

## General Clinical Research Center (GCRC) Functional Responsibilities

### Research Subject Advocate

(K. Salomone)

- Oversight of research for ethical treatment of subjects in consent and participation in studies, and subject safety including adverse events
- Review and approval of investigator data safety monitoring plans, informed consent forms
- Consultation and training for investigators and study staff

### Principal Investigator/

(C. Laurencin)

### Program Directorship

(C. Oncken)

- Overall leadership and oversight of GCRC (grant mgmt, fiscal mgmt, personnel mgmt, planning)
- Scientific oversight of PIs and protocols
- Clinical standards and quality assurance
- Relationship management w/Research Administration, ORSP, SAC, NIH, Sponsors

### Scientific Advisory Committee

(V. Hesselbrock, chair)

(TV. Rajan, co-chair)

- Oversight of GCRC mission and strategic objectives
- Review and approval of PI applications for GCRC support services based on scientific merit, resource requirements
- Oversight of GCRC financial condition and resource utilization
- Liaison between GCRC and larger clinical research community

### Administration

(P. Fall)

- First point of contact for potential projects/ pilots
- Grant administration and reporting to NIH, UCHC RA, ORSP, G&C, SAC, Sponsors
- Fiscal management of contracts, FRS accounts, project budgets, service charges/recharges
- Study and Personnel administration
- Coordination with PIs, other administrative and fiscal department staff, and across GCRC cores

<u>Informatics Core</u> (K. Dugas)	<u>Dental Core</u> (J.R. Kelly)	<u>Administrative Core</u> (P. Fall)	<u>Core Lab</u> (J. Covault)	<u>Biostatistics Core</u> (R. Feinn)	<u>Clinical Core</u> (T. Kiely)
<ul style="list-style-type: none"> <li>• Data management for projects approved by SAC</li> <li>○ Design and development of graphical user interface for demographics, CRFs, test results</li> <li>○ Design and development of data bases for storage and interfaces to receive and send data</li> <li>○ Design of mechanisms for review/ validation of study data</li> <li>• Infrastructure and website maintenance and quality assurance for all cores</li> </ul>	<ul style="list-style-type: none"> <li>• Support dental research projects sponsored by DCRC</li> <li>○ Study coordination</li> <li>○ Subject recruitment</li> <li>○ Subject encounter scheduling and mgt</li> <li>○ Clinical care and quality assurance</li> <li>○ Data collection, entry and quality assurance</li> <li>○ Research record maintenance</li> <li>○ Study closeout and protocol materials disposal/storage</li> <li>• Clinical equipment maintenance</li> </ul>	<ul style="list-style-type: none"> <li>• PD, APD, SAC support</li> <li>○ Education and Training program coordination</li> <li>○ GCRC newsletter and website content</li> <li>• Investigator services</li> <li>○ Contract development and billing with JDH and other UCHC departments, CCMC and vendors for all cores</li> <li>○ Petty cash and subject payments processing</li> <li>• Personnel administration and time-keeping</li> <li>• Housekeeping, Facilities and Public Safety work orders</li> <li>• Operating and Capital budget management</li> <li>• Service Center rate computing and reporting</li> <li>• Maintain GCRC inventories of property and space</li> </ul>	<ul style="list-style-type: none"> <li>• Perform assays and other studies and report results for projects and pilots approved by SAC</li> <li>○ Collect and process specimens for testing</li> <li>○ Record and report lab test results to PI</li> <li>○ Long term storage of specimens and inventory maintenance</li> <li>• Development of new tests and techniques</li> <li>• Maintain lab certifications and quality standards</li> </ul>	<ul style="list-style-type: none"> <li>• Consultations with PI GCRC applicants on design of study, sample size, DSMPs, data management needs</li> <li>• Biostatistical support services to project and pilots approved by SAC</li> <li>○ Review and validation of data assets and analysis</li> <li>○ Consultation on PI statistical findings and interpretation</li> <li>• Development of resources and methods for statistical analyses</li> </ul>	<ul style="list-style-type: none"> <li>• Relationship management w/ PIs, sponsors, subjects, and other clinical areas outside GCRC</li> <li>• Provides clinical research services to projects and pilots approved by SAC: <ul style="list-style-type: none"> <li>○ Study coordination</li> <li>○ Subject recruitment</li> <li>○ Subject encounter scheduling and mgt</li> <li>○ Clinical care and quality assurance</li> <li>○ Data collection, entry and quality assurance</li> <li>○ Research record maintenance</li> <li>○ Study closeout and protocol materials disposal/storage</li> </ul> </li> <li>• Clinical equipment maintenance</li> </ul>