

Clinical Research Center (CRC) Functional Responsibilities

Research Subject Advocate

(K. Tremblay)

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