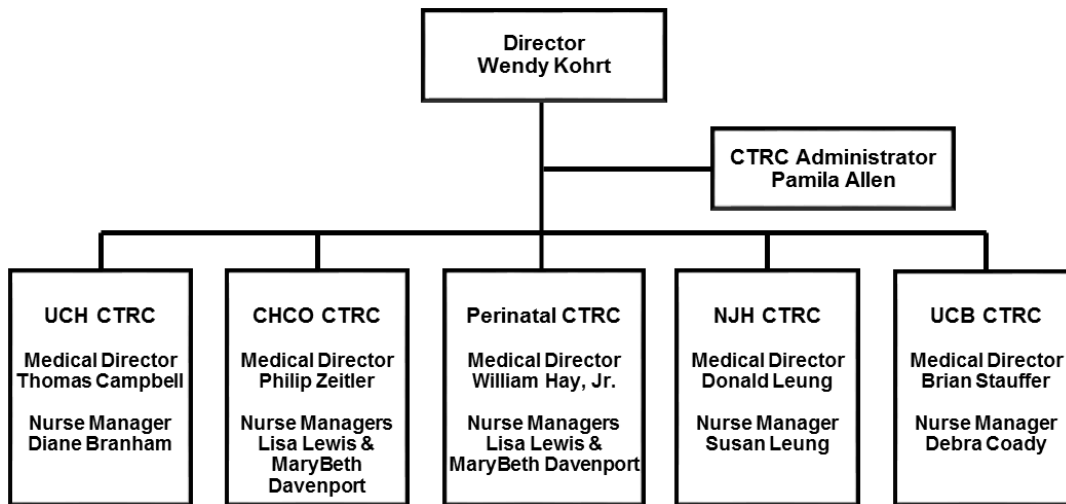


CTRC Description for NIH Resources and Other Resources Page (PHS 398 Part I I-40)

Clinical Translational Research Centers (CTRCs)



Our network of 5 Clinical Translational Research Centers (CTRCs; our clinical research units) provides 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, National Jewish Health, and a mobile perinatal unit at several hospitals. Available CTRC resources include dedicated inpatient and outpatient research space and equipment, expert research nursing, Core laboratories, and nutrition services. An additional mobile Perinatal CTRC operates at UCH, CHCO and Denver Health to facilitate research in pregnant women and newborns. All CTRC services are available to investigators on a fee-for-service basis, since 2015.

Anschutz Medical Campus (AMC)

University of Colorado Hospital (UCH) CTRC

Facility

The UCH 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, VO_2 max 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 UCH CTRC has 7,226 sq ft of inpatient space located on the 12th floor of UCH at the Anschutz Medical Campus, 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 UCH outpatient CTRC consists of 6,000 sq ft of space, which houses an outpatient research clinic. Facilities in the clinic include an infusion room (5 chairs), phlebotomy room (5 stations), exercise testing room (3 stations), muscle function room (isokinetic dynamometer), body composition room (DXA, pQCT), secure medication storage room (approved for FDA controlled substances, including Schedule 1), sample processing room, negative pressure room, 2 interview rooms, 2 large procedure rooms with beds, 4 small procedure rooms with beds (including one for RMR and one for echosonography), and 8 exam rooms with exam tables. There is a charting/work area with 5 computer work stations that can be used by research team members. An adjacent 3,200 sq ft state-of-the-art research exercise training facility is available for exercise intervention research. The CTRC also includes a Bionutrition core, special metabolic kitchen, and a core laboratory. The CTRC clinical outpatient facility is generally open weekdays 7am – 6pm. During these hours, experienced physician assistant, research nursing, health technician, laboratory, and nutrition support is available. Outpatient visits that occur outside of regular opening hours can sometimes be accommodated by inpatient CTRC nursing staff.

The UCH CTRC has 11.4 FTE of research nurses, 1.5 FTE of health technician support, a 1.0 FTE sonographer (shared between UCH and CHCO CTRCs), a 1.0 FTE physician assistant, 0.3 FTE DXA technician, 4.4 FTE of nutrition and metabolic kitchen staff, and 3.6 FTE of core laboratory staff support. 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): Discovery W (Hologic, Marlborough, MA)
- 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)

Children's Hospital Colorado (CHCO) CTRC Facility

The CHCO CTRC provides the space, staff, and equipment necessary to conduct a broad range of research procedures in children, including 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. Nurses are Pediatric and Basic Life Support (BLS) certified. Health technicians are BLS certified.

The CHCO CTRC has up to four inpatient beds located on the 9th floor of CHCO at the 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 and health technician 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 Echocardiography lab, one treatment room, two consult/consenting rooms, three staff workrooms, a secure medication room, and a wet lab for sample processing. 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 – 6pm. During these hours, experienced nurse practitioner, research nursing, health technician, laboratory, and nutrition support is available. Outpatient visits that occur outside of regular opening hours are accommodated by request.

The CHCO CTRC facility has 7.1 FTE of research nurses, 1.0 FTE of health technician support, a 1.0 FTE sonographer (shared between UCH and CHCO CTRCs), 4.4 FTE of nutrition and metabolic kitchen staff, and 5.2 FTE of core laboratory staff support. 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

- Body composition measurement: DXA Discovery A (Hologic, Marlborough, MA), BodPod (COSMED, Concord CA)
- 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-30R centrifuge (Beckman Coulter, Brea CA), and Heraeus Multifuge 3L-R Centrifuge (Thermo Electron Corporation, Madison WI)
- Sample storage: 60082 refrigerator (Kenmore, Brea CA), GIE21 refrigerator (GE Appliances, Pittsburgh PA), Fridge (U-Line), Freezer (Sanyo), FUF20 Freezer (GE Appliances, Pittsburgh PA)
- Cardiac monitoring: Mac 1200 ECG system (GE Healthcare, Pittsburgh PA)

Perinatal (PN) CTRC

Facility

The PN CTRC is a mobile nursing service located on the Anschutz Medical Campus to facilitate research in pregnant women and newborns, primarily at University of Colorado and Children's Hospital Colorado Labor and Delivery (L&D) and Neonatal Intensive Care (NICU) units. This unit facilitates screening, consent, and enrollment of these vulnerable populations as well collecting and processing biological specimens for research. The PN CTRC has 480 sq ft of office and storage space on the 4th floor of the CHCO Administrative Pavilion, directly adjacent to the hospital, and wet lab space for sample processing adjacent to the UCH NICU, within the CHCO NICU, and in the basement of the East Tower at CHCO. All nurses have NICU experience. The PN CTRC is available 24h/7d with staff on call.

The PN CTRC has 4.0 FTE of research nurses and 1.0 FTE of health technician support. This group of professionals has experience conducting research in a broad range of newborns and pregnant women including premature infants and neonates with severe illnesses such as respiratory failure, respiratory distress syndrome, persistent pulmonary hypertension, cardiac disease and extreme prematurity, and pregnant women with pre-eclampsia, premature preterm rupture of membranes, gestational diabetes, obesity, and HIV.

Equipment

- Body composition measurement: PEAPOD (COSMED, Concord CA)
- Sample storage: freezers ULT185-5-A33 and 8603 (Forma, Asheville, NC)
- Sample processing: Refrigerated benchtop centrifuges G032 (Beckman Coulter, Palo Alto, CA), and L017 (Beckman Coulter, Germany)

National Jewish Health (NJH)

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. The unit consists of 4 patient care exam rooms, 1 interview room, and 1 negative air flow room. 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 and 873 square feet of office space. The unit is staffed by 1.5 RN's and is supported by a Nurse Practitioner and 1.0FTE of administration/regulatory support. History and Physical Exams, skin biopsies, consenting subjects for studies, spirometry, skin testing, induced sputum, sweat testing, medication administration, 12 Lead EKG, etc. are performed in the unit. The unit works with the Pharmacy for medication storage and distribution.

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)

University of Colorado Boulder (CU-B)

Facility

The CU-B Clinical and Translational Research Center is the only active NIH-funded CTRC Facility not located at a clinical institution in the U.S. It is an AAAHC-approved health care facility with 4,000 sq ft of dedicated CTRC space on the 3rd of the Wardenburg Health Center at the Boulder Campus. The facility includes 5 outpatient research protocol rooms (one is a Faraday cage which facilitates structured, not electrical, interference), an exercise testing/indirect calorimetry room, a body composition (DEXA) laboratory, a nutritional consultation room and a wet laboratory for processing blood and tissues. The CTRC has 1.25 FTE staff physician coverage (funded in the past by the Chancellor's Office at CU-Boulder), 3.0 FTE research nurse support, an Integrative Physiology Core Laboratory with 1.2 FTE personnel support, a 0.5 FTE bionutritionist, and a 1.0 FTE medical technician. There is an on-call nurse and physician available in the evenings 7 days/week to respond to research participant needs/concerns.

Equipment

- 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
- WinDaq data acquisition software (Dataq Instruments, Akron, OH)

- 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)
- Infusion pumps for saline and vitamin C: Imed Gemini PC-2TX (Alaris Medical Systems, San Diego, CA)
- Arterial Blood Pressure and ECG: Recording system with pressure transducer and ECG amplifiers (Gould ACQ-16, Gould Instruments, Valley View, OH)
- Semi-Automated Resting Blood Pressure Measurements: Datascope Accutorr V (Mindray DS USA, Inc., Mahwah, NJ)
- Ankle-Brachial Index: Transcutaneous Doppler flowmeters 810-A, (Parks Medical, Aloha, OR)
- Body Composition Analysis: Lunar Prodigy Dual Energy X-ray Absorptiometry (DEXA) system and encore analysis software version 15 (GE Medical Systems, Madison, WI)
- Nutritional Analysis: Nutrition Data System for Research (NDSR; Nutrition Coordinating Center, University of Minnesota)
- Exercise Testing: Ultima gas analyzer module with ECG interface (MedGraphics, Saint Paul, MN), BreezeSuite ventilatory data collection software version 7.2C (MedGraphics, Saint Paul, MN), Trackmaster 425 Treadmill and 12-lead ECG-treadmill interface (Full Vision Inc., Newton KS)

CTRC Core Laboratories

Facilities

CTRC Core Laboratories are located at UCH, CHCO, and NJH. The CHCO Core Laboratory is 10,000sq ft of space located in the basement of CHCO, adjacent to the hospital's clinical laboratory. The UCH Core Laboratory is 1,600 sq ft located within the UCH CTRC outpatient space on the third floor of the Leprino Building. 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 (full list at <http://www.ucdenver.edu/research/CCTSI/programs-services/ctrc/lab-services/Pages/Lab-Assays-Pricing.aspx>). There is no redundancy in the services offered by the CCTSI Core Laboratory Network: the UCH Core lab specializes in hormone and metabolite assays (3.6FTE); CHCO Core Laboratory focuses on inflammation markers, fat-soluble vitamin measurement, specific protein and pulmonary fluid processing (5.2 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, 6 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)
- Centrifuges: 6 x Allegra 6r, Allegra X-15R, Avanti 30, Avanti J-20 (Beckman Coulter, Brea CA); Sorvall Legend RT and RT6000D, RC3B Plus (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), 2 x Waters 2487 (Waters, Milford MA), Detector For Hplc ELSD2000 (Alltech, Lexington, KY), 1 x Waters 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)
- Gama 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), Spectro Flow 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: BioPlex Luminex 100, Luminex 200, Luminex FLEXMAP 3D (Luminex Corporation, Austin TX), Aushon Circascan 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 Bionutrition Core Facilities

The CCTSI Bionutrition Core consists of two groups of professionals: 1) scientists and nutritionists with extensive experience in nutrition and metabolism research (2.3 FTE) and 2) food service staff trained to prepare and distribute weighed, metabolic meals from our commercial research kitchen (1.8 FTE). The commercial kitchen is located at the UCH CTRC outpatient facility with a smaller food preparation facility on the 12th floor CTRC at CHCO. 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 methods; measurement of hunger and satiety; growth, body composition, and indirect calorimetry; 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 CTIC and CHCO CTIC: 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.