

AUGUST 17, 2026

# *Mapping the Research Landscape*

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Research Coordinator | Research Outcomes for Children's Surgery (ROCS)



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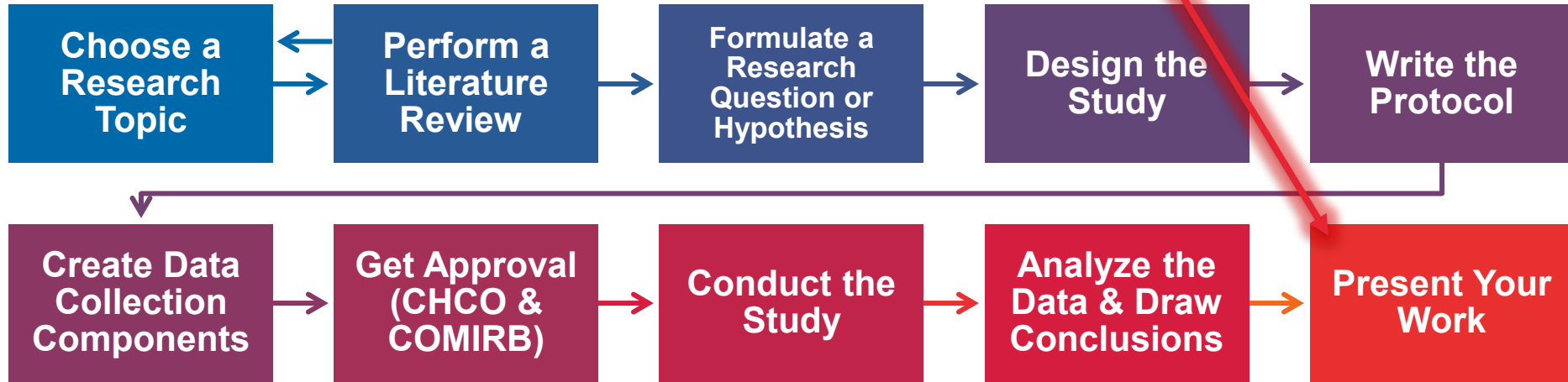
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# Roadmap



**Revise  
your work based off  
peer review**



# RESOURCES



Keep them in mind & use them often!



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# RESOURCES

<https://olucdenver.sharepoint.com/sites/ROCSCoordinatorHub>



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## ROCS Coordinator Hub

[Home](#)[Coordinator Resources](#)[Events](#)[Our Team](#)[ROCS Intake](#)



## Frequently Used Resources

|                                                                                                                                       |                                                                                                            |                                                                                                                                   |                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
|  CU REDCap                                             |  InfoEd                   |  OnCore                                          |  ROCS Intake                                     |
|  Colorado Multiple Institutional Review Board (COMIRB) |  COMIRB Forms - Templates |  HSR Portal - Protocol Assessment/Amendment Form |  Human Subject Research Portal Information   CRS |
|  PRMS - Oncology                                       |  PRMS - Submission Form   |  CU Anschutz Clinical Research Community - Teams |                                                                                                                                   |

## Upcoming Events

See all

+ Add event

- 

**JUN 18**  
Clinical Research Connections  
Wed, Jun 18, 12:00 PM
- 

**JUL 22**  
ROCS Quarterly Research Coordinator Forum  
Tue, Jul 22, 10:00 AM
- 

**JUL 28**  
7th Annual ROCS Research Bootcamp  
Mon, Jul 28, 8:30 AM

in Children's Surgery (ROCS) Coordinator Hub  
es for all research coordinators and staff within  
Surgery.



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# RESOURCES

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

## Colorado Multiple Institutional Review Board (COMIRB)

Regulatory Compliance

Office of the Vice Chancellor  
for Research 

General Information ▼

Submission Guides ▼

Forms ▼

Guidance and Policies

Training

IRB Members ▼

About COMIRB ▼

Clinical Research Guide

Office Hours

Quality Improvement and Program Evaluation

Review Levels

Single IRB Guide

Social-Behavioral Research Guide

Training

What is Human Subject Research?

Initial Submission

Secondary Research

Amendments

Continuing Review

UAPs

Closing a Study



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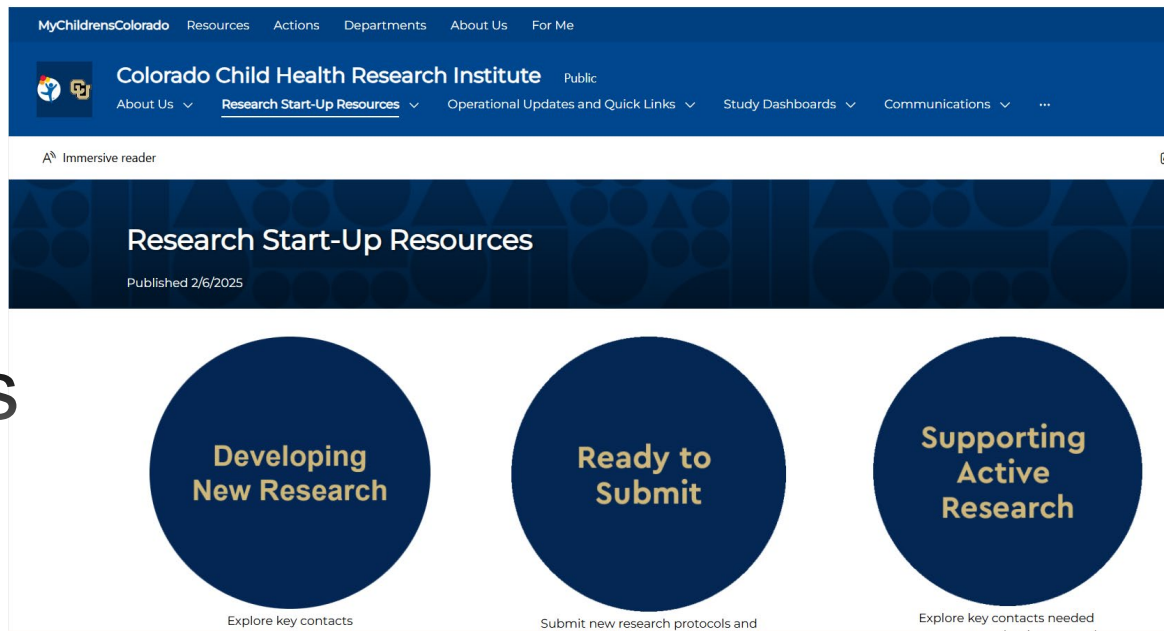
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# RESOURCES

Colorado Child Health Research Institute SharePoint/Intranet

<https://childrenscolorado.sharepoint.com/sites/childhealthresearch>

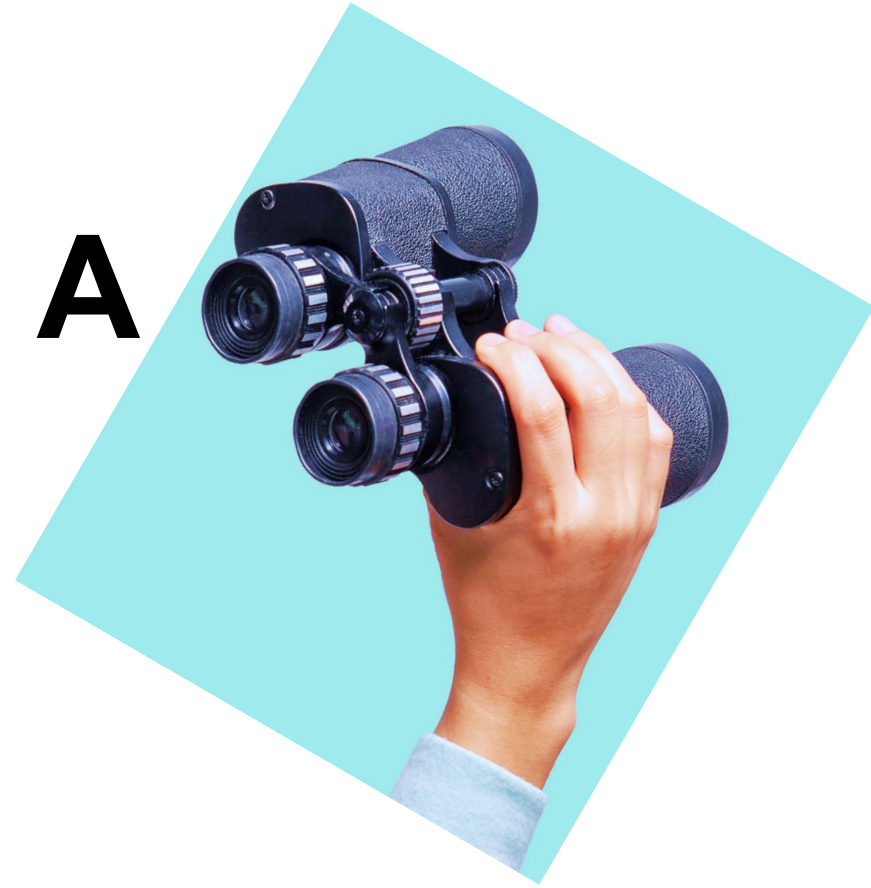
## CHCO Guides & SOPs





# CONDUCTING A STUDY

Required Trainings &  
Responsibilities



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# Required Trainings and Disclosures\*

\*Not a comprehensive list



CITI Program Training: HIPS, Human Subjects Training, and Good Clinical Practice (for NIH-funded studies)



COI Disclosure (InfoEd)



REDCap Training (if working on studies that are utilizing this platform for data collection)



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# Required Trainings(con't)

Register  
in  
Cornerstone



ONCORE Training – If conducting/supporting enrolling studies



Study eBinders: Training is required before you can access the study binder and digitally sign documents.



Epic Research training\* If conducting/supporting enrolling studies

\*CRC/Non-Clinical staff-specific.  
Clinical staff training requirements differ.



# Trainings



## Research Workshops – Hosted by CHCO/ CCHRI *Register in Cornerstone*

- Hospital Policies / “CTRC Hot Tips”
- Tips and Tricks when Working with Pediatric Patients
- Research 101
- Regulatory 101
- ALCOA —Attributable, Legible, Contemporaneous, Original, and Accurate
- Data Management (REDCap Focus)
- Informed Consenting / Mock Consent
- HSRP/Start-up
- OnCore Supplemental



# Trainings(cont)



## Additional Research Workshops – Task/Systems focused

- Vitals / Pregnancy Testing Checkoff / Syringe Transfer Training
- Conducting Monitor Visits
- ECG Checkoff (sponsor-provided machines only)
- Inpatient Research
- CTRC
- IDS (Investigational Drug Pharmacy)
- EPIC Treatment Plans and Smart Sets
- EPIC/OnCore Billing Overview
- EPIC Scheduling Request
- Submitting an EPIC Use Plan (EUP) and Amendment
- Finance Overview
- Contracting Overview
- Lab Manual and Sample Shipping Overview



# Roles & Responsibilities



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# PI RESPONSIBILITIES\*

\*Not a comprehensive list

## Good Clinical Practice

- » Follow all laws, regulations, and policies for Human Subject Research
- » Ensure adequate training and resources are provided for study team

## Regulatory Compliance

- » Ensure research is conducted according to an approved protocol
- » Retain records of original study documents

## Delegation

- » Responsible for delegation of study tasks and study staff conduct
- » You cannot delegate responsibility for the proper conduct of the study

## Reporting

- » Adverse Events, Unanticipated Problems
- » Other non-compliance



# RESEARCH COORDINATOR RESPONSIBILITIES

## YES

- Day-to-day activities
- Prepare study materials
  - Regulatory docs
  - Consent form
  - Enrollment log
- Regulatory submissions
- Consenting, study visits
- REDCap build and data entry

## DEPENDS

- Assist with protocol writing
- Help prepare abstracts, manuscripts, posters

## NO

- Determine cause of AEs
- Sign orders
- Clinical care
- Perform tasks without training



# HOW TO BE A GOOD Principal Investigator (PI)



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# Quality Assurance

Attend regular meetings  
with your research team

Discuss expectations with  
your team

Communicate things you'd  
like brought to your  
attention

## SELF-AUDIT at regular intervals

- ✓ Check for missing data
- ✓ Identify patterns and gaps in processes
- ✓ Check for things that would affect the accuracy of data



# A GOOD PI...

1

**Provides Direction**

2

**Ensures Integrity**

3

**Takes Responsibility**

**YOU ARE THE  
OWNER OF THE  
WORK –  
NO ONE WILL  
UNDERSTAND IT  
OR SHOULD CARE  
ABOUT IT MORE  
THAN YOU DO!**



# *Study Start-Up & Regulatory Basics*



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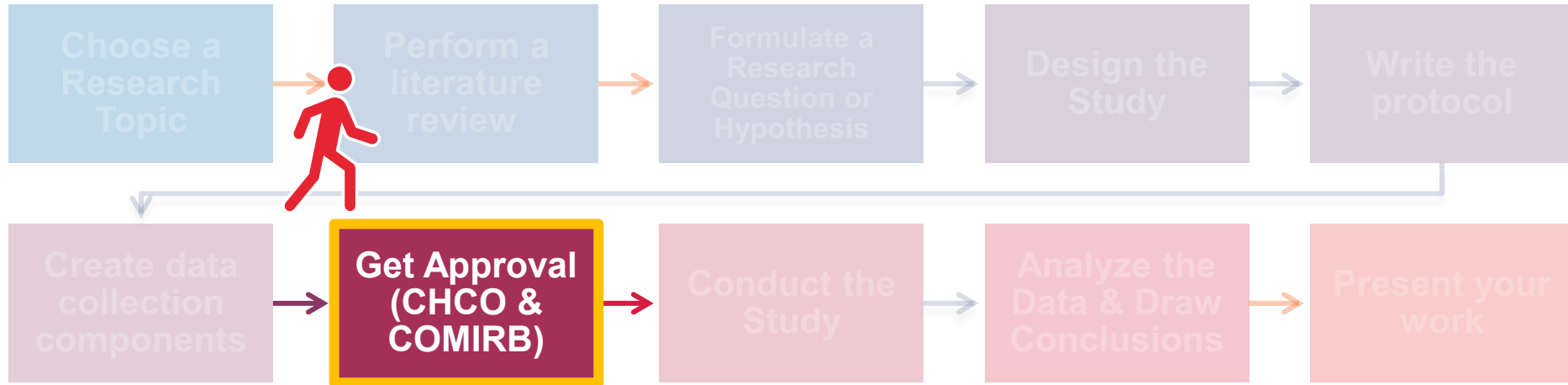
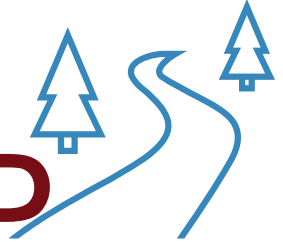
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# ROADMAP



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# STUDY START-UP OVERVIEW

CHCO approval takes 2-4 weeks

IRB approval takes 4-8 weeks

Create Human  
Protocol in  
InfoEd

HSR Portal  
Submission

Submit to  
COMIRB

Approval!

Total average approval  
time is 6-12 Weeks

## Handout 2: Regulatory Guidance



# REVIEWERS & SUBMISSION PORTALS

COMIRB  
(InfoEd)

Colorado Multiple Institutional Review Board

» The regulatory body that oversees all Human Subjects Research

HSR Portal

Human Subjects Research Portal

» Routes protocols to the proper groups across campus for approval

CCHRI

Colorado Child Health Research Institute

» Partnership between CU Anschutz and CHCO

PRMS

Protocol Review and Monitoring System

» Approval required for all oncology-related protocols



# Regulatory Process

A simplified path from submission to study activation



**Key principle: all required regulatory approvals must be complete before the study starts.**



# Application

## Core application package

- ✓ Protocol number
- ✓ Protocol
- ✓ COMIRB application
- ✓ PI attestation
- ✓ Data Variables
- ✓ Personnel form

## Additional items

- ✓ CHCO approval letter (for IRB)
- ✓ Consent / assent forms
- ✓ Surveys
- ✓ Data flow diagram
- ✓ Data agreement template
- ✓ Recruitment materials





# InfoEd / ERA

The screenshot shows the InfoEd / ERA web application interface. At the top, there is a header bar with the University of Colorado Denver | Anschutz Medical Campus logo and navigation links: Home, My Profile, Search for Records, My Messages, and My Action Items. The main content area is divided into two columns. The left column contains a sidebar with links: Proposals, Human Protocol, Conflict of Interest, My Projects, and SPIN. Below this sidebar is a contact box for assistance. The right column displays the 'Human Protocol' section, which includes a 'Create New' button and a 'Create New Human Protocol' button. Below these buttons is a section for 'Accessing Records/Reporting' with 'Search For' and 'Show/List' buttons.

University of Colorado Denver | Anschutz Medical Campus

Home My Profile Search for Records My Messages My Action Items

Proposals

Human Protocol

Conflict of Interest

My Projects

SPIN

For assistance please contact:  
[eRASupport@CUAnschutz.edu](mailto:eRASupport@CUAnschutz.edu)

Human Protocol

Create New

Create New Human Protocol

Accessing Records/Reporting

Search For Show/List



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# COMIRB Template & Portal Links

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Regulatory Compliance

Office of the Vice Chancellor  
for Research

General Information ▾ Submission Guides ▾ **Forms ▾** Guidance and Policies Training IRB Members ▾ About COMIRB ▾

**COMIRB Forms**

Protocol Templates  
Applications  
Consent Templates  
HIPAA

**Protocol Templates**

- [Therapeutic Intervention, IND/IDE Exempt](#)
- [Observational or Non-Therapeutic Intervention](#)
- [Exempt Categories 1, 2, or 3](#)
- [Biorepository Protocol Template](#)
- [Secondary Research Protocol Template](#)



**Human Subject  
Research (HSR)  
Portal**



**Required Training**



**Required  
Documents**



**InfoEd eRA Login**



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