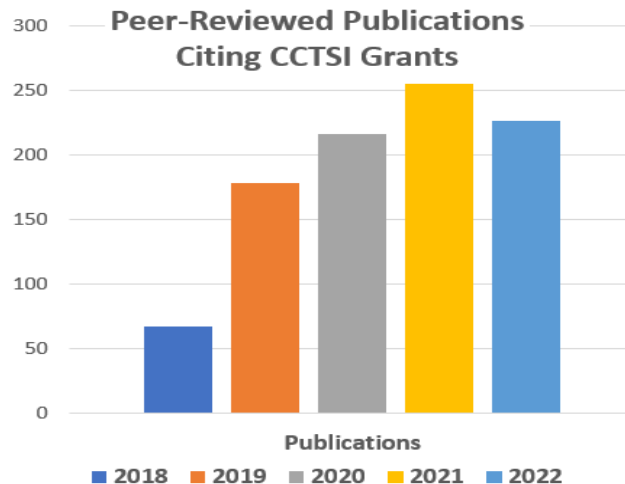


FACILITIES AND OTHER RESOURCES

Peer-Reviewed Publications Resource

The CCTSI infrastructure, Resources and Services, Community Engagement and Health Equity program, training and career development programs, informatics resources, pilot grant funding, and research facilities and personnel support hundreds of new and ongoing research studies and trials each year at CU Anschutz, CU Boulder, Colorado State University and our Partnering Hospitals and Health Care Systems as well as our



Community Organization collaborations. The impact and dissemination of the results of this work is achieved through a number of channels, one of which is through peer-reviewed publications in the biomedical literature. The FOA for this UM1 grant application does not any longer require a list of publications derived from UL1 grant funding in the prior grant cycle. However, to illustrate the valuable research community resource provided by the productivity of the CCTSI Members in this context, the following figure demonstrates the number of PubMed peer-reviewed publications per year in the current CCTSI grant cycle (2018-2023) that cite our CTSA NCATS grant numbers. Following the year that the grant funding has commenced (2018) and after the bulk of the research projects reach fruition (Year 2-3), there are approximately 200-250 peer reviewed publications per year derived from CCTSI support that appear in highly cited and impactful journals. Many more publications utilize some of the CCTSI resources (e.g., REDCap for database or survey management, BERD consultation) but do not cite the CCTSI grant support for these services.

Colorado Clinical and Translational Sciences Institute

The Colorado Clinical and Translational Sciences Institute (CCTSI) was established in 2008 with funding from the Clinical and Translational Science Award (CTSA) initiative of the National Institutes of Health (NIH) and substantial support from the involved institutions. It is a collaborative Partnership including 4 university campuses, 5 hospitals and health care organizations, several state health related agencies, and ~20 community based organizations. CCTSI is headquartered within the office of the Vice Chancellor of Research at the CU Anschutz Medical Campus in Aurora, Colorado. CCTSI aims to transform existing clinical and translational research and training efforts into a shared research enterprise for the state of Colorado. The **Vision of the CCTSI** is to accelerate and catalyze the translation of innovative science into improved equitable health and patient care for all. To achieve this vision, the **Mission of the CCTSI** is to:

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 will address health inequities and disparities.

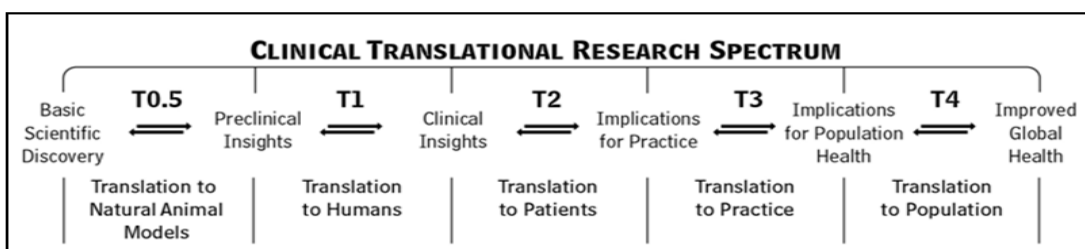
Goal 4: Further develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.

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

The CCTSI is an Institute within the University of Colorado, based at the University of Colorado Anschutz Medical Campus. As such, CCTSI Program Directors and staff are generally housed within their home department, according to faculty affiliation. The Institute’s resources, therefore, are distributed across the schools, campuses, and affiliated hospital that it serves. These include 4 Clinical Translational Research Centers (CTRCs) providing inpatient and outpatient clinical research resources at University of Colorado Hospital (UCH), Children’s Hospital Colorado (CHCO), National Jewish Health (NJH), and CU Boulder; contact points at each hospital; and programs located across CU Anschutz, downtown campus, our affiliated institutions across Colorado, and the hospitals. The CCTSI provides office space for administrative staff in the new Anschutz Health Sciences Building, located on the CU Anschutz Medical Campus. This space also houses conference rooms and open workspaces that allow CCTSI Program Directors and staff to collaborate and work together. The CCTSI supports the full spectrum of translational research, including what we label as **T0.5 translation (Figure 1)** – the translation from basic science and mouse pre-clinical research models into Natural Animal Models of Human Disease (dogs, cats, horses, pigs, others) in which the biology, physiology, genetics and pathology may closely resemble that present in similar human diseases. This allows more rapid testing of new diagnostic and treatment strategies in more realistic animal models before human patients are exposed to these novel approaches.

Figure 1. Spectrum of Clinical and Translational research



An Executive Committee, chaired by the CCTSI Director and Contact Principal Investigator, Ronald J. Sokol, MD, oversees operations and decision making. Dr. Sokol reports to the Vice Chancellors for Research and the Vice Chancellor for Health Affairs (the Dean of the School of Medicine), who in turn report to the Chancellor at CU Anschutz. The CCTSI involves the six health professional schools and colleges located at CU Anschutz; the Schools of Engineering and Applied Science, Liberal Arts and Science, and Education and Human Development at CU Denver; the Colleges of Arts and Sciences and of Engineering and Applied Science at University of Colorado, Boulder; and the colleges of Veterinary Medicine and Biomedical Sciences, Liberal Arts, Health and Human Services, and Engineering at Colorado State University. Affiliated institutions include 5 local hospitals and health care organizations: University of Colorado Hospital (UCH), Children’s Hospital Colorado (CHCO), Denver Health (DH), National Jewish Health (NJH), and Rocky Mountain (Denver) Veterans Affairs Medical Center (DVAMC). Faculty, trainees, and research staff at each of these institutions may become CCTSI Members (through an online membership registration) to access CCTSI resources. Through the CCTSI’s Partnership of Academicians and Communities for Translation (PACT), our community engagement and research program, it has ~20 established Community-Academic partnerships throughout Colorado, involving diverse and underserved populations throughout the state. This collaborative network of universities, hospitals, and the communities they serve have successfully promoted excellence in health care professional training and cutting-edge research programs and innovation for the past 30 years.

Investigators from all areas of biomedical, biobehavioral and health services research use the CCTSI to access resources for innovative interdisciplinary research and clinical and translational sciences training. The CCTSI requires Membership of faculty, research associates and post-Docs, trainees, community members, private companies, and public entities to access and use CCTSI resources, training programs or facilities. As of December 2022 there were > 7,000 CCTSI Members registered among our Partnering Institutions.

CU ANSCHUTZ PROGRAMS AND RESOURCES **University of Colorado Anschutz Medical Campus**

The University of Colorado Anschutz Medical Campus (CU Anschutz) is the largest academic health center in the Rocky Mountain region which brings together on the same campus three major hospitals and educational, administrative, and research facilities for all six health science schools of the University of Colorado. The 11.3 million ft² of state-of-the-art facilities has benefited from over \$4 billion of investments to date. The 230-acre campus provides adjacencies of clinical, educational, and research facilities all within walking distance of each other, building a new culture of collaboration among clinicians, investigators, and educators that invigorates research and innovation. An adjacent biotechnology park helps facilitate close collaboration between University investigators, industry, and the private sector.

CCTSI

Biostatistics, Epidemiology, and Research Design (BERD) Core

Expertise in biostatistics and research study design is a fundamental component of effective science and absolutely essential to the CCTSI. The cost of poor research design, inadequacies in the conduct of research, and bad practice in analysis and interpretation has been well documented in the biomedical literature and in the popular press. As such, the CCTSI has the BERD Core. It is a broadly accessible, yet discrete, study design and analysis resource that fills an otherwise unsupported need with a goal to advancing the efficiency and effectiveness of completing clinical or translational research projects. The CCTSI-BERD Core is fully integrated with the CU Anschutz's campus wide study design and data analysis infrastructure called the Center for Innovative Design and Analysis (CIDA), which is housed administratively in the Colorado School of Public Health (CSPH) with faculty appointments in the Department of Biostatistics and Informatics. This integration includes shared leadership (Dr. Carlson directs both BERD and CIDA and two BERD members Drs. Sammel and Kechris serve as Associate Directors of CIDA). 17 PhD faculty, 13 MS faculty, and 14 student research assistants comprise the faculty and staff of CIDA. Of those, 16 have some portion of effort towards BERD objectives. The BERD Core has four resource areas: 1) consultation and study design, 2) team formation, 3) new tool development (in the informatics section) and 3) education of clinical and translational scientists in biostatistics/study design principles and new to this application, education of BERD members in team science and collaboration skills. In addition, the Core co-develops larger projects to solve problems impacting clinical and translational science. This includes how to transform methods into usable products through R package development, tools for making consultation and analysis more reproducible, and new to this application, data driven strategic staffing and training.

We have a project funding and management system that continues to evolve to be responsive to both the CCTSI and broader CTSA objectives. Projects are funded and managed through three main mechanisms:

First hour free: The initial consult (either through office hours or project registration) is funded with BERD resources. The initial consult may necessitate a longer-term arrangement as outlined below.

Biostatistics Collaboration and Consultation: Guided by a simple scope of work (developed in the initial free 1-hour meeting). Consultations for analysis are fee-for-service or cost-shared using BERD funds for proposal development/study design for high priority investigators or for more extensive study design and analysis for compelling cases.

Long-term collaboration agreement: Agreements that are arranged and funded by individual departments or research units/centers. Collaboration agreements provide salary on a %FTE basis to support an individual biostatistician's collaborative work with investigators in that department, unit, or center.

Prioritization of projects: The project prioritization system is managed by the BERD Executive committee and evaluated at least annually. An initial prioritization could include prioritizing under-represented minorities, projects/proposals addressing an emergent public health issue, junior investigators/trainees from small units not covered under a collaborative agreement, proposals using new data sources or requiring innovative study design. Projects receiving BERD resources are already tracked weekly by each member in our smartsheet system and we will continue that approach for this proposal.

Computer

The CSPH at CU Anschutz Medical Campus is equipped with over 160 computers and workstations. CSPH faculty have computers, and laser printers for their use. University computing facilities provide access to email, Internet, and bibliographic databases. Information technology specialists are available through a SOM-IT contract. We partner with Health Data Compass and extensively use its cloud based Eureka system to conduct analyses requiring a HIPPA compliant computing environment. We also maintain a research computing environment for other large scale projects and methods development and simulation. The server is a Dell PowerEdge R740XD, with Intel Xeon Gold 6152 2.1G X (2) CPU, 44 cores, 1TB memory, 240 SSD X (2) mirrored disk operating system, and 14TB X (6) RAID 6 corresponding to ~50TB of usable disk storage. The operating system is CentOS 7.x, and common research software are available such as R, R Studio, MatLab, Python, and Java.

Office

BERD space is primarily located within the CSPH in the Fitzsimons Building with 25,410 square feet of state-of-the-art office space. In June of 2019 they moved into a newly renovated 4th floor office space with ~10,000 square feet of space shared with the Department of Biostatistics and Informatics. The school provides basic furniture, fax machines, copiers, and non-research related office supplies. In addition, the CSPH facility provides meeting and conference rooms, with video conferencing capabilities, that can be scheduled for project use as needed. The Center of Innovative Design and Analysis and the BERD have a combination of individual and shared offices and additional open office space in Fitzsimons all of its members members. The project managers in the BERD are housed in Fitzsimons adjacent to the Director.

Scientific Environment

In July 1, 2008, the newly established CSPH was the first and only school of public health in the Rocky Mountain Region, attracting top tier faculty and students from across the county, and providing a vital contribution toward ensuring our region's health and well-being. Collaboratively formed by the University of Colorado Denver, Colorado State University and the University of Northern Colorado, CSPH provides training, innovative research and community service to actively address public health issues, including chronic disease, access to health care, environmental threats, emerging infectious disease, and costly injuries.

The mission of the Colorado School of Public Health is to promote the physical, mental, social and environmental health of people and communities in the Rocky Mountain Region and globally. The mission will be accomplished through collaborations in education, population-based research, and community service that bring together institutions, agencies and diverse populations.

Department of Biostatistics and Informatics: This Department of Biostatistics and Informatics is housed in the Colorado School of Public Health. It offers three graduate training programs and provides the major service teaching for the master's of public health training programs. The Department has over 2-dozen research and tenure track faculty, a growing master's training based and more than a dozen research assistant training positions for students. The tenure track faculty maintain their own independent funding in diverse areas such as missing data, smoothing splines, health services research, Bayesian modeling, genetics/genomics, machine learning, causal modeling and imaging analysis of the brain and lung. The Department contributes to over \$85M in collaborative research funding on the Anschutz Medical Campus along. It also leads and maintains substantial collaborations among the premier Centers on the Campus including the Colorado Clinical and Translational Science Institute and the Colorado Comprehensive Cancer Center and directs the campus wide collaboration and consultation center (CIDA described below).

Center of Innovative Design and Analysis (CIDA)

The CIDA is a campus wide resource for establishing and supporting collaborative and consulting relationships with clinical and health researchers, primarily at the CU Anschutz Medical Campus (cida.cuanschutz.edu). CIDA is a campus wide research and resource center for establishing and supporting collaborative and consulting relationships with clinical and health researchers. CIDA has four major businesses: 1) general consulting for short term projects, 2) in-depth collaboration and team formation, 3) external business partnerships and 4) primary analytic research, which includes a goal to establish data coordination units and grow our methodology funding. CIDA has a strong partnership with the BERD, Department of Biostatistics and Informatics of the CoSPH and SOM and has 17 PhD faculty, 14 MS faculty, and 14 graduate student research assistants. All have academic appointments in the Department of Biostatistics and Informatics and a subset of

the faculty and MS participate in the BERD. The range of expertise is substantial and varied. Some areas include: pragmatic trials, innovative study design, analysis of EHR data, Bayesian modeling, clinical trials, causal inference, SEM and mediation analyses, microbiome, 'omics (RNAseq, methylation, proteomics, metabolomics among others), along with more standard approaches of longitudinal analysis, survival analysis, joint modeling, and others. They maintain over 20 collaborative partnerships with campus units represented from every school. They also conduct primary research and have external funding to support research in lung CT imaging, multi-omics analysis, application of SEM methods, data visualization, and innovative clinical trial design.

Clinical Translational Research Centers (CTRCs)

Our network of four CCTSI Clinical Translational Research Centers (CTRCs) are our clinical research units that provide inpatient and outpatient research facilities. The CTRCs have their original foundation in the enormously effective Adult and Pediatric GCRC facilities, which were continuously NIH-funded for 46 and 45 years, respectively, before the NIH transitioned the GCRC grant program to its CTSA initiative.

The CTRCs have been transformed since this transition and now provide resources for all phases of clinical trial development and conduct, critical care (adult and pediatric), and expanded multidisciplinary coordinated clinical research support. CTRC facilities are provided at University of Colorado Anschutz Medical Campus (UCH and CHCO), University of Colorado Boulder, and National Jewish Health. Available CTRC resources include dedicated inpatient and outpatient research space and equipment, expert research nursing, Core laboratories, and nutrition services. All CTRC services are available to investigators on a fee-for-service basis.

Adult CTRC

The adult CTRC provides the space, staff, and equipment necessary to conduct a broad range of specialized research procedures in primarily adults, including measurement of insulin sensitivity (insulin and glucose clamps, OGTT, IVGTT), body composition measurements, medication administration and infusions, bronchoscopies, fat and muscle biopsies, VO₂max and graded exercise tests, echocardiography for vascular and cardiac studies, sleep studies (acute and chronic) with polysomnography, measurement of total energy expenditure and rates of macronutrient utilization, conduct of short- and long-term exercise and dietary intervention studies, and specimen collection and processing. All procedures are supervised by highly-qualified and experienced personnel. All staff receive HIPAA and Good Clinical Practice training. Nurses are Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), and ONS (Chemotherapy) certified. Health technicians are BLS certified.

The Adult Inpatient CTRC has 7,226 sq ft of inpatient space located on the 12th floor of UCH at CU Anschutz, has seven beds in five rooms, and a wet lab for sample processing. Additional unique resources include an inpatient whole room calorimeter for the measurement of 24-hour energy expenditure and substrate oxidation, and a sleep laboratory with adjacent monitoring space for polysomnography. Experienced research nursing and health technician support is available.

The Adult Outpatient CTRC moved to 7,700 sq ft of newly designed space in the Anschutz Health Sciences Building, which opened in April 2022. The adult CTRC outpatient research clinic houses an infusion room (5 chairs), phlebotomy room (4 stations), exercise testing room (3 stations), muscle function room (isokinetic dynamometer), body composition room (DXA, HR-pQCT), secure medication storage room (approved for FDA controlled substances, including Schedule 1), sample processing room, two negative pressure rooms, two interview rooms, two extra-large procedure rooms with beds and private bathrooms (similar to an inpatient room) suitable for conducting neurology studies and hyperinsulinemic euglycemic clamps, four regular procedure rooms with beds (including one for RMR and one for echosonography), and 10 exam rooms with exam tables. There is a charting/work area with 9 computer work stations that can be used by research team members. An adjacent 3,500 sq ft state-of-the-art research exercise training facility (fully equipped for endurance and resistance training) is available for exercise intervention research. The CTRC clinical outpatient facility is generally open weekdays 7am – 4pm. During these hours, experienced physician assistant, research nursing, health technician, laboratory, and nutrition support is available.

The Adult CTRC has 10.9 FTE of research nurses, 2.8 FTE of health technician support, a 1.0 FTE sonographer, 0.5 FTE physician assistant, and 0.3 FTE DXA technician. These research professionals have extensive experience in conducting and documenting research for a diverse patient population from 12 to 90 years of age, both healthy and with a range of diseases such as diabetes, obesity, cardiovascular disease, renal disease, COPD, HIV and AIDS, chronic viral hepatitis, various forms of cancer, alcoholism, etc.

Equipment

- Portable indirect calorimetry (IC): True Max 2400 and TrueOne 2400 Metabolic Measurement Systems (Parvo Medics, Sandy UT), Ultima CPX 5530 (Medgraphics Corp, Saint Paul, MN)
- Maximal and submaximal exercise testing: Corival Ergometer and Lodebike 906900 (Lode Holding Company, Groningen The Netherlands), Velotron Pro exercise bike (RacerMate Inc, Seattle WA)
- Body composition measurement (Dual X-ray Absorptiometer): Horizon W (Hologic, Marlborough, MA)
- Bone and muscle assessment by high resolution peripheral quantitative computed tomography (XtremeCT II HR-pQCT; Scanco Medical, Switzerland)
- Stress Testing: Quinton Q-Stress Cardiac Stress Testing System with treadmill (Mortara, Milwaukee WI)
- CSMi Humac Norm isokinetic dynamometer (Computer Sports Medicine Inc, Stoughton, MA)
- Whole Room Calorimeter: CO₂ Analyzer AO2000 System (ABB Inc, Wickliffe OH), differential O₂ Analyzer Sable FC-2, Oxygen Analyzer (Sable Systems, Las Vegas, NV), Oxymat 6 Gas Analyzer (Siemens, Washington DC)
- *Peripheral Quantitative Computed Tomography (pQCT)*: Large Bore Scanner XCT 3000 (Orthometrix Inc, Naples FL)
- Cardiovascular Imaging: Ultrasound Vivid 7 and Vivid E9 (GE Healthcare, Pittsburgh PA)
- Cardiac Monitoring: M8004a Cardiac Monitoring System (Philips, Andover MA)
- Sample Processing: 3 x Algra 6r refrigerated centrifuges (Beckman Coulter, Brea CA)
- Bronchoscopes: 2 x Olympus Airway Mobile Scope MAF Type TM (Olympus America, Center Valley PA), and 2 x Pentax FB-18BS Bronchoscope (Montvale, NJ)

Pediatric CTRC at Children's Hospital Colorado (CHCO)

Facility

The CHCO CTRC provides the space, staff, and equipment necessary to conduct a broad range of research procedures in children, including, but not limited to, measurement of insulin sensitivity (insulin and glucose clamps, OGTT, IVGTT), body composition measurements, medication administration and infusions, bronchoscopies, fat and muscle biopsies, maximal and submaximal exercise tests, echocardiography for vascular and cardiac studies, measurement of total energy expenditure and rates of macronutrient utilization, and conduct short- and long-term exercise and dietary intervention studies, as well as specimen collection and processing. All procedures are supervised by highly qualified and experienced personnel. All staff receive HIPAA and Good Clinical Practice training. CTRC Nurses are Pediatric (PALS), Advanced (ACLS), and Basic Life Support (BLS) certified.

The CHCO CTRC has up to four inpatient beds located on the 9th floor of CHCO at the CU Anschutz Medical Campus and an adjacent wet lab for sample processing. The CTRC utilizes this space as needed and, if patient rooms are not being utilized, they are released for hospital use. Experienced research nursing support is available 24h/d, 4d/wk.

The CHCO Outpatient CTRC consists of 5,973 sq ft of space located on the 3rd floor of the outpatient pavilion at CHCO which houses four infusion rooms, six exam rooms, an extra-large procedure room with bed, one treatment room, two consult/consenting rooms, three staff workrooms, a secure medication room, and 2 wet labs for sample processing. A third wet lab is located on the fourth floor in the NICU. The body composition (DXA) laboratory is located in the Radiology Department on the 1st floor. The CTRC clinical outpatient facility is generally open weekdays 7am – 5:30pm. During these hours, experienced clinical research nursing, laboratory, and nutrition support is available.

The CHCO CTRC facility has 9 FTE of research nurses. This core of research professionals has extensive experience in conducting and documenting research for a diverse patient population from birth – 49 years of age, both healthy and with a range of diseases such as type 1 and type 2 diabetes, obesity, cystic fibrosis,

cardiovascular disease, chronic hepatitis, rare genetic and metabolic diseases, gastrointestinal disease, cholestatic and fatty liver diseases, HIV, various forms of infectious diseases, etc.

Equipment

- Exercise equipment: Treadmill F85 (Sole, USA), and Ergomatic 828 E (Monark, Vansbro Sweden)
- Sample processing: Allegra X-22R Centrifuge (Beckman Coulter, Brea CA), Allegra X-22R Centrifuge (Beckman Coulter, Brea CA), Allegra X-30R centrifuge (Beckman Coulter, Brea CA), Multifuge 3L-R Centrifuge (Thermo Electron Corporation, Madison WI) Sorvall ST 16 R (Thermo Scientific Company, Hanover Park, IL)
- Sample storage: Forma 8600 Series -80 Freezer (Thermo Scientific, Hanover Park, IL), -20 Freezer, (Thermo Scientific, Hanover Park, IL), -20 Freezer (Whynter, Brea, CA), R134A Refrigerator, (Follet, Easton, PA) Refrigerator (U-Line), , Refrigerator/Freezer (Avanti Weston, FL)
- Cardiac monitoring: MAC 2000 ECG System (GE Medical Systems, Chicago, IL)
- Calorimetry: Vmax Encore 29N (Carefusion, Vyair Medical, Yorba Linda, CA), Vmax Encore 29N (Carefusion, Vyair Medical, Yorba Linda, CA)

CTRC Core Lab Facilities

CTRC Core Laboratories

Facilities

CTRC Core Laboratories are located adjacent to the adult, CHCO, and NJH CTRCs. The adult Core Laboratory is 1,544 sq ft located within the UCH CTRC Outpatient space on the sixth floor of the new Anschutz Health Sciences Building. The CHCO Core Laboratory is 10,000 sq ft of space located in the basement of CHCO, adjacent to the hospital's clinical laboratory. The NJH Core Laboratory is 300 sq ft located in the Goodman Building. All laboratories are College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA)-accredited and provide trained personnel, reagents, equipment, and QC capabilities to conduct over 250 specialized assays for research. There is no redundancy in the services offered by the CCTSI Core Laboratory Network: the UCH Core lab specializes in hormone and metabolite assays (3.4FTE); CHCO Core Laboratory focuses on inflammation markers, fat-soluble vitamin measurement, specific protein and pulmonary fluid processing (5 FTE); and NJH Core lab specializes in flow cytometry, specialized cell culture, and DNA and RNA extraction (1.0 FTE).

Equipment

- Cold Sample Storage: Freezer Forma 923, Ultracold Forma 983, 4 x Ultracold Forma 995, 13 x Thermo Forma 8000 series , Thermo Electron, Forma 989 Dd , 2 x Panasonic -80C (Panasonic Healthcare Corporation of North America, Wood Dale IL), Forma Ultra 990, Undercounter 3.6°C Isotemp (ThermoFisher Scientific, Waltham MA); Ultra 500BX (Sanyo, San Diego CA); 4 x Thermo Scientific refrigerator FRLR/TAX (Thermo Scientific, Waltham, MA); VWR refrigerator (VWR, Radnor, PA)
- Centrifuges: 6 x Allegra 6r, Allegra X-15R, Avanti 30, Avanti J-20, Avanti J-E, Airfuge (Beckman Coulter, Brea CA); Sorvall Legend RT and RT6000D, RC3B Plus, J2-21 (ThermoFisher Scientific, Waltham MA); 2 x Eppendorf 5702R (Westbury, NY), 2 x Centra CL3R (Thermo IEC, Waltham, MA); 2 x Thermo Electron Heraeus Multifuge 3L-R (Waltham, MA); Fisher Accuspin Micro 17, Fisher Marathon 16KM, and Eppendorf 5415C; Shandon Cytospin 3
- HPLC: ICS-3000 (Dionex , Sunnyvale CA), Waters 2487 (Waters, Milford MA), Detector For Hplc ELSD2000 (Alltech, Lexington, KY), 1 x Waters Acquity UPLC with Detector (Waters, Milford MA)
- Real-time Whole Blood/Plasma Chemistry: 2 x 2300D Glucose Lactate Analyzer (Yellow Springs Instruments; YSI, Yellow Springs OH), 3 x Glucose Analyzer GM9 (Analox Technologies, Atlanta, GA); DCA Vantage Hemoglobin A1C analyzer (Siemens, Tarrytown, NY)
- Gamma Counter: Wizard 1470 (PerkinElmer, Waltham MA)
- Spectrophotometers/Plate Readers: Multiskan Spectrum Thermo Lab Sys 1500, Biotek EI-808, Biotek Synergy/HTX and ELx800 Plate Readers (Biotek, Winooski, Vermont), 2 x Beckman Coulter DU650 (Beckman Coulter, Brea CA), Nanodrop Tech ND-1000, Nanodrop One (ThermoFisher Scientific, Waltham MA), SpectraFluor Plus and infinite M200 PRO (Tecan US, Morrisville NC)
- Autosampling: Biolc AS (Dionex Corporation, Sunnyvale CA) Miniprep 60 Basic System, MP60 (Tecan US, Morrisville NC)
- Antek 9000 Series Elemental Nitrogen Analyzer (PAC, Houston TX)

- Chemistry Analyzers: Beckman AU480 and Access 2 (Beckman Coulter, Brea CA), 2 x Cobas Mira Plus (Roche, Indianapolis IN), Nephelometer Dade Behring (Siemens, Washington DC)
- Multiplex assays: Luminex FLEXMAP 3D, MagPix (Luminex Corporation, Austin TX), CiraScan planar multiplex instrument (Aushon BioSystems, Inc, Billerica, MA)
- Electrophoresis System: Capillary electrophoresis system (Waters, Milford MA)
- Microscopes: Nikon Optiphot and Nikon Eclipse E400 (Melville NY), 3 x Olympus (Olympus America, Center Valley PA)
- Immunoassays: Immulite 1000 Analyzer (Siemens, Washington DC); Liaison Chemiluminescence Analyzer (DiaSorin, Stillwater, MN), IDS iSYS Analyzer (Immunodiagnosics Systems, Scottsdale, AZ)
- PCR: Applied Biosys 7500, DNA Engine (BioRad)
- Automated Cell Counter: Invitrogen Countess (ThermoFisher Scientific, Waltham MA)

CCTSI Nutrition Core

Facilities

The CCTSI Nutrition Core consists of scientists and nutritionists with extensive experience in nutrition and metabolism research (3.0 FTE). All staff members are trained to prepare and distribute weighed, metabolic meals from our commercial research kitchen. The commercial kitchen is located at the Anschutz Health and Wellness Center (AHWC) on the CU Anschutz Medical Campus (1,273 sq ft). Smaller food preparation facilities are located in: 1) CTRC at UCHHealth Inpatient Hospital (93 sq ft), 2) Anschutz Health and Science Building (AHSB) (287 sq ft), and 3) CTRC at Children's Hospital Colorado (CHCO) (84 sq ft). The kitchen and all staff designing and preparing diets are ServeSafe certified. Meals are prepared, stored and shipped to CTRC sites for distribution as needed, and are provided on a fee-for-service basis. The CCTSI provides all of the necessary computers, software, office space, and other resources for providing: dietary intake assessment, both traditional and novel, sensor-based methods; measurement of hunger and satiety; growth, body composition, and indirect calorimetry in pediatric populations (Energy Balance Lab provides this service for adults); protocol-specific dietary counseling and instruction; development of study-specific educational materials; consultation on study design and ways to achieve specific dietary intervention targets; design, preparation, measurement, and dispensation of study-specific meals and foods; and design and product development for novel foods and diets (e.g. foods to mimic Agrarian dietary intake that are palatable to Americans; specific allergen-free food items and allergen-added counterparts with equivalent taste, volume, and texture for blinded studies; formulation development for palatable high fiber foods for long-term dietary intervention studies).

Equipment

- Diet design software: ProNutra (Viocare Inc, Princeton NJ)
- Analysis of dietary intake: Nutrient data Systems for Research (NDS-R) software (Nutrition Coordinating Center, University of Minnesota)
- Portable indirect calorimetry (IC): Vmax Spectra-29N and Encore29 metabolic measurement systems (Sensormedics; Yorba Linda, CA)
- High Precision Balances (food weights and stable isotope additions): 5 x Ohaus Pro Scout SP4001, Ohaus Adventurer AX5202 (Ohaus Corporation; Parsippany, NJ), Mettler Toledo New Classic MF (Columbus, OH)
- Refrigeration/freezer storage at UCH inpatient CTRC and CHCO CTRC: T-35 double door refrigerator, T-46 double door refrigerator, T-23 single door freezer, and T-35F double door freezer (True Manufacturing Co; O'Fallon, MO), Manitowoc Freezer UD-140A (Manitowoc Refrigeration, Manitowoc, WI), UF21355 Freezer (Sunpentown International, City of Industry, CA)
- Diet preparation: full commercial kitchen including a walk-in freezer and refrigerator, a Vulcan Hart range, and Hobart commercial dishwasher.

Child Maternal Health (CMH) Research

The overall goal of CMH Research is to support and promote clinical and translational research in children of all ages, pregnant women, and the mother-child dyad to improve child health and prevent diseases, with a focus on rare diseases, thus preempting adverse outcomes that increase disease burden and the cost of health care over the life span. CMH provides specific support for multidisciplinary, integrated, translational research focused on health problems that begin early in life and during childhood. The research initiative in CMH addresses the life trajectory of the mother and child, initiating new collaborations among basic, clinical,

and translational scientists in multiple disciplines and for providing a streamlined infrastructure for development of novel methodologies and pipeline programs to accommodate lifespan research.

CMH promotes research of the highest scientific and ethical quality in special populations by pre-reviewing protocols for scientific merit and insuring that adequate participant protections are specified, and providing information and resources for families considering study participation.

The CMH Perinatal Research Advisory and Facilitation Committee is a group of experienced perinatal investigators, research nurses, and coordinators who assist investigators working with pregnant women, preterm infants, and newborns. This committee assesses the feasibility of each protocol, identifies potential overlap with existing studies and, if so, facilitates sample sharing, fosters collaboration between investigators working in similar areas, and assures that investigators are aware of existing data and biobank resources that could aid their research. This committee is vital to promote collaboration, insure maximal utilization of rare and/or small samples (e.g. from premature infants), and prevent competitive recruitment of vulnerable populations.)

Community Engagement and Research and Health Equity Program (CEHE)

The CCTSI has integrated community-based participatory research (CBPR) into programs that engage the wider community with research into the causes and remedies of health problems and disparities in underserved populations in Colorado and the nation. It has built on a rich history of practice-based and community-based research in the state, which now includes ~20 established community-academic partnerships and 5 large practice based research networks (PBRNs) throughout historically underserved and under-resourced communities in the state. These partner communities include rural, frontier and urban populations, American Indian and Alaska Native, Hispanic/Latino/a, and African American groups, and LGBTQ+ communities, providing a unique opportunity for culturally proficient research emphasizing health disparities. The innovative

Partnership of Academicians and Communities for Translation (PACT)

brings academic and community partnerships into a sustainable and collaborative balanced (equal numbers

of community members and academicians) governance group for bidirectional exchange and fostering public trust in the research enterprise. PACT oversees a variety of activities, including 10 Community Research Liaisons, the Community Immersion Program, Bootcamp Translation program, CE Pilot Grants, training programs, community forums and other activities described more fully in the **Element C2** of the grant application.

Workforce Development (WFD) Program

The WFD program provides clinical-translational scientists, clinical research professional staff, students and trainees with education, training, and career development programs to become highly skilled for the design and conduct of effective and efficient clinical and translational research. WFD offerings span critical periods for investigators and scientists, from the beginning of research training at the pre-doctoral level through senior faculty. There is also a new career ladder and compensation model for professional research staff (including clinical research staff/coordinators) at CU Anschutz which was implemented in 2022. Many new trainings are



now available for research staff professionals working at our universities and hospitals. Pathway Programs provide many opportunities for students from K to 12 and at community colleges and universities to learn about careers in healthcare, STEM and health related research.

For the researcher/scientist, the WFD's goal is to create a robust local research professional workforce and a national leadership pool for clinical-translational researchers who are interdisciplinary, innovative, highly motivated and successful. WFD leverages and integrates educational programs at CU-D and its partners to provide training in strategic areas. Programs are intended to promote innovation and team collaboration, leading to research with broad implications for public health. A cadre of faculty, educators, and administrative staff are dedicated to providing programs of the highest quality. The WFD provides a broad menu of training and career development opportunities for all roles involved in the life span of clinical and translational studies.

Specific Programs

- **Pathway (Pipeline) Programs for Careers in Healthcare and Research:** A rich portfolio of “pathway programs” has been organized by CU Anschutz to stimulate interest in a career in healthcare, STEM and health related research among underserved minority, tribal and rural students. These pipeline programs are coordinated within the office of Educational Outreach and Pathway Initiatives within the office of Dr Regina Richards, the CU Anschutz Vice Chancellor of Diversity, Equity and Inclusion and Community Engagement. Many of these programs are supported by NIH and other federal grants. These pipeline programs, that are distributed across the state of Colorado, are coordinated with local elementary, middle and high schools, community colleges and undergraduate universities and are integrated into our School of Medicine, College of Nursing, School of Public Health, AHEC program, CU Boulder and other programs at the University. The CCTSI supports research opportunities and mentoring for students within Pathway Programs and funds additional positions in the pipeline programs as well as salary support for the coordinator of these programs in Dr. Richard's office, Dr. Dominic Martinez. In addition, our Community Engagement and Health Equity Program promotes these programs through our Community Research Liaisons across Colorado.
- **Clinical Research Staff Professionals (CRSP) Development Program:** is led by two senior CRSP, Hailey Steinert and Patricia Gesualdo, who have over 22 years of collective clinical research coordination and management experience at CU Anschutz. The program is directed by Ben Echaliier MS, MBA, CCRP, Associate Director, Regulatory and Trials Operations and TIN HLT Director. Serving as the nexus for all CRSP career development programming and clinical trial education, this program will include multiple initiatives (see **Table C2 in Element C1**) that follow the recommendations of the CTSA Joint Task Force for Clinical Trial Competency.²⁷ This program encompasses a full curricula of trainings, workshops, and resources to support CRSP competency attainment, career development, and progression through the new CU Anschutz CRSP Career Ladder.
- **TL1 (T32) Team Oriented Training across the Translational Sciences Spectrum (TOTTS) Training program (TOTTS);** The goal of the TL1 Training Program is to build a diverse workforce of clinical and translational researchers (CTR) by enhancing capacity for team-based research training spanning the pre-clinical to population health spectrum. Three groups of future CTR investigators are targeted: a) biomedical PhD students, b) health professional trainees completing their doctorate (pre-doctoral) or post-doctoral medical residents, and c) veterinary post-doctoral trainees, which is a collaborative with Colorado State University Veterinary School. It involves 8 PhD students and 3 post-doctoral fellows each year with an emphasis on underrepresented minorities.
- **KL2 (K12) Career Development Program.** This program provides protected time and opportunities for an intensive, mentored career development experience in CTS of up to 3 years that leads to independent extramural support and leadership positions in CTS and academia. K12 scholars are supported by two faculty mentors, one of whom must be a clinical researcher. This program supports six junior faculty at any one time.
- **Clinical Science Graduate Program (CLSC).** One of the first Clinical Science Graduate Programs in the country, this program awards MSCS and PhD degrees in 3 distinct specialty tracks: Clinical Investigation and Health Outcomes, Health Services Research (a collaborative program with the

Colorado School of Public Health), and Health Information Technology. It also has a Dissemination and Implementation in Health Research Graduate Certificate program that is offered collaboratively with ACCORDS (Adult and Child Consortium for Health Outcomes Research and Delivery Science). The CLSC has 100-115 degree students at any given time and aims to train nationally competitive clinician/clinical translational scientists by providing a formal and structured educational and mentoring program. Graduates are trained to conduct rigorous and relevant patient-based research within stringent ethical and regulatory guidelines, and to translate the evidence for community application. In addition, more than 200 other non-degree students attend CSLC classes each year.

- **Clinical Faculty Scholars Program** focuses on developing junior faculty research independence. This program enrolls 4-5 learners per year and aims to help emerging investigators obtain a career development award (K08, K23 or foundation equivalent), or a first independent, extramural project award (R21, R01 or equivalent) through guided project development, educational seminars, grant writing classes, and mentorship. Each Faculty Scholar develops an individual career development plan and receives regular individual mentorship from four experienced senior researchers. This program acts as a pipeline of promising individuals into the KL2 program.
- **Leadership for Innovative Team Science (LITeS)** is a yearlong program to enhance leadership skills, foster team science by creating a network of colleagues who serve as resources for one another, expand opportunities for cross-disciplinary collaboration, and ensure that clinical and translational scientists have the skills for effective team leadership. To date, LITeS has trained over 300 participants including deans, associate deans, department chairs, vice-chairs, and section heads, as well as senior leadership from hospitals, major research centers, and training programs. This program competitively enrolls 20-30 participants per year to work on solutions to high-level issues chosen by UCD leadership.
- **Mock study section and grant review programs (Pre K and K to R).** Three separate programs support development and submission of competitive grants for pre and post-doctoral awards, career development awards and research operational grants. Each program runs three times/year corresponding with NIH deadlines and consists of six steps: 1) Attend/view "How to prepare your grant" workshop; 2) Submit specific aims page reviewed by program faculty with feedback to applicant; 3) Submit full grant; 4) Grant reviewed by 3 reviewers with written feedback; 5) Applicants attend mock study section to hear all reviews, discuss and pose questions; 6) Meet with faculty for feedback.
- **Colorado Mentoring Training (CO-Mentor)** a formal mentoring program for mentor-mentee dyads. CO-Mentor uses didactic, interactive and applied learning to develop skills related to teams, leadership, managing conflict, and use of Individual Career Development Plans. Over four sessions, held about every 7 weeks, CO-Mentor: 1) develops skills and behaviors consistent with effective mentoring relationships; 2) enhances the mentor-mentee relationship; and 3) builds a network of trained mentors and mentees modeling these best practices for others, leading to a sustainable culture of mentoring.
- **Clinical Research Education Program:** A curriculum to improve regulatory knowledge and compliance, Good Clinical Practice and Responsible Conduct of Research application. Provides required regulatory courses (GCP, RCR, human subject protection including informed consent) for all people involved in Clinical and translational research. Topics include Authorship and Publication; Research Misconduct; Collaboration; Data Acquisition and Management; Conflicts of Interest; Peer Review; Mentor and Trainee Relationships; Industry-Academia Relationships, Industry Funded Research, and, Social Responsibility. A variety of training forums are used: seminars, graduate courses, individual consults, online and modules. Over 700 attendees annually.
- **ATLAS.ti:** TLAS.ti is qualitative data analysis software designed to help manage and analyze non-numerical data. The e-learning modules introduce learners to the foundational building blocks and tools of ATLAS.ti. Designed for learners investigators, trainees and clinical research staff.
- **Teaming for Early Career Investigators:** This curriculum is designed to build your capacity to participate in and lead effective interdisciplinary and translational scientific teams. It addresses the shift

in science from an individual-based approach to a teamwork model of conducting clinical and translational research.

- **Researcher Management & Leadership Training:** A massive open online course on the global learning platform [Coursera](#). This course is targeted to early career researchers and mentors who believe that modern scientific careers require management skills and want to be research leaders—especially current and future principal investigators. The curriculum is designed to deliver skills to effectively implement funded projects, thereby enhancing research career success.

Innovators Ecosystem of Colorado

Innovation Corps (I-Corps™) uses proven customer-discovery methodologies for startups. It was developed for academic researchers by serial entrepreneurs working with the National Science Foundation. I-Corps@CCTSI is a team-based short course designed for faculty, staff and students. The program guides teams through the early stages of customer discovery where they can test the business model hypotheses for their technology or idea to accelerate the translation of innovations from the lab to clinical practice. I-Corps@CCTSI leverages and partners with other entities which promote innovation such as CU Innovations Technology Transfer Office, CU Boulder Ventures, CSU Ventures at Colorado State University. These partnerships facilitate collaboration, access to a large knowledge base and investor pool, access to proof-of-concept funds, and interdisciplinary expertise.

Resources planned for the planned RC2-SIP application (in the next grant cycle) that is currently under development include the Research Triangle Institute's (RTI) iCanvas matrix, edited for regionally available programming and services to expand efforts throughout the CCTSI region to enhance collaboration and sharing of academic entrepreneurial and innovation-forward resources. Entrepreneurial Studios One and Two will provide expert mentoring and advising for early-stage to commercial launch Innovators regarding next steps required to achieve optimal patient impact through additional focused development and potential licensing, collaborative research with external companies, financial resources, and/or company development.

Two Affinity groups are under development. Affinity group one will focus on female entrepreneurs and Affinity group two will focus on underrepresented minorities. The groups are designed to provide support, as well as to focus on identifying solutions to overcome barriers specific to women and underrepresented minorities as they navigate the innovation pathway.

Ask the Expert is a monthly live interview that is recorded as a podcast for asynchronous viewing. Entrepreneurial experts from both industry and academia are invited to participate in a dialogue with an interviewer. Audience participation is encouraged and attendees are given ample time to ask the expert about their pathway to success.

In collaboration with the Chancellor's Office, a promotion and tenure review committee is launching that will work to develop, support and implement matrix criteria to enable innovation career paths and promotion for entrepreneurially-minded faculty, students and staff.

The PI, Dr. Bodine is housed in Bioscience III, an innovation hub recently opened in the CU-Anschutz adjacent Bioscience Tech Park with office space, computing resources, conference rooms and collaborator spaces with administrative support co-located in the reception area. Office space for faculty and administrative staff is also provided in the newly opened Anschutz Health Sciences Building on the CU Anschutz campus. This space houses conference rooms and open workspaces that allow planned SIP RC2 Program Directors and staff to collaborate and work together. CSU and CU Boulder partners are housed in their respective Technology Transfer Offices, and have office space, computing resources and other materials available on their campuses.

Regulatory Knowledge and Support Core (RKS) in collaboration with the Clinical Research Support Center (CRSC)

RKS helps CCTSI members navigate through regulatory requirements and provides training and consultation in the responsible conduct of research. The RKS and CRSC share 5,000 sq ft of office, conference room, and collaboration space on the ground floor of Fitzsimons Building at the CU Anschutz Medical Campus. This consists of 3 conference rooms, 27 cubicles, 4 offices, a storage room, a communal lunchroom, and collaborative spaces including open, communal printer/ copier and seating areas. This "google-style" space

houses RKS staff as well as staff from CU Anschutz contracting, CCTSI Scientific and review Committee (SARC) and research education, the Trial Innovation network (TIN), CU Innovations, OnCore team members, and UCHHealth billing. This novel arrangement, housing parties within a functional cross-institutional team space rather than in space assigned by each staff member's employer spread over campus, facilitates collaboration and direct access to the knowledge and expertise necessary to assimilate information quickly, brainstorm and resolve problems in real time, and provide solutions, workflows, and training opportunities that are consistent across the CU Anschutz Medical Campus. In addition, RKS space is the same building as many entities essential for the safe and efficient conduct of translational research such as COMIRB, COI and other regulatory offices, and the Dean's Office, which provides further team building and collaboration opportunities.

The Trial Innovation Network (TIN) Hub Liaison Team (HLT)

The Trial Innovation Network (TIN) Hub Liaison Team encourages, supports, and promotes multi-center investigations, and provides an environment where NIH-supported clinical trials are conducted efficiently, compliantly, and with the highest quality. The HLT team consists of the Hub PI, Director, Medical Directors for both adult and pediatric studies, a project manager, central IRB liaison, contracting liaison, recruitment facilitator, research navigator and an honest broker for recruitment. The TIN team will build on the strong clinical research structure currently in place to support clinical trials within the CCTSI and expand the opportunity to both propose multi-center trials via the TIN and recruit patients locally for TIN-sponsored trials. The TIN team has members that are imbedded in the same space as the Regulatory Knowledge and Support Core and the CCTSI office space to facilitate collaboration, leverage existing expertise, and contribute to the overall goal of streamlining the startup and coordination of multi-site clinical trials.

Director – Adit Ginde, MD, MPH is Professor of Emergency Medicine and Anesthesiology at the University of Colorado School of Medicine. He is Vice Chair for Research in Emergency Medicine and Director of Clinical Research in Anesthesiology. In these leadership roles, he develops clinical research infrastructure, allocates resources, collaborates extensively with many other Departments/Divisions at CU Anschutz, and oversees implementation of all clinical research protocols for these Departments. Dr. Ginde also actively practices and teaches emergency medicine at UCHHealth University of Colorado Hospital. In his own research, Dr. Ginde has extensive experience with leading translational clinical trials in acute care research, funded by NIH (including NHLBI, NINDS, NIA, NCATS), DoD, CDC, foundation, and industry sponsors. Specifically, he has a strong track record in designing, overseeing, and implementing clinical trials in a variety of clinical environments including outpatient, emergency department, perioperative, and inpatient (including intensive care unit) settings, particularly in the areas of respiratory failure and sepsis/infection. He has been the lead investigator for 5 large multicenter clinical trials and participated in the design (as protocol committee member) and implementation (as site PI) of over a dozen other clinical trials. *He will be responsible for overall operations of the CCTSI TIN Hub, participation in conference calls and meetings, and communications with TICs and RICs and NCATS.*

Medical Director (Adult health) – Thomas Campbell, MD

Dr. Campbell is Professor of Medicine, Division of Infectious Diseases, and has also served as Medical Director of the UCH CTRC since 2008. His research focus is the use of antiretroviral agents to treat and prevent HIV infection and AIDS-related complications. He is Site Leader for the UCH Clinical Research Site in the NIAID AIDS Clinical Trials Group (ACTG) and a member of the ACTG Executive Committee. He led the design, implementation, and dissemination of 3 NIH-funded international clinical trials from 2002-2016. He has served as the local PI for 52 ACTG and HIV Vaccine Trials Network clinical trials and 33 pharmaceutical industry clinical trials. Dr. Campbell served as a liaison for the establishment of new ACTG clinical trials sites in Zimbabwe and South Africa from 2003-2008. *He will be responsible for operations and implementation of adult clinical trials of the TIN.*

Medical Director (Child health) – Jesse Davidson, MD, MPH, MSc

Dr. Davidson, Associate Professor of Pediatrics, is the Associate Medical Director for the Children's Hospital Research Institute and works with investigators to optimize clinical research operations at CHCO in this capacity. Clinically, Dr. Davidson is a pediatric cardiac intensivist and medical imager in the Children's Hospital Colorado Heart Institute. Dr. Davidson's NIH-funded research focuses on the metabolomic and proteomic

response to pediatric congenital heart disease surgery and postoperative acute organ injury. *He will be responsible for operations and implementation of child health clinical trials of the TIN.*

TIN Project Manager – Ben Echaliier, MS, MBA

Dr. Echaliier is the Assistant Vice Chancellor for Clinical Research Operations at CU Anschutz and Director of the Clinical Research Support Team (CReST) at CU Anschutz and has worked to support regulatory submissions, data entry and other general coordination for clinical trials in multiple specialties. He has over 15 years of experience managing clinical research teams in the academic research environment. *He will be responsible for project management and implementation of TIN protocols at our site.*

Central IRB Liaison - Christy Williamson, CCRP

Ms. Williamson is the Senior Facilitation Manager with the Clinical Research Support Center at UC Denver and has a strong background in clinical research and regulatory and IRB coordination. She has been an Education Consultant in the same group and has extensive experience working with multiple IRBs, including with the central IRB mechanism, throughout her career. *Her responsibilities will be to ensure timely and compliant IRB reliance agreements, facilitate use of central IRBs, and streamline local IRB processes for TIN studies.*

Contracting Liaison – Deborah Barnard

Ms. Barnard has over 20 years of experience in research regulatory compliance with a demonstrated track record of excellence; an in-depth knowledge and understanding of complex regulations and international guidelines; a keen understanding of Good Clinical Practice guidelines, successful track record in working in and across very complex organizations. She has an ability to understand and interpret regulations and requirements translating these ideas into policies, procedures, and a sound operational system. She is exceptionally skilled at analyzing problems and providing appropriate yet practical solutions. *Her responsibilities will be to facilitate timely and complete execution of contracts related to TIN studies.*

Recruitment Facilitator - Barbara N. Hammack, Ph.D.

Dr. Hammack has been the Research Subject Advocate (RSA) for the CCTSI since 2008. She has taught regulatory science and research ethics and is the director for an investigator focused clinical trials course. She has close connections and has organized multiple recruitment resources at UC Denver and nationally that put her in a strong position to facilitate recruitment at our site. *Her responsibilities will be to develop, implement and facilitate research participant recruitment and retention strategies in coordination with the RICs.*

Honest Broker for recruitment – TBA

The Honest Broker will be a new position to facilitate the identification of subjects for clinical trials by working closely with the Health Data Compass team (our research data warehouse which includes patient data from UCHealth, CHCO and CU Medicine. This Honest Broker will work closely with investigators to identify and contact potential participants with whom the investigators do not have a treatment relationship.

Clinical site operations coordinator

- CHCO – Erin Sandene, BSN, Director of Research Administration and Operations, CHCO Research Institute
- UCHealth – Laurie Blumberg-Romero, MA, CRA, Director of Research Administration for UCHealth

Health Informatics

The CCTSI Health Informatics Program is a critical function of the CCTSI. The CCTSI Informatics team includes dedicated systems administration, information security, web development, software engineering, project management, and data management personnel. The team has deep experience with research computing using a wide variety of operating systems, database engines, regulatory and security environments, and software stacks. The team maintains 85+ virtual and physical servers running several applications, at the department and enterprise level, for data management needs across the CCTSI. In addition, the team manages backups, security, networking, access controls, and desktop support for the CCTSI administration core and CTRCs, and CCTSI website development. CCTSI Informatics also supports Colorado Profiles, Scheduler, and the CCTSI research laboratory information system. CCTSI Informatics maintains NIST SP 800-53 compliance for its on-premises virtualized server farm. The CCTSI Informatics Information Security Officer establishes and monitors the necessary controls to maintain this level of compliance. The data center includes

fault-tolerance and disaster recovery capabilities as well as annual third-party audits and penetration testing. COLORADO Profiles, a web-based searchable faculty biomedical research database for the entire University of Colorado system (<http://profiles.ucdenver.edu>), is managed by the CCTSI Informatics team. It receives over 30,000 page views per month.

REDCap

CCTSI Informatics has provided a fully subsidized HIPAA-compliant REDCap data management service since 2008. In doing so, we have fostered regulatory compliance and good data practices by enabling investigators to follow best-practices via no-cost access to secure user-friendly data management services. We provide free training including video tutorials (used worldwide) and 1:1 hands-on tutorials and consultations and currently support >5,000 active users and >16,000 active projects. Our REDCap team are national and international leaders and are regularly invited to present at REDCap Con and other community conferences.

CCTSI website

The CCTSI website (cctsi.cuanschutz.edu) is the online portal where faculty, trainees, research associates, university staff, and the public and private sector may access our services, resources, funding, and training opportunities. As of September 2021, the website receives an average of 9,634 page views per month and 5,769 sessions per month. CCTSI membership is required to utilize services and training programs, with membership exceeding 6,000 as of September 2021. Membership is available to faculty, trainees, research associates, community members and the private and public sectors and is obtained through an online registration form.

Health Data Compass (Compass)

Health Data Compass (HDC) is a multi-institutional enterprise data warehouse funded by the University of Colorado Health System, Children's Hospital Colorado, CU Medicine, and the University of Colorado School of Medicine. It is located on the Google Cloud Platform and all data that comes from UCHHealth, CHCO, and CU Medicine contains PHI. No data are de-identified or scrubbed. Therefore, Compass can link additional data from sources outside of these institutions such as the Colorado All Payer's Claims Database (APCD) from the Center for Improving Value in Health Care (CIVHC). Thus, Compass is a vital source of multi-institutional integrated data and analytic services designed to transform data-driven processes into clinical research, operational excellence, molecular discovery, and personalized medicine. Compass has been integrated into the newly established Anschutz Medical Campus Research Informatics Office under the inaugural campus Chief Research Informatics Officer.

Established in 2017, Compass is the world's first integrated large-scale clinical, administrative, genomic, and population-based research data warehouse on the Google Cloud Platform (GCP). It is NIST 800-53 secure and HIPAA-compliant. It serves as the clinical and translational research data hub for the Anschutz Medical Campus. Compass is specifically designed to support data discovery and data science methodologies that integrate, harmonize, and link large-scale biological, clinical, administrative, regional, state and national data sets. Compass integrates patient clinical data from the separate EHRs at UCHHealth and Children's Hospital Colorado. HDC is able to link patient records from both institutions to create a longitudinal record that does not exist within either EHR alone. Governance and secure data integration pipelines are established to link EHR data with Colorado death registry, vaccination, and all-payer claims data, state and national environmental data sources, Colorado Center for Personalized Medicine (CCPM) genomic Biobank resources (currently ~200,000 patients and growing), and to make those data available to investigators for high-impact linked analyses. Compass staff have academic and industry experience in computational infrastructure, data engineering, common data models (CDMs), data quality and harmonization, terminologies and ontologies, regulatory and honest broker requirements, study design, and clinical and translational research. Compass uses OHDSI/OMOP as its primary CDM. OMOP includes national and international standardized terminologies such as the CMS/ONC Meaningful Use terminologies. Compass data are surfaced to investigators for cohort discovery using a variety of technologies including Leaf (in beta) and external applications such as TriNetX, i2b2, and Tableau. Custom data extracts are delivered to approved investigators that use REDCap and other HIPAA-compliant tools. To date, Compass has delivered ~1500 datasets for research.

EUREKA

Compass also provides the EUREKA HIPAA-compliant cloud-based analytics platform to

investigators. This innovative service deploys powerful cloud-VM (computational and storage) environments to service a variety of advanced analytics needs, from statistics and visualizations to bioinformatics processing and deep learning. Because Eureka users pay only for the time during which their virtual machines are in use, they can provision much more power than could normally be afforded - all with the assurance of meeting health system and regulatory HIPAA security and compliance standards. Compass currently hosts ~200 users in Eureka environments.

CU Anschutz Informatics-Relevant Academic Units, Centers, Offices, and Educational Programs:

CU SOM Department of Biomedical Informatics

The CU SOM formed the Department of Biomedical Informatics (DBMI) on 01 July 2022 as an academic community for researchers in data-intensive biomedical research. The DBMI is the primary academic home for ~30 tenure-track faculty and ~120 total FTE including staff and trainees. DBMI continues to hire new faculty. DBMI faculty bring excellence in various domains of informatics including genomics, computational biology, translational bioinformatics, personalized medicine, clinical research informatics, and clinical informatics while developing and applying tools and techniques in areas such as artificial intelligence (AI) and machine learning (ML), cloud computing, ontologies, and knowledge engineering to biomedical challenges. DBMI faculty deploy genome-scale biology, multiscale modeling, data integration, simulation, and mathematical and predictive analytics to marry disparate but related aspects of the CU Anschutz clinical and research portfolios to advance knowledge and improve healthcare. Most DBMI labs are housed in the new Anschutz Health Science Building (AHSB); wet labs are housed in the Research Complex (RC) 1 or RC2 buildings (accessible via enclosed bridge). This highly localized structure provides an optimal framework for collaboration within the department and between DBMI faculty and other campus partners.

CU SOM Center for Health Artificial Intelligence

The University of Colorado School of Medicine formed the Center for Health AI in November 2020, recognizing that biomedical research is increasingly becoming a data-driven endeavor that requires computational skills. Investments in data-intensive research technology provide limited returns without appropriate expertise and creativity in the workforce. Further, the learning curve for many computational skills is both long and steep. CHAI fosters a thriving community of researchers at CU Anschutz who invent and deploy advanced analytics. This Center's mission is to make CU Anschutz a leader in translating data into advances in research practice, healthcare delivery, and population health and scaling these to provide nationwide benefits through innovative technologies. The Center operates an ongoing membership application process to recruit additional on-campus faculty into the unit. CHAI is in the newly constructed AHSB and occupies 9700 square feet of dedicated space.

Colorado Center for Personalized Medicine

The Colorado Center for Personalized Medicine (CCPM) is a collaboration among the CU SOM and UHealth that reports to the Vice Chancellor for Health Affairs. CCPM is multi-disciplinary and multi-functional unit, encompassing research, data analysis, clinical operations, and educational components. The Center's mission is to develop and maintain programs that advance the clinical and research efforts of the campus through predictive, personalized care. As part of this mission, CCPM has developed a biobank that aims to reflect the diversity of the State of Colorado and the surrounding Mountain West and Great Plains regions to support a broad agenda of research, operational and clinical quality improvement goals. By integrating predictive, personalized, preventive, and participatory medicine into the existing healthcare delivery systems, CCPM exploits the power of big data to educate the next generation of clinicians and bioinformaticians.

CU Anschutz Research Informatics Office

The Research Informatics Office (RIO, <https://research.cuanschutz.edu/rio>) is led by the Chief Research Informatics Officer, Melissa Haendel, PhD. The RIO provides strategic direction and informatics expertise to maximize the impact of CU Anschutz's research and data assets, recognizing the need for socio-technical integration and shared sound governance among stakeholders. The RIO will serve as a primary liaison between biomedical researchers and information technology (IT) teams, analytics initiatives, and data science education efforts on campus. It will assume a central brokerage role in identifying gaps among existing

resources, designing evidence-based collective decision making processes and policies, coordinating new initiatives and programs, and driving innovation.

CU SOM Computational Biosciences Program

The Computational Biosciences Program (CBP) was founded by Lawrence Hunter, PhD, and is currently led by Katerina Kechris, PhD. It includes a National Library of Medicine (NLM)-funded informatics graduate training program. CBP is in the Research Complex 1 (RC1) building at CU Anschutz. The CBP currently serves approximately a dozen graduate students and several post-doctoral fellows.

CU Anschutz Computational Resources

Alpine

The Anschutz Medical Campus has recently co-invested with CU-Boulder and Colorado State University in a new high-performance computing (HPC) cluster (Alpine). This cluster will support investigator needs for genomics and computational biology computing on data that does not include PHI. The new cluster is currently online for beta users and will be made available to other campus users later in 2023. Overall, Alpine includes 1,088 CPU cores, 12 graphics processing units (GPUs) optimized for deep learning, and >5 TB RAM, with planned future expansion. This multidisciplinary, robust computing resource is designed to foster omics-based research using high-dimensional data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches.

Anschutz High Performance Computing Exchange (AHPCE)

The Translational Informatics and Computational Resource (TICR) has been an integral component of the Colorado Center for Personalized Medicine (CCPM). This in-house, comprehensive, stand-alone biocomputing unit supports a multidisciplinary, robust computing resource to foster omics-based research using high-dimensionality data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches.

TICR Computer Cluster

The Translational Informatics and Computational Resource (TICR) has been an in-house, comprehensive, stand-alone biocomputing unit supports a multidisciplinary, robust computing resource to foster omics-based research using high-dimensionality data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches. TICR hardware is at end of life and this functionality is currently being replaced by Alpine and EUREKA. The TICR computer cluster was designed with a minimum of 768 cores (Xeon E5-2680 v3 at 2.5Ghz), 4TB of RAM and 3.7 PB of useable storage. This cluster includes all necessary HPC components, including but not limited to a scheduler (SLURM), manager nodes, master nodes, login nodes, compute nodes, storage and cluster management software. The storage array is designed to provide a minimum of 3.7 PB of useable data storage for both home directories and scratch, using IBM General Parallel File System (GPFS). The processing network for the compute cluster consists of Infiniband switches, providing a low latency and high bandwidth interconnect for parallel computations and storage access. The compute cluster has redundant 10 gigabit Ethernet connectivity to OIT's current network core and management switches, and can easily expand both in terms of network, compute and storage capacity based on need. The HPC environment also includes an application cluster, which consists of six physical servers running VMware vSphere virtualization, plus a dedicated fibre channel SAN. The application cluster is designed for redundancy and high availability. Each server has a minimum of 36 Xeon v3 cores at 2.3Ghz and 256GB of RAM. The fiber channel SAN is dedicated to the application cluster and includes 30TB of solid-state disk. This array is able to be easily expanded to support future storage growth. The application cluster has redundant 10 gigabit Ethernet connectivity to OIT's current network core and management switches, and can be easily expanded in terms of computation resources and storage. The TICR compute cluster currently includes one additional high memory compute node with 36 Xeon v4 cores and 1.5 TB RAM, to support high memory workloads such as experimental sequence alignment techniques.

Evaluation Center: The Evaluation Center is situated within the School of Education and Human Development at the University of Colorado Denver (CU - Denver). Since its inception in 2004, the Evaluation Center has provided program evaluation services to clients within and outside of the University functioning as an independent, self-supporting cost center with access to all campus research resources. The Evaluation Center has a staff of 23 full- and part-time evaluators who work across the Center's projects. The team is strong in quantitative, qualitative, and mixed methodologies and has experience implementing a wide range of evaluation theories, approaches, and dissemination methods. Located near CU Denver's downtown Auraria campus, the Center occupies over 3,000 square feet of office space in downtown Denver. The Evaluation Center has provided the evaluation components as the Evaluation Core for all CCTSI programs since the inception of the CCTSI in 2008.

Learning and Development Program: The Learning and Development Program is situated within Human Resources at the University of Colorado Denver and provides service to faculty and staff at the Anschutz Medical Campus and the Downtown Campus. Since its inception in 2018, the Learning and Development Team has provided a wide range of professional and organizational development services to staff and faculty. The Learning and Development Team has four full-time professionals who design, facilitate, and manage all aspects of our programs. In addition, the team provides organizational development services such as employee engagement surveys, team and individual coaching, and customized training based on gap analysis evaluations. The team is strong in curriculum design, data analytics, and eLearning technology.

CU BOULDER

CU Boulder hosts an outpatient clinical research unit (CTRC) that is part of the CCTSI's CTRC network. The CU Boulder CTRC is located within the translational biomedical research wing of the Ramaley Biology building on the CU Boulder campus. The unit occupies ~3,500 sq ft of discrete CTRC-dedicated space which houses a central nursing and charting/work area, nutrition core, phlebotomy stations, wet lab for sample processing, 4 large procedure rooms with beds, body composition room (DXA) and an Integrative Physiology Core Laboratory (IPCL). The IPCL provides research support in four general areas of investigation: 1) autonomic nervous system/cardiovascular physiology; 2) body composition; 3) exercise testing and intervention; and 4) indirect calorimetry.

Because the CU Boulder CTRC is located on an undergraduate campus and the majority of its investigators are PhD scientists, daily on-site physician and nursing coverage ensures that all protocols are performed safely with optimal medical oversight. The CU Boulder CTRC facility has 1 on site physician, 2 research nurses, 1 medical technician, 1 nutritionist, 1 exercise physiologist, and 1 research subject advocate. Moreover, the CU Boulder CTRC has a comprehensive medical oversight plan and clinical staff is available 24/7 for medical consultation. An on-call physician service is available in the evenings 7 days/week to respond to participant needs/concerns. All staff receive HIPPA and Good Clinical Practice training and are Basic Life Support (BSL) and Advanced Cardiac Life Support (ACLS) certified. These clinical research professionals have extensive experience conducting and documenting research across the adult age-range involve both healthy individuals and those with disease such as obesity, prediabetes, cardiovascular disease, HIV-1 and chronic kidney disease. The CU Boulder CTRC is open weekdays 7am-4pm and the first and third Saturday (7am-12pm) of each month.

The CU Boulder CTRC has a cooperative partnership with the Intermountain Neuroimaging Consortium involving the use of their fMRI machine. This partnership allows CTRC approved protocols involving the fMRI facility to receive full clinical support from the CU Boulder CTRC for the conduct of these studies.

The location of the CU Boulder CTRC on an undergraduate campus provides a unique opportunity to facilitate training opportunities for undergraduate and graduate students to be involved in translational research. By providing opportunities for these students to be exposed to clinical/translational research and gain "hands-on" research experience, it is possible to establish an intellectual interest that will, at least for some, lead to a career as a clinical scientist. In this regard, undergraduate and graduate students involved with CTRC investigators and their approved CTRC protocols are eligible for academic credit through the campus Independent Study, Laboratory Rotations, and Research Projects course offerings. These mechanisms allow students to identify CTRC faculty investigators of interest, develop a mutually agreeable research training plan, and work with CTRC-supported investigators while obtaining up to 3 hours per semester of academic credit.

Use of 2 or more of these mechanisms provide the student an opportunity to engage in a singular (or multiple) research effort(s) over a period of 2-3 years, which will greatly enhance the quality of their research experience.

Equipment

- SunTech 24/7 casual blood pressure monitors (Suntech Medical, Inc., Morrisville, NC);
- Cardiovascular Imaging: Xario XG multi-specialty ultrasound imaging system (Toshiba America Medical Systems, Inc., Tustin, CA) with high-resolution (7.5 and 12 MHz) linear array transducers;
- Vascular Imaging Acquisition and Analysis: Vascular Analysis Tools software version 5.10.9 (Medical Imaging Applications, LLC, Coralville, IA) equipped with Top Performance Analysis Integrated System with imager and frame grabber (DICOM, Rosslyn, VA), vascular ECG-gating module (University of Iowa, Iowa City, IA) and MIA Vascular Research Tools 5 analysis software;
- Forearm Cuff Occlusion: E20 Inflator AG101 Air Source, Rapid Version Cuffs (Hokanson, Inc., Bellevue, WA);
- Hokanson blood flow plethysmography units (Hokanson, Inc., Bellevue, WA);
- Infusion pumps: Imed Gemini PC-2TX (Alaris Medical Systems, San Diego, CA);
- Body Composition Analysis: Lunar Prodigy Dual Energy X-ray Absorptiometry (DEXA) system and Encore 2008 analysis software version 12.20.023 (GE Medical Systems, Fairfield, CT);
- Nutrition Analysis: The Food Processor software version 8.2 (ESHA Research, Salem, OR), Nutrition Data System for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN);
 - Ankle-Brachial Index: Transcutaneous Doppler flowmeters 810-A (Parks Medical, Aloha, OR);
 - Exercise Testing: Ultima gas analyzer module with ECG interface (MedGraphics, Saint Paul, MN), BreezeSuite ventilatory data collection software version 6.2C (MedGraphics, Saint Paul, MN), Trackmaster 425 Treadmill and 12-lead ECG-treadmill interface (Full Vision Inc., Newton KS);
- Parvo Machine (Salt Lake City, UT) to support resting metabolic rate studies
- Finapres to support continuous mean arterial pressure measurements
- Collins physiological monitors (Ohmeda, Madison, WI)
- Various centrifuges and freezers (for temporary sample storage)

CHILDREN'S HOSPITAL COLORADO (CHCO)

See above description of CCTSI Facilities for description of Pediatric CTRC facilities, research nursing, Nutrition Core and Core Laboratory located at CHCO.

The Precision Diagnostics Laboratory at Children's Hospital Colorado established a scalable and expandable genomics testing infrastructure that supports the needs of patients and providers at Children's Colorado while enabling growth required to keep up with precision advancements and evidence-based changes to clinical practice, which evolves rapidly. In addition, research capabilities will be added in 2023 using new sequencers that will be purchased in 2023, allowing for more rapid and scalable sequencing and bioinformatics interpretation of results. The fully integrated genomics infrastructure includes a single ordering access point within the EHR, multimodal laboratory technologies, tailored bioinformatics solutions, data architecture that support FAIR data principles, integrated and transparent clinical interpretation processes and discreet data ingestion of genomics data into the EHR. The integrated system is well positioned to support development and validation of subsequent clinical decisions and novel research efforts. Since the operationalization of the infrastructure in 2020, the laboratory has resulted in close to 3,500 diagnostic tests. Leveraging the connectivity to the EHR and custom analytical processes the overall clinical utility of the current pediatric tests is over 60% with an average turnaround time of 10 days, reducing the time to a precise diagnosis and profoundly impacting clinical management of the patients. The laboratory has a range of high throughput sequencing equipment, namely three Miseq, a Nextseq 550 and a NovaSeq 6000. Additionally to support the complex genomic operations the lab has 3 automated nucleic acid extractors and several liquid handlers.

The Precision Diagnostics Laboratory at Children's Colorado is a centralized clinical resource in the Department of Pathology and Laboratory Medicine which performs clinical and research genomic sequencing and analysis. The services of this group include development, validation and implementation of genomics-based technologies, consultation on experimental design, library preparation, and data analysis. The Scientific Director, Dr. Alisa Gaskell (NIH Biosketch included), oversees a team of 10 genomics experts and drives the design of necessary

data systems and genomic tools to support the collection and use of genomic data within Children's Colorado and our partners. The Precision Diagnostics Laboratory is a fully integrated genomics infrastructure interfaced with the EHR. This bidirectional connectivity has ensured discreet resulting of genomics data as well as integration of clinical phenotypes into the genomics interpretive workflow. The Precision Diagnostics team has experience developing new laboratory and analytical methodologies, provides a range of genomic and metagenomic data assemblies and analysis services leveraging the state-of-the-art software pipelines.

The Precision Diagnostics Laboratory will be a key component of a planned CTSA RC2 SIP grant submission, that is under development, in which clinical EHR data from maternal records will be merged with their infant's data from the outside hospital and the medical record at CHCO, for pediatric patients with underlying conditions or genetic diseases, and will be merged with genotyping and other types of "big data". These efforts at maternal, fetal, newborn and child data integration will be the basis for novel research hypotheses and testing which will be the focus of the RC2 SIP grant application.

COLORADO STATE UNIVERSITY (CSU)

CSU, located in Fort Collins, Colorado, has a broad range of core facilities containing equipment that perform unique measurements and generate large datasets for translational research. These are available to faculty and students that are CCTSI members and provide training as well as access and training in use of the equipment.

Human Performance Clinical Research Laboratory

The HPCRL is a designated CSU Program of Research and Scholarly Excellence, and serves as a center for interdisciplinary research, training, and outreach efforts that address the etiology, prevention, intervention and treatment of major chronic diseases including cardiovascular disease, diabetes, obesity and degenerative conditions associated with aging. The original HPCRL facility, which opened in May 2000, contained 6200 sq ft of research and clinical outreach space. In July 2008 an addition of 1100 sq ft of wet lab space was added; and, a new 4000 sq ft research addition opened in January 2010. In 2017 a \$2.5 million expansion of ~ 4500 sq ft was completed. Most recently, in 2021, an \$800,000 conversion of an underutilized space resulted in a 1570 sq ft open concept wet-lab multi-user space. With recent additions, the HPCRL now houses 17,400 sq ft of clinical administrative, and analytical research space.

Laurie Biela the Manager of Research Operations serves the Human Performance Research Laboratory as a whole by overseeing all shared resources, maintaining regulatory compliance, oversight of human participants, laboratory safety and training, and managing the clinical Resources for CSU Researchers and community Fee- For-Service programs. The MRO supervises 3 assistants (a total of 2.5 PTE) who perform quality control activities such as data verification, source document reconciliation, organization of site training binders, equipment maintenance and calibration, investigational product and reagent temperature monitoring, and fee based clinical research activities- such as exercise testing, phlebotomy, IV catheter placement, DEXA scans VO2 max testing and other services upon request.

Administrative core facilities:

- Reception Area and Lobbies: (reception area 344 sq ft, south lobby 92 sq ft, and north lobby 293 sq ft). The newly constructed reception area serves the clinical/outreach, teaching, and research needs of the HPCRL. This area serves as the check in point for research participants. The area also houses computers, phone, fax, facilities scheduling services, and other administrative functions. In this area is a lobby that serves as a waiting room for research participants.
- Graduate Research Assistant Offices (combined 625 sq ft): Offices for masters and PhD students.
- Storage/Facilities Maintenance (combined 105 sq ft): Four small storage/plumbing/electrical closets are located in the administrative core.

Clinical core facilities:

Clinical Research Exercise Screening and Performance Flex Spaces (312 and 350 sq ft):

- Room 1: Space and equipment for multiple stress tests, with either treadmills or cycle ergometers, while capturing expired gases using metabolic carts and recording ECG traces.
- Room 2: Equipped for clinical stress testing using cycle ergometers (Velotron, Lode Bike or KickR), ECG and indirect calorimetry.

Clinical Research Procedural Flex Spaces (145 and 280 sq ft): These rooms contain a research bed, a sink, and storage cabinets. The space can be used for obtaining muscle and adipose tissue biopsies, blood samples for screening purposes, resting metabolic rate, and oral glucose tolerance data as well as other IRB approved research procedures. The room has the power requirements for a centrifuge to spin blood samples and for instrument sterilization equipment.

- Sleep and Metabolism Laboratory (SAM Lab) The SAM Lab of two specially built, sound-attenuated, light- and temperature-controlled sleep and circadian research suites, private bathroom and observation/instrument room and all necessary equipment for conducting rigorous sleep and circadian studies with a total space of 1000sqft.
- Sensorimotor Neuroimaging Laboratory: The primary laboratory for CO-PI Dr. Brett Fling's research consists of a 7922 ft laboratory, an attached electronics/fabrication shop (982 ft), an adjacent examination room for clinical evaluation (3062 ft), and office space for up to 5 personnel. The equipment available in the laboratory includes the following: MagVenture MagPro X100 Transcranial Magnetic Stimulator with angled, double-cone coil. Brainsight-2 NeuroNavigation system for navigated TMS: coil tracking hardware, integrated iMac computer with neuronavigation software, a positioning system that includes a full-body supportive reclining chair, head stabilization unit, and coil stabilization arm. An instrumented, split-belt treadmill with two Bertec force platforms (Model 4060-10, Bertec Corp, Columbus, OH) to record body kinetics. The instrumented treadmill is integrated with a high resolution 10-camera Vicon (Denver, CO), 3-dimensional motion analysis system linked with Nexus (Vers 2.3) to record body kinematics. A Magventure MagPro X100 transcranial magnetic stimulation system (Magventure Inc. Alpharetta, GA) synched with a 6-channel surface EMG system from Biopac (Biopac Systems, Inc. Goleta, CA) to assess muscle activity. Two 6- channel Opal wireless inertial sensor systems from APDM (APDM Portland, OR) to assess static and dynamic movement kinematics during over-ground walking and a NeuroCom Balance Master Clinical Research System (Natus Medical Inc. Pleasanton, CA) to assess balance.
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- Test Article Preparation and Nutritional Kitchen (360 sq ft): This room serves as a 'clean' room for test article dispensation, food preparation, and preparation of anything that is intended for human consumption. The room houses a refrigerator/freezer combo, a dish washer, a sink, locking cabinets for secure storage of test articles, and counter space.
- Clinical Exercise Outreach Testing lab (768 sq ft): The clinical exercise-testing lab. This room has three treadmill/ECG stations, three exam tables for participant prep, a medical "crash" cart, extensive storage, sink, and miscellaneous exercise testing equipment.
- Shower/Lavatories (combined 232 sq ft): The three shower lavatory facilities are available for research participants. Each room contains a shower, lavatory, sink, and lockers.
- Participant Interview Rooms (188 and 2-94 sq ft): Each room has a small conference table and four

chairs for participant/client activities such as obtaining informed consent, screening, or follow up visits in a private room.

- DEXA Room (180 sq ft): Houses a dual-energy X-ray Absorptiometry (DEXA) unit used for body composition and bone densitometry analysis.
- BodPod Room (122 sq ft): Houses a Cosmed BodPod, scale, and weights for non-x-ray sources of body composition determination, along with cabinetry and a sink.
- Blood Draw Room (93 sq ft): Contains a phlebotomy chair, blood draw supplies for on-site blood analysis, and centrifuge.

Analytical core facilities

- Wet Laboratory 1 (1393 sq ft): A multiuser facility for molecular biology, biochemistry, and other analytic needs of multiple groups. The lab allows for the analysis of DNA, RNA, protein, lipid, carbohydrate, and other analytes from human rodent tissue, *C. elegans* and isolated cells (see equipment section for details of equipment).
 - Instrument Area (500 sq ft): Houses two GC-MS and GC-QQQ instruments, centrifuges, and upper metal case work for general supplies, and lower metal case work for acid and base storage.
 - The Microscopy/Imaging Laboratory (50 sq ft): Contains a shared fluorescence microscope/camera.
 - Cell Culture Room (180 sq ft): Contains 3 biosafety cabinets, clean bench, 3 incubators, centrifuges, water baths, and cell culture supplies.
 - Wet Laboratory 2 (1126 sq ft): An open concept multi-user lab space for biochemical/molecular analyses and short-term rodent studies. Contains 3 acid neutralizing fume hoods, vented chemical storage cabinets, 2 biosafety cabinets, 4 sinks with di-ionized water supply and eye wash station, safety shower, lab grade dishwasher, 7 work station benches with upper and lower metal cabinets and power and data along the length of the benches, 3 moveable benches with storage, accommodate up to ~20 work areas. Power requirements and space to add refrigeration/freezer units.
 - Animal Housing Area (132 sq ft): Intended for weekly short term housing for rodents also equipped with proper hourly air exchange rate and a biosafety cabinet.
 - Animal Behavioral Area (160 sq ft): Dedicated space to perform rodent studies using treadmills and other behavioral equipment. Also contains a sink and storage cabinets. Easily cleanable surfaces for disinfecting in between rodent studies.
 - Student Office Area (152 sq ft): Flex desk space/lounge for students performing work in the connect lab areas.
 - Storage for consumable lab supplies (400 sq ft)
 - Freezer Room (440 sq ft) Housing for 5 ultra low temperature freezers, -20C freezers, and fume capture hood for a speedvac. All freezers are equipped with remote temperature monitoring and connected to emergency back-up power.
 - Compressed Gas Tank Storage (133 sq ft): Area to secure various types compressed gas tanks ~50 full sized tanks.
 - Biohazard Closet (26 sq ft): Biohazards storage area for pick-up and disposal by commercial contracted company.
 - Capacity to house additional -80C freezers within the building as needed **(300 sq ft)**.

Standard Equipment:

Fume hoods (6; 3 are acid neutralizing fume hoods); MilliQ ultrapure water system; ventilated chemical storage cabinets; BSL2 laminar flow biosafety cabinets (5); laminar flow cell fractionation/isolation work stations (2); refrigerated centrifuges and microfuges (6); autoclaves (2); CO2 incubators (3) including one with dual CO2/O2 control); RT-PCR (ABI) and thermocycler (ABI); Bio-Rad electrophoresis/immunoblotting stations (5) and rapid transfer station; NanoDrop spectrophotometer; agarose electrophoresis apparatus (2); chemiluminescent/UV imaging equipment and automated Wes capillary electrophoresis/immunoblotting unit (Protein Simple); plate readers (2, luminescence/ fluorescence/ absorbance); pH meters; stirring/heating plates; rockers; Rainin pipeter sets; analytical balances; refrigerators (4); -20°C freezers (4); -80°C freezers (8); sonicator; and equipment for

4 different approaches to tissue homogenization; Molecular Devices UV/VIS/fluorescence plate reader and ELX-808 Bio-Tek Instrument.

A specific set of standard equipment (centrifuge, analytical balance, Rainin pipeter sets, and a Molecular Devices UV/VIS/fluorescence plate reader) is designated for use with GxP research. All equipment is routinely calibrated and use is tracked with user sign-in.

Specialized Equipment:

For high resolution mitochondrial function: OROBOROS Oxygraph-2k instruments (2), one with a fluorescence module.

Isotope analyses/proteome maintenance assays: Glascol nitrogen concentrator (3); Fisher block heaters (3); Restek ion exchange manifold (2); speedvac; Waters Oasis HLB DNA cleanup manifold; 2 Agilent gas chromatography-mass spec instruments (Agilent 7890 GC and 5975 MS); Agilent gas chromatography-triple quad mass spec (Agilent 7890 GC and 7010 QQQ); Agilent HPLC 1200 series HPLC with multi-wave and fluorescent detector.

Measurement of extracellular vesicle abundance via nanoparticle tracking analysis: three-laser Manta/Horiba ViewSizer 3000 particle analyzer; Horiba Aqualog for comprehensive fluorescence characterization of bulk samples.

C. elegans research: TriTech research stereomicroscope for daily C. elegans maintenance; NemaLife semi-automated microfluidic system for C. elegans lifespan experiments; TriTech Research incubators for C. elegans maintenance (2).

Microscopic imaging: Invitrogen EVOS M7000 automated scanning microscope with four fluorescence channels, high-resolution 2-100x optics and Celleste digital deconvolution software; EVOS FL manual fluorescence microscope; Nikon TE2000 fluorescence microscope with a CoolSnap HQ camera and NIS Elements software); Olympus light microscope with digital color imaging; Nikon light microscope for daily cell imaging; Additionally, abundant access to the CSU Microscope Imaging Network (<https://www.research.colostate.edu/min/>) expands imaging instrumentation to include Keyence All-In-One Fluorescence Microscope; Nikon+Bruker atomic force and spinning disk confocal microscope; Nikon Eclipse Ti Total Internal Reflection Fluorescence (TIRF) microscope with N-STORM super resolution imaging capability; Nikon Inverted Epifluorescence Microscopes; Olympus inverted IX81 FV1000 confocal laser scanning microscope; Olympus inverted IX83 spinning disk confocal microscope; Zeiss LSM510 meta laser scanning confocal microscope; Zeiss LSM800 laser scanning confocal microscope.

Hypoxia research: Coy hypoxia glove box; walk-in environmental/hypoxia chamber.

Clinical Research Equipment:

All preparatory equipment and instrumentation for safe and sterile tissue collection including blood, adipose, and skeletal muscle sample collection are available.

Also available is equipment for insulin clamp procedures; multiple hospital beds (available in "flex spaces" as needed); 15 reusable Bergstrom biopsy needles; syringe pumps; autoclaves; refrigeration; 2 YSI glucose analyzers (2300 Stat Plus); Piccolo blood chemistry analyzer (Xpress Blood Analyzer).

Equipment for clinical and exercise testing includes a Hologic Horizon A DEXA scanner; digital and manual (balance) body mass scales; 3 stations equipped with treadmill and ECG for cardiac screening (Quinton TM65 and Quinton Q-Stress); 1e station with treadmill, ECG and indirect calorimetry (Parvo True Max); 2 cycle ergometers (Lode and Velotron) with indirect calorimetry (Parvo True Max) and ECG (Quinton Q- stress); pulmonary function testing (Medgraphics); a "crash cart"; multiple portable defibrillators.

Equipment Specific to the Sensorimotor Neuroimaging Laboratory:

The equipment available in the laboratory includes the following: MagVenture MagPro X100 Transcranial Magnetic Stimulator with angled, double-cone coil. Brainsight-2 NeuroNavigation system for navigated TMS: coil tracking hardware, integrated iMac computer with neuronavigation software, a positioning system that includes a full-body supportive reclining chair, head stabilization unit, and coil stabilization arm. An

instrumented, split-belt treadmill with two Bertec force platforms (Model 4060-10, Bertec Corp, Columbus, OH) to record body kinetics. The instrumented treadmill is integrated with a high resolution 10-camera Vicon (Denver, CO), 3-dimensional motion analysis system linked with Nexus (Vers 2.3) to record body kinematics. A Magventure MagPro X100 transcranial magnetic stimulation system (Magventure Inc. Alpharetta, GA) synched with a 6-channel surface EMG system from Biopac (Biopac Systems, Inc. Goleta, CA) to assess muscle activity. Two 6-channel Opal wireless inertial sensor systems from APDM (APDM Portland, OR) to assess static and dynamic movement kinematics during over-ground walking and a NeuroCom Balance Master Clinical Research System (Natus Medical Inc. Pleasanton, CA) to assess balance.

CSU Core Equipment:

As necessary, we also have access to a variety of “omics,” imaging, and flow cytometry facilities located either on campus or in the surrounding area. The CCTSI Genomics Shared Resource provides Illumina Next Generation Sequencing (HiSeq 2500/4000, MiSeq), LifeTech IonPGM sequencing, Illumina BeadArrays, Agilent Microarrays, Affymetrix GeneChips® Microarray or Plate Arrays, SomaLogic SOMAScan (proteomics), and Fluidigm C1, BioMark HD, Juno, and AccessArray for Single Cell Genomics. The Rocky Mountain Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research includes a Genomics and Proteomics Core with instrumentation including an Agilent Q-TOF tandem mass spectrometer, Affymetrix Gene Chip 3000 microarray system, an Arcturus Autopix laser-capture microdissection unit, a Bruker MALDI/TOF mass spectrometer, and the SOLiDTM System are available to CSU personnel. The CSU Proteomics and Metabolomics Facility houses a Waters G2 TQ-S coupled with nanoUPLC, Bruker Ultraflex MALDI-TOF/TOF tandem mass spectrometer, and a Thermo LTQ ion trap mass spectrometer, and licenses for Mascot and other proteomics software. The CSU Central Instrument Facility, among many other capabilities, has Mass Spectrometry (GCMS, LCMS, LC-TOFMS, FTICRMS) and Magnetic resonance (NMR/EPR up to 600MHz). The Microscope Imaging Network has a JEOL 1400 and a JEOL 2000 Transmission Electron Microscopes, 2 Zeiss LSM510 meta laser scanning confocal microscopes, Olympus inverted IX81 FV1000 confocal laser scanning microscope, Olympus inverted IX81 spinning disk confocal microscope, Nikon Eclipse Ti Total Internal Reflection Fluorescence (TIRF) microscope with N-STORM super resolution imaging capability, 2 Nikon inverted epifluorescence microscopes. The CSU Flow Cytometry Core Facility has a wide variety of instrumentation for state-of-the-art flow cytometry and cell sorting, services, and expertise to support CSU research. Additionally, CSU has an excellent Glass Shop that is housed in the Department of Chemistry and machine shop services are available in the Department of Chemical and Biological Engineering and the College of Engineering.

Next Generation Sequencing Facility

The Department of Microbiology, Immunology, and Pathology (MIP) and OVPR operate a self-service facility that houses Illumina MiSeq and NextSeq next generation sequencers. The facility also provides an open access library preparation laboratory and other instruments required for sample processing, library prep, and library quantification and QC. Mark Stenglein, PhD is Director.

Services include:

- Training in the operation of the MiSeq and NextSeq instruments.
- Loading of libraries on MiSeq and NextSeq
- Pre-run library QC (qPCR-based library quantification and tape station analysis)
- Consumables useful for library prep and NGS
- Flow Cytometry Facility – This core provides cost effective access to state-of-the-art flow cytometry and cell sorting instrumentation, services, training and expertise for all researchers. Instrumentation includes:
 - BD FACSAria III
 - Cytex Aurora Spectral Cytometer
 - Beckman Coulter Gallios
 - HyperCyt Rapid Sampler for High Throughput Flow Cytometry
 - CyAn1-ADP 7 Color
 - CyAn1-ADP 9 Color

High Performance Computing

The \$3.55 million system was awarded under the auspices of the Rocky Mountain Advanced Computing Consortium (RMACC; www.rmacc.org). The Summit system architecture is comprised of general compute

nodes, GPU compute nodes, high-memory compute nodes and Phi nodes. Compute time is allocated following review of applications.

Proteomics and Metabolomics Facility

The facility contains state of the art mass spectrometry instrumentation and can facilitate experiments in all aspects of protein and metabolite analysis including both non-targeted global profiling and targeted quantitative assays. Equipment includes:

- Waters G2 TQ-S Coupled with nanoUPLC
- Waters G2 TOF coupled with UPLC
- Waters G2 Q-TOF coupled with UPLC
- Elan DRC-ICP-MS
- Thermo Trace ISQ with liquid autosamplers
- Bruker Microflex LRF
- Thermo Orbitrap Velos MS coupled with nanoUPLC

Other cores include: Experimental Pathology Facility, Central Instrument Facility (mass-spec, NMR, X-ray diffraction, Optical Spectroscopy), Molecular Quantification Core (digital PCR and Typhoon Imaging), Lab Animal Resources, BSL3 Facilities, BioMARC cGMP Manufacturing, Protein Purification Facility.

All of these cores are available to CVMBS researchers. The Office of the VPR provides opportunities for Core Facilities to apply for funds to purchase additional equipment. Recent purchases include a Digital PCR System, and a Cytex Aurora 48 channel flow cytometer.

Animal Facilities

- a. Painter Center – This is the central animal facility with conventional, barrier and biocontainment animal housing, a surgical suite, the cage wash facility serving the entire university and offices for staff in the Department of Laboratory Animal Resources (LAR).
- b. Pathology Building – A conventional animal facility, located 30 yards from the Painter Center, is used by Pathology Department faculty.
- c. Physiology Building – A conventional animal facility located 75 yards from the Painter Center, has a surgical suite that can be used for small ruminants or rodents, one room for short-term post-surgical holding, and a hypo/hyperbaric chamber used for pulmonary and cardiovascular physiology research.
- d. Infectious Disease Research Center (IDRC) - The IDRC is composed of a series of several interconnected and one stand-alone buildings that includes approximately 175,000 sq. ft. of research space. These include the Biocontainment Research Building (BRB), the Rocky Mountain Regional Biocontainment Laboratory (RMRBL), and the Small Animal Research Annex (SARA). Within these facilities there are multiple isolated suites housing animals in ABSL3 conditions. The BRB contains three major animal housing areas: Immunology and Virology suites (BRB I), and Discovery suite (BRB II). The RMRBL adjoins the BRB, was completed in 2007, and was approved for select agent work in 2008. This facility was the first of the 13 RBLs to achieve this designation, and remains ABSL3 approved by both USDA and CDC. The RMRBL is a high containment facility for infectious disease research. It has both ABSL2 and ABSL3 animal holding rooms, procedure rooms, necropsy facilities and aerosolization rooms. The animal holding areas and supporting laboratories are divided into modules to allow separation of the agents under study. The SARA building is a stand-alone facility adjacent to the BRB and RBL facility that contains four large ABSL3 animal holding rooms. The building also contains an aerosol, necropsy and decontamination room, a staging area, and locker rooms. The Research Innovation Center (RIC) is a \$52M multi- functional project with 8,000 sq. ft. of research space. The RIC includes versatile ABLS2 animal space, 'incubator laboratories' for industrial partnerships, a GMP stand-alone facility, and an infectious disease-imaging core.
- e. Animal Disease Laboratory – A containment animal facility with design and construction features which allow for its use as a large animal biocontainment level II/III facility.
- f. Animal Reproduction and Biotechnology Laboratory (ARBL) – Contains a large animal surgical suite and indoor animal space currently used for rabbits, mice, chickens and sheep, a 1,500 sq. ft. stall barn for housing large animals, 5 acres of corrals for cattle, and an outdoor sheep facility

Veterinary Teaching Hospital Research Animal Facilities

- a. VTH Research Animal Facility – This is primarily a dog facility, in addition to space for conventional cat and rodent housing. There is also limited space for large research animal housing in stalls of the large animal barn and in outdoor paddocks (2.5 acres).
- b. Research Barn – This pole barn is used to house groups of sheep, primarily used in orthopedic research, in indoor pens with access to fenced outdoor pens. It is located 40 yards from the VTH.
- b. The VTH also houses complete advanced diagnostic facilities including imaging, clinical and histopathology laboratories, large animal surgery suites, microbiology and virology diagnostic laboratories, central supplies, and pharmacy. These facilities can be utilized for research animal diagnostics and procedures by arrangement. A 15,000 sq. ft. animal facility (Bay Facility) is currently in advanced planning phases to provide state of the art research animal housing at the CSU Veterinary Health Systems campus, with ground breaking planned for late 2019.

Graduate School Professional Development Series.

The Graduate School offers a series of free professional development events each fall and spring semester.

Graduate Center for Diversity and Access.

The Graduate Center for Diversity and Access (GCDA) is a comprehensive academic framework providing professional development and additional opportunities for graduate students of color to address systematic issues that may impede their progress in their graduate programs. It provides an opportunity to interact with diverse faculty and students, as well as professional development.

Resources for Disabled Students.

RDS provides support for students with both permanent and temporary limitations and chronic illness/health conditions (physical and mental health). Any student who is enrolled at Colorado State University and who self-identifies with RDS as having a disability or chronic health condition is eligible for support from RDS. Specific accommodations are determined individually for each student and must be supported by appropriate documentation and/or evaluation of needs consistent with a particular type of disability or health condition. Support services fall into three categories: accommodations, awareness, and advocacy. These three services areas relate to and complement one another to help lessen the negative effects that limitations or disabilities may have on students in an academic environment. Accommodations are designed to give students access to the programs offered by Colorado State University. Awareness activities are related to improving the climate on campus for students with disabilities. Advocacy efforts are to ensure the needs of students with disabilities or chronic health conditions are addressed both in individual situations as well as in policies and procedures of the university.

Student Diversity Programs and Services

Supports students in a variety of ways and provide opportunities to successfully participate in, and contribute to, the diverse campus environment. While each office listed may emphasize a specific segment of the student body, services and programs are available to benefit all students at CSU.

- The Asian Pacific American Cultural Center is committed to inclusion and interculturalism, the Asian Pacific American Cultural Center creates and supports opportunities for interaction among University and community constituencies to provide a learning environment that supports all students.
- The Black/African American Cultural Center promotes a diverse, inclusive campus environment and serves as a resource to the campus community as well as surrounding communities, through academic, professional, cultural and personal development programs that embrace Black and African American experiences.
- El Centro provides an inclusive learning environment that welcomes all students. El Centro supports and strengthens the academic and cultural experience of students by providing workshops, leadership opportunities and Latina/o cultural awareness programs that promote student success and retention.
- The Native American Cultural Center was established in 1979. The four primary advocacy and service areas include recruitment, retention, graduation and community outreach. The office embraces and encourages a supportive environment based on the traditions and cultures of Native American peoples.
- The GLBT Resource Center seeks to foster a campus free of prejudice, bigotry, harassment, and violence by providing a space for all members of CSU communities to explore and increase their understanding of aspects related to sexual orientation, gender identity and expression in an open and non-judgmental environment.

- Women and Gender Advocacy Center provides programs and resources focusing on all genders, social justice, and interpersonal violence prevention. Additionally, WGAC provides advocacy and support for victims of sexual violence, stalking, sexual harassment and relationship violence. Our purpose is to provide a safe and affirming space for the students we serve at Colorado State University, while supporting systemic change to end all forms of oppression within our community.

Colorado BioSciences Association & Colorado Bioscience Institute.

Colorado BioScience Association serves as the hub of Colorado's thriving bioscience sector by connecting innovators to funding, infrastructure, research and talent. From promising young companies to established corporations and institutions, they provide opportunities for networking, education and professional development. CBSA grows the bioscience workforce and lead business expansion policies to advance the industry in our state. CBSA represents more than 350-member organizations, including biotechnology, pharmaceutical, medical device, diagnostic, ag bio and mobile digital health companies, research and academic institutions and service providers. The Colorado BioScience Institute is a 501(c)3 non-profit that provides education, workforce and career development, innovation support and resources for life science professionals, companies, students and educators related to the bioscience industry in Colorado. Together these two agencies offer training opportunities and connections with local biotech industry for DVM/PhD student career development and networking.

DENVER HEALTH AND HOSPITALS (DH)

Denver Health and Hospitals (DH) is an integrated academic health care system that serves as the primary safety net for citizens living within the City and County of Denver, Colorado. DH has maintained an affiliate relationship with the University of Colorado's School of Medicine since 1947 with medical students and residents rotating through DH for many decades. DH-employed physicians/clinicians and doctoral researchers hold faculty appointments at the University promoting many research collaborations and joint grant submissions, with rank commensurate to their experience and professional development.

Facility

DH has a 525-bed acute care hospital that is an academic Level 1 Adult and Pediatric Level II Trauma Center. Additionally, we run 11 federally qualified community health centers, 18 school-based clinics in the Denver public school system, a 100-bed non-medical detoxification facility, correctional care services for Denver's jails, the Rocky Mountain Poison and Drug Safety Center. Within the Denver Public Health department, which provides a variety of services, we provide many health services including the largest STD clinic in the state with embedded primary care; innovative work in health informatics and public health research; innovative programs for health care delivery and cost containment; and educational services for a 17-state region.

DH served 191,325 patients and provided for 1,055,945 outpatient encounters and 21,579 inpatient admissions during FY 2021. This included 18,369 African-American, 852 American/Alaskan Native, 71,259 Hispanic/LatinX, and 6,276 Asian patients. In its history, has provided billions of dollars in uncompensated care. A large proportion of DH patients are members of racial/ethnic minority groups (69% non-white Caucasian in 2018) and DH provides care to a large number of homeless patients each year.

DH has been an active collaborator in development and information sharing through a virtual data warehouse (VDW) model with multiple distributed research networks, including the CCTSI, and developing business intelligence tools for research activities in a broad array of health services and research domains. DH is making efforts to include patient-reported health status within the EHR as a means to provide care that is more patient-centered and availability of self-reported outcomes for research. DH's Coherent Research Platform focuses on opportunities that blend research with clinical and operational innovation to reduce health disparities, and advance quality of care and service excellence. Plans are being developed for DH EHR data to be included in the CU Anschutz enterprise research data warehouse, Health Data Compass, in coming years.

Workforce Training and Development

The Investigator Development program, operated in partnership with University of Colorado Denver (UCD), fosters the skills and provides mentorship to emerging DH investigators to conduct research using scientifically rigorous methods that meet the methodological standards and philosophy of the Patient Centered Outcomes

Research Institute (PCORI). To accommodate investigator and research growth at DH, we now support a pilot study program to provide funding for junior investigators.

Action Networks

DH is a collaborating organization within two of AHRQ's networks of provider organizations that conduct rapid-cycle field-based research. The ACTION IV network program is designed to promote innovation in health care delivery by accelerating the diffusion of research into practice. DH also is a member of a Center for Care Innovations (CCI) action network.

1. DH is a principal member of the network led by Intermountain Healthcare: "Health Care Delivery in ACTION IV." The other principal members are Mayo Clinic, Providence Health & Services, Baylor Health System, Dartmouth-Hitchcock, the Colorado Health Outcomes center (COHO), and the Veterans Affairs Medical Centers in Denver and Salt Lake City.
2. DH is a principal member of the network led by the University of Colorado: "Denver: Colorado ACTION Partnership." The other principal members are Avera Health, Children's Hospital Colorado, University of Colorado Health, and University of Oklahoma Physicians.
3. DH is a member of the network led by John Snow, Inc.: "Safety Net Partnership." The other healthcare organization members are AltaMed Health Services Corporation, Boston Medical Center, Keck Medicine of USC, Penobscot Community Health Center.

OnCore Clinical Trials Management System

DH has partnered with the CCTSI, University of Colorado School of Medicine, UHealth, and Children's Hospital of Colorado to use the OnCore Clinical Trials Management System. OnCore increases operational efficiency and directly benefits study teams by: providing transparency into start-up processes and financial management; improving invoicing; improving billing compliance; improving patient protection; centralizing study management; and allowing study teams to generate useful study metrics.

REDCap

DH has implemented Research Electronic Data Capture, (REDCap), a secure web application for building and managing online surveys and research databases. REDCap can be used to collect virtually any type of data in any environment, including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR. REDCap is geared to support online and offline data capture for research studies and operations. The Office of Research has a dedicated team of REDCap Administrators that help maintain this specific instance, assist with research projects and data management across DH, and our presence in the larger REDCap network.

NATIONAL JEWISH HEALTH (NJH)

NJH hosts an outpatient clinical research (CTRC) unit and Core Laboratory that are part of the CCTSI's CTRC network. Note that the Core Laboratory equipment and services are listed under "CTRC Core Laboratories" due to central integration of management for all CTRC Core Labs. This change has reduced overall operating costs and increased efficiency of these operations across the CTRC network.

CTRC Facility

The NJH CTRC provides space, nursing services and core laboratory services for a broad range of research specializing in, but not limited to, pulmonary, asthma, immunology and allergy for adult and pediatric populations (including newborns). The unit consists of 4 patient care exam rooms and 2 negative air flow rooms. Two rooms are equipped with oxygen flow meters. There are 593 square feet of dedicated space for patient care use located on the third floor of the Goodman Building, plus the use of an exam room on the second floor by the pediatric care unit for oral food challenges. The unit is staffed by a nurse manager and 3 RN's, and is supported by a Nurse Practitioner and 0.8FTE of administration/regulatory support. There are 4 clinical research coordinators, including a registered dietician, available to support protocols as well. Consenting for studies, history and physical exams, skin biopsies, spirometry, skin testing, induced sputum, sweat testing, medication administration, 12 Lead EKG, standardized photography, are performed in the unit. The unit works with the Pharmacy for medication storage and distribution.

The unit also has 873 square feet for office space that houses nurses, study coordinators, and an administrative manager who assists in regulatory paperwork and protocol preparation. Computers are

available for word processing, data collection and analyses. A CTSC funded statistician is available to support investigators with study design and statistical analyses.

Equipment

- EKG machine: ELI380 (Mortara Instrument, Inc., Milwaukee, WI) and MAC5500 CLR STD ENG NA AHA, (GE Medical Systems Information Technologies, Wauwatosa, WI)
- Spirometry: 2 x MCG Diagnostics (Breeze Suite version 8.1) (Medgraphics Corp, Saint Paul, MN)
- Sweat Testing equipment (MacroDuct)
- Vitals machines
- Stadiometer and scale
- Sputum induction equipment (Nouvag)
- Trans-Epidermal Water Loss (TEWL) machine: Biox Aqua Flux® AF200, STE, Inc., Towson, MD, USA)