

AUGUST 26, 2024

CONDUCTING A STUDY



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Center for Children's Surgery

SCHOOL OF MEDICINE

UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



Research Outcomes in
Children's Surgery (ROCS)

UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



Children's Hospital Colorado

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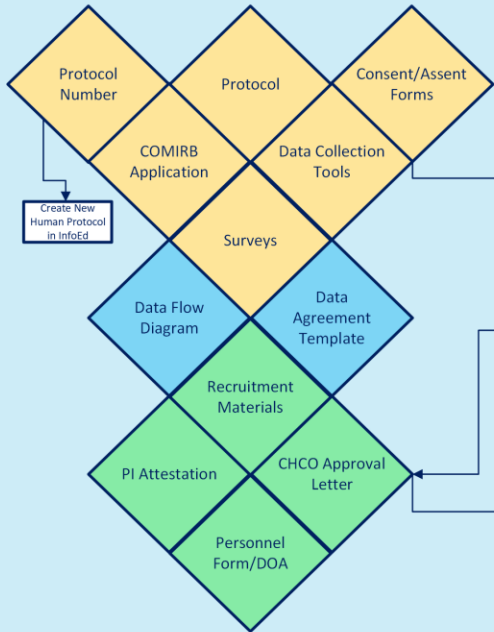
OVERVIEW

- 1 Regulatory Process
- 2 After Approval
- 3 PI Responsibilities
- 4 Coordinators Responsibilities
- 5 Quality Assurance



Regulatory Process Overview

Application

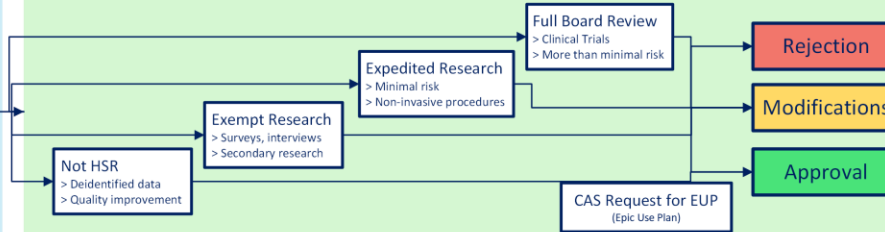


Regulatory Approval

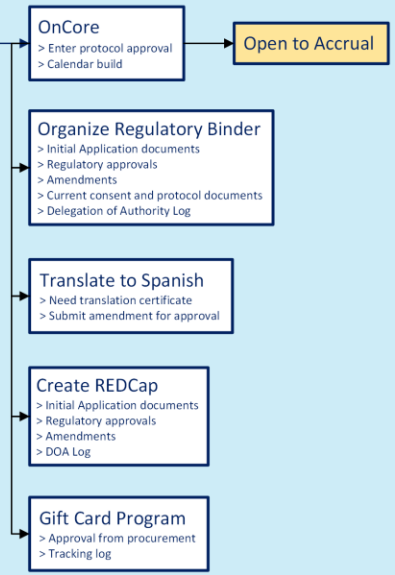
Submit to HSR Portal



Submit to COMIRB



Pre-Accrual



AFTER APPROVAL

OnCore:
Open to Accrual

Epic Use Plan

REDCap:
Build your database

Gift Card Program

Regulatory Binder:

- Initial app & amendments
- DOA, training log
- Consent forms, recruitment log
- Participant data

Screening & Recruitment



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

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
- Consenting, study visits

DEPENDS

- Assist with protocol writing
- Prepare abstracts, manuscripts, posters

NO

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



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 accuracy of data



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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RESOURCES

Colorado Child Health Research Institute SharePoint

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

Colorado Child Health Research Institute Public ★ Following

About Us ▾ Research Start-Up Resources ▾ Study Dashboards ▾ Operational Updates and Quick Links ▾ ...

COLORADO
**Child Health
Research**
INSTITUTE

LEARN MORE ABOUT OUR CAMPUS PARTNERSHIP →

Pediatrics Research Day: Call for Nominations! Nominate a Child Health Faculty Research Leader by August 23

Research Start-Up Resources



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Research Toolkit

OBGYN Research Toolkit

 Onboarding for Research Faculty & PRAs	 Regulatory Processes Maps	 Regulatory Submission Process	 Statistical Support	 Scientific Editing
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Requirements for Human Subjects Researchers/Personnel

There are three requirements to be approved as an investigator or research personnel on a study that uses identifiable data or specimens from humans. These include:

1. Submit a **Conflict of Interest (COI)** disclosure. 
2. **Upload your CV** into the InfoEd system.
 - Go to [InfoEd eRA](#)
 - Select your campus to log in (**Denver**).
 - Login using your CU Anschutz username and password.





THANK YOU

Questions?



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