

# Clinical Research Development and Operation Center Services



## Mission:

The UK Clinical Research Development and Operations Center (CR-DOC) mission is to aggregate, integrate and enhance the necessary infrastructure and core services essential for the efficient and ethical conduct of high quality clinical and translational research.

## Development:

- Linking investigators to CR-DOC services
- Methodologic consultation
- Biostatistical review
- Database design
- Assistance with assembly of interprofessional teams
- Protocol review

## Administrative and Regulatory:

- Overall project coordination
- Development of regulatory documents
- Submission of IRB forms
- Budget development
- Investigational new drug applications
- Veterans Affairs Medical Center research submission
- Study feasibility assessment
- Subject availability information
- Grant management
- Development of electronic tools & forms

## Operations and Study Coordination

### Nursing Services:

- Coordinate inpatient & outpatient trials
- Coordinate clinical procedures for research
- Obtain, process, and ship laboratory specimens
- Patient education
- Administer survey/questionnaires
- Adverse event surveillance
- Research subject advocate



## Education:

- Development of resource manuals and training programs
- Clinical research investigator training
- Monthly clinical research workshops offered through "brown bag" luncheons
- Volunteer education and outreach
- Individual or customized training presentations

## Compliance:

- Monitor for university and federal cost accounting standards
- Billing management and fiscal compliance
- Provide compliance assistance and guidance
- Quality assurance, improvement standards, and review

## Participant Recruitment/Marketing:

Proactive centralized volunteer recruitment program including:

- Develop and design marketing plans for recruitment of volunteers
- Radio copy writing and placement
- Layout of advertising flyer for distribution
- Stationary wall mounts to display research flyers in three locations. (UKMC, UK Clinic Pharmacy, and University Health Services)
- Portable kiosk used for public and UK events
- Central link to industry
- Initiate confidentiality agreement
- Coordinate pre-site visit
- Provide UKPR, FDA compliance assistance
- Recruitment of study volunteers
- Community Outreach
- Representation of UK research at national meetings
- Collaborate with UKMC Public Relations and UK Marketing



## Web sites:

- Center for Clinical and Translational Science: [www.ccts.uky.edu](http://www.ccts.uky.edu)
- For Clinical Trial Volunteers (research studies for volunteers) [www.UKclinicalresearch.com](http://www.UKclinicalresearch.com)
- CenterWatch profile (UK & KY demographics) [www.centerwatch.com/professional/pro711.html](http://www.centerwatch.com/professional/pro711.html)
- Facebook: University of Kentucky Clinical Research

Service  
Support  
Success



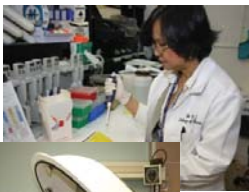
**Clinical Operations Unit  
Outpatient Unit:**

- Located on 1st floor of the Kentucky Clinic
- Reception area, nine exam rooms, and one infusion room with two chairs
- Lab processing and shipping area
- Designated monitoring areas with remote computer connections
- Charting areas
- Refrigerator available for patient food or medications



**Inpatient Unit:**

- Located on the 5th floor of the UKCMC
- Fully staffed nursing unit
- 15 inpatient beds (8 rooms)
- Metabolic kitchen
- Lab processing and shipping area
- Conference rooms



**Biochemical Analysis Laboratory:**

- Methodology consultation
- Performs assays not routinely available through the Hospital Clinical Laboratory, e.g. cytokines, growth factors, hormones
- Capabilities to run assays on the Luminex, Affymetrix gene array, Immulite, chemiluminescence plate reader, and endotoxin analysis
- Networked with other laboratories greatly enhancing assay capability

**Functional Assessment and Body  
Composition Core:**

- Methodology consultation
- Exercise Physiology lab (DEXA, BOD POD, PFT, metabolic cart, GXT)

**Delta Dental of Kentucky Clinical Research Center:**

- 10,000 square feet of clinical research and laboratory space
- Three fully equipped dental examination room and four study coordinators
- Capability to analyze complex clinical, salivary microbiologic, and inflammatory markers of disease
- Three spanish language interpreters; two bi-lingual recruiters/administrators

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*Advancing Health Care*



Clinical Research  
 Development and Operations  
 Center (CR-DOC)



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