Clinical Research Unit at the Cincinnati VAMC

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CRU: History

• Established 2004 by Stephen Strakowski and Peter Walzer as a joint initiative between VISN 10, the Cincinnati VAMC, CCHMC and the UC COM.

• Became the second VHA-based General Clinical Research Center facility in 2005

• Affiliated with the CCTST as the Clinical Research Unit (CRU) 2009.
Clinical Research Unit at the Cincinnati VAMC

• 3,000 ft² clinical research space located on the 4th floor Cincinnati VAMC
  – 5 fully equipped exam rooms-computers with internet access
  – 2 monitored, procedure rooms
  – Cardio-pulmonary physiology laboratory
  – Polysomnogram laboratory
  – Nurses station
  – Phlebotomy and sample processing/storage laboratory
  – Full time Investigational pharmacy
CRU Staff

• Dedicated research pharmacist
• Nursing
  – 2 research nurses: certified clinical research coordinators, IATA certified
  – Greater than 50 years experience in clinical research
Cincinnati Education & Research for Veterans Foundation

- Director, Ron Hakes
- Assists with contracting and regulatory processes for NIH, DOD, Investigator Initiated and Industry Sponsored Studies
- Financial accounting and invoicing
  - IPA’s with UC or Children’s
- [www.cervf.org](http://www.cervf.org)
• **All study sponsors**
  – VHA
  – Department of Defense
  – NIH
  – Intramural
  – Industry

• **Subjects**
  – Veterans and non-Veterans
  – Men and women

• **Protocols**
  – Phase I (pharmacokinetics)
  – Phase II and III studies
  – Overnight studies can be performed

• **Study sites**
  – Primary
  – One of multiple sites

• **Investigators, research assistants, and coordinators**
  – Primary appointments may be at VA, UC, and Children’s
  – Requires VA or WOC (without compensation) appointment

• **Regulatory**
  – UC or VA Central IRB
  – VA Research and Development approval
  – VA consent
CRU client base 2003-present

• > 50 investigators from 6 UC departments and 5 DOM divisions.
• Site for Multi-center Trials: SCORE, ACCORD, GRADE, ISCHEMIA
• Support for 5 VA merits, 5 K-awards, 3 R01
• Industry studies for Nephrology, Psychiatry, Cardiology, Endocrinology, Surgery, Neurology, Pulmonary, Immunology, Oncology
Current CRU Research Portfolio

- 12 physicians (Internal Medicine and Psychiatry)
- 24 clinical studies
- Funded by VHA, non-VHA federal, and industry sponsors
Translational Trials

- ISCHEMIA
- GRADE
- Translational Pulmonary Science Center Bronchoscopy Core
- A Translational, Multicenter Study to Evaluate Sputum MMP9 Levels and Enzyme Activity in Subjects w/COPD compared to Healthy Matches