Welcome CCTSI EAC to Colorado
April 10-11, 2024
External Advisory Committee

Steven Dubinett, MD
Dean, David Geffen SOM; Senior Associate Dean for Translational Research at UCLA, Director of Clinical and Translational Sciences Institute; UCLA (CTSA PI)

Alexander Krist, MD, MPH
Director of Community-Engaged Research at the Wright Center for Clinical and Translational Research, Professor of family medicine and population health at Virginia Commonwealth University
External Advisory Committee

Cynthia Morris, PhD, MPH
Sr. Associate Director and co-PI, Oregon Clinical and Translational Research Institute, Professor of Medical Informatics and Clinical Epidemiology, School of Medicine, OHSU

Tesheia Johnson, MBA, MHS
Deputy Director and Chief Operating Officer of Yale Center for Clinical Investigation and the Director for Clinical Research for Yale School of Medicine
External Advisory Committee

Dan Cooper, MD
Interim Executive Director of Institute for Precision Health at UC Irvine, Associate Director of Institute for Clinical Translational Science, Professor of Pediatrics

Peter Embi, MD, MS
Chair and Senior Vice President for Research and Innovation, Department of Biomedical Informatics, Vanderbilt University Medical Center
External Advisory Committee

Jareen Meinzen-Derr, PhD, MPH

Co-Director, Center For Clinical and Translational Science & Training, Professor Dept. of Pediatrics, Co-Director, Faculty Diversity, Equity & Inclusion, Cincinnati Children’s Hospital Medical Center, University of Cincinnati SOM (CTSA MPI)
NCATS Program Officer

Pablo Cure, MD

Program Director, Division of Clinical Innovation, NCATS, Digital & Mobile Technologies Section of NCATS
This Year’s Format for EAC Meeting

• In person/virtual sessions Wednesday pm, evening and Thursday am.
• Overview & Plans for year 1 of the UM1 grant cycle
• Emphasis this year will be on plans for CCTSI 4.0 (2023-30)
• Reports from Leaders of Modules within new structure
• Closed EAC Session
• Feedback Session
Progress Report of UM1 Yr. 1 and Summary of Future Directions and Goals

Ronald J. Sokol, MD, FAASLD
Director and M.P.I. of CCTSI
Assistant Vice Chancellor of Clinical and Translational Science
Chief Scientific Officer, Child Health
University of Colorado – Anschutz Medical Campus
Clinical and Translational Research Leadership – CU Anschutz

Vice Chancellor of Research

Thomas Flaig, MD
Professor of Medicine
Oncology
Clinical and Translational Research Leadership – CU Anschutz

Chief Clinical Research Officer UC Health
Associate Dean Clinical Research SOM

Thomas Campbell, MD
Professor of Medicine
Infectious Disease
Clinical and Translational Research Leadership – CU Anschutz

Chief Scientific Officer, Child Health
Associate Dean for Child Health Research, SOM

Ronald Sokol, MD
Distinguished Professor of Pediatrics
Pediatric GI, Hepatology, Nutrition
Clinical and Translational Research Leadership – CU Anschutz

Director of Operations, MPI, CCTSI
Vice Chair Research, Dept. of Medicine, SOM

Janine Higgins, PhD
Professor of Medicine
Endocrinology, Diabetes, & Metabolism
New Clinical and Translational Research Leadership – CU Anschutz

Director of Adult & Child Center for Outcomes Research and Delivery Science (ACCORDS)

Jerica Berge, PhD, MPH

Professor of Family Medicine, SOM
New Clinical and Translational Research Leadership – CU Anschutz

Executive Director, Center for Health Equity
CU Anschutz (new center on campus)

Deborah Parra-Medina, PhD, MPH
Professor of Family Medicine, SOM
Transitions
Stepping Down from Dean Position

John J. Reilly, Jr., MD
Dean, School of Medicine
Vice Chancellor for Health Affairs

Search for new Dean nearing completion
Transitions
Leaving CU Anschutz April 2024

Melissa Haendel, PhD
Former Chief Research Information Officer
Co-Director of Health Informatics Element
Professor of Biomedical Informatics, Biochemistry and Molecular Genetics
New Director of Health Informatics - pending
CCTSI Vision

Accelerate and catalyze the translation of innovative science into improved, equitable health and patient care for all
Spectrum of Translational Research
Emphasis in UM1 Grant

1. Address translational science – remove Roadblocks/Obstacles to efficiency, success and job satisfaction

2. Address diversity and inclusion at all levels
   Leadership, faculty, students, staff, community partnerships, enrollment in clinical research and trials, education, etc.

3. Address health disparities and health equity

4. Innovation – bring our research and data science to the community and to all patients/persons in need – disseminate and implement

5. Engage stakeholders, communities, build partnerships & trust and bidirectional communication channels

6. PEET – pragmatic, decentralized clinical trials embedded in EHR system (Element E)
CCTSI 4.0 UM1 Overall 6 Strategic Goals

**Goal 1:** Advance CTS by developing, demonstrating, and disseminating innovative programs to improve the efficiency and impact of translation across the entire T0.5 to T4 spectrum

**Goal 2:** Promote collaboration, team and data science, and partnerships to accelerate CTR locally, regionally and nationally

**Goal 3:** Partner locally, regionally and nationally with institutions, stakeholders and communities to develop innovative research programs that address health inequities and disparities
CCTSI 4.0 UM1 Overall 6 Strategic Goals

**Goal 4:** Develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research

**Goal 5:** Promote a safe and nimble research environment that can rapidly respond to urgent public health needs

**Goal 6:** Develop and disseminate CTS training programs that educate and sustain a resilient, diverse team of clinical research professionals
CCTSI 4.0 Grants

- **UM1** Funded in September 2023
  - UM1 Funding Period: Sept. 14, 2023 - July 31, 2030
- **Predoctoral T32:** Sept 20, 2023 – August 31, 2028
  - Lisa Cicutto, PhD, RN
- **Postdoctoral T32:** Sept 18, 2023 – August 31, 2028
  - Lisa Cicutto, PhD, RN
- **K12:** Dec. 1, 2023 – November 30, 2028
  - Ellen Burnham, MD
- **Total funding** from grants ~ $64 Million
CCTSI Leadership Team

**Director:** Ronald Sokol, MD, MPI

**Director of Operations:** Janine Higgins, PhD, MPI

**DFA:** Tim Lockie, MS, MBA

**Associate Directors:**
- Wendy Kohrt, PhD
- Lisa Cicutto, PhD, RN
- Alison Lakin RN, JD
- Donald Nease, MD, MPH
- Natalie Serkova, PhD
- Thomas Campbell, MD
- Adit Ginde, MD, MPH
- Bethany Kwan, PhD
Diverse Representation Among Leadership

CCTSI Leadership:

- 50% Female
- 50% PhD or equivalent

Representation across Schools & Depts in SOM, CON, CSPH, Engineering

CCTSI Exec Committee:

- 52% Female 55% PhD or other
- 2 URM Community Representatives

Representation across AMC Schools and Depts, and all Partnering Institutions (Universities and Hospitals)
CCTSI Community Partners

• >20 Community-Academic partnerships throughout the state, including multiple PBRNs (SNOCAP)

• Community Engagement & Health Equity (PACT Council)
  • Under-Resourced Populations:
    • Native Americans, LatinX, African-Americans, Rural populations, Nursing partnerships, Catholic churches, Ranching, LGBT, etc.
  • PACT Focus Groups:
    • San Luis Valley, Stapleton 2040, American Indian/Alaskan Native Programs, High Plains Research Network, Kaiser Patient/provider, LUCHAR
CEHE Reach in Colorado

CRL = Community Research Liaisons

% People of Color

PBRNs = SNOCAP
CCTSI Members

CCTSI Monthly Membership Growth

CCTSI Membership by Academic Affiliation

- Missing or Not reported
- Colorado State University
- Kaiser Permanente of Colorado
- Other
- University of Colorado Anschutz Medical Campus
- University of Colorado Boulder
- University of Colorado Denver

Total Members: 8,127
Total Research Grants – CU Anschutz

CU ANSCHUTZ SPONSORED RESEARCH FUNDING

- FY19: $553M
- FY20: $599M
- FY21: $654M
- FY22: $692M
- FY23: $705M

FEDERAL

NON-FEDERAL

27% increase since FY19

VCR – 2023 State of Research
Federal Grants Breakdown

FY23 SPONSORED AWARDS BY TYPE

$704.8M Total

$390.6M in Federal Funds

FY23 Federal Fund Breakdown

- NIH, 83% $322 M
- Other, 1%
- DHHS, 7%
- DOD, 6%
- VA, 2%
- NSF, 1%

VCR – 2023 State of Research
FY23 Research Metrics
CU Anschutz

1.5K+
Principal Investigators on Campus

800K
Square Feet of Laboratory Space

14K+
People Enrolled in Research Studies in FY23

3.5K+
Active Clinical Trials

18%
Growth in Clinical Research Studies since FY20

VCR – 2023 State of Research
Child Health Research Enterprise is the centralized administrative, operational and scientific home for child health research at Children’s Hospital Colorado and CU Anschutz.

150+ Team members at Children’s Colorado

1,100 Active clinical research studies supported

$69M Philanthropy raised in support of child health research since 2018

#8 Ranking for NIH funding*  
*Dept of Pediatrics and Children’s Colorado combined

Ronald Sokol, MD  
Chief Scientific Officer, Child Health

Jenae Neiman, RN, BSN  
Vice President, CHCO Research Operations

VCR – 2023 State of Research
IRB Timeline Improvements

Expeditied Median Days to Approval:
- FY17: 50
- FY18: 40
- FY19: 30
- FY20: 20
- FY21: 18
- FY22: 14
- FY23: 10

Full Board Median Days to Approval:
- FY17: 50
- FY18: 40
- FY19: 30
- FY20: 20
- FY21: 16
- FY22: 14
- FY23: 12

60% decrease from FY17 to FY23
54% decrease from FY17 to FY23

COMIRB application to be shortened from 76 to 20 pages

VCR – 2023 State of Research
Helping investigators to conduct, safe, successful, compliant research

5577 Active human subject research protocols

795 Confidentiality Disclosure Agreements (CDAs) completed

487 Clinical Trial Agreements (CTAs) completed in FY23

37.7 Tons of chemical waste safely disposed of in 2023 (to date)

Alison Lakin, RN, LLB, LLM, PhD
Associate Vice Chancellor
Office of Regulatory Compliance
Taking cellular therapy and precision medicine to new heights

2020 Human clinical trials launched using CAR T-cells developed at CU Anschutz

2022 Historic $200M philanthropic commitment established the Gates Institute with Terry Fry, MD at helm

2023 Gates Institute celebrates official launch at Transforming Healthcare event
ANNUAL HIGHLIGHTS

189
Patents filed last year

145
New inventions by faculty

41
New licensing deals

$35M
Gross revenue to campus

Ranked a Top 5 Innovation Hub by the NIH and No. 4 Leading Academic Institution by Nature’s Innovation Index.

CU Innovation’s Women-Led Innovation Event, April 2023
Publications “Ranking”
University of Colorado – Anschutz

Deep postnatal phenotyping of a new mouse model of nonketotic hyperglycinemia.


The study was supported by a grant (CNS-X-19-103) from the University of Colorado School of Medicine and the Colorado Clinical Translational Science Institute, which is supported by NIH/NCATS Colorado CTSA Grant Number UL1 TR002335. Contents are the authors' sole responsib ...
Ongoing CCTSI Response to COVID-19

• **CHCO CTRC** – facilitated largest enrollment center (10% of all enrollees – 80 sites, 2,268) for Pfizer/BioNTech COVID vaccine trial in 5-11 yr-old children (NEJM Nov 9, 2021)

• **Adult and Pediatric CTRCs** - facilitated numerous adult and child vaccine and therapeutic trials

• **CEAL** site for Colorado (Nease)   **ONGOING**
  NHLBI

• **mAb** - Monoclonal Ab Real World Evidence study (Admin Supplement – Ginde-led Team)
  NCATS

• **RECOVER** (Long COVID) – Clinical Cohort Site (Mtn. States Consortium - Erlandson), and Real-World Evidence Data Center- N3C (Haendel, Bennett)   **ONGOING**
  NHLBI
Diversity, Equity, Inclusion, Social Justice

CCTSI DEI/SJ Committee and CEHE PACT Council

- DEI and Land Acknowledgement Statements posted on our home page
- Examining our programs and hiring practices for systematic racism
- Surveyed our staff for DEI training readiness
- Mandatory DEI training for all CCTSI staff
- Considering mechanism to train all Clinical Research Coordinators on campus (n=600) in DEI/SJ
- Revising Selection Processes for WFD programs
- Coordinate with Regina Richards PhD, VC DEI &CE, and Dominic Martinez, Asst VC Diversity, Equity, Inclusion & Community Engagement – Pathway (Pipeline) Programs and many others
- Coordinating with new Center For Health Equity
- Posted “COVID-19 Impact on Latinos” Fact Sheet on website
Professional Workforce Development

1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=25) – Pathway Program

2. T32 Pre-doctoral and Post-doctoral training programs

3. Clinical Sciences Graduate Program (PhD, Masters)

4. K12 Research Scholar program - up to 3 yrs. of support

5. Clinical Research Training and Education (CRSC)

6. Support for Clinical Faculty Scholars Program
Professional Workforce Development

7. Colorado Mentor Training Program (CO-Mentor)
8. K-to-R Transition Grant Review
9. Pre-F Award grant Review
10. Pre-K Award Assistance and Grant Review
11. Research Studios
12. Innovation Corps (I-Corps)
13. Teaming and Leading for Early Career Researchers
14. Communicating Your Science to the Public
Clinical Translational Research Centers (CTRCs)

- UCH, CHCO, NJH & CU B
  - Inpatient and outpatient facilities and mobile teams
  - Nursing, Nutrition, metabolic kitchen, whole room calorimeter, body composition, exercise physiology, vascular ultrasonography and ECHO, Core laboratories & specimen processing
  - **Microgrants** to Jr. Investigators ($10,000/yr. x 3)
  - **200 Pl’s > 500 CTRC Protocols** each year (10,000 - 15,000 visits/yr)
Trial Innovation Network Hub Liaison Team

- **Director**: Adit Ginde, MD, MPH
- **Medical Directors**: Tom Campbell, MD (UCH) and Jesse Davidson, MD (CHCO)
- **Project Manager**: Ben Echalier
- **Contracting Lead**: Amanda Peng
- **Central IRB Lead**: Christy Williamson
- **Recruitment (Participants) Lead**: TBD
- **Navigator**: Cynthia Sneddon

  Local Website, workflow, educational materials, etc.
National CTSA Consortium Involvement

- Ronald Sokol, MD – National CTSA Steering Committee 2020-2023
- CD2H - Melissa Haendel, PhD
- N3C – Melissa Haendel, PhD and Tell Bennett, MD, MS
- Members of all Enterprise Committees
- U01 CCIA grant – Telehealth Research in Pediatrics (SPROUT)
- Northern LITeS (University of Minnesota CTSA)
- I-Corps@CTSA national expansion – Cathy Bodine, PhD (UAB U01)
- COHA – Sue VanDewoude, DVM, Dean Veterinary School CSU
- Several CCIA U01 grants undergoing review
- mAb, CO-CEAL, RECOVER
## CCTSI Operating Budget: FY 2024

(Yr. 1 of new grant cycles)

<table>
<thead>
<tr>
<th>CCTSI Programs</th>
<th>NIH CTSA Grants (Total)</th>
<th>Chancellor &amp; VCR Funds</th>
<th>UCH Support</th>
<th>SOM Support</th>
<th>SOM Addn'l Support</th>
<th>CHCO Support</th>
<th>TOTAL</th>
<th>Percent Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Strategic Management</td>
<td>$1,044,677</td>
<td>$491,573</td>
<td>$133,263</td>
<td>$169,621</td>
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<td>$1,839,134</td>
<td>14%</td>
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<tr>
<td>C1. Workforce Development</td>
<td>$714,361</td>
<td>$152,133</td>
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<td>$-</td>
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<td>$866,493</td>
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<tr>
<td>C2. Community Engagement</td>
<td>$877,455</td>
<td>$134,263</td>
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<td>$-</td>
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<td>$1,011,718</td>
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<td>D1. Resources &amp; Services (CTRC-RKS-BERD-Ethics-)</td>
<td>$2,821,333</td>
<td>$392,029</td>
<td>$1,154,502</td>
<td>$30,380</td>
<td>$200,000</td>
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<td>$4,598,243</td>
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<td>D2. CTS Pilot Grants</td>
<td>$669,754</td>
<td>$10,594</td>
<td>$10,594</td>
<td>$500,000</td>
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<td>$1,190,942</td>
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<td>D3. Health Informatics</td>
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<td>$327,506</td>
<td>$40,726</td>
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<td>$2,625,823</td>
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<td>E. CTS Research Program</td>
<td>$415,753</td>
<td>$2,731</td>
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<td>$-</td>
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<td>$418,484</td>
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<tr>
<td>Other: Innovation Ecosystem &amp; Early Life Exposures</td>
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<td>$259,238</td>
<td>$-</td>
<td>$-</td>
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<td></td>
<td>$259,238</td>
<td>2%</td>
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<tr>
<td><strong>Total UL1 Program</strong></td>
<td><strong>$7,700,924</strong></td>
<td><strong>$1,770,067</strong></td>
<td><strong>$1,339,086</strong></td>
<td><strong>$500,000</strong></td>
<td><strong>$200,000</strong></td>
<td><strong>$1,300,000</strong></td>
<td><strong>$12,810,077</strong></td>
<td><strong>100%</strong></td>
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<td>Total K12 Program (6 Scholars)</td>
<td>$1,081,441</td>
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<td>$1,081,441</td>
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<tr>
<td>Total T32-Postdoc Program (4 Trainees)</td>
<td>$376,003</td>
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<td>$376,003</td>
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<td>Total T32-Predoc Program (8 Trainees)</td>
<td>$356,292</td>
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<td>$356,292</td>
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<td><strong>Total CCTSI Program Budget</strong></td>
<td><strong>$9,514,660</strong></td>
<td><strong>$1,770,067</strong></td>
<td><strong>$1,339,086</strong></td>
<td><strong>$500,000</strong></td>
<td><strong>$200,000</strong></td>
<td><strong>$1,300,000</strong></td>
<td><strong>$14,623,813</strong></td>
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