

Clinical Research Development and Operation Center Services

The University of Kentucky 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.

Administrative and Regulatory

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

Operations and Study Coordination Nursing Services

- Coordinate inpatient & outpatient trials
- Phase I, II, III, and IV studies
- Clinical procedures for research
- Obtain, process, and ship lab specimens

Marketing

- Central initial link to industry
- Advertising and recruitment of study participants
- Outreach to potential research participants

Kentucky's Health Profile

Kentucky's top health burdens include high incidences of cancer, metabolic syndrome, and cardiovascular diseases.

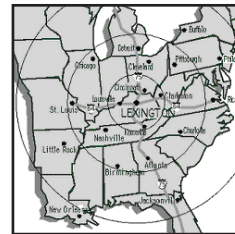
Kentucky's National health rankings:
(Data from United Health Foundation)

- Ranked 37th among the states in overall health
- 28.2 percent of the population smokes, ranked 49th
- 28.7 percent of the population is obese (BMI <30), ranked 40th
- 3.6 percent have poor mental health outcomes, ranked 38th

Kentucky health outcomes:

- 343.3 deaths/100,000 population (pop.) from cardiovascular disease, ranked 44th
- 226.2 deaths/100,000 pop. from cancer deaths, ranked 50th
- 9,059 years of life lost/100,000 pop. due to premature death, ranked 42nd
- 8.1 deaths/100,000 pop. from occupational fatalities, ranked 41st
- 113.8 discharges/100,000 pop. for preventable hospitalizations, ranked 49th

Lexington, Kentucky is centrally located in the eastern half of the United States



Courtesy of Lexington Convention Visitors Bureau

Participant Recruitment

Proactive centralized volunteer recruitment program including:

- Participant Recruitment Web sites
www.UKclinicalresearch.com
www.ukhealthcare.uky.edu/patient/clinicalresearch.asp
- CenterWatch profile (UK & KY demographics)
www.centerwatch.com/professional/pro711.html
- Radio and newspaper development and advertising
- Stationary wall mounts to display research flyers in five locations.
- Portable kiosk used for public and UK events
- Other outreach activities tailored and specified for each study

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)

Highlights

The University of Kentucky Medical Center (UKMC) is nationally recognized in: aging, cancer, cardiology, drug abuse, pharmacy, transplant, stroke, and surgery.

UK is one of the few universities in the country with a research and teaching campus within its medical center.

The new Delta Dental of Kentucky Clinical Research Center (DDKRC) provides a state-of-the-art facility for clinical research studies.

The Medical Institutional Review Board (IRB) meets six times each month. UK has three Medical IRB approval boards.

UKCMC is affiliated with and adjacent to the Veterans Affairs (VA) hospital.

The Investigational Drug Service maintains a secure storage, dispensing, and accountability system available 24 hours a day.

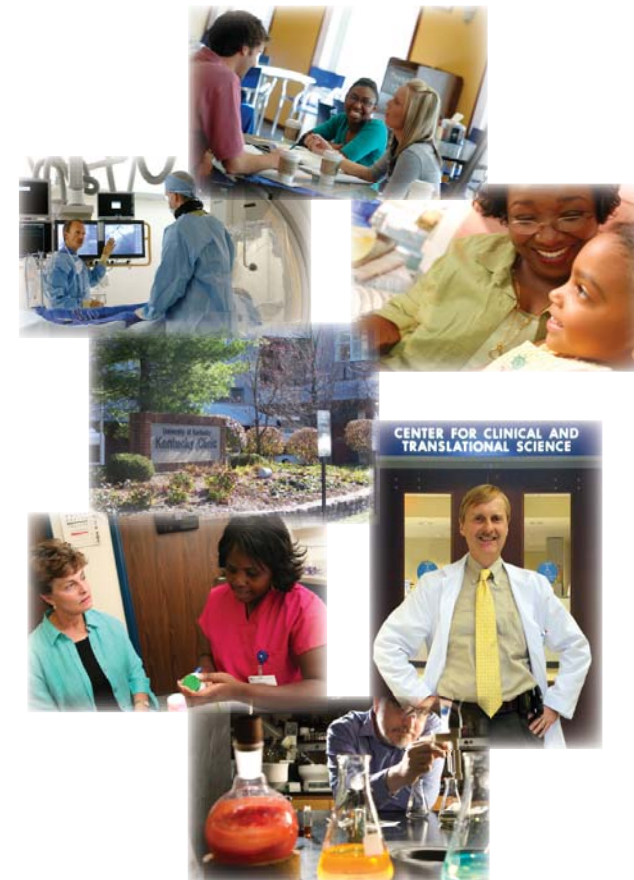
The Clinical Trial Agreement Administrator is dedicated exclusively to negotiating clinical trial agreements.

Based on benchmarking data, study initiation averages 45 working days.

UK has an exceptionally strong basic, translational and clinical research program.



Opening in 2011, the new UK Albert B. Chandler Hospital promises to be both the leading patient-centered medical center in Kentucky and a landmark architectural statement in the heart of Lexington.



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