billables: 3 studies not submitted for PRA prior to enrollment/IRB approval: **Medicine, Infectious Diseases (2), and Family & Preventative Medicine (1).**

Non-EHC Billables: 9 studies not submitted to OCR for activation in ERMS

As of March 1, 2024, Emory was listed as a sponsor in clinicaltrials.gov for 1,297 studies (304 active studies with 72 problem records)

9 study records currently suspended* due to COVID-19 (*suspended records are still considered active)

Clinicaltrials.gov inquiries for problem updates: 285 ; ERMS review for NCT numbers required for billing compliance: 97

OCR-initiated study registration for 13 studies, updated 112 study records, addressed 10 QA Review Comments, updated records for 17 amendments, and entered results for

12 studies

% of Clinical Trials registered prior to 1st subject enrolled: 13/13 100% ; % of Results reported before deadline: 11/12 92% ;

OCR Invoicing Team

Active Studies: 1,003 ; Active Research Participants with Invoicing Activity: 1880 ; Research Visits Reviewed: 5,508

Outstanding Invoices This Quarter (excluding withheld): \$8,052,915 ; To Date: \$13,021,049

Outstanding Monies Withheld This Quarter: \$3,784 ; To Date: \$885,345

Payments Received & Reconciled This Quarter: \$10,402,031 ; To Date: \$419,832,139

Overpayments This Quarter: \$92,792 ; To Date: \$986,804

Advance Payments This Quarter: \$0 ; To Date: \$3,456,439

Study Expenses Paid by OCR This Quarter: \$438,044 ; To Date: \$6,754,336