

The University and faculty have licenses for the following statistical and pharmacokinetic data entry and management systems:

- SAS
- WinNonLin
- Full PK/PD analysis
- Data entry
- Analysis
- Reporting capabilities

Research labs are available for identifying special populations, biomarker analysis, and genetic testing.



University of Kentucky Medical Center

The University Kentucky Clinical Research Organization and the UK College of Pharmacy collaborate to conduct Phase I trials.

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Advancing Healthcare

UK
UNIVERSITY OF KENTUCKY

*Clinical Research Organization
and the
College of Pharmacy*

Phase I Research



An Equal Opportunity University

The University of Kentucky Clinical Research Organization (UKCRO) encompasses the combined strengths of several medical center programs with a long history of Phase 1 clinical research.

Since the 1970s, Phase I clinical research had been principally conducted through the College of Pharmacy-based Drug Product Evaluation Unit (DPEU) with collaboration from the Colleges of Medicine Dentistry and Nursing.

The reorganization of the clinical research enterprise at the University of Kentucky Chandler Medical Center merges the capability of the DPEU with additional units to provide a comprehensive contemporary clinical pharmacology research capability. The reorganization integrates administrative, regulatory, facilities, data management and specialized research labs with a common purpose.

Phase I clinical research studies conducted at the University of Kentucky include:

- First in Man Studies
- Drug metabolism
- Special populations
- Bioavailability/bioequivalence
- Drug-drug & drug-disease interaction studies
- Intrathecal, epidural & intraputamen delivery
- Intranasal delivery
- PK/PD in stable inpatients and outpatient
- Drug delivery system evaluation
- Vaccine testing
- Single & multiple dose PK studies
- Dose tolerance and safety



UKCRO Administrative Services: IRB submission, regulatory documentation, contract/budget and other procedures are managed by the UKCRO. The unit prepares source documents and when necessary case report forms for data collection.

Investigational New Drug (IND): Administrative services for Investigational New Drug submissions for single and multiple clinical projects.

Recruitment and Database: The UKCRO conducts ongoing outreach to potential volunteers and maintains a database of healthy participants. www.UKclinicalresearch.com

Outpatient Unit:

- Located on the 2nd floor of the Kentucky Clinic C201
- The UKCRO facility is available for all research investigators conducting trials
- Reception area, nine exam rooms, and infusion room with 3 chairs
- Lab processing and shipping area
- Four monitor areas with remote computer connections
- Conference rooms, secured storage, and cold kitchen
- Access to University of Kentucky Chandler Medical Center (UKCMC)

Inpatient Unit

- Located on the fifth floor of the University of Kentucky Chandler Medical Center in the General Clinical Research Center (GCRC)
- 14 inpatient rooms
- GCRC laboratory
- Metabolic kitchen



The Investigational Drug Service (IDS): Is a dedicated facility that maintains a secure storage, dispensing, and accountability system available 24 hours a day.

