Office of Clinical Research "State of the Office"

December 2011
Study Coordinator Meeting
STC/Morsani





Agenda

- New Staff
- Fiscal Update
- Progress Towards Goals
- Coming in 2012



New Staff

Kim Bare

- Previously at USF Research Financial Management
- Primary fiscal contact for all studies opened at USF

Gayatri Nair

- Previously worked as a study coordinator with the Division of Emergency Medicine and Tampa General Hospital
- Provide study coordination support on a 'fee for service' basis

Tequilla "Monique" Green

- Previously employed at ICON (CRO)
- Provide regulatory support for all USF relied upon IRBs on a 'fee for service' basis

Elizabeth Klingelhofer

- Previously employed as a student worker at the USF Pediatric Epidemiology Center and the USF Provost's Office
- Will act as the point of initial contact for the study intake and contracting process



Fiscal Update

 Information will be provided on request. Please send request to <u>OCRFM@health.usf.edu</u>



Business Process Goals – FY12

- Purchase and implement a clinical trial management system
 - Clinical Trial Management System "Invitation to Negotiate" posted on October 13, 2011, evaluation committee selected and we hope to begin implementation in early 2012.
- Integration and alignment between USF & Tampa General Hospital and USF & USFPG
 - USFPG: established clinical trial rate for services (150% of Medicare), meeting regularly with Revenue Cycle
 Operations (OCR) leadership to improve research scheduling, billing compliance, continued discussion of use of EMR
 information for clinical research
 - TGH: meeting regularly with TGH OCR, established USF Purchasing process, discussing joint support of research teams
- Documentation of Processes/Procedures
- Development of master purchasing agreements with common vendors
- Review and update sponsor master agreements to improve contracting time (reduce from 106 days to 80 days)
 - Initiated a Quality Improvement process for study initiation process and updated goal half of contracts received after July 1, 2011 to be executed in 80 days
 - since July 1, 2011 21 new contracts (3 executed), 17 new amendments, 18 new Confidentiality Disclosure
 Agreements: Current Average Days on-site = 93
- Regulatory and Study Coordinator Support
 - Hire staff and develop request for services, fee schedule and chargeback processes for staff
 - Regulatory/Study Coordinator positions filled



Communication Goals – FY12

- Expand and update website
- Develop and publish "Frequently Asked Questions"
- Clinical Research email to new faculty
- Attendance at department meetings
 - 172 attendees at coordinator meetings
 - Presented at Family Medicine departmental meeting
 - Held fiscal meetings with Byrd, Internal Medicine, and Psychiatry
- Publication of Quarterly Newsletter
 - Fall Newsletter
- Build and increase business with sponsors



Growth Goals – FY12

- Increase 'book of business' to \$6,000,000
 - As of 10/31 ~ \$2.1 million
- Add 10 new physicians to research
 - Five new faculty
- Patient Recruitment
 - Continue Florida Clinical Trials project
 - Develop process to identify studies with slow/low patient activity and intervention strategies to increase recruitment/retention
- Morsani Clinical Research Center
 - Expand use of CRC space to 70% capacity
 - Completed initial space use study at CRC in Morsani



Coming in 2012

- ClinCard
 - What is it and what does it mean?
- Clinical Trial Management System Implementation
 - Selected by 12/23/11
 - Implementation process to start in February 2012
- Transfer on-going clinical trials to FAST
- Close all accounts in USF Research Foundation
- Florida Clinical Trials

