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CONDUCTING A STUDY

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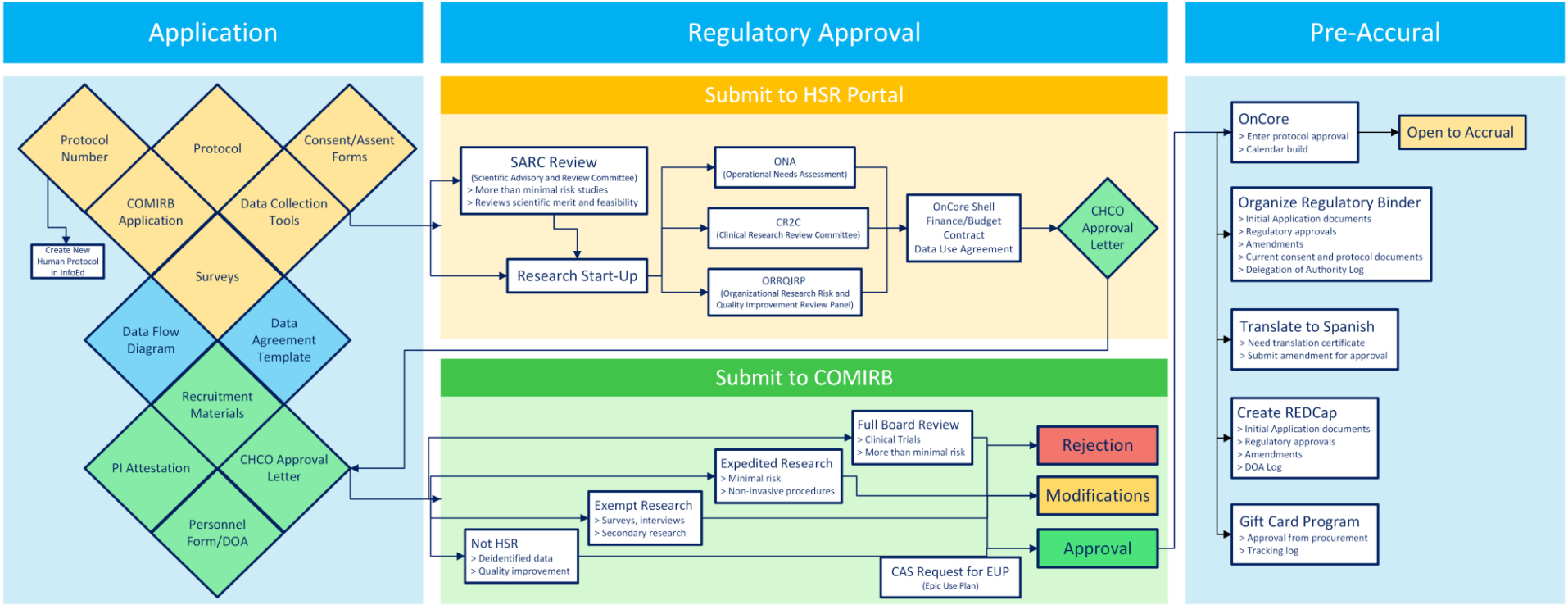
OVERVIEW

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

Regulatory Process Overview



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

RESOURCES

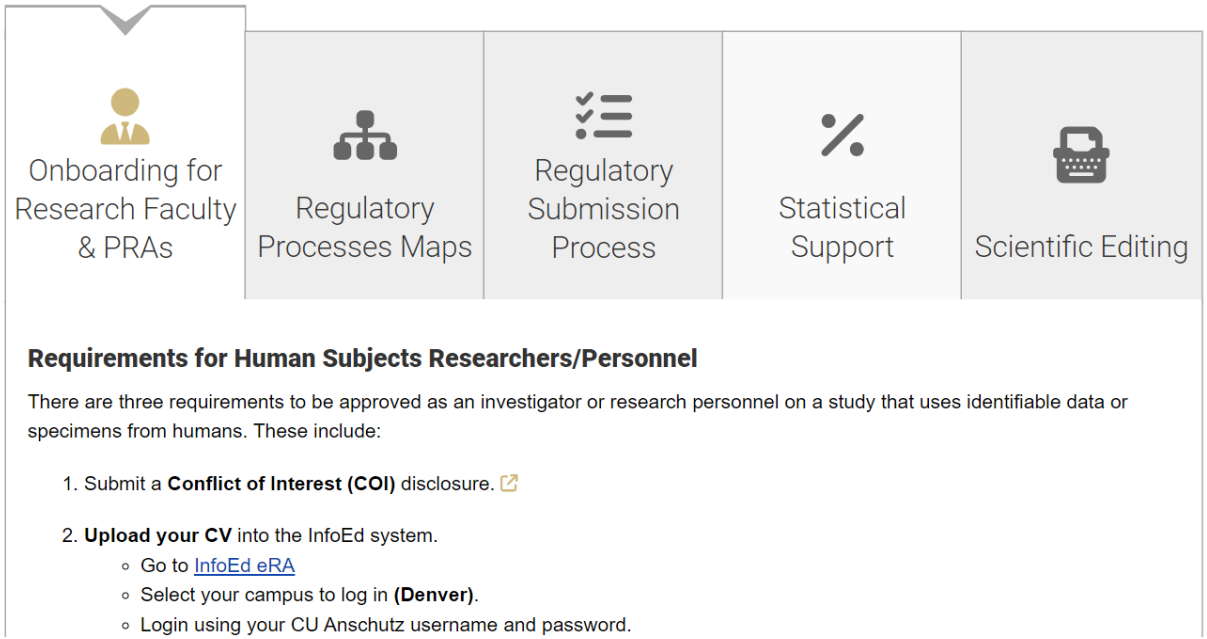
Colorado Child Health Research Institute SharePoint

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

RESOURCES

https://medschool.cuanschutz.edu/ob-gyn/research/researcher-toolkit

OBGYN Research Toolkit



THANK YOU

Questions?