

CCTSI Update - 2020 Town Hall

Ronald J. Sokol, MD

Director and P.I. of CCTSI

**Assistant Vice Chancellor of Clinical and Translational Science
University of Colorado – Anschutz Medical Campus**



Colorado Clinical and Translational
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

CTSA Program

- An NIH-funded national consortium of biomedical research institutions collaborating to transform how clinical and translational science is conducted nationwide
- Currently, 60 funded Hubs, many of which include multiple universities and hospitals.
- CTSAs provide many local resources, facilities, research personnel, pilot funding, regulatory and informatics support, research units and education & training programs
- Grants originate from NCATS at NIH



Colorado Clinical & Translational Sciences Institute

- CCTSI is the Colorado CTSA Hub
- Created in 2008, refunded in 2013, 2018
- Substantial institutional support (funding)
- Supports all faculty, post-docs, trainees involved in clinical or translational research at **3 universities** and **6 hospital partners**
- “Disease – agnostic”
- Infrastructure, facilities, education and training, pilot grant funding, special functions and more



CCTSI Vision

Accelerate and catalyze the translation of innovative science into improved health and patient care



CCTSI 3.0 Mission

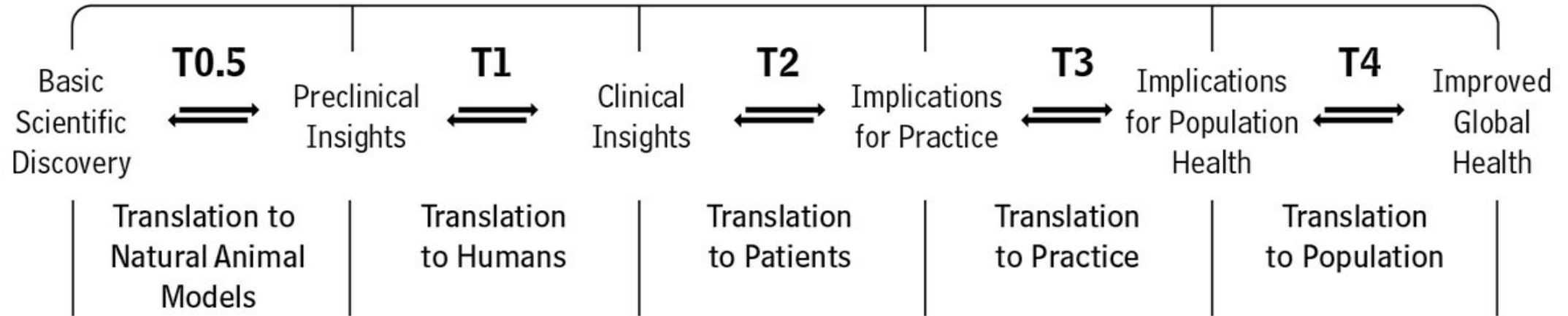


- **Catalyze** and enhance scientific discovery, innovation, dissemination and translation across the lifespan
- **Educate** and sustain a resilient, innovative and diverse translational science workforce
- Promote and ensure an efficient, safe, collaborative and integrated **research environment**
- **Engage stakeholders and communities** across the entire translational spectrum

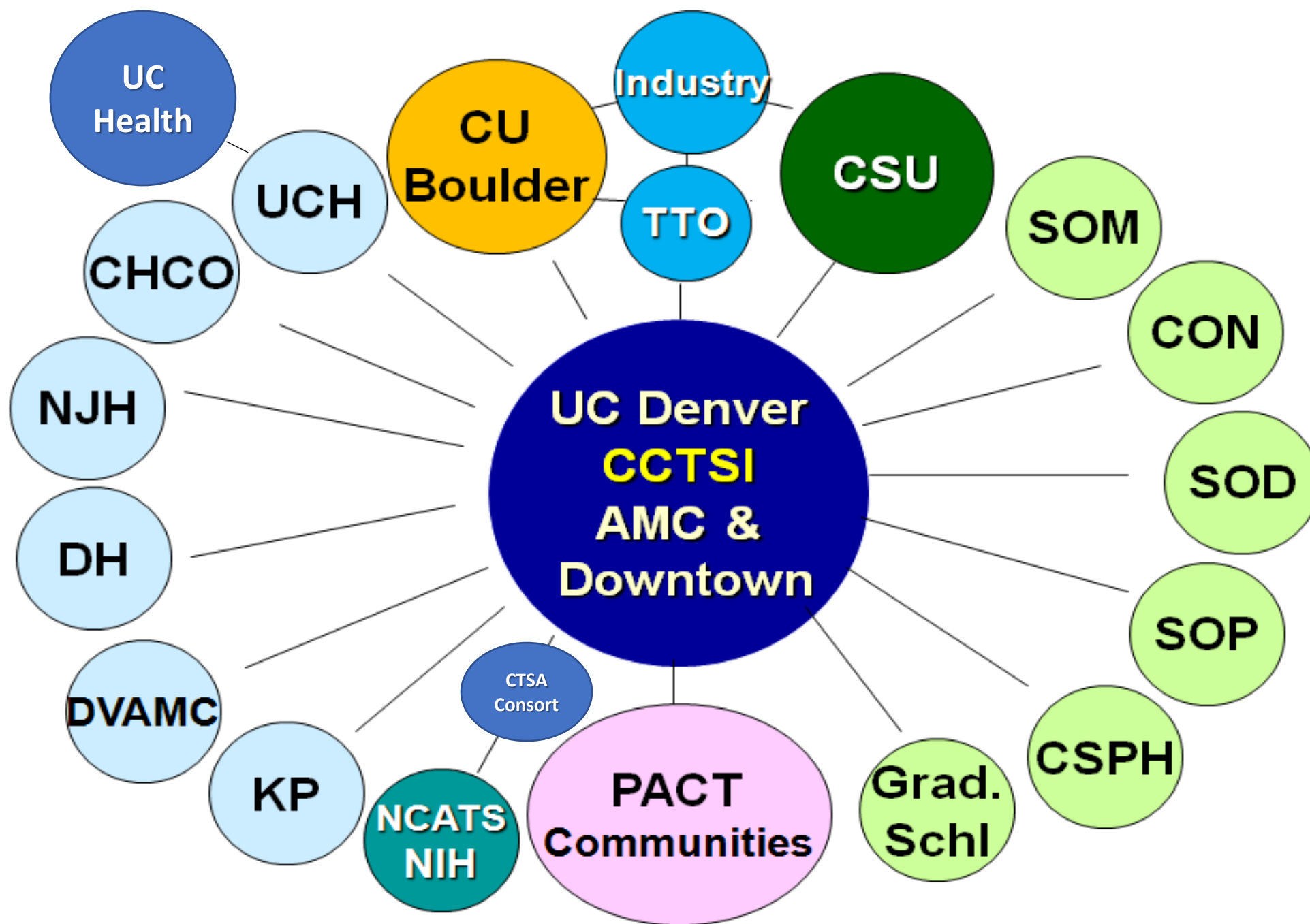
Spectrum of Translational Research

- Bi-Directional
- Collaboration
- Team Science

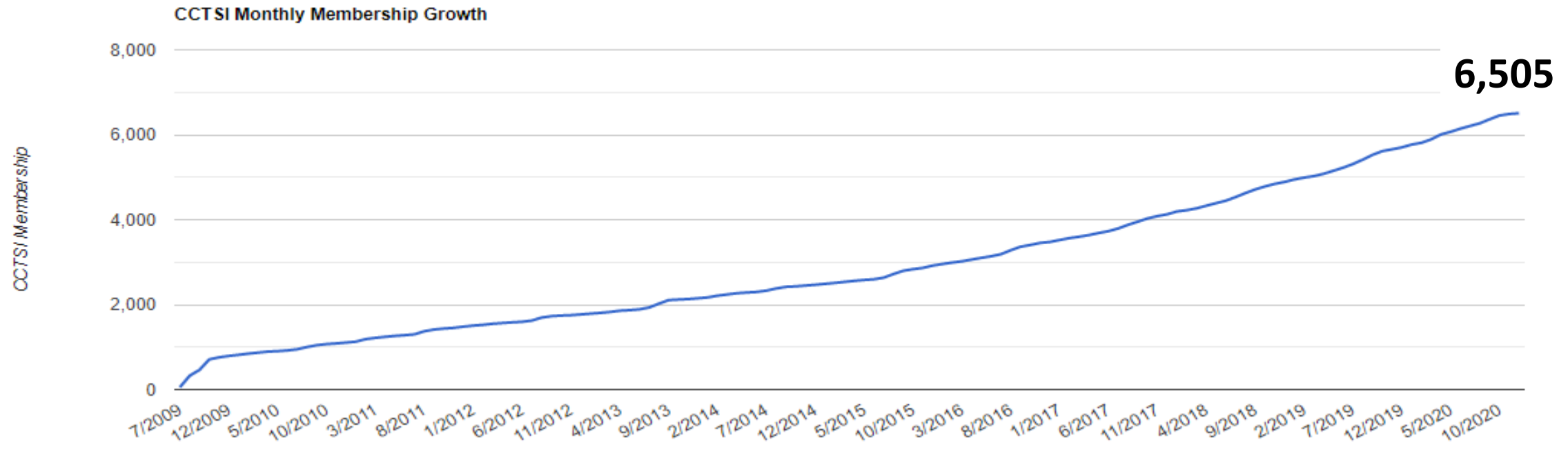
CLINICAL TRANSLATIONAL RESEARCH SPECTRUM



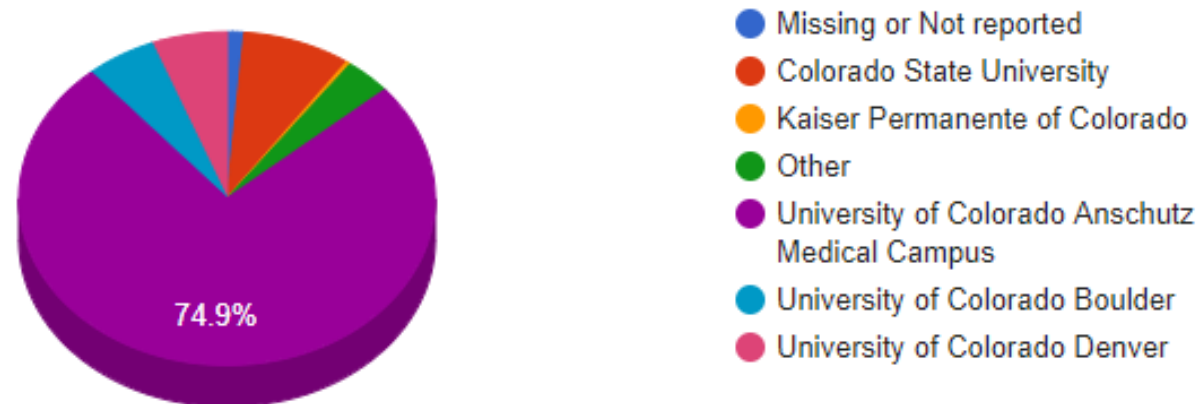
CCTSI Hub & Spokes



CCTSI Membership



CCTSI Membership by Academic Affiliation



CCTSI Leadership

Director: Ronald Sokol, MD **DFA:** Tim Lockie, MS, MBA

Director of Operations: Janine Higgins, PhD

Associate Directors:

- Wendy Kohrt, PhD
- Tell Bennet, MD, MS
- Alison Lakin, RN, JD
- Donald Nease, MD, MPH
- Thomas Campbell, MD
- Lisa Cicutto, PhD

CSU: Susan VandeWoude, PhD

CU- Boulder: Chris Desouza, PhD



CCTSI Programs & Resources

1. **Education, Training and Career Development** – KL2, TL1, CLSC, LITeS, etc.
2. **Clinical Research Resources & Facilities** (CTRCs – inpt., outpt., mobile; CReST)
3. **Community Engagement & Research** – Don Nease
4. **Dissemination – Implementation Research** – Bethany Kwan, PhD
5. **Team Science** – Jeni Cross, PhD
6. **Biostatistics, Epidemiology and Research Design** – CIDA (Nichole Carlson, PhD)
7. **Translational Informatics** – Tell Bennett, MD, MS
8. **Research Bioethics** – Marilyn Coors, PhD
9. **Regulatory Knowledge and Support** – Alison Lakin JD, RN
10. **Pilot Grant Programs** – Natalie Serkova, PhD
11. **Trial Innovation Network** – Hub Liaison Team
12. **Innovation and Entrepreneurship** – Cathy Bodine, PhD
13. **Early Life Exposures Program (ELEP) Research** – Teri Hernandez, PhD



CCTSI Website

- <https://cctsi.cuanschutz.edu/>

or “Google” CCTSI

WEBSITE:

6,000 - 7,000 visits per month

PROFILES:

15,000 – 20,000 visits per month

- Portal of entry
- Information, applications, links to services, RFAs, training, announcements, etc.
- **Membership** online – *quarterly Newsletter* (Found in Translation – Wendy Meyer)
- **Colorado Profiles**



Colorado Clinical and Translational Sciences Institute

<https://cctsi.cuanschutz.edu/>

Resources ▼


Training ▼

Funding ▼

Community Engagement ▼

News and Events ▼

About Us ▼

Volunteer for a Study 



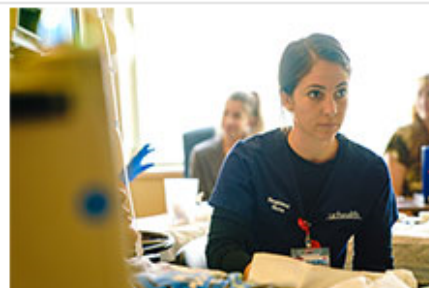
ACCELERATING RESEARCH TO IMPROVE HEALTH

The CCTSI helps build research teams of the future, speed the development of new treatments and improve human health



Resources and Services

CCTSI supports translational research by providing resources, integrating facilities and services, developing innovative research tools and catalyzing interdisciplinary research programs.



Funding

Each year, the CCTSI awards more than \$2 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. You can find more information on each grant and how to apply



Education, Training and Career Development

The Education, Training and Career Development (ETCD) program provides clinical-translational scientists and trainees with knowledge, training and career skills



Clinical Translational Research Centers

The CTRC provides infrastructure, resources and dedicated space to conduct clinical research.

Cite our grant

Become a member

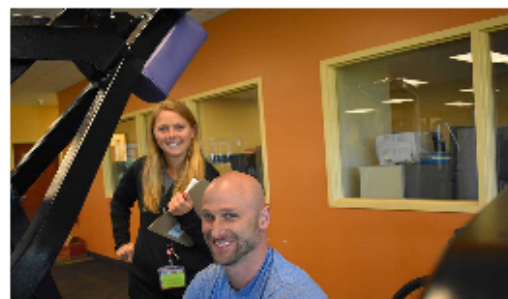
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Found In Translation
News from around the CCTSI



Mapping Our Molecules »

Jun 25, 2019, 12:00 AM by Wendy Meyer

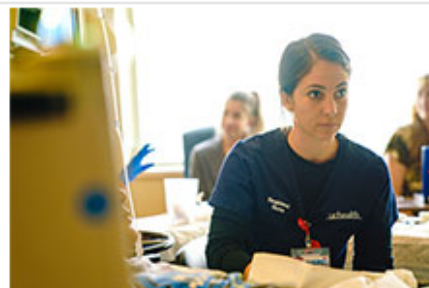
Why know that exercise is good for us. Professor Wendy Kohrt aims to find out why. She is leading an exercise study called MoTrPAC to develop a so-called molecular map of tissue-specific and circulating signals produced by physical activity.

Full story »



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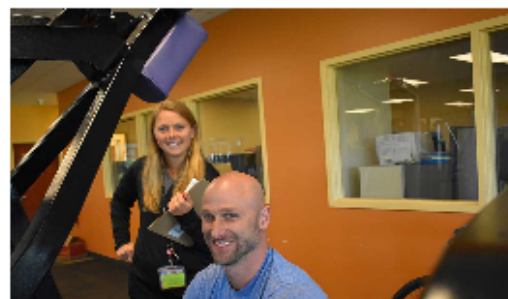
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Full story »



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[Jonathan Harris](#)

September 30, 2019

added a publication from: Applied and environmental

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Search for Investigators by Key Words



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[Carmen Ledesma-Feliciano](#)

October 2, 2019

added a publication
from: JFMS open
reports

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**Search for Investigators
by Key Words**



Keywords

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Search Results (38)

Click the **Why** column to see why a person matched the search.

Sort

Show

[More Search Options](#)

Name	Institution	Why
Cara Lynn Mack	University of Colorado Denver - Anschutz Medical Campus	Why?
Ronald J Sokol	University of Colorado Denver - Anschutz Medical Campus	Why?
Frederick M Karrer	University of Colorado Denver - Anschutz Medical Campus	Why?
Amy G. Feldman	University of Colorado Denver - Anschutz Medical Campus	Why?
Shikha Seksaria Sundaram	University of Colorado Denver - Anschutz Medical Campus	Why?
Rebecca Michelle Tucker	University of Colorado Denver - Anschutz Medical Campus	Why?
Frederick J Suchy	University of Colorado Denver - Anschutz Medical Campus	Why?
Michael R Narkewicz	University of Colorado Denver - Anschutz Medical Campus	Why?
Alexandra Leigh Kilgore	University of Colorado Denver - Anschutz Medical Campus	Why?

Ranked List of Researchers At CU

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Results: Contact info, Grants, Publications from PubMed, Networking

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Clinical Translational Research Centers (CTRCs)



- **UCH, CHCO, NJH, CU-B and Perinatal**
 - Inpatient and outpatient facilities – **no charge for space (industry studies excluded)**
 - Research **Nursing** – inpatient, outpatient, mobile teams (NICU, PICU, ED, etc.) – subsidized fee for service
 - Bio-nutrition, metabolic kitchen, whole room calorimeter and body composition
 - Vascular Ultrasonography and ECHO
 - Core laboratories & specimen processing
 - **Microgrants** to Jr. Investigators (\$10,000/yr. x 3)
 - SARC review of all protocols
 - **200** unique PI's conduct research on **>500 CTRC** Protocols each year (10,000- 15,000 visits/yr)



CTRC Medical Directors

- **UCH/Adult** – Thomas Campbell, MD
- **CHCO/Pediatrics** – Phillip Zeitler, MD, PhD
- **Perinatal** – Christopher Baker, MD
- **NJH** – Donald Leung, MD, PhD



<https://www.nationaljewish.org/research-science/clinical-and-translational-research/ctrc>

- **CU-Boulder** – Chris DeSouza, PhD and Brian Stauffer, MD
<https://www.colorado.edu/ctrc/>

Pilot Grant Awards

Natalie Serkova, PhD

- **5 Pilot Grant programs** – CO-Pilot, CMH, Community Engagement, New Methods, CU-CSU Collaboration Award
- **~\$900,000 available**
- **\$20,000, 30,000, \$60,000 levels**
 - Letter of Intent in August
 - Deadline September (end)
 - Peer Review in November- December
 - Start-up in January-April



CCTSI Rapid Turn-Around COVID-19 Pilots

- **March, 2020: CCTSI leadership developed \$100,000 C2R2 Pilot Grant Program and issued RFA in 3 days; applications due in 7 days**
- **60 letters of intent received; 55 applications received**
- **Review committee: 22 experts across affiliated institutions (reviews completed in 4 d)**
- **Awards issued and speedtypes activated and funded 3 days later**

CCTSI COVID-19 Research Related (C2R2) Pilot Program Awards (\$25,000)

PI	Affiliation	Project Title
David Prawel, PhD	Colorado State University	Additive Manufacturing of Certified PPE: A Path Towards Mass Production
J. David Beckham, MD	Anschutz Medical Campus	A prospective, observational cohort trial for the treatment of hospitalized COVID19 patients with high-titer anti-SARS-CoV2 convalescent serum
Anna Maw, MD	Anschutz Medical Campus	Rapid Point of Care Lung Ultrasound Implementation in the Evaluation of Hospitalized Patients with COVID
Brian Montague, DO	Anschutz Medical Campus	Prospective Identification of SARS-CoV2 Infection in Healthcare Workers



Translational Informatics

Tell Bennett, MD, MS

- **REDCap** – operated for entire campus by CCTSI – >9,000 users, >6,000 active projects
- **Health Data Compass** – enterprise-wide research data warehouse – Michael Kahn, MD, PhD Previous Director
- Colorado **PROFILES**, Scheduler, Harvest, LIS, Freezerworks
- **Data Delivery & Cohort Discovery** – TrinetX, Compass, ACT, N3C
- **Multiple applications** to support Grant Review and Education programs



Translational Informatics Team

- **Director:** Tell Bennett, MD, MS
- **REDCap team**
 - Amanda Miller, REDCap Senior Administrator and Team Lead
 - Jenn Mauck, REDCap Administrator
- **Infrastructure and Services Team**
 - Tom Yaeger, Director
 - Melanie Tsosie, Associate Director and Applications Specialist
 - Chris Caldwell, Web Manager
 - Matt Latus, Information Security Officer
 - Ambreen Zaver, Developer
 - Open Position, Systems Administrator

National COVID Cohort Collaborative (N3C)

- A **centralized**, secure portal for hosting **national** patient-level COVID clinical EHR data and deploying statistical methods and tools for clinicians, researchers, and healthcare – to answer pressing clinical and research questions
- **EHR data (UCH, CHCO)** entered by CTSA program institutions, distributed clinical data networks (e.g., PCORnet, OHDSI, ACT/i2b2, and TriNetX), and many other clinical partners and collaborators
- <https://ncats.nih.gov/n3c>



National
COVID
Cohort
Collaborative

Key N3C Stats – 6 Dec 2020

COVID-19 Positive
Patients*

372,716

Total Patients

2,146,059

Sites

34

Total Rows

2.0b

Procedures

152.5m

Lab Results

955.0m

Drug Exposures

359.1m

Visits

92.0m

Observations

120.6m

[Click to see more COVID Cohort key stats >](#)

N3C Data Enclave Access

- Researchers can access the **N3C Data Enclave**, a centralized national COVID-19 data analytics platform to enable the rapid

Contact Tell Bennett, MD, MS - Informatics Core for more details and access

- Secure data platform with powerful analytics capabilities
- Data – robust in scale and scope
- Harmonized data set
- Video: https://www.youtube.com/watch?v=0JPjw1_iRKY

Education, Training and Career Development

Lisa Cicutto, PhD



1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=14)
2. TL1 (T32) Pre- and Post-doctoral PhD training program
3. Clinical Sciences Graduate Program (Masters, PhD)
4. KL2 (K12) Research Scholar program - up to 3 yrs. of support – Ellen Burnham, MD
5. Support for Clinical Faculty Scholars Program – Anne Libby, PhD
6. Clinical Research Training and Education Program (CRSC)

Education, Training and Career Development

Lisa Cicutto, PhD, APN, RN



8. Leadership in Innovative Team Science (LITeS) – Judith Albino
9. Colorado Mentor (CO-Mentor) Training Program – Greg Austin MD
10. K-to-R Transition Grant Review – Maggie Wierman MD
11. Pre-K Award Assistance and Grant Review – Paul MacLean, PhD
12. Research Studios – Jane Reusch MD, Alan Prochazka MD
13. Innovation Corps @ CCTSI – Cathy Bodine, PhD
14. Teaming for Early Career Researchers – Jeni Cross, PhD



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Pre-K Grant Review Program

- Assist junior faculty and their mentors write successful career development awards
 - 5 criteria (candidate, career development, mentors, environment, and research plan)
- Mock grant reviews: 3 times a year
 - Applicants and mentors attend
 - K24 awardees, K12 directors, biostats, other K awardees are reviewers
 - Format: reviewers and then panel discusses, followed by Q&A
- Helpful materials on website relevant to K applicants



Letter of Intent due December 28, 2020



K to R Transition Program

- Pre-submission mock grant review process
- Faculty with K-level awards who are submitting first R-level grant award or any R-level grant submission
- Submit grant proposal for internal review about 4-6 weeks before submission to funding agency
 - Deadline for Letter of Intent
- Mock study section and written reviews
- PI and mentor - attend mock study section
- 3 cycles – NIH grant application deadlines
- **Maggie Wierman, MD 303-724-3952**



Research Studio Program

Jane Reusch, MD and Alan Prochazka, MD

- **Expert Panel** (5-6 person) formed to provide targeted advice about research project, grant application, idea generation, etc.
- T1-T2 or T3-T4 research topics
- **Studio sessions** are Face to Face (over Lunch)
 - ❖ 90 Minutes
 - Investigator presents brief summary (10-15 minutes)
 - Focused discussion with experts for 3 or 4 predetermined questions from the investigator - focus on problem-solving and the development of helpful solutions (60-70 minutes)
 - Moderator and panelists provide summarized comments (10-15 minutes)



Research Studio Process

- Web-based Consult Request – CCTSI website
- Studio Consult Categories:
 - ❖ hypothesis generation
 - ❖ study design – specific aims
 - ❖ grant review
 - ❖ implementation
 - ❖ analysis and interpretation
 - ❖ manuscript review
 - ❖ translation



Research Studio Dates

- Next Dates: Jan. 28, April 1, June 4 (4-5 Studios per session)
- Contact:

Dan Holtrop, MA

Studio Program Manager

Daniel.Holtrop@cuanschutz.edu



Excellent feedback and usefulness

"Very beneficial service and significantly improved the quality of my research project"

- *Investigator*

i-Corps@CCTSI

Cathy Bodine, PhD

- **i-Corp @ CCTSI**
- Teams of faculty, staff or students with a biomedical discovery or health innovation idea.
- Uses customer discovery methods for startups for academic researchers
- A team-based short course designed for faculty, staff and students
- Guides teams through early stages of customer discovery
- Test the business model hypotheses for a technology or idea
- Spring 2021 session - website



Innovation & Entrepreneurship Ecosystem at AMC



Technology Transfer Office

Accelerating

**Opportunity
Identification**

CCTSI

Fundamentals

Launch

AMC
Accelerator

Pitch Competitions

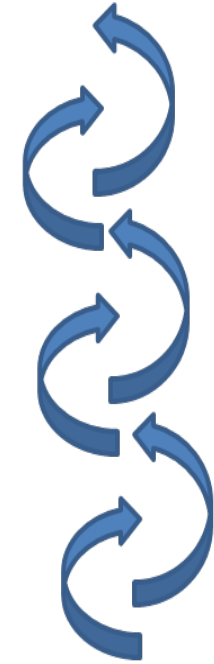
Incubating

Vetting

Idea Generation and Team Formation

Entrepreneurial Education Curriculum and Culture

*A virtuous cycle
of innovation and
entrepreneurship*



I-Corps
@NCATS
Team Training
Pilot Program

Community Engagement & Research Programs

Don Nease, MD

- Community Research Liaison (CRL) program
- Colorado Immersion Training in Community Engagement (CIT)
- Research Readiness Certification for Community Based Organizations
- Community Engagement Consults
- CE Pilot Grant Program
- Boot Camp Translation for Patient-Centered Outcomes: Facilitator Training
- Introduction to CBPR for Community-Academic Partnerships



Trial Innovation Network (TIN)

trialinnovationnetwork.org

- National CTSA Consortium effort to facilitate design and conduct of Multi-Site (NIH) Clinical Trials
- Provides local and national support for the entire study lifespan
 - Study design, central IRBs, study operations, data collection and analysis, recruitment and retention strategies, etc.
 - TIN Hub Liaison Team – Local linkage to national TIN
- Investigators can request a single service (e.g., single IRB) or complete study life cycle assistance
- First contact the Hub Liaison Team for assistance and guidance



Trial Innovation Network Hub Liaison Team

- **Director:** Adit Ginde, MD
 - **Medical Directors:** Tom Campbell, MD (UCH)
Jesse Davidson, MD (CHCO)
 - **Project Manager – Aaron Mobley PhD** Phone: 720-848-5523
aaron.mobley@cuanschutz.edu
 - **Contracting Lead** – Deb Barnard, MS, TK Keith, JD
 - **Central IRB Lead** – Christy Williamson
 - **Recruitment (Participants) Lead** – Barbara Hammack
- Local TIN Website, workflow, educational materials, etc.



RKS - Clinical Research Support Center (CRSC) — Alison Lakin, RN, JD

- FDA submissions
- Education and training on all aspects of study start up and management
- Assistance with IRB submissions
- Access to and maintenance of ClinicalTrials.gov records
- Research agreements (confidential disclosure agreements, clinical trial agreements and materials transfer agreements)
- Study drug/device management advice
- OnCore, the clinical trials management system

<https://research.cuanschutz.edu/crs>



Anschutz Health Sciences Building

- Planned occupancy Fall 2021
- All CCTSI Leprino 3rd Floor operations moving to 6th floor
- Two large procedure rooms (~300sf) to accommodate some activity that is currently performed IP
- Two negative pressure rooms
- Five chair infusion suite
- Building will have a dedicated research pharmacy



Diversity, Equity, Inclusion, Systematic Racism

- Education of CCTSI Staff
- Leadership education and commitment
- Position statement of commitment - accountable
- Expanding diversity of Leadership
- Incorporation of Community Members in CCTSI oversight committees
- Address inequities through CE&R program, pilot grant awards
- Diversity supplements



CCTSI is here to support you!

- <https://cctsi.cuanschutz.edu> or google CCTSI
- Become a Member (quick, free, powerful)
- Become familiar with the website
- Use PROFILES often
- Cite our Grants



QUESTIONS?

