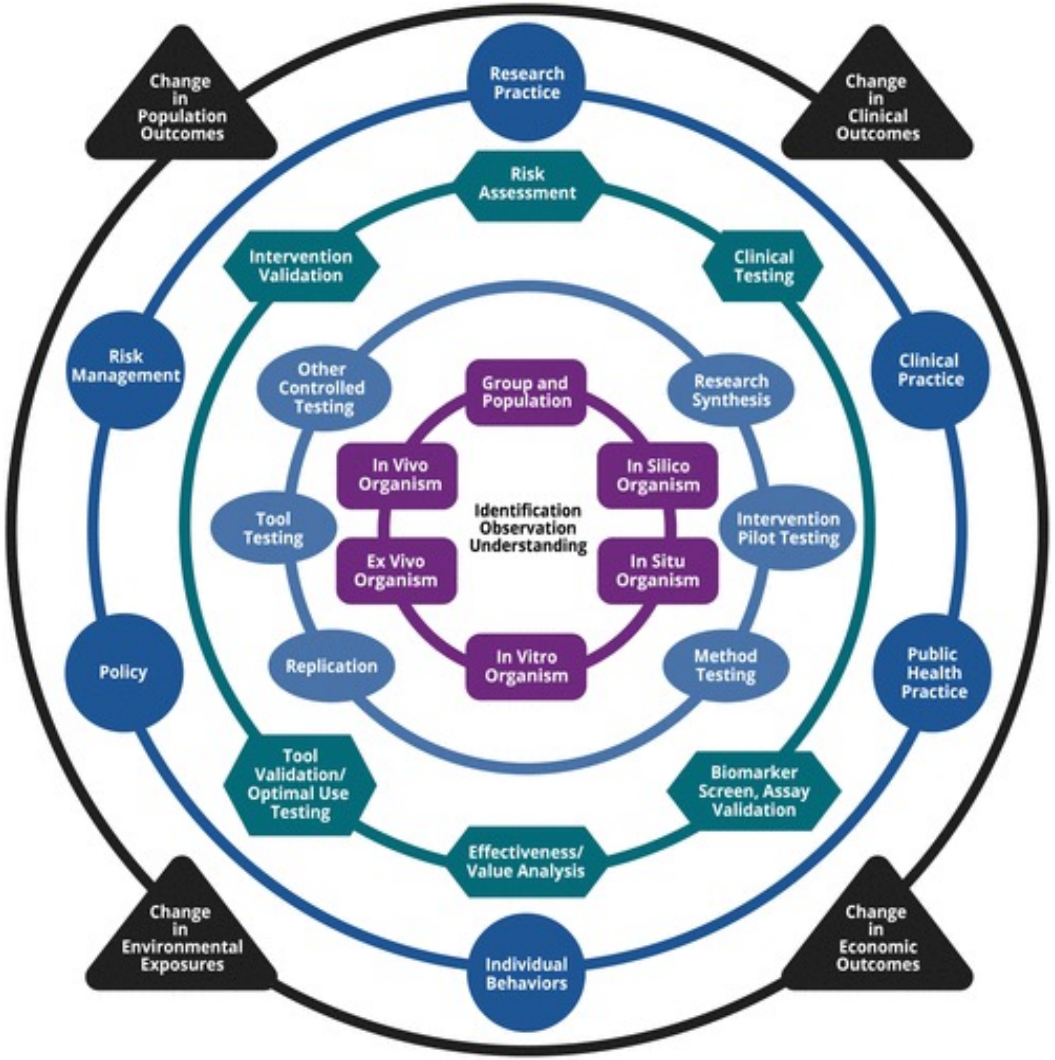
environmental health sciences research center

Translational Research Support Core (TRSC)

"The National Institute of Environmental Health Sciences (NIEHS) introduces a new translational research framework that builds upon previous biomedical models to create a more comprehensive and integrated environmental health paradigm."
-- Pettibone et al.



EHP July 2018

Director - Clinical:
Alejandro Comellas, MD (alejandro-comellas@uiowa.edu)

Associate Director - Imaging:
Eric A. Hoffman, PhD

EHSRC website: https://ehsrc.public-health.uiowa.edu/

TSRC

Aims:

- Provide the infrastructure to carry out clinical and translational studies relevant to environmental health science.
- Ensure that clinical and translational studies relevant to environmental health science are carried out safely and that subject confidentiality is maintained.
- Provide the infrastructure for training of young clinical/translational investigators with an interest in environmental health science.
- Enhance experience and support for EHSRC investigators who utilize the Institute for Clinical and Translational Science (ICTS) and promote new multidisciplinary research collaborations.

TRSC

Components

- Research participant recruitment
- Lung physiology
- Imaging Component (Dr. Eric Hoffman).
- Biologic Sampling
- Vascular Health
- Ecological momentary assessment and health-symptom sampling for environmental health researchers.

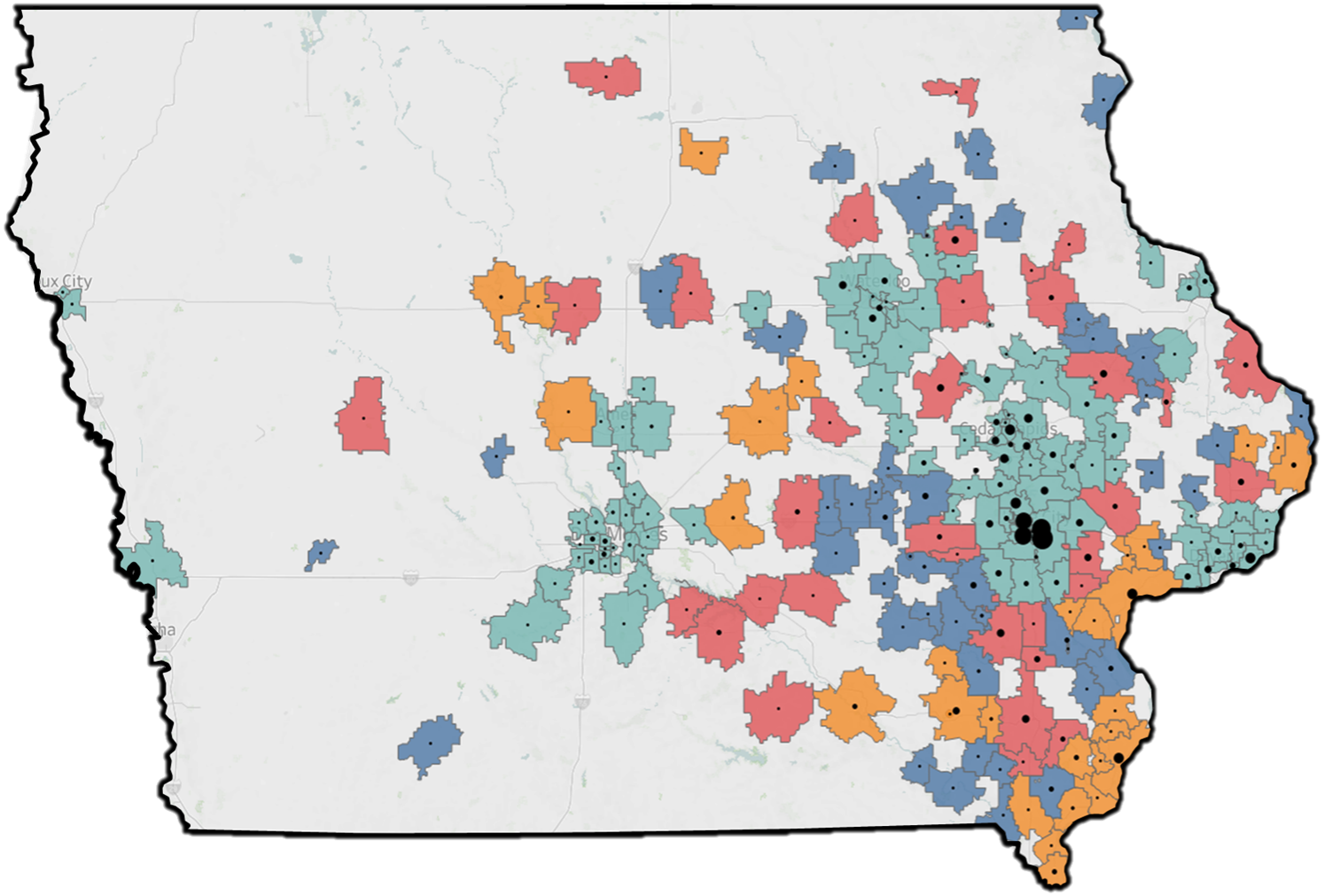
TRSC

- TRSC is currently supporting several clinical projects that are determining the lung structural changes in subjects with Chronic Obstructive Pulmonary Disease (COPD), such as:
  - Phase-3 NIH funded COPDGene: One of the largest studies (10,000 participants ever to investigate the underlying genetic factors of COPD
  - SPIROMICS: (3000 participants) SubPopulations and InteRmediate Outcome Measures In COPD Study (SPIROMICS) supports the prospective collection and analysis of phenotypic, biomarker, genetic, genomic, and clinical data from subjects with COPD for the purpose of identifying subpopulations and intermediate outcome measures

TRSC

- Source: (700 participants) looks for early signs of lung changes in younger smokers to better understand the first stages of COPD
- Lung Health Study: (4000 participants) overarching objective of the ALA-LHC is to establish a national cohort of young adults for the purpose of defining lung health and developing targets to intercept chronic lung disease at its earliest stages
- University of Iowa Post-COVID cohort: > 600 participants are part of the UI registry

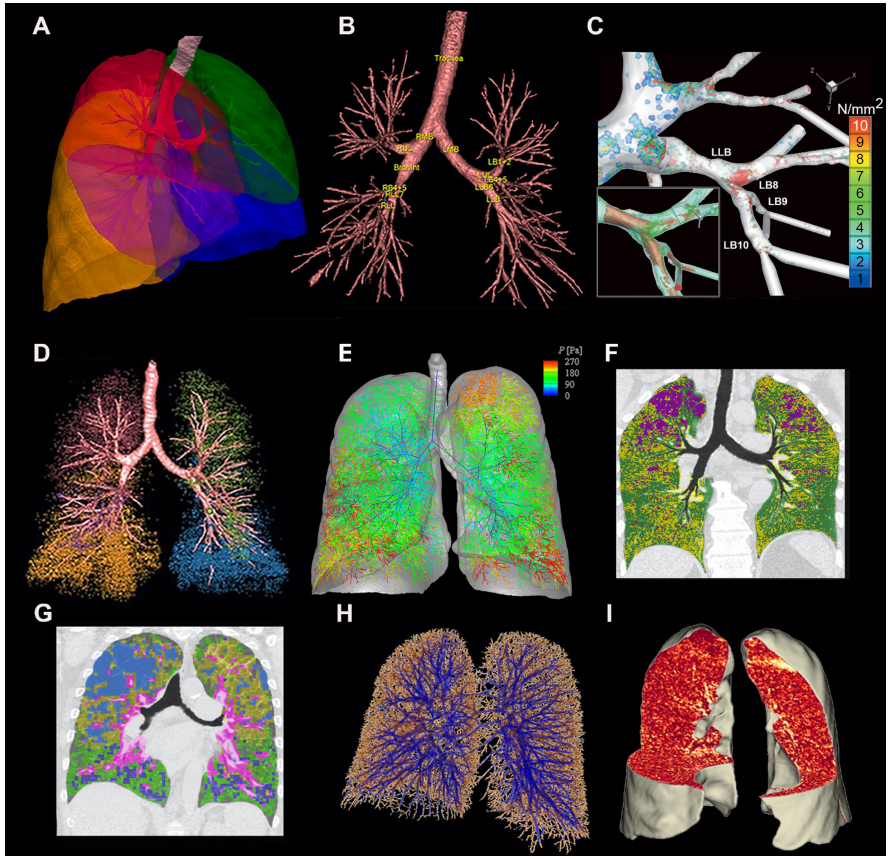
Statewide COPDGENE Recruitment by Zip Code and Rural/Urban Classification



environmental health sciences research center

Lung physiology and imaging

environmental health sciences research center



Hoffman EA. Br J Radiol. 2022 PMCID: PMC9153696.

Imaging Technologies

environmental health sciences research center

Dual Energy CT

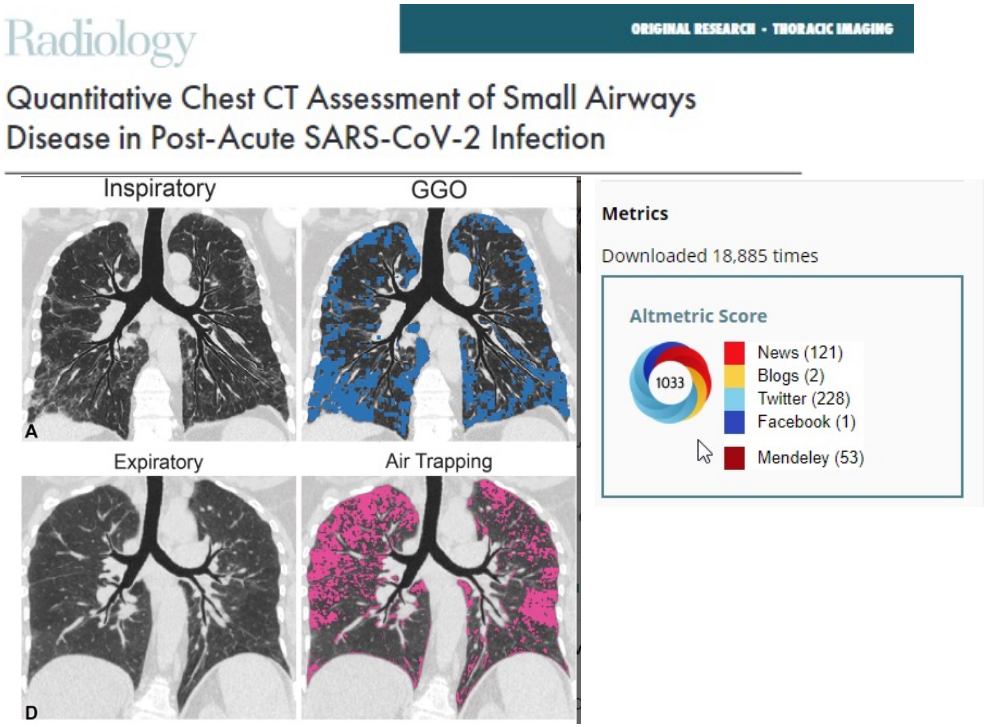
Micro CT

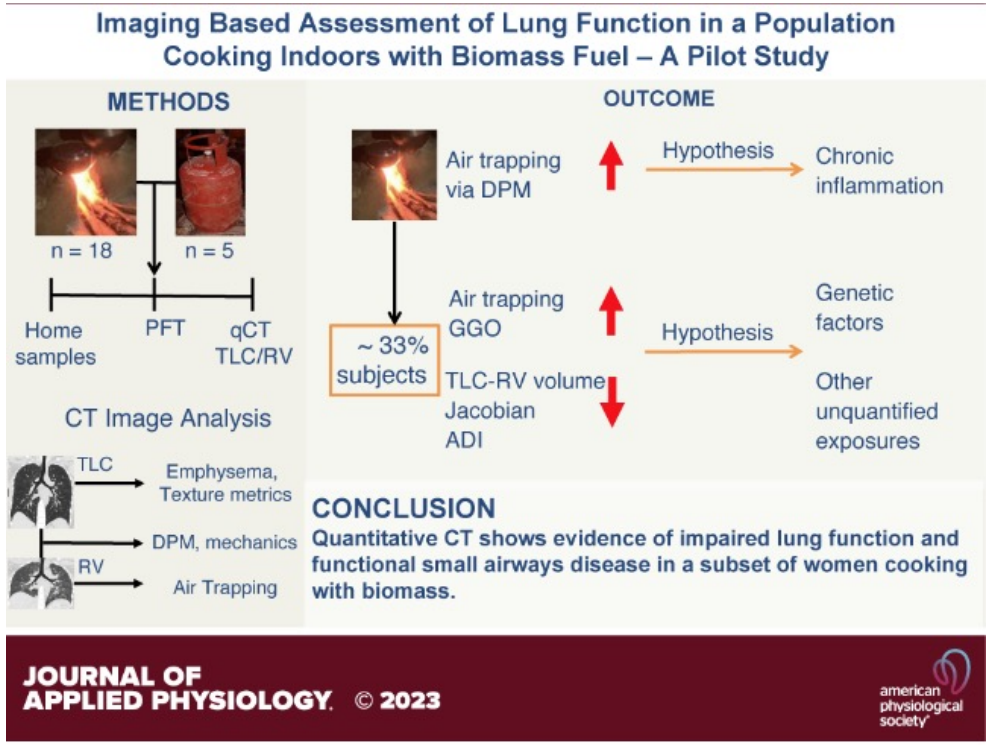
Polarized Gas MRI

TRSC

- The TRSC has supported several translational research projects as well as an international project

environmental health sciences research center





Cho JL, et al. Radiology. 2022 Jul;304(1):185-192. PMC9270680.

Kizhakke Puliyakote AS, et al. J Appl Physiol. 2023 Mar 1;134(3):710-721. PMC10027118.

Clinical Research Unit

environmental health sciences research center

Inpatient and outpatient

20,000 sq ft

- 16 examination rooms
- 6 consultation rooms
- 3 procedure rooms
- 7-bed infusion suite
- A conference room & work stations

Specific facilities for

- Pediatric, oncology, bariatric, and neuroscience studies
- Metabolic research kitchen and dining facility
- Pulmonary function, vascular physiology, and body composition labs
- Inherited Neuropathies Consortium weekly clinic

Clinical Research Unit

environmental health sciences research center

- Provide unique resources to:
  - Enable high quality clinical research
  - Support the recruitment of new faculty interested in clinical research
  - Support the career development of early-stage clinical and translational investigators
- Promote interactions between basic and clinical research faculty and the translation of laboratory discoveries to humans.

Clinical Research Unit

environmental health sciences research center

- 100 new protocols annually; >200 protocols currently open
- Investigators from UI College of Medicine, Public Health, Pharmacy, Nursing, Dentistry, Liberal Arts, Law, Engineering, Education, and Business
- Sponsors include NIH, Veterans Affairs, Foundations, Pharmaceutical/Device Industry, and Internal funds.

2024-2025 (CC & RC)

environmental health sciences research center

CC Personnel	**41**
Clinical Research Manager	1
Nurse Clin. Trial Research Specialist	1
Nurse Clin. Trial Research Associate	7
Clin. Research Associate	12
Clin. Trials Research Assistant	12
Admin Service Coordinator	2
Students	4
Financial Analyst	1
Senior Business Analyst	1

RC Personnel	**6**
Clin. Regulatory Manager	1
Clin Trials Regulatory Research Associate	2
Clin. Trials Regulatory Research Assistant	2
Student	1

Regulatory Core

environmental health sciences research center

6 Regulatory Coordinators assist with regulatory submissions (IRB submissions, clinicaltrials.gov submissions and reporting, IND/IDE consultation and submission, protocol development, sIRB grant submissions, NIH NCATS Human Subjects submissions).

This core also assists with NIH required completion and documentation for animal, genetic, and human subject approvals ,which has improved efficiency of NIH approval for CTSA sponsored pilots and trainee projects.

The Regulatory Core provides individual or group regulatory education and training to researchers and study staff or study groups.

CTMS initiatives

environmental health sciences research center

- Single solution across the enterprise
- Integrates with Epic, IRB, financial systems (Possibly ICART?)
- Reduces duplication of effort/entry
- Financial consistency
- Regulatory consistency (centralized, more efficient)
- Efficiencies – CVs, re-useable forms, e-sigs
- Provides streamlined management and regulatory oversight of multi-site trials

Vascular Health

- Vascular aging
- Endothelial function
- Arterial stiffness
- Central blood pressure
- Exercise physiology
- Oxidative stress and Inflammation

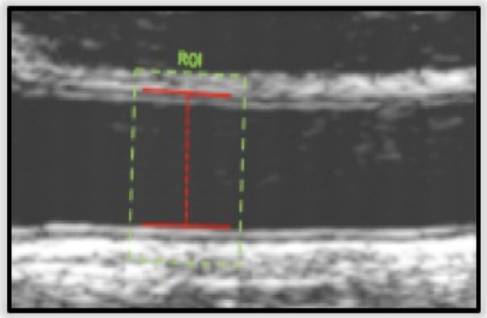
Vascular Health

environmental health sciences research center

Carotid artery stiffness

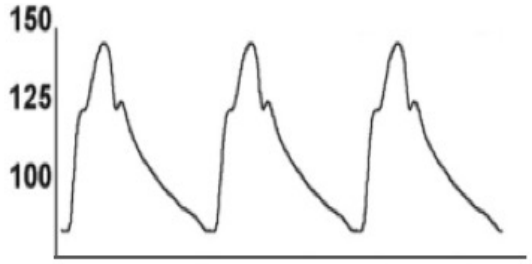
Acquire changes in carotid diameter and pressure for each cardiac cycle (for 15 sec)

Carotid diameter



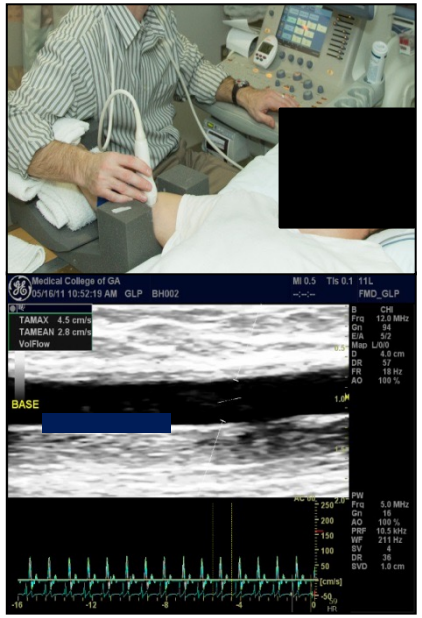
High-resolution ultrasonography

Carotid pressure



Applanation tonometry

Brachial artery flow-mediated dilation (FMD)



Normal FMD%: 8-12%
Abnormal FMD%: 0-4%

FMD expressed as relative change (%Δ) and absolute change (mmΔ)