NAVIGATING THIS GUIDE:
This PDF is user-friendly and easy to navigate. Simply click on the **bookmark** icon located on the vertical bar to the left or right of your screen. This will open a list of chapters and topics that link directly to specific pages, allowing you to quickly find the information you need.

TABLE OF CONTENTS

CHAPTER 1: PURPOSE OF THE CTRC RESEARCH USER GUIDE

The **CTRC Research User Guide** serves as a valuable resource for both new and experienced members of our research teams. It offers essential information on various aspects of research, including processes, policies, portals, systems, and technologies. Specifically, it focuses on facilitating successful research at two of our institutions: the **Adult CTRC (both Outpatient AHSB and Inpatient UCHealth Units)** and the **Children's Hospital Colorado CTRC**. Although the guide is primarily designed for Research Coordinators, Research Assistants, and Research Project Managers, it provides useful insights for all team members involved in research endeavors.

CHAPTER 2: ABBREVIATIONS

AHSB	Anschutz Health Sciences Building
AHWC	Anschutz Health & Wellness Center
APP	Advanced Practice Provider
CAP	College of American Pathologists
CAS	Clinical Application Services
CCHRI	Colorado Child Health Research Institute
CCTSI	Colorado Clinical & Translational Sciences Institute
CHCO	Children's Hospital Colorado
CLIA	Clinical Laboratory Improvement Act
CTRC	Clinical & Translational Research Center
CTSA	Clinical and Translational Science Awards
CU	University of Colorado
CURP	University of Colorado Research Pharmacy
EHR	Electronic Health Record
EMR	Electronic Medical Record
EPIC	Electronic health records system for hospitals
G0	CHCO Research Billing Account Code (needed in EPIC for any CHCO study)
HIPAA	Health Insurance Portability and Accountability Act
HSR	Human Subjects Research Portal
IC	Indirect Calorimetry
IP	Inpatient
IRB	Institutional Review Board
IT	Informatics
IV	Intravenous
LOS	Letters of Support
MAR	Medication Administration Record (in EPIC)
MG	MicroGrant
MRN	Medical Record Number
NIH	National Institutes of Health
NJH	National Jewish Hospital
ONA	Operational Needs Assessment
ONS	Oncology Nursing Society
OP	Outpatient
PAF	Protocol Assessment Form
PI	Principal Investigator
PK	Pharmacokinetic
RN	Registered Nurse
SOC	Standard of Care
ST	Speedtype (General Ledger coding for transactional systems)
UCH	University of Colorado Hospital

CHAPTER 3: CCTSI, CTRC & RELATED RESEARCH RESOURCES AT-A-GLANCE

CTRC LOCATIONS (CU ANSCHUTZ MAPS)

Children's Hospital Colorado Map
University of Colorado Anschutz Outpatient CTRC (outpatient participant parking. Parking code will be provided by the study coordinator to research participants)
University of Colorado Anschutz Inpatient CTRC (parking is free)

HOURS OF OPERATION

Adult CTRC Nursing
CHCO CTRC Nursing
CTRC Core Laboratory (Adult & CHCO CTRCs)
CTRC Nutrition (Adult & CHCO CTRCs)

CCTSI & CTRC RESEARCH RESOURCES

Resources	Description
Adult CTRC Equipment Information	Equipment used for nursing services
Adult Outpatient CTRC Parking Instructions	The parking code is for CTRC participant parking only. Personal use of the parking code by research teams or participants parking outside of scheduled CTRC visits will be subject to citation
Adult Inpatient CTRC Parking instructions	Log in with CU username and password
Adult Outpatient CTRC Visit Status Dashboard	Includes link to the CTRC Visit Status Dashboard tool
Adult Outpatient CTRC Visit Status Dashboard Help Document	Quick Start guide on using the electronic CTRC Visit Status Dashboard and helps you track participants' progress during their Adult CTRC outpatient visit, from arrival through service provision to discharge
Cardiovascular BioImaging (echocardiology, fibroscans, etc.)	Provides a list of services offered and contact information for this core
CTRC User Guide	A "How-To" resource for conducting research visits at the Adult and CHCO CTRCs. Ideal for new and experienced research teams.
CHCO CTRC Epic Use Plan Guidance	Guidance on how to complete EUP request form and completed examples of common CTRC procedures like phlebotomy, infusion, etc.
CCTSI	Link to CCTSI homepage, which provides access to various CCTSI components, including CTRCs
CHCO CTRC SharePoint page	Provides CHCO CTRC-specific resources for study teams and monitors, including sponsor documents, equipment details, supply storage requests, and liaison assignments
Core Lab Assays	A searchable database of assays conducted by the CTRC Core Lab
Core Lab – Accreditation - CAP	College of American Pathologists (National Laboratory Accreditation)
Core Lab – Accreditation - CLIA	Clinical Laboratory Improvement Amendments (National Laboratory Accreditation)

Resources	Description
Core Lab Data Folder Authorization REDCap Form	Needed for study team members to request access to CTRC lab data
Citing our CTSA grant – suggested language	Any publications, patents, or projects that benefit from any CCTSI resources (including use of REDCap) must credit the CTSA Grant
CTRC Scheduler - Access request REDCap form	Required for study team members to request access to the CTRC Scheduler system. Only the Principal Investigator (PI) can complete the form to grant access to study team members
CTRC Scheduler program (VPN required)	Enables you to self-schedule visits for Adult CTRC participants
Exercise & Body Composition (DXA & HR-pQCT) Core- EBAC	Offers detailed information on testing, pricing, and contact details for services provided by the CTRC affiliated Core, including body composition, DXA analysis, RMR, HR-pQCT, and more
Human Subject Research Portal (HSR)	This portal streamlines the protocol submission process, allowing for real-time tracking and simultaneous reviews by the CTRC, hospital, and scientific review committee
Informatics - INFORM ticket	To request help with CCTSI related IT issues only. Contact CU Anschutz OIT (Office of Information Technology) for all other non-CCTSI related informatics issues
Nutrition Core - methods, surveys, and materials	Metabolic meals, Dietary assessment tools, Metabolic testing etc.

GENERAL RESEARCH SUPPORT

Resources	Description
OnCore	A campus-wide platform to manage clinical research and facilitate fiscal and operational compliance. Need to log in with CU username and password
OnCoreSupport	Can assist with granting access to and questions related to OnCore
COMIRB office hours and help desk	COMIRB ensures that research complies with ethical principles and regulatory requirements, safeguarding the rights and welfare of research participants
Clinical Research Support Team (CReST)	Provides a pool of experienced study coordinators, regulatory, and administrative staff to assist with clinical research study start-up, implementation, and closeout

UCHEALTH SPECIFIC RESEARCH SUPPORT

Resources	Description
UCHealth EPIC	A fully integrated, CMS-certified electronic medical record (EMR) system
UCHealth EPIC Access/Support	Supports research studies in 13 hospitals and numerous clinics across Colorado, southern Wyoming, and western Nebraska. They enhance research across the system by improving processes, increasing efficiencies and ensuring robust compliance with regulatory requirements
UCHealth Research Administration Support	Provides guidance on UCH research processes and policies
UCHealth Badging and ID request	For requesting hospital ID badge during onboarding process

CHCO SPECIFIC RESEARCH SUPPORT

Resources	Description
CCHRI Research Start-Up Resources (need CHCO access)	Provides guidance and contacts for research startup at CCHRI entities
CHCO Clinical Application Services CAS work request	To initiate a work request and choose 'research study' to access to latest Epic Use Plan blank form. Need CHCO access
CHCO Research startup	To reach out for any guidance on CHCO study startup process
CHCO Research-Start-Up Status Tracker - Power BI (Need CHCO Access)-	Tracking dashboard tool that provides status of studies during startup process at CHCO
CHCO EPIC helpdesk (24/7)	720-777-4357

CCTSI CONTACTS

Contacts	Email/ Link	Phone
CCTSI	cctsi.helpdesk@ucdenver.edu	303-724-1222
CTRC General and Administration	cctsi.helpdesk@ucdenver.edu	303-724-1222
CTRC MicroGrants	cctsi.helpdesk@ucdenver.edu	303-724-1222
Adult CTRC Nursing	cto-ctrc.rnprotocols@cuanschutz.edu	Inpatient: 720-848-7907 Outpatient: 303-724-1225
CHCO CTRC Nursing	pediatricctrc@childrenscolorado.org	720-777-2581
CHCO CTRC Admin	ctrc@childrenscolorado.org	n/a
Adult CTRC APP	ctrcapp@cuanschutz.edu	303-724-1225
CV Bioimaging	CCTSIBioimaging@cuanschutz.edu	303-724-4151
CTRC Scheduling – OP, IP, mobile	CTRCScheduler@ucdenver.edu	n/a
CTRC Core Lab, CHCO	CoreLab@childrenscolorado.org	720-777-8209
CTRC Core Lab, AHSB	CTRCCoreLab@cuanschutz.edu	303-724-4093
CTRC Nutrition core	CTRC.Nutrition@ucdenver.edu	303-724-1219
CCTSI Informatics Core	Informatics Support ticket	n/a

CHAPTER 4: CTRC FACILITIES & SERVICES

ADULT CTRC NURSING & APP SERVICES

The Adult CTRC offers the space, staff, and equipment needed to conduct a broad range of specialized research procedures. Services are provided on a fee-for-service basis, with subsidized rates available for federally funded studies. All procedures are overseen by highly qualified and experienced personnel, ensuring the highest standards of care and compliance. Staff members receive comprehensive training in HIPAA and Good Clinical Practice. Nurses are certified in Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS), while health technicians are BLS certified.

Only protocols that have received IRB approval can request CTRC services.

- List of Adult CTRC Nursing and Advanced Practice Provider (APP) Services

OUTPATIENT CTRC AT AHSB

The Adult CTRC Outpatient (OP) occupies 7,700 sq ft of space on the 6th floor of the Anschutz Health Sciences Building (AHSB) and includes:

- Infusion room (5 chairs)
- Phlebotomy room (3 stations)
- Exercise testing room (3 stations)
- Muscle function room (isokinetic dynamometer)
- Body composition room (DXA, HR-pQCT)
- Secure medication storage room (for FDA controlled substances)
- Sample processing room (1)
- Negative pressure rooms (2)
- Interview room (1)
- Extra-large procedure rooms (2) with beds and private bathrooms for conducting longer-stay studies, such as, neurology studies and hyperinsulinemic euglycemic clamps
- Regular procedure rooms (4), two are available for scheduling study visits
- Exam rooms (8)
- Charting & computer workstations (9) for research teams
- Adjacent 3,500 sq ft state-of-the-art research exercise training facility for exercise intervention research

INPATIENT CTRC AT UCHEALTH

The Adult CTRC Inpatient (IP) unit occupies 7,226 sq ft of space on the 12th floor (AIP I) of UCHealth at CU Anschutz. It features six beds across five rooms and includes a wet lab for sample processing. Unique resources available in this unit include an inpatient whole room calorimeter for measuring 24-hour energy expenditure and substrate oxidation, as well as a sleep laboratory with adjacent monitoring space for polysomnography. The unit is supported by experienced research nursing staff.

ADULT CTRC EQUIPMENT

- Portable indirect calorimetry (IC)
- Maximal and submaximal exercise testing

- Body composition measurement (Dual X-ray Absorptiometer)
- Stress Testing with treadmill
- Isokinetic dynamometer
- Whole Room Calorimeter
- High Resolution-Peripheral Quantitative Computed Tomography (HR-pQCT)
- Cardiovascular BioImaging
- Cardiac Monitoring
- Centrifuges (refrigerated and room temperature)
- -80° freezer, - 20° freezer, refrigerator for short-term (less than 48 hrs) sample storage

For detailed information on location and specifications on each piece of equipment, refer to the Adult CTRC Equipment document.

CHCO CTRC NURSING

The CHCO CTRC offers the space, staff, and equipment necessary to support a wide range of research procedures in children. It accommodates both investigator-initiated studies, including multi-center NIH studies, and industry-initiated protocols. Services are provided on a fee-for-service basis, with subsidized rates available for federally and investigator-initiated funded studies in pediatric, adolescent, and neonatal populations. All procedures are overseen by highly qualified and experienced nurses who are trained in HIPAA and Good Clinical Practice, and hold certifications in Pediatric Advanced Life Support (PALS), Advanced Cardiovascular Life Support (ACLS), and Basic Life Support (BLS).

Only protocols that have received IRB approval can request CTRC services.

- List of CTRC CHCO Nursing Services

OUTPATIENT CHCO CTRC

The CHCO outpatient CTRC consists of 5,973 sq ft of space located on the 3rd floor of the outpatient pavilion at CHCO and includes:

- Infusion rooms (4)
- Exam room (6)
- An extra-large procedure room
- Treatment room (1)
- Consult/consenting rooms (2)
- Secure medication room
- Wet labs for sample processing (2)

INPATIENT CHCO CTRC

Nursing services within the inpatient units at CHCO are also available. Experienced research nursing support can be provided upon request by investigators.

EQUIPMENT

- Centrifuges (4) for sample processing
  - Reserved in Epic via Decision Tree
- Short-term Sample Storage (-20˚C, 4˚C) (less than 48 hrs)
- EKG Machine (2)
- Metabolic Testing Cart (2)
  - Reserved through Nutrition Core via CTRC Scheduler Application.
- Bodpod
  - For use, contact Lauren Shomaker or Kristen Nadeau

CTRC CORE LABORATORIES (ADULT & CHCO)

The CTRC Core Laboratories are conveniently located adjacent to the Adult, CHCO, and NJH CTRCs. The Adult Core Laboratory spans 1,544 sq ft and is situated within the CTRC outpatient space on the sixth floor of the Anschutz Health Sciences Building. The CHCO Core Laboratory occupies 10,000 sq ft in the basement of CHCO, adjacent to the hospital's clinical laboratory.

EQUIPMENT

- Cold Sample Storage, -80˚C, -20˚C, 4˚C
- Centrifuges (refrigerated)
- UPLC
- Real-time Whole Blood/Plasma Chemistry
- Gamma Counter
- Spectrophotometers
- Autosampling
- Nitrogen Analyzer
- Chemistry Analyzers
- Multiplex analyzers
- Electrophoresis Systems
- Immunoassay Analyzers
- PCR Analyzers

NUTRITION CORE (ADULT & CHCO)

The CCTSI Nutrition Core is comprised of dietitians and nutritionists with experience in nutrition and metabolism research. All staff members are trained to prepare and distribute weighed metabolic meals from our commercial research kitchen, located at the Anschutz Health and Wellness Center (AHWC) on the CU Anschutz Medical Campus, which spans 1,273 sq ft.

Additionally, there are smaller food preparation facilities located at:

- CTRC at UCHealth Inpatient Hospital (93 sq ft)
- Anschutz Health Sciences Building (AHSB) (287 sq ft)
- CTRC at Children's Hospital Colorado (CHCO) (84 sq ft)

The kitchen and all staff involved in designing and preparing diets are ServeSafe certified. Meals are prepared, stored and shipped to CTRC sites for distribution as needed, and these services are provided on a fee-for-service basis.

- List of CTRC Nutrition Services

EQUIPMENT

- Diet design software
- Analysis of dietary intake software
- Portable indirect calorimetry (IC)
- High Precision Balances
- Refrigeration/freezer storage
- Diet preparation (full commercial kitchen including a walk-in freezer/refrigerator)

CARDIOVASCULAR BIOIMAGING CORE

The SOM Cardiovascular Bioimaging Core, affiliated with the CCTSI, provides a comprehensive range of ultrasound imaging services to assess cardiovascular health in both children and adults. The Bioimaging Core is comprised of board-certified sonographers who have advanced training and multiple certifications in sonography. Services provided include:

- Echocardiogram (ultrasound imaging used to assess cardiac structure and function)
- Real-time three-dimensional (3D/4D) echo technology
- Speckle tracking imaging/Global longitudinal strain assessment (assesses left and right ventricular contractile function and muscle fiber shortening)
- Definity (ultrasound image enhancer administered via IV to visualize left ventricular function and wall perfusion, perfusion of skeletal muscle, pancreatic perfusion, etc.)
- Renal artery flow velocity
- Fibroscan (utilizes elastography to assess liver stiffness and fatty changes)
- Carotid Intima-Media Thickness (cIMT) (2D ultrasound to image the intimal layer of the common carotid artery)
- Flow-Mediated Dilation (FMD) (2D ultrasound and pulsed wave Doppler to image the brachial artery)
- Brachial artery endothelial function testing
- Arterial stiffness
- Intimal-medial thickness

EQUIPMENT

- GE Vivid E9 with Xdclear
  - 9L- transducer used for vascular ultrasound
  - M5Sc-D- transducer used for echocardiography
  - 4V-D- used for 4D echo imaging
- FibroScan 502
- Hokanson Rapid Inflator for FMD

- Brachial Analyzer- software used to analyze FMD
- Carotid Analyzer- software used to analyze cIMT
- ViewPoint (VP)- used for storage of all imaging performed by the Bioimaging Core

CTRC SCHEDULER CORE

- The CTRC Scheduler is a secure, HIPAA-compliant, web-based application for study teams to self-schedule research participants on the Adult CTRC outpatient and inpatient settings simultaneously. These services included in scheduler are nursing, nutrition, EBL/DXA, Nurse Practitioner/Physician Assistant (APP), and cardiovascular CV Bioimaging. This streamlined scheduling process helps ensure efficient coordination and management of research participant appointments.

  - CTRC Scheduler Instructions
  - CTRC Scheduler- Cancer Center instructions
  - CTRC Scheduler Study Set-Up template (this template identifies each study visit, resources needed, and length of time needed for each visit, filled out by the study team)

  Accessing CTRC Scheduler:
    - CTRC Scheduler program (VPN required) (allows you to self-schedule Adult CTRC participant visits)

INFORMATICS CORE

The CCTSI Informatics Team offers infrastructure support for your project needs on a fee-for-service basis. If you require assistance with data management, software development, or other informatics services, they can provide the necessary resources and expertise to help ensure your project's success.

Services available include but are not limited to:

- Database Hosting/Storage
- Web Design and Consulting
- REDCap QI Project Hosting

CHAPTER 5: PROTOCOL SUBMISSION – INITIAL SUBMISSION & AMENDMENTS

INITIAL PROTOCOL SUBMISSION

CTRC services are only offered to IRB-approved protocols.

The CTRC systematically reviews each submission, whether initial or amended, to assess feasibility and grant approval for the use of its services and facilities. The review process differs between the Adult CTRC and CHCO CTRC due to variations in institutional procedures. Detailed start-up steps for each location are outlined in Chapter 6.

New protocol submissions are entered into the CU Anschutz Human Subject Research (HSR) Portal.

- **Entering Protocol Specific Information into HSR**
  - Protocol information is entered into the HSR portal on the Protocol Assessment Form (PAF), which will route to relevant entities involved in implementing the study (UCHealth, OnCore, SARC, CTRCs, Pharmacy, etc.).
  - It is important to carefully select specific CTRC sites- Adult CTRC or CHCO CTRC, to trigger the notification to the intended site.
  - Also, be sure to select all relevant cores within the given CTRC site (Nursing, Lab, Nutrition, etc.) to ensure they receive the relevant protocol information.

- **Making the correct selections for ancillary services/cores**
  There are several similarly named cores on the Protocol Assessment Form. These operate independently of each other. Some of the frequently confused ones are listed below with links to their websites to help users choose the correct core/service.
  - Laboratories
    - CTRC Core Labs (CTRC Peds Lab at CHCO Basement and CTRC Adult lab at AHSB 6th floor)
    - CHCO Main Lab – Clinical lab at CHCO Basement level
    - UCHealth Clinical Lab - Leprino Office bldg.
  - Pharmacies
    - UCHealth Pharmacy
    - CU Research Pharmacy
    - CHCO Investigational Drug Services (IDS) Pharmacy
  - The SOM Cardiovascular Bioimaging Core, which is an affiliate of the CCTSI, offers a wide range of ultrasound imaging techniques to support research specific study requirements

SUBMITTING PROTOCOL AMENDMENTS

- **Submitting Amendments through the HSR Portal**
  This submission process manages amendment submissions that impact OnCore, the study calendar, and information in OnCore.

  The following changes must be submitted through the HSR Portal:
  - Change to PI
  - Changes to budget
  - Changes to calendar
  - Changes to Medicare Coverage Analysis (MCA)
  - New arm/new procedures
  - New location
  - Correction to calendar/financials
  - CTRC resource requests and/or requesting a microgrant (if not initially or previously requested)

The Clinical Research Support Team (CReST) provides a comprehensive module on HSR submissions. To access this, select Clinical Research Operations, then 'Clinical Research Onboarding' to self-register for the onboarding courses in Canvas. Log in with your CU credentials, select 'COURSES,' and then choose the 'Clinical Research Onboarding' course. One of the modules specifically focuses on HSR submissions."

CHAPTER 6: CTRC STUDY START-UP PROCESS

ADULT CTRC STUDY START-UP

This represents the process for the Adult CTRC only. Additional steps may be required by the University or the hospital where your visits will take place**.**

*Required documents include draft MD orders and lab manual, as applicable
**Study MUST be OPEN TO ACCRUAL in OnCore before it can be activated in CTRC Scheduler

1. CTRC Review

If the Adult CTRC is selected as a site for research visits on your HSR Portal submission form, a notification will be sent to all selected Adult CTRC CORES for review and approval.

The Adult CTRC will conduct a feasibility and budget review within 14 days, provided all necessary details are available. Each CTRC Core involved in the study will assess the service request for feasibility and will either approve, deny, or request clarification. The study team will be informed of the approval or denial of CTRC utilization.

2. Adult CTRC Welcome Letter & Utilization Approval

The Adult CTRC Welcome Letter & Utilization Approval is an introductory document that briefly outlines the next steps in the study start-up process and provides links and a list of primary CTRC contacts. This letter is emailed to the Principal Investigator (PI) and study contacts listed on the HSR PAF. The start-up steps for studies requiring ROOM ONLY or AFTER-HOURS services are significantly shorter and will be specified in the welcome letter.

3. Submit Documents

The study team must submit the MD orders using the Adult CTRC Study Startup Dashboard System —a centralized, HIPAA-compliant platform for creating and editing MD orders. Tips for successfully completing MD orders draft and examples of completed orders can be found here. Submission of these MD orders drafts is required to proceed to the next step.

4. Protocol Implementation Meeting

Once the above documents have been received, the CTRC will arrange a protocol implementation meeting between the study team and relevant cores to discuss operational logistics. During this meeting, the CTRC will address the study team's needs to request access to any of the following:

- Core Lab REDCAP authorization (to request lab data)
- CTRC Scheduler Access Request
- Adult Outpatient CTRC Visit Dashboard Access Request

A follow-up PI meeting is required if your study does not commence within 6 months of the original PI meeting.

5. Approve Documents

It is essential for each of the core specific documents to be approved by the study PI prior to scheduling the first visit for the study. These documents include:

- Finalized, signed MD Orders
- Core Lab requisition form (if applicable)
- Nutrition materials and menus (if applicable)
- CTRC Scheduler study template build - study visits are built in the CTRC Scheduler system. Instructions on access and use of CTRC Scheduler can be found on the CTRC Scheduler webpage.

6. Study OPEN in CTRC Scheduler!

All cores must have approved documents, AND the study status must be OPEN TO ACCRUAL in OnCore in order to be made OPEN in CTRC Scheduler. Once active, the study team can begin scheduling CTRC visits in CTRC Scheduler system.

CHCO CTRC STUDY START-UP

This represents CHCO CTRC processes only. Additional steps may be required by the University or the hospital where your visits will take place**.**

Without the approved documents, CTRC will not provide services for the visit.

1. ONA Ancillary Review/Approval

ONA virtual review is conducted biweekly at CHCO. During these reviews, the CHCO Research startup team, study teams, and all ancillary cores (including CTRCs and Pharmacy) can ask questions based on their prior review of documents. CTRC cores will review the provided documents and may reach out via email before the ONA if the queries are complex. Study teams can use the ONA time to clarify any points regarding ancillary services.

Once specific CTRC Cores have approved the requested services listed in the protocol, the CTRC Protocol Specialist will complete the CTRC approval via redcap and include the following information:

- Summary of CTRC services that have been approved
- Any caveats to consider
- CTRC Budget (all cores included)

This approval and budget are completed within 2 weeks from the ONA meeting via a redcap form that is routed to the study PI and/or coordinator.

2. CTRC Welcome Letter

The CTRC Welcome Letter is an introductory document that briefly summarizes the next steps in the study startup process and provides a list of primary CTRC contacts. The letter is sent out within 2 weeks of the CTRC approval via email to PI and other main study contacts listed on the HSR form.

3. Liaison Assignment

Each participating core will assign a team member as liaison for the study. The role of the liaison is to work with the study team on the core needs and serve as a point of contact for that core for any questions or concerns. The Nurse liaison will work with study team to develop nursing guidelines that are detailed reference documents for the CTRC RNs to indicate nursing services required by the protocol.

4. Protocol Implementation Meeting (PI)

This startup meeting is held to discuss any operational logistics of conducting the study at the CHCO CTRC. The meeting is scheduled close to the CHCO Epic Use Plan (EUP) meeting so that study teams are prepared with study details. CTRC will arrange this meeting with the study team once the EUP request is received. Simple protocols with blood draws/processing and space only visits may not need this meeting and can be coordinated via email. However, protocols with any of the following factors will benefit from this meeting between the study team and all relevant CTRC cores.

- High-Risk Medications
- New PI to CTRC
- New Coordinators
- Long PK Days
- Visits that may be outside CTRC Hours
- Inpatient Visits
- Mobile Nursing
- Studies needing other CTRC cores like Nutrition and core lab
- If Nurse liaison requests for any other reason

At this meeting CTRC will discuss need for study team to request access to Core Lab REDCAP authorization (to request lab data).

A follow-up PI meeting is required if your study does not commence within 6 months of the original PI meeting.

5. Approve Documents

It is essential for each of the core specific documents to be approved by the study team prior to scheduling the first visit for the study. ***Without the approved documents, CTRC will not provide services for the visit.*** These documents include:

- Nursing guidelines
- Core Lab requisition form (if applicable)
- Nutrition materials and menus (if applicable)

6. Study Open to Start!

All documents need to be approved prior to study is activated in EPIC. Once the study is OPEN TO ACCRUAL in OnCore and ACTIVE in CHCO EPIC, only then the study teams can begin scheduling CTRC visits.

CHAPTER 7: FINANCE SETUP DURING STUDY START-UP

iLAB SETUP (ADULT & CHCO CTRC STUDIES)

CTRC cores including Nutrition, Energy Balance Core, and the Laboratory, utilize the iLab system for billing. If a study is utilizing any of these cores, the charges will be billed to the project through iLab. Payment of charges is automatic, and teams access their invoices through their iLab accounts. To access and/or request an iLab account please follow the instructions below.

Accessing the iLab Site:

1. Go to https://cu.corefacilities.org/account/login
2. Log in to my.cu.edu using UCD credentials.
    a. From the left-hand menu, select Business Tools.
    b. Click on the iLab Solutions tile.

Creating an Account in iLab:

1. Principal Investigators (PIs) should send an email to Finance.ServiceCenters@ucdenver.edu
    a. requesting a PI account. Include employee ID# and desired speedtypes
2. Study team members follow these steps:
    a. Visit https://cu.corefacilities.org/account/login
    b. Select "UC Denver" from the dropdown and click "GO."
    c. Sign in with CU Anschutz credentials, leading to the iLab registration page.
    d. Complete all required information and choose the affiliated lab (usually the PI).

CHILDREN'S HOSPITAL (CHCO) ACCOUNTS (G0 ACCOUNT SETUP) TO PAY FOR CHCO BASED SERVICES

A G0 account is the most common account type used to pay for research services based at Children's Hospital Colorado (CHCO). It is important to note that services at CHCO cannot be directly billed to a university speedtype. If you are starting a research study that will need to pay for CHCO services, you will need a G0 account.

Applying for G0 account-

- For funding residing at CHCO (Department or Division funds) please work with your CHCO financial delegate to request a G0 account.
- For funding residing at CU Anschutz please work with your Grants Specialist to submit a work order by completing this form.

The key contact for G0 account is msaworkorder@childrenscolorado.org for any queries.

CHAPTER 8: CONDUCTING STUDY VISITS AT ADULT CTRC

Prior to First Study Visit

Perform these checks as applicable for your study:

- ✓ MD orders need to be up to date. Nursing can only perform procedures listed on the MD orders signed by the study provider
- ✓ All Core services (Nursing, Lab, Nutrition, and Cardiovascular BioImaging) must have the approved materials and details needed for your study
- ✓ A tour of the Adult CTRC is offered to all new PIs and coordinators and should be completed before the first visit. This is extremely helpful to get familiar with the clinic area and facilities.
- ✓ Study is open in CTRC Scheduler
- ✓ Communicate any changes or necessary information with CTRC Nursing prior to your visit via CTRC Nursing email

Parking Details for Participants

Provide participants with up-to-date information on parking code by clicking the 'parking codes' button on this link.

Dining Options

AHSB - T- Street Kitchen restaurant and coffee shop, 1st floor
UCHealth - Hospital cafeteria (AIP) and coffee shop (AOP), 1st floor
LOB Parking Structure, 1st floor

- Jimmy John's
- Dazbog Coffee
- Subway
- Green House by Etai's
- Rosa's Mexican Kitchen by Etai's
- Chai & Chai

On-Campus Transport - Campus circulator service

- Monday thru Friday (7:00am – 3:30pm)
- Call Ext 41777 or 303-724-1777 to request a ride

VISITS AT OP CTRC CLINIC (AHSB)

Participant Check-In

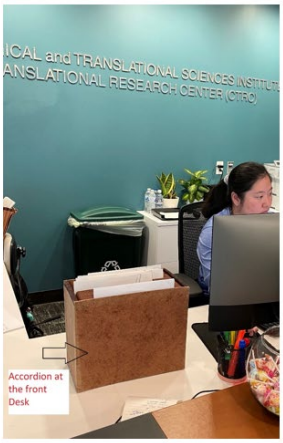
- The participant will check in at the front desk. The study team should follow instructions on participant check-in and dashboard use. Study teams need to sign-in at the front desk with their contact information in case a CTRC team member needs to contact them about the visit. If a study team member is present, they will room the participant. If no study team member is present, CTRC nursing staff will room the participant.
- For any other rooming or visit issues, the study team should communicate with the CTRC front desk to resolve issues.

Study Visit Packets

Study visit packets are located at the front desk. These packets include participant labels, Core Lab requisition form (if needed), and billing forms provided by the CTRC clinic. The study team should provide the Clinical Beaker slip if UCHealth clinical labs need to be collected, and this should be added to the packet prior to or at the start of the visit.

Please note that UCHealth SOC labs cannot be collected in the Adult OP CTRC Clinic, as the Adult OP CTRC clinic is a CU Medicine facility.

Remember to collect study packets for visits needing nursing services located in nurses station.



Study packets for visits *not* needing any nursing support are located at the front desk. For example, room-only visits.

DASHBOARD USAGE

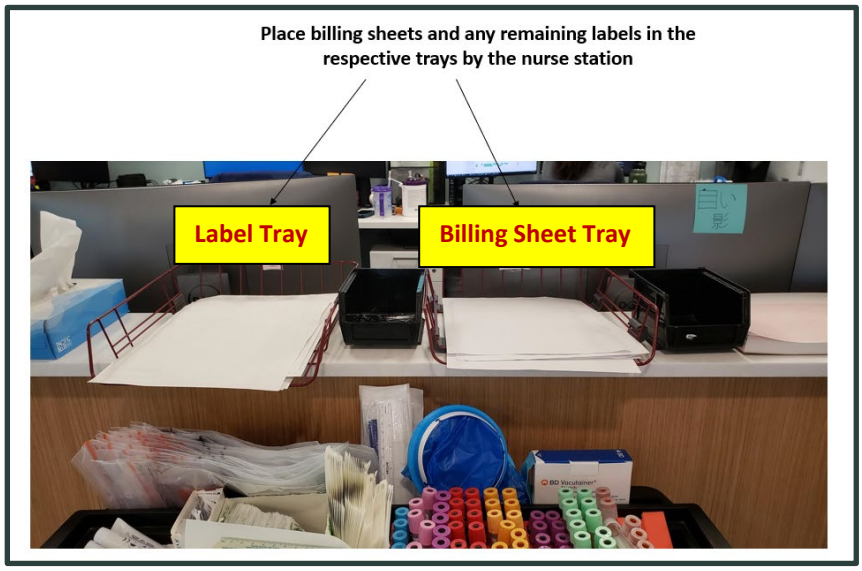
The Adult Outpatient CTRC Visit Status Dashboard app should be used to communicate with the RN and APP during the visit. It is important to update the dashboard in real time, especially during check-out. The length of the study visit for billing purposes is determined by check-out time. Additional charges will apply if participants are not checked out in a timely manner on a repeated basis. Checking out participants is also important to ensure they depart from the clinic, as this can be a safety concern in the event of an emergency.

Color coded system for Dashboard

Color Code	Visit status	Who needs to update
	Participant scheduled	CTRC front desk
	Participant checked-in	CTRC front desk
	Blood draw	Study team
	Assigned	CTRC Nursing
	ECG Only	Study team
	Nurse Practitioner	Study team
	Nurse Done	CTRC Nursing
	Participant checked-out	Study team

Billing Sheets and Remaining Labels –

- Must be returned to the nurse's station and placed in the respective designated trays.
- For visits not utilizing CTRC Nursing support, study teams need to complete billing sheets for any supplies used from the CTRC and the amount of time the room was used.
- Billing sheets are crucial for ensuring accurate billing and preventing related issues.



Linens and Blankets

The linen cart is in the corridor across from the infusion suite, P12- 6038. Warm blankets are available in the blanket warmer next to the linen cart.

Interpreter services

In the OP CTRC, an iPad with interpreter services can be reserved through CTRC Scheduler, and its use is billed to the study on a per-minute basis. Please email the CTRC Scheduler team to request a translator template if you need to reserve this service for your visits.

Visitors

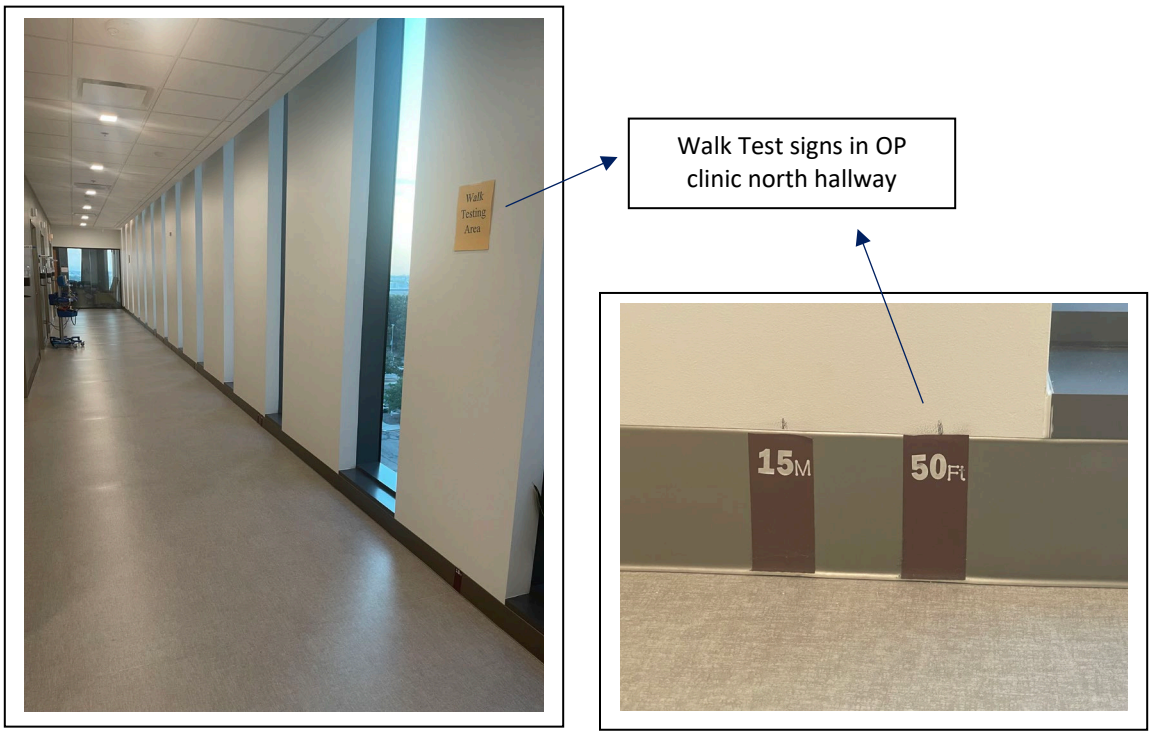
Participants may bring up to two support people (with no age restriction) to accompany them during research visits, if needed. If a visitor experiences a medical emergency in clinic, CTRC nursing will assess the situation and either send the visitor to the emergency department or call 911 for further evaluation, if necessary.

EPIC

Study teams must link the visits in EPIC to research studies latest by end of business day, as billing is processed at midnight on the day of the visit. Failure to do so in a timely manner may result in billing being charged to the participant. Ideally, the linking of visits can be done prior to the visit as appointments are created in EPIC one week in advance. Additionally, the study team should complete documentation in EPIC for any procedures during the visit.

Walk Testing Area

The Walk Testing Area is located in the north hallway of the CTRC OP Clinic between Rooms 1-5. The distances are marked near the floor.



When Visits Go Longer Than Expected

The study team should contact the Adult CTRC OP Clinic front desk if the visit will exceed the scheduled time window by 15 minutes or longer. CTRC staff will allocate the participant additional time for the participant in that room and move the next participant to a different room. If this occurs repeatedly, the study team should consider increasing the visit duration in CTRC Scheduler visit templates by emailing the CTRC Scheduler Team.

If the visit continues beyond the OP CTRC's closing time, two members of the study team with BLS certification must be present to continue the visit. If this is not possible or if CTRC clinical care is needed beyond OP hours, please discuss with the CTRC staff and CTRC Scheduler team about the possibility of transferring the participant to the IP unit.

Ordering UCHealth Clinical Labs-

- Outpatient CTRC: Clinical labs need to be ordered using a Beaker Requisition Build. If a Beaker Requisition build is needed, the study team must indicate this during protocol submission within the HSR portal form.
- Inpatient CTRC: Clinical labs can be ordered on a Beaker Build or submitted directly in Epic by CTRC nursing. However, the method of ordering must be pre-approved by UCHealth Research Administration in OnCore. Please contact UCHealth Research Administration with questions.

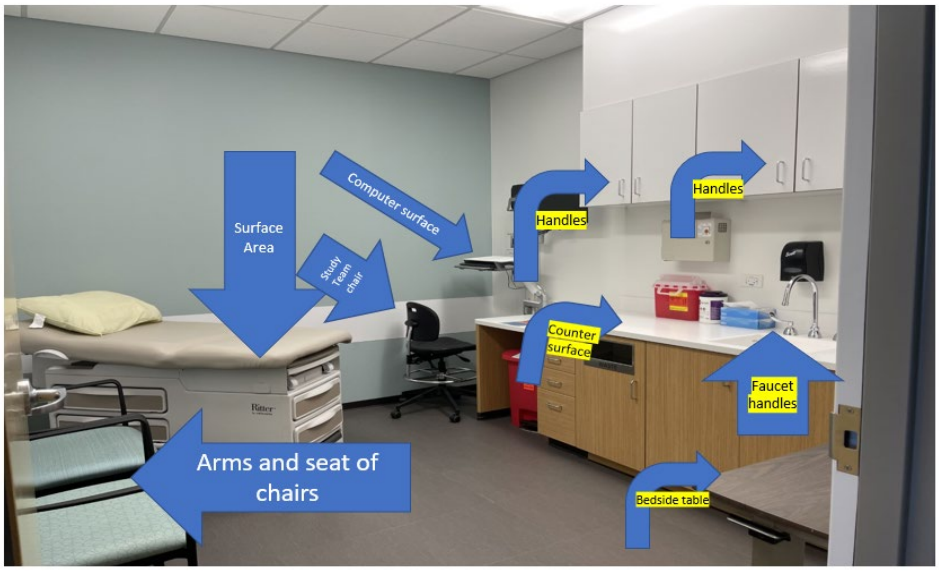
OP Clinic CTRC Processing room - Room P12-6050A, just to the left of the phlebotomy room when you leave the clinic. Review the Core Lab guidelines for using this shared space.

Transporting Laboratory samples from CTRC OP clinic to Clinical lab in Leprino Building
CTRC OP Nursing will no longer be able to transport the samples to Leprino Bldg. Study teams are recommended to walk these samples over to Leprino or use a courier service that handles prompt delivery of STAT labs. One of the Lab courier services available is: Lab Logistics.

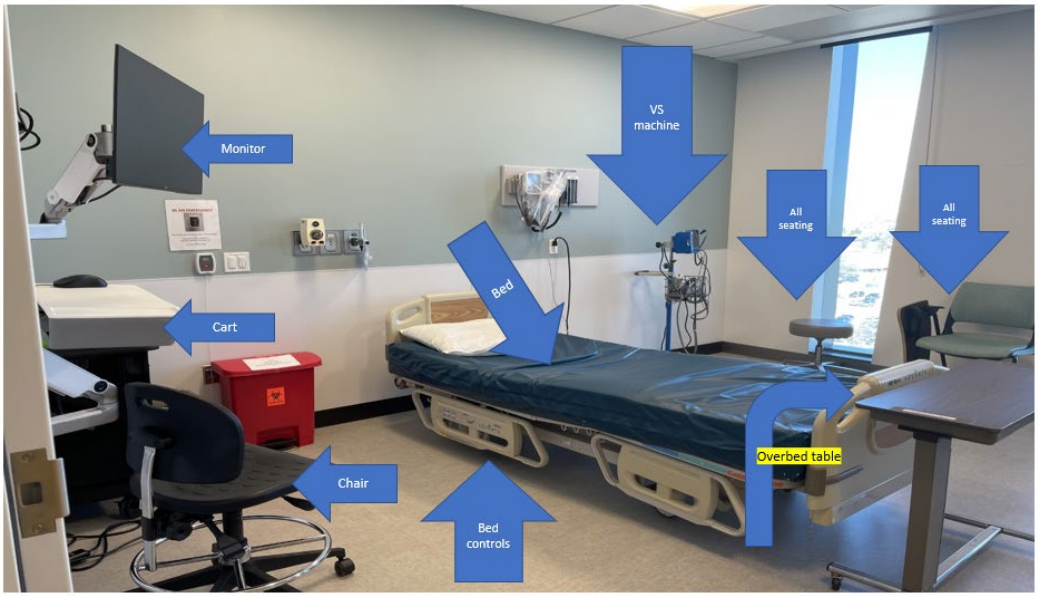
Room Cleaning

- To prepare the room for the next participant, each study team is responsible for cleaning the room immediately after their visit and prior to departing.
- Return the tables and chairs where you found them.
- Equipment should not be moved from room to room (i.e., taking a chair from the next door exam room) without notification to the nursing/front desk staff and that any relocated equipment should be returned after the visit is completed.
- Put the CTRC equipment in designated spots and plug them in (example-Vital Sign machines should be in the hallway and plugged in)
- There are Cavi-Wipes in every room. Using gloves, clean the surface areas of the "touch points" in the room.

All "touchpoints" must be cleaned by the Study Team prior to leaving the room



All “touchpoints” must be cleaned by the Study Team prior to leaving the room



VISITS AT IP CTRC UNIT AT UCHEALTH

Participant Check-In

- Participants check-in at the nurse’s station at the CTRC IP unit entrance with our CTRC Nursing Team. Room information is displayed on the whiteboard in the front desk area. Once checked in, a CTRC nurse will bring the participant and study team back to the room.
- CTRC Nursing or the study team will collect height and weight if needed on the way to the room.
- CTRC Nursing or the study team will inform the participant of bathroom location, call light and bed control functionality, how to order meals from the UCHealth kitchen if applicable, and any other special instructions for their visit.
- For any other questions, the study team can communicate with the nurse designated to their participant for that study visit day.

Study Visit Packets

These packets are located at the nursing station. The packets include participant labels, Core Lab Requisition Form (if needed), and billing forms for each participant scheduled.

Meals During Visits

Meals provided by CTRC Nutrition core are charged through the Nutrition Core, but hospital meals are provided by UCHealth, are included at no charge. However, guests need to pay for hospital meals.

Linens & Blankets
Two linen carts are in the alcove across from room 1215 and another one in the hallway across from the visitor bathroom near room 1223. Warm blankets are available in the warming oven next to room 1223.

Interpreter Services
Inpatient CTRC has an iPad with interpreter services available. Please indicate in the CTRC Scheduler Comments that you will need this iPad when you schedule your visit. This service is free in UCHealth Buildings.

Visitors
For IP CTRC, overnight visitors are typically not allowed unless approved by CTRC Leadership in advance. In the event of a visitor medical emergency, nurses will transport the visitor to the emergency department for further evaluation. If unable to transport the visitor, a rapid response team or CODE team will be called. UCHealth visitor policy will apply to all visitors.

Transporting participants across campus for procedures

- Study personnel will transport research participants to designated area of campus for the study procedure.
- If the participant has a peripheral IV (PIV), the Research RN will ensure it is patent and secured appropriately for transport across campus and assess PIV for patency upon return to the Adult CTRC inpatient unit.
- Research personnel and the participant will utilize intra-campus transport (golf cart or van) when available.
- **On-Campus Transport** – Campus circulator service
  Monday thru Friday (7:00am – 3:30pm)
  Call Ext 41777 or 303-724-1777 to request a ride
- In case of emergency during transport, if within a UCHealth Building, call Ext 85555 or 720-848-5555. If anywhere else on the CU Anschutz campus, research personnel will call 911 from any CU Anschutz campus phone and/or (303) 724-4444 from any cell phone for assistance.

IP CTRC Sample Processing Room – Room 12.014 Inpatient CTRC, between patient rooms 1223 and 1224. Door Code 0190#.

- The CTRC IP Unit has a refrigerator, -20°C, and -80°C freezers in Room 12.014 where study teams can store samples short-term (less than 48 hrs) during study visits. Any samples being analyzed by the CTRC AHSB Core Lab can be left in the freezers and these will be sent to the CTRC AHSB Core Lab by CTRC nursing staff.
- It is the responsibility of the study team to clear out any samples from the freezers, refrigerators, and ambient samples that do not need to go to Core Lab by **4pm on Friday of each week**.
- **CTRC does not offer sample courier**. Study teams are responsible for all sample transport other than to the CTRC AHSB Core Lab.
- **CTRC Adult Nursing does not offer complex sample processing involving additives, slides or smears.** These samples need to be sent to the UCH Clinical Lab. Study teams need to provide UCH Clinical Lab Requisition form with study tubes to CTRC Nursing staff when they need this kind of advanced processing ordered through clinical lab.

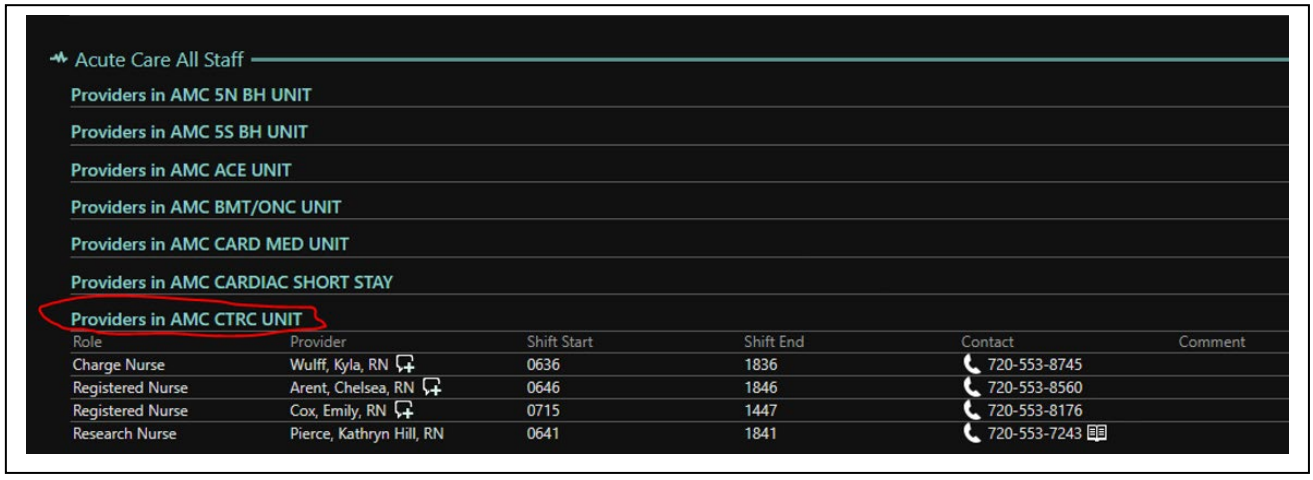
Room Cleaning
Environmental services will clean the room following the visit in accordance with hospital policy. CTRC Nursing is responsible for removing linens and cleaning CTRC equipment after the visit. Each study team is responsible for their own equipment cleaning and returning it to its designated area.

EPIC
Study teams must link the visits in EPIC to research studies before the end of the day, as billing is processed at midnight on the day of the visit. Failure to do so in a timely manner may result in billing being charged to the participant**.** Additionally, the study team should complete documentation in EPIC for any procedures during the visit.

COMMUNICATION WITH IP CTRC RN VIA EPIC CHAT

EPIC Chat is an efficient way to communicate with IP CTRC nurses. Follow these steps to use EPIC Chat or to find the contact information for CTRC RNs working on a given day.

1. Open EPIC
2. Select the Chat function
3. In the left corner select 'AMC Signed in Staff'
4. Scroll all the way down within the report viewer to the 'Acute Care All Staff' list
5. Find 'AMC CTRC Unit', select
6. The drop down will list the names and contact number for each nurse currently working on the inpatient unit.



Billing and Study Packets – CTRC Nursing will complete billing and properly dispose of study packets after the visit.

CHAPTER 9: CONDUCTING STUDY VISITS AT CHCO CTRC

SCHEDULING VISITS AT CHCO CTRC

For details on scheduling visits in the Pediatric CTRC, reference the CCHRI CTRC Space and Scheduling Guidance document on the CCHRI CHCO SharePoint site Standard Operating Procedures and Guidance Documents (sharepoint.com). This document includes details on the CTRC space, step by step scheduling process and helpful tips for coordinators.

Prior to First Study Visit

Perform these checks as applicable for your study:

- ✓ Nursing can only perform procedures listed on the Nursing guidelines. PI approval of the nursing guidelines is *required* prior to first visit.
- ✓ The CHCO CTRC tour is offered to all new PIs and coordinators and should be completed before the first visit. This is extremely helpful to get familiar with the clinic area and facilities.
- ✓ All Core services (Nursing, Lab, Nutrition) must have the approved materials and details needed for your study.
- ✓ Make sure that the study is Active in CHCO EPIC.

CHCO access needed for several links included below

Participants Needs

Prior to a study visit in the CTRC, consider participant needs:

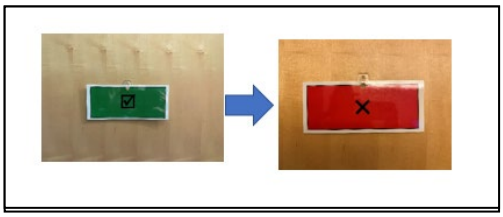
- Will you need an interpreter?
  - If yes, when you complete your Research Appointment Request in Epic, select **Yes** where it asks **Interpreter Needed**.
- Do you need Child Life?
  - Prior to your visit, call the Child Life office (x-67070) to put participant on their schedule.
  - Child Life can help with visits with procedures like blood draws, IV placement, EKGs, etc., and provide the participant with coping mechanisms to decrease distress.
- Will a parent be bringing other siblings?
  - Review the Visiting Guidelines Policy (need CHCO access) for updated information. During respiratory season or outbreaks, this policy may change so it is important to check before allowing parents to bring other siblings.
  - For participants or family members with COVID-19 or exposure to COVID-19 check the Coronavirus: Novel Coronavirus 2019 (COVID-19) Policy for updated information on visitation restrictions.
  - For younger siblings or longer visits, you can call the Creative Play Center (720-777-6999) where siblings can go and play during the study visit
- Do you need to request special equipment for your visit (bariatric chair, gurney, hoyer lift, commode)?
  - Notify CHCO CTRC Charge (720-777-2581) at least one week in advance of your visit to arrange for equipment

- Is the participant bringing in equipment from home?
  - For Inpatient Visits, any home medical equipment brought in by the family for participant needs should be checked by Biomed during regular business hours. Contact the ZIPP line (720-777-9477) and ask for Biomed to have equipment checked.
- Is the participant on Special Respiratory Precautions?
  - Review policy Isolation Procedures: Special Respiratory Precautions (need CHCO access). Notify CHCO CTRC Charge RN prior to visits requiring any type of contact precaution (720-777-2581)

CHECKING-IN & ROOMING THE PARTICIPANT

Outpatient CTRC Clinic

- For visits occurring in the OP CHCO CTRC, participants will check-in via the self-service stations or with personnel at the check-in desk.
- Once the participant is checked-in, the schedule in Epic will indicate that the participant has arrived.
- Collect the participant wristband from the printer in the Research Workstation area.
- Confirm the participant's room in the CTRC either at the assignment board or in Epic. Assigned rooms are documented in the Appointment Request (Epic ▶ type *Appt* in the search box. Select *Appts*, select patient. When Appointment Desk page opens, click on the *Future* tab to see scheduled visit. To utilize the Snapboard, please reference Quick Start Guide Revenue Cycle Appointment Request Snapboards.docx (sharepoint.com for navigation assistance. To view CTRC rooms select *CTRC Research-Rooms* under *Available Reports*. Contact the Epic Help Desk at 720-7774357 for assistance with either of these functionalities.



- Bring the participant to their room and flip the door sign from GREEN (check) to RED (x).
- Verify participant information on ID wristband is correct per CHCO policy (Identification of the Participant).
- ID band can be attached to the participant's clothing or kept with a parent or legally authorized representative in the vicinity of the participant.
- If any study equipment is stored in D or E hallway, store it on the same side of the hallway as the infection control carts – equipment can only line one side of the hallway.

Inpatient Floor

- If using IP CHCO CTRC Nursing for your visit, call the CHCO CTRC Charge RN (720-777-2581) to confirm floor/room for visit.
- If you are not using CHCO CTRC Nursing, call the Charge RN for the floor that you have been assigned. During times with high participant volume, assignments may change multiple times prior to visit.
- Meet participant at the CHCO Main Entrance

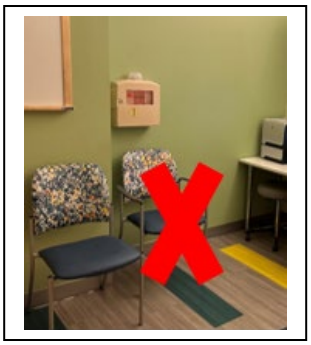
- After entry screening, the participant will be directed to check in at the check-in counters in the main atrium
- Once checked in, escort the participant to their inpatient bed. If using CTRC notify CTRC Charge RN and if not using CTRC, contact the unit Charge RN where the participant is being brought to.

DURING THE VISIT

- If any extra equipment (strollers/wheelchairs) need to be stored in the hallway, store it on the same side of the hallway as the infection control cart (only ONE side of the hallway can be used for equipment storage)

- When done with DynaMAP, clean off machine and cuff with Sani-Cloths and bring it back to E Hallway by Nourishment Room and plug it in to the electrical outlet.

- In the room, do not put or store anything under the sharps containers or sinks



1. TRANSPORTING PARTICIPANTS ACROSS CAMPUS FOR PROCEDURES

For Outpatient Participants:

- If the participant has a peripheral IV (PIV), the Research RN will ensure it is patent and secured appropriately for transport across campus and assess PIV for patency upon return to CHCO.

For Inpatient Participants

- An order will be in the participant's chart by the study Principal Investigator stating that the participant will be going across campus for a procedure.
- CHCO CTRC nursing team will complete the **Temporary Absence Form** (CHCO access needed) prior to participant leaving the inpatient unit.
- If the participant has a peripheral IV, the Research RN will ensure it is patent and secure it appropriately for transport across campus and assess PIV for patency upon return to CHCO.

For All Participants:

- Study personnel will transport research participants to designated area of campus for study procedure.
- Research personnel and the participant will utilize intra-campus transport (golf cart or van) when available.
- In case of emergency during transport if on CHCO Campus (on or within CHCO sidewalks) call 720-777-7555.
- If anywhere else on Anschutz Medical Campus (once past CHCO sidewalks) research personnel will call 911 for assistance.

LINKS: My Children's Colorado Home (sharepoint.com)
CHCO PolicyTech: *Temporary Absence Information Form*

2. USING CHCO CTRC PROCESSING ROOMS

Locations

- Room B3542 (D Hallway Processing Room) is used by the CTRC during business hours:
  - Specimen processing for all samples done by CTRC team or
  - Point-of-Care Testing (POCT) (e.g., urine pregnancy test)

- Room B3482 and B3882 (both 3rd Floor Back Hallway) are available to be scheduled by study staff. These processing rooms are available for:
  - Study teams not using a CTRC team member for specimen processing or
  - Specimens that require special handling (e.g.- large adapters)

Specimen Processing Procedure

- Prior to use of centrifuges in the CTRC, study coordinators are required to complete training provided by CCHRI on use of centrifuge and proper balance techniques. Reach out to CCHRI Educator (Research Onboarding and Education Workshops) for training schedule.
- Processing rooms are reserved prior to use through the appointment request in Epic using the **Research Appointment Decision Tree** in Epic.
  - For day-of use of processing room or request for CTRC for specimen processing, call CTRC Charge RN (x-72581)
- To locate assigned processing room, information can be found via the following:
  - Weekly schedule for centrifuges in B3482 and B3882 are posted on the doors to the processing rooms.
  - Snapboard (see all processing rooms and reference room numbers listed below). To see you have access, type **Snapboard** into Epic Search Field. Choose **CTRC – Research**. If you do not have access, call Epic Help Desk (720.777.4357) and they can give you access to this schedule.
- Processing rooms are intentionally double-booked to accommodate multiple study needs and it is the responsibility of study coordinators to communicate with each other to plan study processing.
- When sharing space with others, do not monopolize shared equipment. If you need to leave samples or aliquots on the counter while you step away, leave space for others to

work and leave a note with contact information (name/study/phone number) and when you are returning to complete processing.

- When in the processing room, make sure all samples are labeled and properly stored (i.e., lab tubes in racks, tighten lids on urine containers, use of biohazard bags and labels, etc.).
- Study Coordinators processing samples in CHCO CTRC areas are responsible for cleaning exposed surfaces including centrifuge, carriers, and surrounding workbench with 10% Bleach, Sani-Cloths, or appropriate disinfectant after each use.
- Maintenance is performed at 6 months and 12 months or as needed by Bio Med.
- If the centrifuge is not working or gives you an error message:
  - Call ZIPP Line (720-777-9477) or place Biomed Ticket on MyChildrensColorado site.
  - Leave a sign on the centrifuge with date and ticket # of ZIPP line request.
  - Notify CTRC Charge RN (x-72581) that the centrifuge is not working so that you can be reassigned to another centrifuge.

3. RESEARCH SAMPLES:

- Research samples collected and/or processed in the CHCO CTRC must be labeled per CHCO policy CHCO in PolicyTech: *Laboratory: Collection, Handling and Transportation of Specimens.*
  - Specimens found that are unlabeled, unidentified, or unaccounted for will be discarded **each Friday at 2pm**.
- Participant specimens are considered biohazardous material and cannot be stored in a refrigerator or freezer where food, medical supplies, and other sensitive materials are stored.
  - **Each Friday at 2 p.m**., any remaining research samples are cleaned out of CTRC refrigerators and freezers.
  - **CTRC does not offer sample courier**. Study teams are responsible for all sample transport.

AFTER THE VISIT

- For specific information on room cleaning refer to CHCO policy: Patient Room Cleaning: Isolation and Non Isolation Procedure for Ambulatory - Patient Room Cleaning: Isolation and Non Isolation v.10
- If there is no time to clean room, contact Charge RN at x-72581 and notify that you are unable to clean room.

- **For Participants not on Isolation Precautions:**
  - Remove ALL participant health information (including wristbands) and place it in shredder bin
  - Clean/disinfect exam table with a hospital-approved disinfectant wipe after each patient.
  - Disinfect equipment with a new hospital-approved disinfectant wipe, including keyboards and visitor chairs as required.
  - Change paper or linen on exam table
  - If there is no time to clean room, contact Charge RN at x-72581 and notify that you are unable to clean room

- **For Participants on Isolation Precautions:**
    - Room is not to be used for another patient until cleaned by clinical team members or by EVS if feasible.
    - If patient visit is less than two hours, clinical team is responsible to disinfect room.
    - Patient visit is more than 2 hours, contact EVS for room clean. This can be done either by calling 720-777-4476 or in Epic by selecting Service Task - CTRC Room Clean – and fill in location details. ,

- **Dining Options**
    - CHCO - Hospital cafeteria and coffee shop, 1st floor

COMMUNICATION WITH RN DURING THE VISIT

When using CHCO CTRC nursing for a procedure:

1. Check the white board at end of Hallway E to identify nurse and room assignment.
2. Introduce yourself and the study team to the nursing staff.
3. Provide CHCO CTRC RN with the following information:
    a. Participant Identifier
    b. Study
    c. Room
    d. Procedure Requested
4. For visits with venipuncture or other nursing procedures:
    a. Check that orders in the treatment plan are released. Refer to Treatment Plans, under Research Core Training Materials in the Epic Research Coordinator Dashboard for instructions. Contact the Epic Help Desk at 720-777-4357 if there is an issue with the treatment plan.
    b. If using EMLA (Eutectic Mixture of Local Anesthetics) or LMX (lidocaine topical cream for numbing blood draws), ensure the order is verified by pharmacy before requesting the CHCO CTRC RN.
    c. Have collection tubes ready and labeled (unless the CHCO CTRC RN will be providing tubes)
    d. Verify with provider if clinical labs will be drawn and, if so, notify CHCO CTRC RN.

CHAPTER 10: USING THE CTRC CORE LABORATORIES

Information regarding specific assays, sample types, container or tube types as well as methods and multiplexing can be found on the Core Lab webpage.

CORE LABORATORY REQUISITION FORM

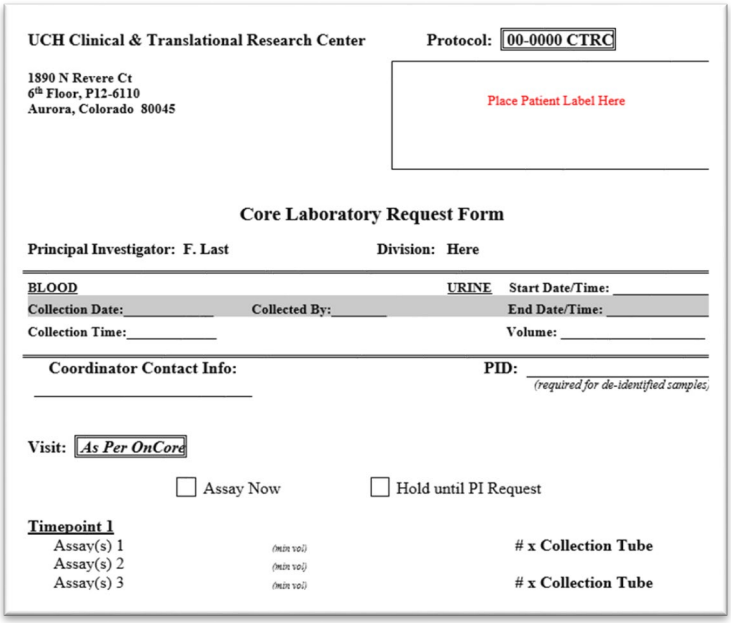
1. **Core Lab Requisition Form (Lab Requisition)**
   All studies utilizing the CTRC Core Lab are required to submit a **lab requisition form**. This form is crucial for detailing the specifics of the samples being collected, including any special processing instructions, to ensure proper handling and processing by the lab team. The lab requisition form must accompany all research samples sent to the CTRC Core Lab.

   There are two types of lab requisition forms, depending on the nature of the study:
   - **Investigator-Initiated Studies**: These forms are designed for studies created and managed by academic or clinical investigators.
   - **Industry-Initiated Studies**: These forms are used for studies initiated by industry sponsors, such as pharmaceutical companies or biotechnology firms.

   Using the correct form ensures that the lab can properly process the samples according to the specific requirements of the study protocol.

   These forms include:
   - Visit numbers (must match OnCore visit naming)
   - Time points per visit
   - Analytes to be assayed at each visit and timepoint
   - Sample type
   - Participant ID (if applicable) and de-identified participant ID (for industry studies and PI samples sent off-campus)

   ➢ **Investigator-initiated studies** example (form will be filled completed by CTRC Core Lab):



UCH Clinical & Translational Research Center

Protocol: 00-0000 CTRC

1890 N Revere Ct
6th Floor, P12-6110
Aurora, Colorado 80045

Place Patient Label Here

Core Laboratory Request Form

Principal Investigator: F. Last Division: Here

BLOOD URINE Start Date/Time: _____
Collection Date: _____ Collected By: _____ End Date/Time: _____
Collection Time: _____ Volume: _____

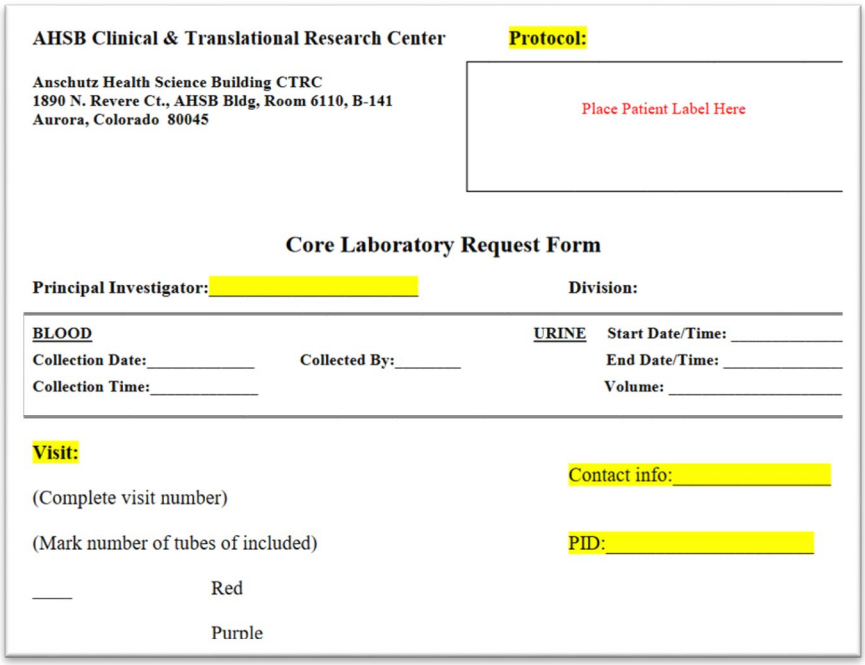
Coordinator Contact Info: _____ PID: _____ (required for de-identified samples)

Visit: As Per OnCore

☐ Assay Now ☐ Hold until PI Request

Timepoint 1
Assay(s) 1 (min vol) # x Collection Tube
Assay(s) 2 (min vol)
Assay(s) 3 (min vol) # x Collection Tube

- **Industry-initiated studies** example (yellow highlighted sections to be filled out by study staff, either electronically or printed and filled out by hand):



AHSB Clinical & Translational Research Center

Protocol:

Anschutz Health Science Building CTRC
1890 N. Revere Ct., AHSB Bldg, Room 6110, B-141
Aurora, Colorado 80045

Place Patient Label Here

Core Laboratory Request Form

Principal Investigator:_____ Division:

BLOOD URINE Start Date/Time: _____
Collection Date:_____ Collected By:_____ End Date/Time: _____
Collection Time:_____ Volume: _____

Visit:

Contact info:_____

(Complete visit number)

(Mark number of tubes of included)

PID:_____

____ Red

Purple

2. Core Lab Requisition Form Use During the Visit

The Core Lab requisition form must be approved by the Principal Investigator (PI) before the study begins. It is the coordinator's responsibility to ensure that the latest and approved version of the lab requisition is being used during each visit. The CTRC Nursing staff will collect the samples, and the CTRC Core Lab will process and perform assays strictly according to these instructions in the requisition form.

- A printed copy of the CTRC Core Lab requisition will be located with the participant's visit documents in the visit folder at the front desk upon check-in.
- The coordinator must cross out the samples on the lab requisition that are not being collected and initial and date.
- During Visits at AHSB:
  - The nurse will include the draw date and time and sign with their initials on the lab requisition.
  - The coordinator is responsible for verifying this information for accuracy and completeness.
  - The samples being processed through Core Lab should be taken to the lab at the earliest possible opportunity.
  - Upon entering the Core Lab, the Core Lab requisition form must be time stamped to indicate when the samples were delivered. **Time for last drop off is 3pm.**
  - Samples going to UCHealth clinical lab or outside labs are the responsibility of the study team.

During Visits at CHCO

- The nurses or coordinator may process the samples, or the samples will need to be taken to the Core Lab for processing based on what is determined on the Core Lab requisition.
- At the CHCO CTRC Core Lab, the study teams drop off the sample AND let a staff member know that they have left the samples. **Time for last drop off is 3pm.**

During Visits at UCHealth IP CTRC

- Samples are processed by the nurses then stored in the freezer (AIP I, room 12.014).
- Any samples being analyzed by the CTRC AHSB Core Lab can be left in the freezers and these will be sent to the CTRC AHSB Core Lab.
- *It is the responsibility of the study team to clear out any samples from the freezers, refrigerators, and ambient samples that do not need to go to Core Lab by **4pm on Friday of each week**.*
- **CTRC does not offer sample courier**. Study teams are responsible for all sample transport.

SAMPLE LABELING

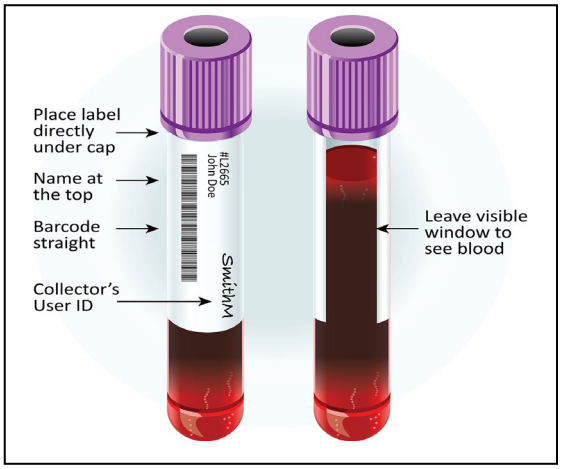
AHSB OP

EPIC participant labels should be used for labeling specimen collection tubes. The labels are printed and kept in the participant folder for coordinator to use. Sponsor provided de-identified labels may be used for some studies on specimen collection tubes. The study team is responsible for bringing de-identified labels to the CTRC prior to the visit and labeling any collection tubes they want de-identified prior to collection by CTRC nursing to ensure that the right de-identified label is attached to samples from the correct participant. Core Lab generates labels used for aliquots or uses pre-made labels provided by study teams for Investigator initiated studies. Aliquot labels can include participant information or be de-identified, if study ID information is provided on the Core Lab requisition. Both the name and de-identified value must be listed in the lab requisition for confirmation in the lab.

UCHealth IP & CHCO

The EPIC labels are used on collection tubes and study specific labels are used on aliquot tubes after processing. These labels are created using a template by the nurses at both locations.

ALL LOCATIONS - labels should be placed on the container/tube to leave a visible window to view sample volume (shown in figure).



ADULT OP CTRC SAMPLE PROCESSING ROOM USAGE

Equipment available

- Refrigerator, -20°C,
- Freezers, -80°C freezers
- Centrifuges (2)
- Balance
- Critspin

Training – contact the **CTRC Lab** for centrifuge operation.
Recommended training course - https://www.cdc.gov/labtraining/training-courses/fundamentals-centrifuge-safety.html#print

Best Practices for Sample Processing Equipment Use:

Please use the shared space appropriately by cleaning up after yourself, limit use of shelf space, and limit use of consumables.

- Study teams can process and store samples for short-term (less than 48 hrs) during study visits.
- Limited dry ice, scissors and package tape is available for shipping. Dry ice is limited due to storage and once-per-week delivery, so use only what you need to ensure others have enough to ship.
- When sharing space with others, do not monopolize shared equipment. If you need to leave samples or aliquots on the counter while you step away, leave space for others to work and leave a note with contact information (name/study/phone number) and when you are returning to complete processing.
- When in the processing room, make sure all samples are labeled and properly stored (i.e., lab tubes in racks, tighten lids on urine containers, use of biohazard bags and labels, etc.).
- Study Coordinators processing samples in CTRC areas are responsible to clean exposed surfaces including centrifuge, carriers, and surrounding workbench with 10% Bleach, SaniCloths, or appropriate disinfectant after each use.
- **Study teams must clear out any samples from the freezer and refrigerator by 4pm on Wednesday**. After this cut-off time, the Core Lab will discard any remaining samples.
- Any samples being analyzed by the CTRC AHSB Core Lab can be dropped off in the core lab (Room 6110)
- If the centrifuge is not working notify a CTRC Core Lab team member on the Outpatient CTRC, 303-724-4093.

SAMPLE DROP-OFF

Coordinators must check and ensure that all samples, study specific documents/items, and lab requisitions are present during drop off. **Time for last sample drop-off is 3pm.** Study teams are responsible for shipping samples.

BATCH DROP-OFF USING PARTICIPANT MANIFEST EXCEL

Batch drop-off samples do not need a CTRC Core Lab requisition but rather can use a participant manifest created in excel to convey the details to the lab.

- Schedule the sample drop off with lab by emailing CTRC Core Lab in advance.
  - AHSB Core Lab drop off, email: ctrccorelab@cuanschutz.edu
  - CHCO Core Lab drop off, email: corelab@childrenscolorado.org
- Prepare the sample batch drop-off sheet using template posted here.
- Title and save the template with study COMIRB # and PI Name.
- The completed sample batch drop-off sheet should be emailed and a printed version should be included with the samples.
- Unless the samples are sent by FedEx, manifest should be time stamped when batch samples are delivered. The time stamp is located at the entrance of each laboratory.

SPECIMEN STORAGE

Specimen storage for samples that *are* analyzed in Core Lab

Storage for the duration of sample analysis

- Storage for samples which have analysis to be performed by the Core Lab is done at no charge.

Storage after sample analysis is complete

- PI's will be notified via email by the Core Lab that the analysis for their study is complete. PI's will be offered two options for sample disposition:
  - PI's can arrange for pickup of the samples
  - PI's can instruct the Core Lab to destroy the samples
- If the PI fails to reply within 30 days, the CTRC Core Lab will destroy the sample at the end of the 30-day period.
- If the PI requests samples to be picked up, the CTRC Core Lab staff will pull the samples and have them available for pickup. The study team must come and retrieve them *within 2 weeks.* If the PI fails to collect in the 2-week timeline, then Core Lab will charge a fee per aliquot, monthly, for storage.

Specimen Storage for samples that *are not* analyzed in Core Lab

- **PI samples (samples collected for PI use)** – there will be an **upfront charge per box** for labor and consumables, then a monthly charge per box thereafter.
- **Industry studies - Each Wednesday at 4 p.m.**, any remaining industry samples, excluding same day, are cleaned out of CTRC refrigerators and freezers. Coordinators must ship or move samples prior to this timeline each week.

REQUESTING ACCESS TO CTRC CORE LAB RESULTS

1. PI Authorization Form

- At the **study startup**, the study team must complete a PI Authorization form. This form is essential for gaining access to the designated **protocol folder**, which will hold the lab results.
- Upon receiving the PI Authorization form, the **CCTSI Informatics team** will create a **data result folder** on the network drive. This folder will store all assay results generated by the Core Lab.
- The same **PI Authorization form** must be submitted for **adding or removing users** who need access to the protocol folder. This ensures that access is properly managed throughout the study.

2. Lab Results Population

- Lab results will automatically populate in the designated folder the night the assays are performed. However, it's important to note that the results are organized by the **date the assay was performed**, not the collection date. Study teams should keep this in mind when reviewing data to ensure accuracy in interpretation.

3. Handling Samples on Hold

- If certain samples need to be placed on hold for later analysis, the study team must notify the Core Lab during PI meeting so it can be included on the lab requisition. If it is determined after the study starts, the study team must notify the core lab via email (**corelab.corelab@childrenscolorado.org** for samples at the CHCO CTRC Core Lab & **ctrccorelab@cuanschutz.edu** for samples at the Adult CTRC Core Lab). The team should also specify the date or conditions under which the samples can be released for analysis. This communication ensures that the samples are processed only when appropriate, as indicated by the study protocol.

The team should also specify the date or conditions under which the samples can be **released for analysis**. This communication ensures that the samples are processed only when appropriate, as indicated by the study protocol.

ACCESS TO CTRC CORE LAB SPACE

Due to regulatory requirements, **direct badge access** to the CTRC Core Lab is **not permitted** for study teams. Access to both the Adult and CHCO labs is strictly limited to business hours when **lab staff are present**.

This restriction ensures that all interactions with lab facilities are supervised and compliant with regulatory standards. Study teams should plan their lab visits and sample drop-offs accordingly to ensure they are completed within the lab's operating hours.

CHAPTER 11: USING THE CTRC NUTRITION CORE

SCHEDULING DIET PICK-UPS

If the visit requires a **diet component**, study staff are required to schedule **7 business days (10 calendar days) ahead of the visit**. The Nutrition Core will not see or be alerted to any diets scheduled within 10 calendar days and the request will not be filled. If a visit falls within 10 days of a participant visit that requires a diet, the study team **MUST** call or email Nutrition Core first to make sure the services can be fulfilled.

All Nutrition Services Require Scheduling Requests
Meals and Lead-in Diets
Metabolic Test Meals
Ad lib and Weigh-back Meals
Standard Meals: Breakfast, Lunch, Dinner, Snack
Other Services
24-hour diet recall
Counseling
Anthropometrics
Food Frequency Questionnaires (FFQ)

How to Schedule All Other Nutrition Services:

- Other services provided by Nutrition Core such as 24-hour diet recalls, Counseling, Anthropometrics, and FFQs must be scheduled through CTRC Scheduler before the Scheduler 7-day cut-off will not require any additional information in the Nutrition comments box as these services are already built in the participant visit workflow.
    - However, Oral Food Challenges (OFC) Outlook requests at CHCO will include participant information. Enter Participant #, DOB, and visit number into the comment box in the CTRC Scheduler.
- For 24-hour recalls being conducted via phone, please include the participant's name and phone number in the Nutrition Comments box, or in the Outlook invitation (for non-scheduler users).
    - Example: John Doe; 123-456-7890
- For specialty counseling, please include any relevant information including calorie level, arm, visit number, etc. in the Nutrition Comments box. Separate each item using a semicolon (;).
    - Example: Jane Doe; High Fiber arm; 2000kcal

Entering in Dietary Requirements for Meals and Lead-in Diets:

- Visits requiring meals or lead-in diets will require dietary details in the **Nutrition Comments Box** that *must be followed exactly*.
    - First diet date; Last diet date (for one day diets this will be the same as the first diet date); Pick-up date; Pick-up time (military time); Pick-up location; OP kcals; IP kcals (if there is an IP stay, please enter even if the same as OP kcals); meal selection (if not a personalized diet) or study/participant specific note (i.e. dinner eaten inpatient, participant allergies, etc.)
    - It is important to separate each category with a semicolon.

Example:

6/10/2022; 6/13/2022; 6/9/2022; 1400; AHSB; 2015kcal; 1852kcal

The above comments indicate a 3-day lead-in diet (6/10-6/12), a 1-day inpatient diet/meal (6/13), a pickup date/time of 6/9 at 2:00pm, and daily calories of 2015 for the lead-in diet and 1852 for the inpatient diet.

Non-Scheduler Users

- Non-scheduler users may schedule with the Nutrition Core via Outlook Invitation to ctrc.nutrition@ucdenver.edu
- The Outlook Invitation must include all comments typically entered (see previous sections) for a Nutrition Core diet appointment, or the required information (see previous sections) for a non-diet appointment.

Additional information

- Available locations for pick-up and delivery are:
    - AHSB (Anschutz Health Sciences Building)
    - CHCO (Children's Hospital Colorado)
    - AIP (Anschutz Inpatient Pavilion)
    - Other locations can receive diets via paid courier service by emailing the Nutrition Core and including a complete address, 2-hour time window for the diet to be delivered within, and entering "Courier" in the location section of the comments for the visit.

- If a protocol has a long-term diet (more than 4 days), study staff will need to enter additional entries in Scheduler for diet pick-ups. For example: if a participant is on a 30-day diet, the first 3-day diet will be attached to a study visit, and remaining days are entered as 3- day and 4-day diets that require separate appointment requests for the remainder of the study. A maximum of 4 days of food can be provided at any one time to maintain food safety and freshness.

- If a participant has an inpatient stay, on-unit meal, or ad-lib meal attached to a lead-in diet, please DO NOT enter two sets of comments. Include the inpatient day(s), ad-lib meal day, etc. on the lead-in comments.
    - For example, for a one-day lead-in diet with breakfast and ad-lib the following day, the CTRC Scheduler comments would read: 2/3/2022; 2/4/2022; 2/2/2022; 1500; AHSB; 1750kcal.

- Please write dates in the following format: m/d/yyyy – do not include zeros in the month and date format
    - For example – 1/2/2023 (as opposed to 01/02/23)

- Please do not include text such as "First day diet: 1/2/2023; Last day diet: 1/3/2023; Diet pick up: 1/1/2023"

Examples of correctly formatted Scheduling comments:

- 3-Day Lead-In Diet with a 1-day inpatient stay:
    - 6/8/2023;6/11/2023;6/7/2023;1500;AHSB; 3000kcal;2800kcal;
        - Lead-In start date, last diet date (including inpatient day), pickup date, pickup time, pickup location, lead-in kcals, inpatient kcals

- 1-Day Lead-In Diet with a test breakfast and ad-lib lunch following:
    - 6/8/2023;6/9/2023;6/7/2023;800;AHSB;1800kcal;B/F 0830
        - Lead-In start date, last diet date (including test/ad-lib day), pickup date, pickup time, pickup location, lead-in kcals, test breakfast start time

- 1-Day Lead-In (picking up the same day of starting the diet)
    - 6/8/2023; 6/8/2023; 6/8/2023; 0730; AHSB; 2000kcal
        - Lead-In start date, last diet date, pickup date (same day as the start/end date), pickup time, pickup location, lead-in kcals

- 2-Day Lead-In Diet with the Day 2 dinner being eaten inpatient
    - 6/8/2023;6/9/2023;6/7/2023;1200;AHSB;2010kcal;Day 2 Dinner IP
        - Lead-In start date, last diet date, pickup date, pickup time, pickup location, lead-in kcals; Note of the dinner location difference

- 30-Day Diet:
    - 6/8/2023;6/10/2023;6/7/2023;800;AHSB;2000kcal
        - Next Appointment:
    - 6/11/2023;6/14/2023;6/11/2023;800;AHSB;2000kcal
        - Next Appointment:
    - 6/15/2023;6/17/2023;6/15/2023;800;AHSB;2000kcal

      And so on until the diet is completed. Note that nothing more than 4 days may be dispensed at one time, and each diet pickup appointment must be made SEPARATELY in scheduler (i.e. one appointment per diet pickup)

TYPES OF DIETARY ASSESSMENT TOOLS

Accurately assessing dietary intake is an essential element of metabolic research. The CTRC Nutrition Core uses several, well-established methods for collecting dietary intake data. Each method has its own pros and cons and suit different populations and research settings. The main methods include:

- Diet Records (photo or written)
    - Analyzed with the NDS-R software (version updated annually)
    - May be collected by: Written record, MealLogger (or other logging apps), Google Voice line/text message
- 24-Hour Recalls
    - Performed with the NDS-R Multipass Method
- Food Frequency Questionnaire (FFQ)
    - Typically performed with the NutritionQuest Block FFQ

Method	Advantages	Disadvantages
Diet Record	• Intake is quantified • Does not require recall • Allows self-monitoring which can influence behavior change • Provides typical meal and food pattern information	• High subject burden • High staff cost and burden • Can alter eating behaviors • Requires literate population • Requires multiple records over several months to capture habitual intake
24-Hour Recall	• Intake is quantified • Less subject burden • Does not alter eating behaviors • Does not require literate population	• High staff cost and burden • Relies on subject recall • Requires multiple recalls over several months to capture habitual intake
Food Frequency Questionnaire (FFQ)	• Less subject burden • Less staff burden • Does not alter eating behaviors • Captures habitual intake	• Relies on subject recall • Not as quantifiably precise • Requires literate population • Does not provide meal pattern information • Cannot be used over short time periods

Data obtained from these dietary assessment methods is used in the following ways:

- To assess whether a subject is qualified for a study
- To provide baseline intake data at the start of a study
- To track changes in intake during an intervention
- To track compliance with a prescribed diet
- To provide reference for protocols assessing certain biomarkers

DIETARY ANALYSIS RESOURCES

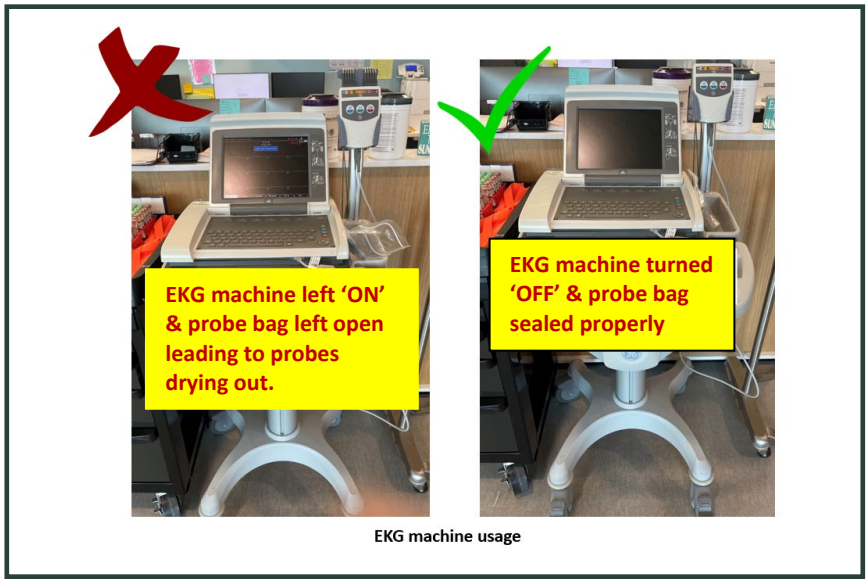
1. Food Frequency Questionnaires, three-day diet diary & photo diet record instructions: https://cctsi.cuanschutz.edu/resources/ctrc/services/nutrition
2. Three-day diet diary instructions video: https://www.youtube.com/watch?v=BKKwH9MK9n8&t=66s

SUBMITTING DIET RECORDS FOR ANALYSIS

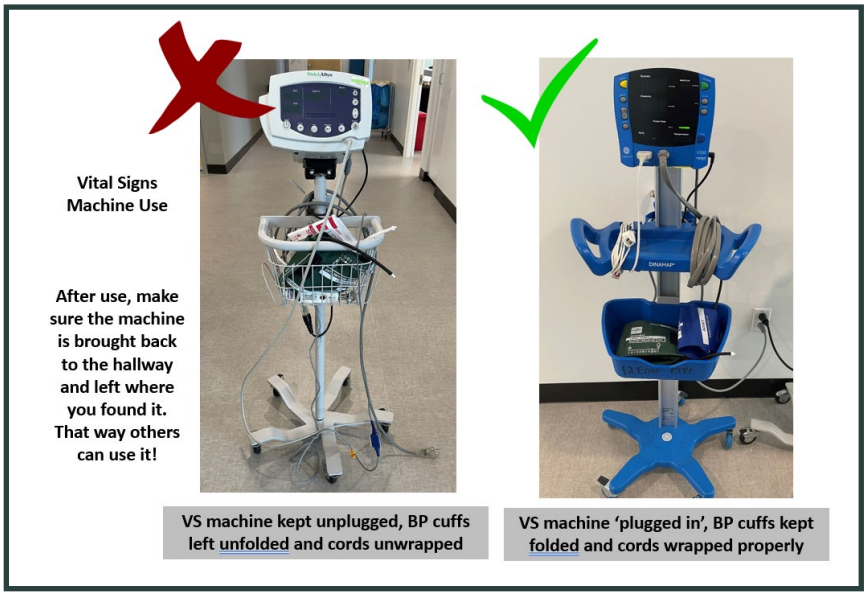
Diet records must be uploaded as they are received. Do not upload diet records in batches. If diet records are uploaded in batches, **they may take up to 9 months to analyze, depending on batch size**. The study team will scan the completed diet record form and save it in their respective PI-User folder. Diet records are analyzed using Nutrition Data System for Research (NDS-R) software. Results are exported to Excel, and then saved in the PI-User folder.
To request access to the PI-Users folder, complete the following link:
https://datastore.cctsi.ucdenver.edu/surveys/?s=JNYCP8FTTA
If using written diet records, all new study team members must attend a diet record instruction training in person or virtually, email ctrc.nutrition@ucdenver.edu to schedule.

CHAPTER 12: CTRC EQUIPMENT USE, STORAGE & MAINTENANCE

Use of CTRC Equipment - Equipment, such as vital sign machines and EKG machines, should be used with care. Place equipment back in their allocated spot, cleaned with appropriate type of wipes (purple or orange top except screens which require gray top), and ready for the next participant. Ensure that the electrical cords are tied back and ready for next use.



EKG machine usage



ADULT CTRC EQUIPMENT STORAGE AND MAINTENANCE

Storing and Maintaining Equipment and Supplies

- Any equipment belonging to the study team that needs to be stored at the Adult CTRC must receive prior approval from the CTRC Nurse Manager or Charge Nurse. All stored equipment and supplies are the responsibility of the study team. The study team is to ensure items are not expired and in good condition. The study team is responsible for ensuring that equipment is stored per regulatory requirements in the building where it is located. Joint Commission and UCHealth specific requirements, as well as contacts to the Regulatory team for any questions, can be found on the UCHealth Regulatory website.
- Equipment and supplies cannot be stored in corrugated cardboard boxes.
- Nothing can be stored within 18 inches of the ceiling.
- Nothing can be stored on the floor.
- Any signs placed in rooms, hallways, or the calorimetry room chamber must be laminated, contain no tape, and be hung with command strips.
- For approval of compressed gas cylinders storage reach out to EBL inbox and they will provide guidance on the correct storage method.
- Tape cannot be used on equipment or supplies that will be used for participants.
- When equipment (like exercise equipment, dumbbells, thermometers) acquire cracks, it must be replaced. Contact the CTRC nursing team for further guidance.
- Equipment and supplies should be stored in a clean storage room.
- Office supplies should not be stored with clinical equipment.
- Food should be stored in the nutrition room only (IP 12.017) and not left in cabinets and closets on the unit. Label food with COMIRB study number and PI name.
- Sterile supplies should be stored in a clean storage supply room with negative pressure.
- Clean and SPD processed respiratory equipment (VO^2 masks and mouth pieces, RMR hoses) should be placed in a clean plastic bag and placed in the sterile supply room (IP 2.015).
- Flammable chemicals must be stored in the flammable chemical cabinet in the specimen processing room on IP CTRC (12.014).
    - Study teams must provide OSHA Safety Data Sheets (MSDS) for any chemicals stored.
    - Once chemicals are no longer needed, they should be removed immediately and properly following OSHA regulations.
- Any multi-dose medications (including Hibiclens), ultrasound gel, multi-dose lotions/cream/gels, and lidocaine must be labelled with an expiration date. The expiration date is 28 days from opening. It must be thrown away after this expiration date.
- Opened ECG and EEG sticker packages must be placed in a plastic bag with a 28-day expiration date written on the front. Once opened, the manufacturer cannot guarantee the gel will not dry out and continue to be effective or maintain cleanliness.
- No power strips are allowed in patient rooms due to fire risk in the clinic.
- All storage areas should be kept clean and tidy.
- Expired supplies and equipment cannot be used on a participant and must be disposed of by study teams.

Cleaning Equipment

- Cleaning study-specific equipment is the study team's responsibility.
- The study team should be able to provide details on how the equipment is properly cleaned and disinfected, via the manufacturer's instructions for use (IFU). IFUs are found on OneSource.
    - If equipment needs sterilization, pre-cleaning is required at point-of-use and must be done in a soiled utility room (IP 12.051).
        - Pre-Clean with a manufacturer and facility approved pre-cleaning recommended product per IFU instructions to remove visible debris or bioburden.
        - Items labeled as single-use/disposable are disposed of and not reused or reprocessed.
        - Use foam, gel, spray solution, and/or a moist towel as indicated by the manufacturer to keep instruments and devices moist during transport.
    - Post the IFU for your equipment in the dirty utility room or provide CTRC with a record of this.
    - If CTRC does not carry the cleaning product necessary to clean your product properly, it is the study team's responsibility to purchase the product.
- Disposable equipment should never be reused on a participant.

Applicable Policies and Quality, Regulatory, and Infection Prevention Information
Applicable in both CTRC OP and IP units

- UCHealth Quality Department
    - UCHealth Infection Prevention
    - UCHealth Regulatory Information
- UCHealth Policies
    - Annual Medical Equipment Risks Management Plan Policy
    - Compressed Gas Cylinder Use and Storage Policy
    - Food from Outside Sources and Food Heating Policy
    - Hazard Communication Policy
    - High Level Disinfection Policy
    - Sterile Processing

CHCO CTRC EQUIPMENT STORAGE & MAINTENANCE

1. Studies requiring supplies or equipment to be stored in the CHCO CTRC must also be utilizing CHCO CTRC Nursing services. Storage requests are reviewed individually and will be evaluated based on the information provided by the study team through the QR code below. Reach out to the CTRC Clinical Manager (720-777-4700) with any questions.
2. Use of CHCO CTRC storage space for supplies or equipment must be approved prior to storage.
3. To request approval for use of space for supply/equipment storage use this link or QR Code: https://forms.office.com/r/rXwtTK8ukU (need CHCO access)

4. CTRC will review the request and reach out to the coordinator directly to either approve or deny the request.
5. For Supplies:
    a. If approved supplies must be labeled with IRB number, PI name, PRA name, contact number, and expiration date. PRA must also provide MSDS sheets from the manufacturer.
    b. The designated study team member must complete monthly checks using QR code found in the unit at this link: https://forms.office.com/r/jLDvnkigTh to document that supplies have been checked and are unexpired:

6. For Equipment:
    a. If approved, equipment must be checked off with biomed (with biomed label on equipment) prior to storage and use in the CHCO CTRC.
    b. Equipment must be labeled with an IRB number, PI name, PRA name and contact number.
    c. Study teams are responsible for ensuring equipment is still within current use with the following QR code for an initial check:

    d. The designated study team member must complete monthly checks using QR code found in the unit at this link: https://forms.office.com/r/jLDvnkigTh to document that equipment has been checked and is unexpired

7. If study teams are unable to keep up with monthly checks on supplies and ensure that equipment is kept up to date, storage privileges will be revoked.

Related Documents/References

CTRC Supply Request and Monthly Tracking (sharepoint.com) Need CHCO Access

8. Other Storage:

   Reagents and other research supplies may be stored long-term in CHCO CTRC refrigerators but must first be approved for storage by the CHCO CTRC Nursing Manager and labeled with the following:

   i. PI Name
   ii. IRB Name
   iii. Contact Name
   iv. Contact Number
   v. Expiration Date

CHAPTER 13: ADULT CTRC CLINICAL POLICIES & PROCEDURES

PRINCIPAL INVESTIGATOR RESPONSIBILITY

The Principal Investigator is responsible for ensuring that all study team members have completed the necessary compliance training through CU Skillsoft (Percipio) relevant to their specific roles. This includes courses on topics such as:

- Bloodborne Pathogens
- Chemical Waste Management
- Shipping Biological Materials
- Lab Safety
- Regulated Medical Waste Management

The PI should maintain records of completed courses and verify that each team member is up-to-date with their training. Regular audits and reminders can help ensure compliance and maintain a safe research environment.

CTRC CLINICAL PROCEDURES

CTRC OP Clinic follows CU Research Policies

- Bloodborne Pathogens, Exposure Control & Hepatitis B Vaccination
- Utilization of OnCore for Clinical Research - CU Anschutz
- Utilization of University of Colorado's Research Pharmacy Services - CU Anschutz

CTRC IP Unit follows UCHealth Research Policies
Policy Stat is a hub of all policies at UCH including clinical research policies.

Clinical Procedure (Specific Policies - Lippincott) – Web-based international database for health care professionals on how to conduct clinical procedures. Search by procedure name.

Vital Signs Measurement (CTRC OP Clinic & IP Unit)
Study staff can conduct vitals on participants if they have successfully completed the vitals training class CTSA3.

Phlebotomy & IV Placement
Adult CTRC OP Clinic
CTRC Nursing or study staff who have successfully completed phlebotomy and/or IV certification, can perform blood draw and/or IV placement on participants. The PI for the study is responsible for verifying, completing, and storing competencies related to Phlebotomy and/or IV certification for their staff. *UCHealth SOC labs cannot be collected in the CTRC OP clinic as OP clinic is a CU medicine facility.*

Refer to CTRC Phlebotomy attempts SOP for details on the number of IV attempts that are allowed in the CTRC by certified licensed professional or CTRC Nursing staff.

Adult CTRC IP Unit
CTRC Nursing or study staff with appropriate licensure or who have successfully completed phlebotomy and/or IV certification and UCHealth competency, can perform blood draw and/or IV placement on participants. Contact Research Administration, then complete competency with a UCHealth staff member).
UCHealth: Research Administration Website

Picking Up Medications from Pharmacies
CTRC OP Clinic & CTRC IP Unit
Study staff can pick up medications from the pharmacy at both inpatient (IP) and outpatient (OP) locations. The study physician should order the study drug through the UCHealth pharmacy for IP dispense and CU Research Pharmacy (CURP) for OP dispense. Below are policies for each location related to medication pick up:
CU Anschutz: University of Colorado's Research Pharmacy Services - CURP
UCHealth IDS: Research Administration Website

Medicine Verification & Administration
CTRC OP Clinic & CTRC IP Unit
CTRC staff must verify and administer all medications for on-site administration. Study team members can administer medication if the individual has clinical training and active licensure by the State of Colorado and there is a delegation log authorizing that individual to administer research medication(s). Distribution of study drug to a study participant for self-administration off-campus can be done by a study APP or RN, or unlicensed study coordinator, if delegated and if initiated by an order via a research note from a physician or APP in the EHR system. Definity is a medication and can only be given by licensed study personnel or CTRC nurse. Distribution/ administration of any study product or medication must be documented in the Electronic Medical Record.
CU Anschutz: UCD campus policy 6009
UCHealth: Medicine Management Policy & Independent Double verification of meds

CTRC IP Unit
For research visits that occur at the IP CTRC, CTRC nursing staff must follow the applicable hospital policies regarding product dispensing and administration. Any medications linked to the MAR need to be administered by the CTRC Nursing staff on the IP unit. IP CTRC Nursing can only administer medications dispensed by a UCHealth Pharmacy. Distribution/administration of the product must be documented in the Electronic Medical Record.
UCHealth: Medication Management Policy and Independent Double-Check of Medications Policy

High-Risk Medication Administration
CTRC OP Clinic & CTRC IP Unit
A team of 2 CTRC Nurses and/or licensed professionals can administer high-risk medications. A list of high-risk medications can be found in the UCHealth policy below, which CTRC follows for both OP and IP settings:
High Alert Medications Policy and Independent Double-Check of Medications Policy

Non-Medication Administration
CTRC OP Clinic & CTRC IP Unit
Non-Medications items like oral glucose, Boost, etc., are considered food. Study teams or Nursing can distribute the food item and no additional training or certification is needed. Distribution must be documented in an EPIC note.

Observing Medication Self-Administration
CTRC OP Clinic & CTRC IP Unit
CTRC staff or unlicensed study team personnel can observe participants taking medications from home. Administration needs to be documented in the notes section in EPIC since they are not in the MAR.
UCHealth: Medication Management Policy and Independent Double-Check of Medications Policy
Policy: UCD campus policy 6009

Participant Observation
CTRC OP Clinic & CTRC IP Unit
CTRC Nursing or study nurse/licensed professional can conduct participant observation post-medication administration or post-procedure.

6 min. Walk Test
CTRC OP Clinic & CTRC IP Unit
CTRC Nursing or study nurse/licensed professional can conduct the walk test per Lippincott procedures guidance.

Urine Sample Collection
CTRC OP Clinic & CTRC IP Unit
CTRC Nursing or study team personnel can conduct urine sample collection. Collection should be documented in EPIC.

ECGs
CTRC OP Clinic & CTRC IP Unit
CTRC Nursing or study team can perform ECGs if they have the required competency, detailed in the policies below. PI is responsible for verification, completion, and storage of ECG competencies. Lippincott procedure followed at both sites.
UCHealth: Research Administration Website

Lavages & Brushings During Bronchoscopy
CTRC IP Unit
Bronchoscopy can only be performed on the IP unit due to the administration of moderate sedation. Moderate sedation can only be administered by CTRC Nursing. Study team members on the delegation of authority log can assist with some aspects per PI discretion. PI is responsible for ensuring that study staff have completed competencies for the allocated tasks.
UCHealth: Lippincott Procedures

Moderate Sedation

CTRC IP Unit

Moderate sedation can only be administered and monitored by licensed, credentialed, and trained healthcare providers and personnel per UCHealth Policy. All Healthcare Providers administering moderate sedation must have privileges at UCHealth, be ACLS certified, and obtain the required credential and training through the Medical Staff Office.

UCHealth: Moderate Sedation Policy

Invasive Medical Procedures or Interventions

CTRC OP Clinic & CTRC IP Unit

All invasive procedures, including, but not limited to bronchoscopies, right heart catheterizations, arterial line placement, bone biopsies, muscle biopsies, lumbar punctures, skin, and punch biopsies, performed in both locations require informed consent and universal protocol. Universal protocol requires a time out or pause for safety to be performed and documented in the EHR. Charting in clinical research forms is not adequate and documenting in EHR is mandatory for these procedures in both CTRC locations.

UCHealth: Universal Protocol

UCHealth: Informed Consent/Pause for Safety

CHAPTER 14: CHCO CTRC POLICIES & PROCEDURES

PRINCIPAL INVESTIGATOR RESPONSIBILITY

The Principal Investigator is responsible for ensuring that all study team members have completed the necessary compliance training relevant to their specific roles. The PI should maintain records of completed courses and verify that each team member is up-to-date with their training. Regular audits and reminders can help ensure compliance and maintain a safe research environment.

CTRC CLINICAL PROCEDURES

CHCO CTRC follows hospital policies for all clinical procedures. These policies can be accessed via PolicyTech.

1. All CHCO institutional policies are stored in PolicyTech.
2. To access PolicyTech, go to CHCO Homepage - [My Children's Colorado Home (sharepoint.com)]
3. Click on **PolicyTech** in the upper right-hand corner (see image)

4. A new window will open with a search box.
5. Enter in the name of policy or key search words and click on **Search**.
6. A list of related documents will show up and you can click on the relevant policy document.
7. Policies should never be saved to a separate file (as they are updated on an ongoing basis) or shared directly with study monitors.

Relevant CHCO policies to Pediatric CTRC Operations include, but are not limited to:

- Venipuncture
  - **Venipuncture for Obtaining Blood Specimens**
- Shadowing in Clinic
  - **Shadowing – Professional Visitors and Observers**
- Medication Administration:
  - **Medication Preparation and Administration**
  - **Investigational Medications** (working on updates on self-administration in Ambulatory setting)
  - **Medications not Supplied by Children's Hospital Colorado**
- Dress Code:
  - **Dress Code**
- Room Cleaning (Environmental Services):
  - **Participant Room Cleaning: Isolation and Non-Isolation**
- Visitors:

    - **Visiting Guidelines**
- Legal Guardians:
    - **Release of Participant to an Authorized Person other than Parent/Legally Authorized Representative**
    - **Authority to Consent by Person Other than Parent or Legally Authorized Representative**
    - **Patients/Families/Legally Authorized Representatives Rights and Responsibilities**
    - **Grievance Mechanism, Patient/Family/Legally Authorized Representative**
- Isolation and COVID-19 Precautions:
    - **Isolation Procedures: Special Respiratory Precautions**
    - **COVID-19**
- CHCO PolicyTech on CCHRI webpage– Refrigeration of Patient Family Staff Food Meds and Specimens (need CHCO access)
- CHCO PolicyTech on CCHRI webpage: Laboratory Collection, Handling, and Transportation of Specimens (need CHCO access)

CHAPTER 15: FUNDING

The Colorado Clinical & Translational Sciences Institute (CCTSI) offers a variety of funding opportunities, including pilot grants and microgrants. Each year, the CCTSI awards over $3 million in these grants, along with pre-doctoral and post-doctoral research scholar awards.

CCTSI PILOT GRANTS

Pilot grants are designed to support cross-disciplinary and collaborative research in clinical and translational science. These grants are typically one-year awards aimed at helping researchers develop preliminary data for future funding applications.

CO-Pilot Grants

One-year pilot grant awards to mentored and junior investigators to provide initial support for proof-of-concept projects and to CU-CSU teams. Encouraging new cross-disciplinary and collaborative projects in clinical and translational medicine to address **translational science roadblocks**.

Child and Maternal Health Pilot Grant (CMH-Pilot)

One-year pilot grant awards to mentored and junior investigators to provide initial support for proof-of-concept projects focused on children of all ages as well as pregnant women and mothers of newborn and young infants. The projects should address translational science roadblocks and improve child and maternal health.

Community Engagement and Health Equity Pilot Grant (CEHE-Pilot)

Supports community-academic partnerships to perform pilot studies that will strengthen relationships and produce preliminary data for future competitive grant applications.

Translational Methods Pilot Grant (TM-Pilot)

The TM-Pilot Program supports the development of novel methods and innovative technologies for clinical and translational medicine to address translational science roadblocks. This includes the development of new assays, methods, software, technologies, and animal models which are not currently available to the CU Anschutz campus and CCTSI affiliated institutions.

CTRC MICROGRANTS

Microgrants are smaller, more flexible funding options that can be used to purchase services from the CTRCs for research protocols conducted at various affiliated hospitals. These grants are generally available to junior investigators. These awards can be used to pay for CTRC resources and services necessary to conduct CTRC-approved protocols at University of Colorado Hospital, Children's Hospital Colorado and Perinatal CTRC. Eligible services include CTRC Research Nursing, CCTSI Nutrition, CTRC Core Laboratory, CTRC Echocardiography & Vascular Imaging, CTRC Exercise Testing, CTRC Indirect Calorimetry, DXA body composition analyses, and some eligible hospital expenses (clinical laboratory charges, research pharmacy charges, and radiology charges). There will be no charge to investigators for use of CTRC inpatient beds or outpatient facility space.

Final SARC approval must be obtained *before* MicroGrants may be awarded. Study team will be notified of the status of the MicroGrants application within one month of full SARC approval.

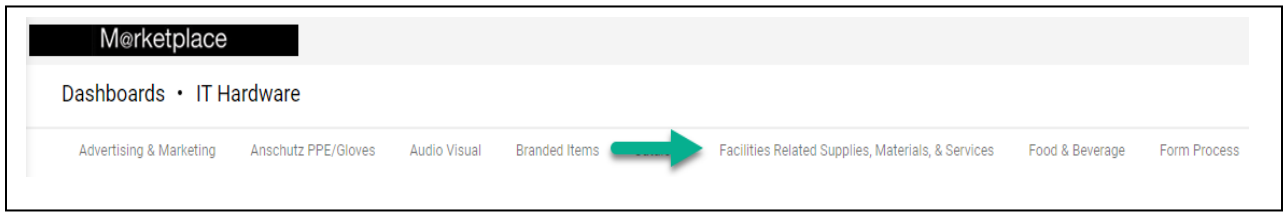
CHAPTER 16: BILLING

ADULT CTRC BILLING

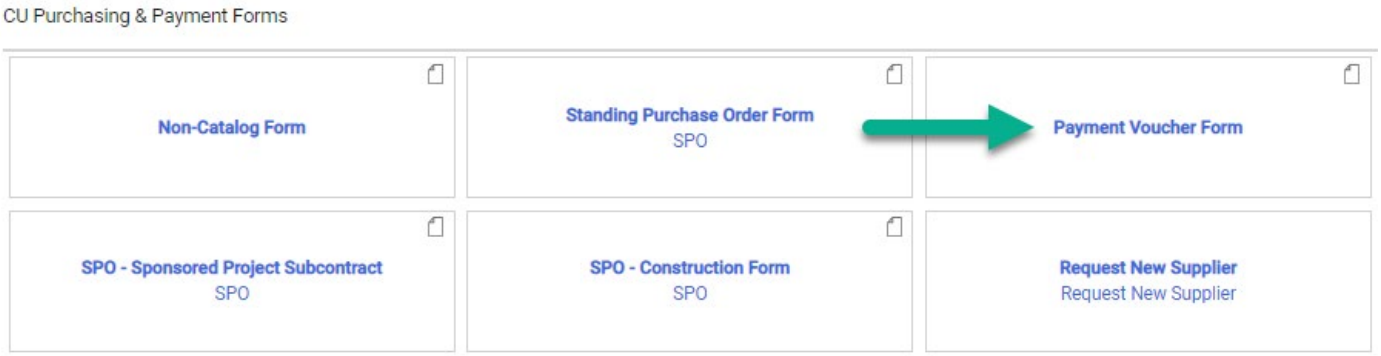
- **UCHealth EPIC (IP visits) and CU Medicine EPIC (OP visits)** – The EPIC Electronic Medical Record (EMR) system is a fully integrated, CMS-certified platform widely used across the United States. It allows for seamless sharing of patient records between hospital and outpatient environments, ensuring comprehensive and coordinated care.
  Adult CTRC Nursing, APP, and Cardiovascular Bioimaging expenses are billed through the EPIC platform.
- **iLab system** - The CU iLab billing system is a comprehensive platform used for managing core facility services and billing at the University of Colorado. It allows researchers to reserve equipment, submit service requests, and handle billing for core services efficiently.
  The Nutrition core, Energy Balance core and Core Lab utilize the iLab billing platform.

EPIC INVOICES ARE PAID THROUGH CU MARKETPLACE

- CU medicine invoices are emailed from a CU medicine staff email and the title typically includes 'IRB number CTRC Date Dollar amount'. The instructions to pay the invoice are attached to the email.
- UCHealth invoices come from the *UCHealth Research Billing* email address.
- The research team should review invoices and submit payment through CU Marketplace.
- The study team should confirm the charges are accurate and the participant is enrolled. If errors are identified, follow the instructions on the invoice.
- When ready to pay, create a Payment Voucher Form in CU Marketplace through the CU Denver Portal.
- Select **Catalogs** (image of shopping cart)
- Select one of the commodity dashboards at the top of the page (any commodity will work)



- Scroll down to **Payment Voucher Form**



- Scroll down to the **Showcases** section and select the **Payment Voucher Form** from CU PURCHASING & PAYMENT FORMS:
- The form will open. Enter the **Supplier** under **Supplier and Item Information** or click the search icon. Select the appropriate supplier from the list of results, ensuring to select the location the purchase order should be distributed from using the **+** icon.
- **Make sure to use the correct location in CU Marketplace** (see below) as mentioned in the instructions sent with the invoice. *The location numbers are revised periodically so avoid using old information as that can lead to errors.*

Supplier **Fulfillment Address for UCHealth**	**University of Colorado Hospital Authority** 7901 E Lowry Blvd Suite 350 Mail Stop F-402 Denver, CO 80230-6510 US
Fulfillment Address for CU Medicine	**University of Colorado Medicine** PO Box 110247 Aurora, Colorado 80042-0247 US

- The instructions to pay UCHealth or CU invoice are posted here.
- Please **do not** upload the documentation into the CU Marketplace – University policy requires the department to maintain the back-up documentation if needed for a review/audit. **CU Marketplace is not HIPAA compliant and cannot contain PHI.**
- Please process payments in a timely manner; payment is due 20-25 days from receipt of invoice.

INVOICES THROUGH ILAB BILLING

- Instructions on how to create and/or access iLab account can be found in Chapter 7 of this guide.
- When invoices are created in iLab from a CTRC Research Core, electronic links to the invoices are emailed to the PI (and financial contact listed in the PI's iLab account). Alternatively, invoices can be accessed by logging into the PI's iLab account and navigating to the invoices tab. Guidance on navigating the iLab system can be found here
- iLab is fully integrated with the CU Peoplesoft system and speedtypes are already associated with each PI lab within iLab.
- The invoiced charges in iLab are automatically applied to the speedtype associated with the project in the PI's iLab account.
- Study teams should review their iLab invoices for accuracy and dispute charges as needed by directly contacting the respective CTRC core.
- This review process should be undertaken regularly and timely; charges will be automatically paid, and errors will not be corrected unless study teams bring issues forward directly to the respective core.
- No further action is needed by PI or study team unless there is a dispute.

CHILDREN'S HOSPITAL COLORADO (CHCO) CTRC BILLING

CHCO CTRC Nursing charges are billed to the study G0 account through CHCO EPIC.

- Charges are billed through EPIC by CHCO CTRC nurses on the day of service.
- Charges are then reviewed and reconciled against OnCore by the CHCO Research Billing Team.
- In case of discrepancies, the billing team will reach out to the study team and/ or CTRC Nursing manager to seek clarification.
- Once resolved, the charges posted in EPIC for CTRC services are applied by CHCO Finance to the G0 account associated with that study through the EPIC use plan.
- Questions related to research billing should be directed to the Research billing team.
- CTRC charges are automatically applied to the respective G0 account for the study. No further action is needed by the study teams for this process.
- Instructions on requesting G0 account can be found in chapter 7 of this guide.
- Additional training related to CHCO billing review can be found in Cornerstone. Look for **'Research Tier One Billing Review'** course.
- **Best practice:** Study teams should keep OnCore up-to-date and accurate for research visits to facilitate accurate billing over the course of the study.

- **CTRC Nutrition and CTRC Core Laboratory services** supporting CHCO CTRC protocols are billed to studies through the iLab system described previously.

CHAPTER 17: SUGGESTED LANGUAGE FOR PROTOCOLS & GRANT APPLICATIONS

The Colorado Clinical & Translational Sciences Institute (CCTSI) provides recommended language for protocols and grant applications to help researchers effectively communicate their use of CCTSI resources. Properly citing the CCTSI grant is essential to demonstrating to Congress, the NIH, and our institutional partners that the CCTSI is effective in facilitating translational research.

- Citing the CTSA Grant - Any publications, patents, or projects that benefit from any CCTSI resources (including use of REDCap) must credit the CTSA Grant
- CCTSI Facilities and Resources

CHAPTER 18: CCTSI & CTRC GENERAL POLICIES

CTRC COMMUNICATION

Any new CTRC policies and changes will be systematically communicated to the study teams via monthly CTRC Communication sent via email to all CTRC users. We highly encourage all to read the monthly CTRC communication in entirety as we try to disseminate valuable information and upcoming changes to prepare study teams in advance.

CCTSI DRESS CODE POLICY

- Outpatient CTRC Dress Code Policy
- Inpatient (UCHealth) Dress Code Policy

The CCTSI adheres to the professional dress codes at all clinic locations.

To be consistent across both adult CTRC units and within CCTSI spaces, we request that anyone in CTRC and CCTSI spaces refrain from wearing blue jeans, shorts, spaghetti-strap tops, tank tops, mini-skirts, sun dresses, sweatshirts/hoodies, flip-flops, etc. Clothing with logos, pictures, cartoons, slogans, or potentially offensive words/terms. CU or study branded apparel is acceptable. Any clothing that is short, tight, and overly revealing is inappropriate for the workplace. Participant and family confidence is enhanced when staff are professionally attired. Study staff members are responsible for their personal appearance in the workplace and for learning and abiding by this policy.

Clothing: Clothing should fit properly, be clean, pressed, in good condition, and of a length and style that does not interfere in performing job duties.

Slacks, Pants, and Suit Pants

- Slacks that are similar to Dockers and other makers of cotton or synthetic material pants, wool pants, professional synthetic pants and capris are acceptable. Inappropriate items include, but are not limited to denim, sweatpants, exercise pants (except for exercise supervision duties), shorts of any kind, bib overalls, and any spandex or other form-fitting pants such as those worn for biking (except for exercise supervision duties).
- Any tops worn with leggings must fall to mid-thigh level and be appropriate for a business environment in coverage, material thickness, and garment length.

Shirts, Tops, and Jackets

Business casual shirts, dress shirts, sweaters, tops, golf-type/polo shirts, and turtlenecks are acceptable attire for work. Suit jackets and sport jackets are acceptable for the office. Inappropriate attire for work includes tank tops; midriff tops; shirts with potentially offensive words, terms, logos, pictures, cartoons, or slogans; halter-tops; sweatshirts; and tee shirts unless worn under another blouse, shirt, jacket, or dress.

Footwear

Only closed-toe footwear is allowed in CTRC and CCTSI spaces. Heel height should be appropriate and safe for the type of work performed. Thongs, flip-flops, beach sandals, and Five Fingers (or similar footwear) are prohibited. Additional restrictions or

protective footwear may be required in certain work environments, such as the CTRC Laboratory.

Jewelry

Jewelry must not interfere with job performance or safety. Ear piercings, including studded earrings and small hoops, must not create a safety hazard. Pins, buttons, jewelry, emblems, or insignia bearing a political, controversial, inflammatory, or provocative message are not permitted. Anyone providing direct participant interactions may be required to limit jewelry and accessories for safety reasons.

Tattoos

Tattoos that may be construed as vulgar or offensive must be covered.

Identification Badge

An Identification Badge must be always worn and remain visible. Badges should be unaltered, worn at the waist or above and either clipped to a belt, to clothing, or around the neck attached to a break-away lanyard and must adhere to department guidelines and regulatory requirements.

INCLEMENT WEATHER POLICY

In the event of extreme weather that may disrupt on-campus operations and travel, the safety of CTRC staff and participants is our highest priority.

- **Decision Making**: CU Anschutz executive leadership will decide if a delay or physical campus closure is required based on predicted and actual weather conditions.
- **Study Team Responsibilities**: If hazardous weather is expected, research study teams are responsible for notifying participants to cancel and/or reschedule their visits.
- **Hospital and Clinical Site Operations**: Please note that weather-related decisions for the CU Anschutz campus do **not** affect the operations of University of Colorado Hospital, Children's Hospital Colorado, or other clinical sites. These facilities will operate as normal unless stated otherwise by their respective leadership.

- CU Anschutz Administrative Policy on Campus Closures/Delays
- UCHealth Emergency Operations Plan

INSTITUTIONAL POLICIES

- UCHealth policies
- UCD Campus policies
- CHCO policies
- Preventing Targeted Violence (Active Harmer training)

CTRC RECOMMENDED BEST PRACTICES SUMMARY

- ✓ **Bookmark the CTRC website** for hours of operation, holiday closures and latest updates.
- ✓ **Study team must review and approve** all the necessary core-specific documents prior to first study visit.
- ✓ All **CTRC Scheduler appointments** must be made 7 CALENDAR DAYS IN ADVANCE. Contact the CTRC Scheduler staff if you need to schedule within 7 calendar days.
- ✓ Communicating with CTRC cores is best done via **core-specific emails** to ensure a timely response.
- ✓ **For Nutrition core**, remember to include all **the necessary information** in the right format when sending scheduling requests.
- ✓ At AHSB OP Clinic, remember to **'checkout' your participant in the visit status dashboard** when the visit ends, to avoid additional room charges.
- ✓ **CTRC processing rooms are a shared space** and the study team using the equipment is responsible for cleaning it after use.
- ✓ Cut-off time for sample drop-off in Core lab (AHSB & CHCO) is **3pm M-F.**
- ✓ Cut-off time for clearing samples from CTRC fridges or freezers each week is **Friday 2pm at CHCO CTRC processing room** and **Wednesday 4pm at Adult CTRC OP processing room.**
- ✓ **Cleaning and storing CTRC equipment after use** in its designated place helps with the overall efficiency of workflow.
- ✓ Review the monthly CTRC communication for **AHSB parking code**, latest updates, and important reminders.
- ✓ Coordinators are required to have training and competency check-off through CCHRI before doing any processing in the CHCO CTRC.
- ✓ **The PI should maintain records of completed courses** and verify that each team member is up-to-date with their training related to procedures at CTRC.