

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



CRU: Universal Use

- **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