



## CLINICAL RESEARCH BILLING COMPLIANCE

### ROLE OF OFFICE

The Clinical Research Billing Compliance (CRBC) department assures adherence to research billing regulations and policies at the federal, state and health system level. Our office reviews all Epic related billing for patients associated with clinical studies conducted within Johns Hopkins Medicine facilities located in the Baltimore-Washington Metropolitan area.

#### Leadership

- Toya Campbell, Sr. Director, Compliance & Training
- Scott A. Streibich, Director
- Liza Rodriguez, Associate Director
- Pat Robertson, Manager

### PERFORMANCE IN THE PAST YEAR

Our compliance review function, known as adjudication, involves any clinical trial that may incur physician or hospital related charges at a Baltimore/DC area academic/community hospital or outpatient site. From July 1, 2018 through June 30, 2019, the CRBC adjudicated over \$256M in charges for research participants in studies with a Prospective Reimbursement Analysis (PRA). The 28,038 active research participants in our Clinical Research Management System (CRMS) represent a 2.8% increase over FY2018. During this period 1,278 studies with PRAs were subject to our review, led by 602 Principal Investigators.

Since the initial Epic implementation in 2013 we have further reduced our average days of revenue held pending review from 7.4 across the project lifespan (Hospital and Physician Billing), to 4.2 days in the first six-months of 2019.

Clinical Research Billing Compliance also maintains the mandatory e-learning course called "Clinical Research Billing Orientation." Successful completion of this MyLearning course module is mandatory for key study team members if the study has a Prospective Reimbursement Analysis (PRA). In the past twelve months, 966 study team members completed training - a 9.9% increase over FY2018, when 879 study team personnel completed the training activity.

During FY2019 CRBC Management team members presented at four sessions of "The Complete Guide to Clinical Research Billing Compliance", a half-day, face-to-face "deep dive" for study

coordinators, research nurses, and department research financial analysts. The small-group activity setting builds effective lines of communication into study conduct areas, while at the same time delivering crucial compliance and billing process insights.

### **CHANGES IN THE PAST YEAR**

Use of Epic’s Encounter Linking workflow to trigger the prospective review of research related charges resulting in a patient-level hold was rolled out enterprise-wide in early spring of 2019. Monitoring early compliance results has identified significant challenges that would potentially impact research billing compliance operations. Successful Encounter Linking adoption relies upon global adoption of key Epic processes by study team staff. In addition, turnover of staff supporting clinical research and retention of material learned present continuing challenges for training resources to overcome.

### **NEW DEVELOPMENTS FOR THE UPCOMING YEAR**

New communication channels were implemented by the CRBC management team to improve statement accuracy and staff productivity. “New Study Review” meetings now take place after the first several participants are enrolled onto a clinical trial. Additionally, CRBC staff serve as a point of contact to support any study related billing compliance issues. As of June 30, 2019, staff have completed nearly 90 “New Study Reviews.”

“Research Billing Buzz” is the new monthly online newsletter developed by CRBC and introduced in 2019 to broaden the Hopkins research community understanding of key research billing compliance concerns, including financial clearance, encounter linking, and federal penalties for false claims. Each issue is distributed to nearly two thousand study coordinators and research nurses. Guided by three editorial staff, the “Buzz” is four issues old as of July 2019.

Refinements in the application of reduced pricing for research services billed to study budget accounts will continue to be a focus for improving Investigator satisfaction and strengthening the competitive position of Johns Hopkins Medicine to conduct cutting edge clinical trials. Costs to studies for services reimbursed by study budgets are reduced from standard charge rates to represent market pricing among academic research organizations.

### **BEST WAY TO WORK WITH PROGRAM**

We support your study team and research participants through a focused review of study related billing, insurance clearance, and other compliance-related workflows.

Our department website of essential contacts, resources and links is accessible at: <https://www.hopkinsmedicine.org/research/resources/offices-policies/CRBC/resources.html>. Please reach out to us for help with any research billing related concern about a patient.