

AUGUST 17, 2026

RESEARCH BY DESIGN

From Questions to Protocols

Samantha Wilson, MS

Team Lead | Research Outcomes for Children's Surgery (ROCS)



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START WITH THE QUESTION



WHERE DO RESEARCH QUESTIONS COME FROM?

-  Clinical practice
-  Gaps in the literature
-  Patient needs
-  Curiosity
-  Prior research findings



TYPES OF RESEARCH



BASIC SCIENCE RESEARCH

Explores fundamental biological mechanisms and processes to expand scientific knowledge.



TRANSLATIONAL RESEARCH

Bridges the gap between basic discoveries and their application in patients and communities.



CLINICAL RESEARCH

Studies new treatments, devices, and interventions in people to evaluate safety, effectiveness, and outcomes.



OUTCOMES RESEARCH

Evaluates the impact of healthcare interventions on patient and population outcomes.



QUALITY IMPROVEMENT (QI)

Uses systematic methods to improve clinical processes, patient safety, and the quality of care.



MEDICAL EDUCATION RESEARCH

Studies teaching, learning, and assessment to improve education for health professionals and trainees.



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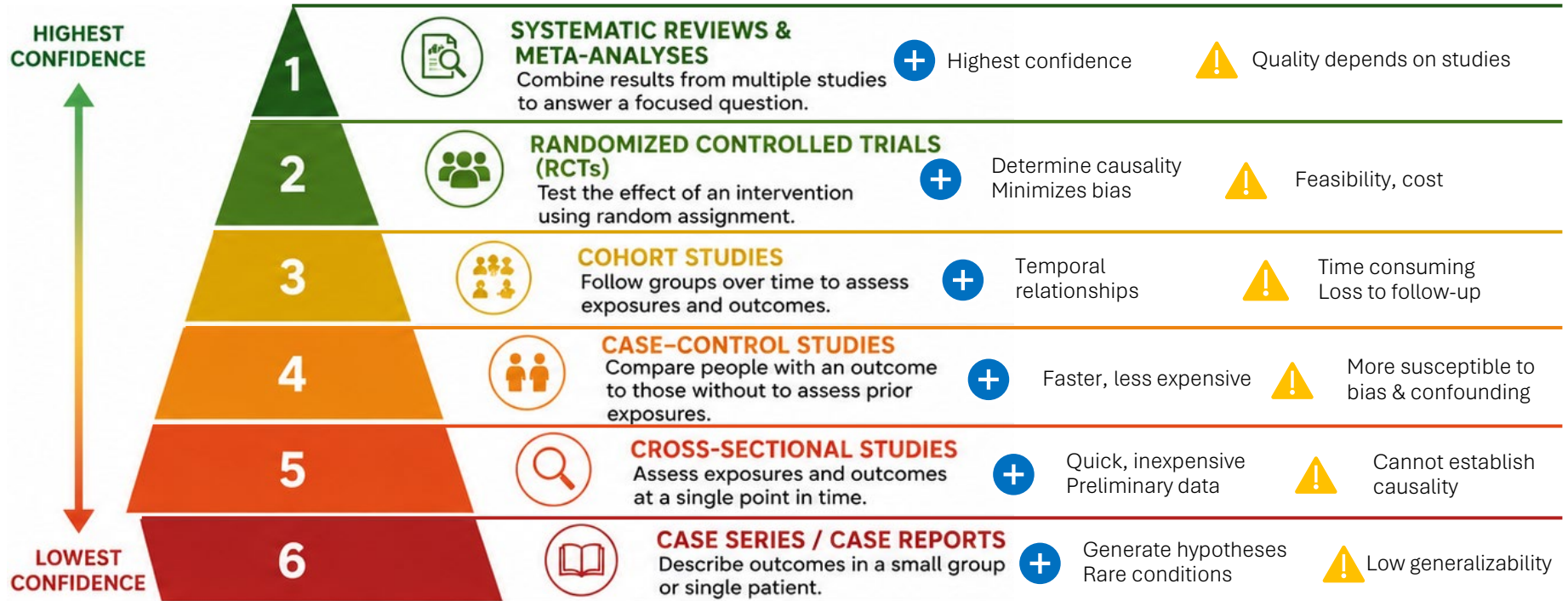
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HIERARCHY OF EVIDENCE



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CHOOSE THE RIGHT STUDY DESIGN



How common is a condition or outcome?

Recommended Design

CROSS-SECTIONAL STUDY



Does an exposure increase the risk of an outcome?

Recommended Design

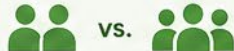
COHORT STUDY



What exposures are associated with a rare outcome or disease?

Recommended Design

CASE-CONTROL STUDY



Does an intervention or treatment lead to better outcomes?

Recommended Design

RANDOMIZED CONTROLLED TRIAL (RCT)



What is happening and why? What should we study next?

Recommended Design

EXPLORATORY STUDY, QUALITATIVE STUDY, OR CASE SERIES



CONSIDER PRACTICAL CONSTRAINTS

What factors will influence your design choice?



Time



Cost



Ethics



Available Data



Recruitment



Expertise / Resources



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COMPARING DATA SOURCES

DATA SOURCE	TIME	COST	IRB / REGULATORY	TYPICAL SAMPLE SIZE
 Prospective Data Collection	 High	 High	 High	 Small–Moderate (tens to hundreds)
 Retrospective Chart Review	 High	 Low	 Low	 Moderate–Large (hundreds to thousands)
 Existing Databases & Registries	 Low–Moderate	 Variable	 Low	 Large–Very Large (thousands to millions)
 Survey / Patient-Reported Data	 Moderate	 Low–Moderate	 Moderate	 Variable (depends on response rate)
 Qualitative Interviews / Focus Groups	 High	 Moderate	 Moderate	 Small (tens of participants)



TYPES OF DATASETS



LIMITED

- Most identifiers removed
- May include dates & locations
- DUA required



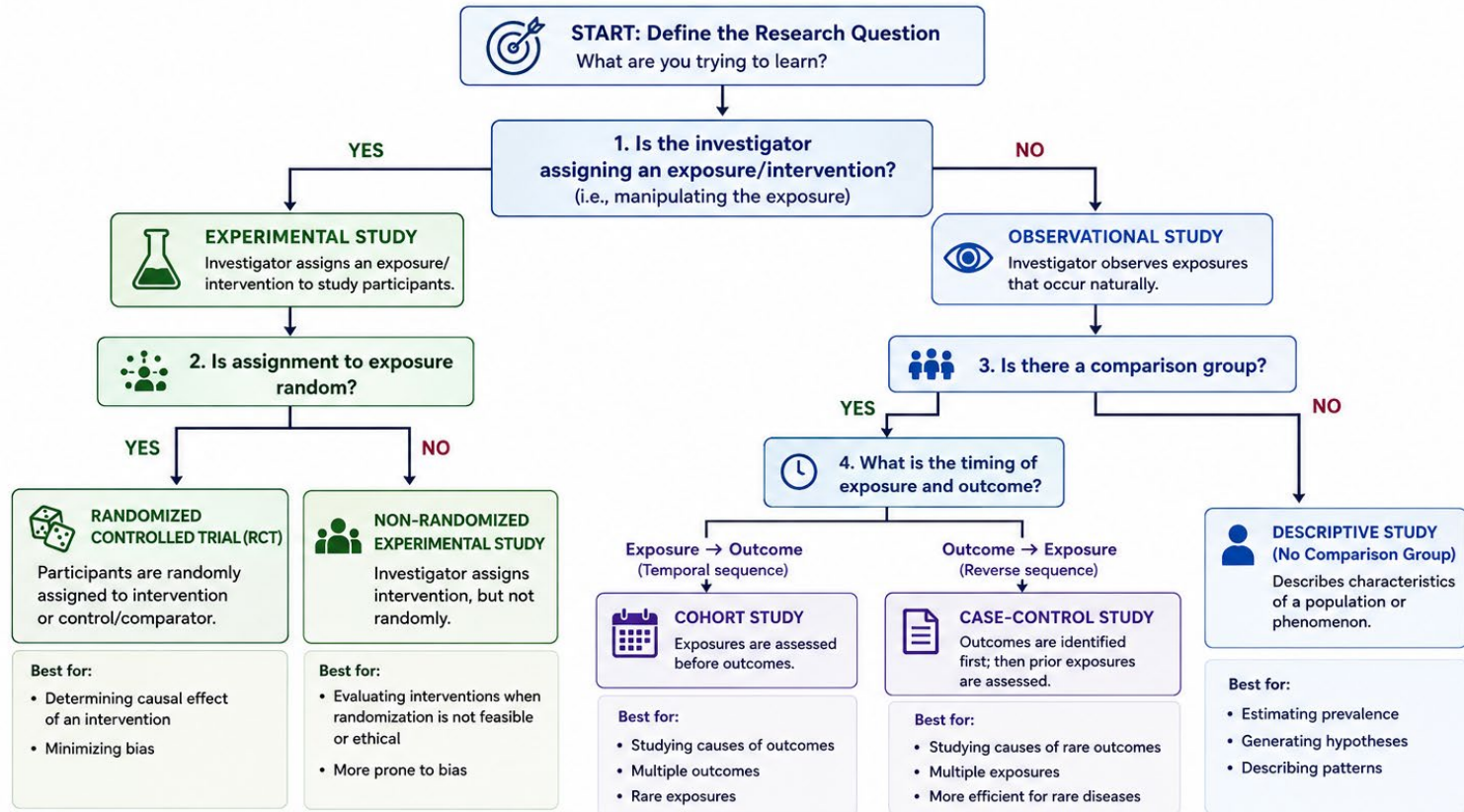
DE-IDENTIFIED

- All 18 identifiers removed
- Cannot be readily re-identified
- No DUA required



CLASSIFICATION OF CLINICAL RESEARCH

An algorithm to distinguish types of clinical studies



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PROTOCOL WRITING



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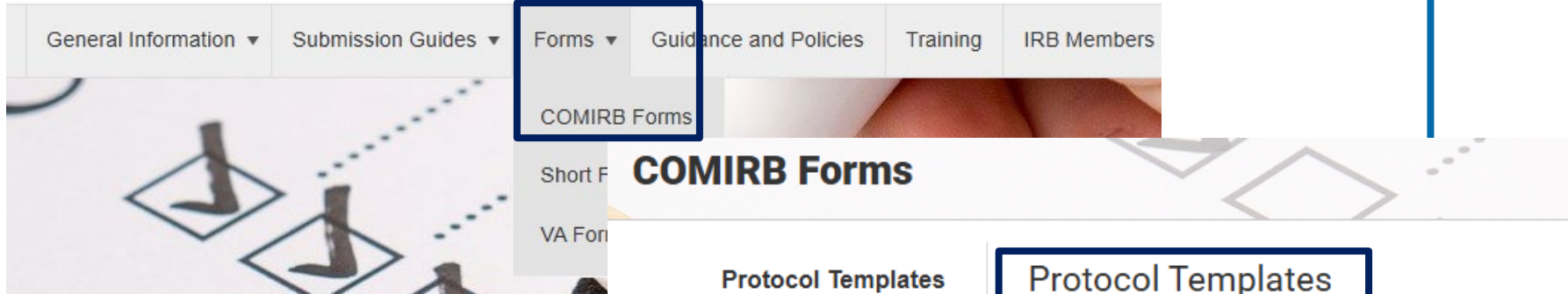


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Colorado Multiple Institutional Review Board (COMIRB)

Regulatory Compliance



The screenshot shows the top navigation bar of the COMIRB website. The 'Forms' menu item is highlighted with a blue box. Below it, a dropdown menu is visible, listing 'COMIRB Forms', 'Short F', and 'VA For'. The background of the website features a close-up image of a person's hand holding a pen over a document with checkboxes.

COMIRB Forms

- Protocol Templates
 - Applications
- Consent Templates
- HIPAA
- Continuing Review
- Incident Reports

Protocol Templates

- [Therapeutic Intervention, IND/IDE exempt](#)
- [Observational or Non-Therapeutic Intervention](#)
- [Exempt Categories 1, 2 or 3](#)
- [Secondary Research Protocol Template](#)
- [GCP Protocol Template for drug investigations](#)
- [NIH Protocol Templates for Clinical Trials](#)
- [HDE Protocol Template](#)



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PROTOCOL WRITING

WHY ARE YOU DOING IT?



1 STUDY RATIONALE

- Why is this study important?
- What gap in knowledge does it address?



2 BACKGROUND

- What is already known?
- Summary of relevant literature and evidence



3 OBJECTIVES / HYPOTHESIS / SPECIFIC AIMS

- Primary objective or hypothesis
- Secondary objectives / specific aims



WRITING GOOD OBJECTIVES

CHARACTERISTICS OF STRONG OBJECTIVES:



Specific and clear



Focused on the expected outcome



Feasible and ethical



Measurable / assessable



Aligned with study design



Limited in number (typically 2-5 primary aims)

USE AIM WORDS:



Describe



Compare



Determine / Assess



Evaluate



Explore / Identify



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WRITING GOOD OBJECTIVES

TOO VAGUE: *To study burnout among residents.*

STRONGER:

CROSS-SECTIONAL

To determine the prevalence of burnout among residents and identify factors associated with burnout.

CASE-CONTROL

To compare workload, sleep, and program characteristics between residents with and without burnout.

INTERVENTION/RCT

To evaluate whether implementation of a resident wellness program reduces burnout rates within a residency program.



PROTOCOL WRITING

HOW WILL YOU DO IT?



4 STUDY DESIGN

- Overall design (e.g., RCT, cohort, cross-sectional)
- Setting and duration
- Key design features (randomization, blinding, etc.)

Put the plan on paper.



5 STUDY POPULATION

- Inclusion criteria
- Exclusion criteria
- Recruitment plan and sample size



6 STUDY INTERVENTIONS, ASSESSMENTS & PROCEDURES

- Description of interventions (who, what, how, when)
- Assessments and outcomes
- Study procedures and timeline



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PROTOCOL WRITING

HOW WILL YOU ANALYZE & PROTECT PARTICIPANTS?



7 RISK / BENEFIT ASSESSMENT

- Potential risks and burdens
- Potential benefits
- Risk mitigation strategies
- Overall risk/benefit summary



8 DATA ANALYSIS / STATISTICS

- Primary and secondary endpoints
- Statistical methods and models
- Sample size justification



9 INFORMED CONSENT

- Information to be provided to participants
- Voluntariness and rights
- Consent process and documentation





PLAN YOUR ANALYSIS



What is my primary outcome?



What type of data am I collecting?



What comparisons am I making?



How large of a sample do I need?

**INVOLVE A STATISTICIAN DURING STUDY DESIGN,
NOT AFTER DATA COLLECTION.**



RESEARCH PITFALLS



1

Designing the Wrong Study

The most ambitious design isn't always the right design.



2

Too Many Specific Aims

Too many aims can dilute your focus—and your chances of finishing.



3

Not Consulting a Biostatistician Early

Don't learn the hard way that your data can't answer your question.



5

Participant Burden & Incentives

A 30-minute survey feels a lot longer when you're doing it for free.



4

Unrealistic Recruitment Goals

The math may say 500—but can you find 500 willing to participate?



6

Underestimating Time & Resources

However long you think it will take—it will take longer.



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BUILDING A RESEARCH TEAM



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RESEARCH ACROSS CAMPUS

Tapping Into a Network of Resources & Expertise

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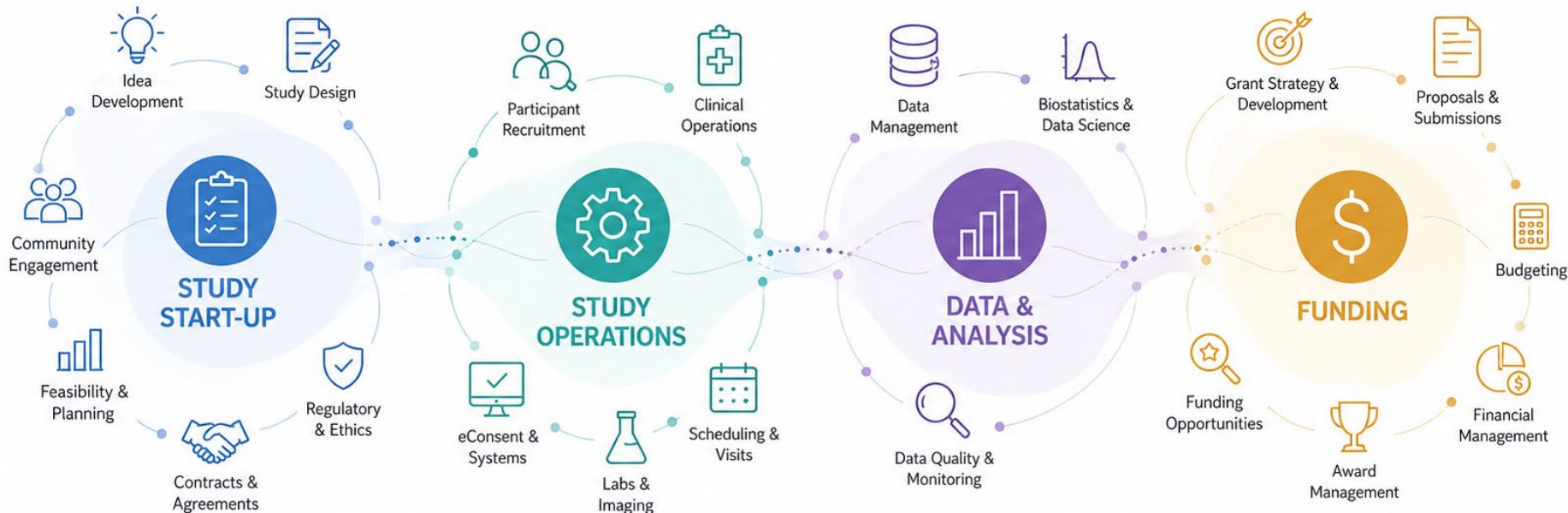
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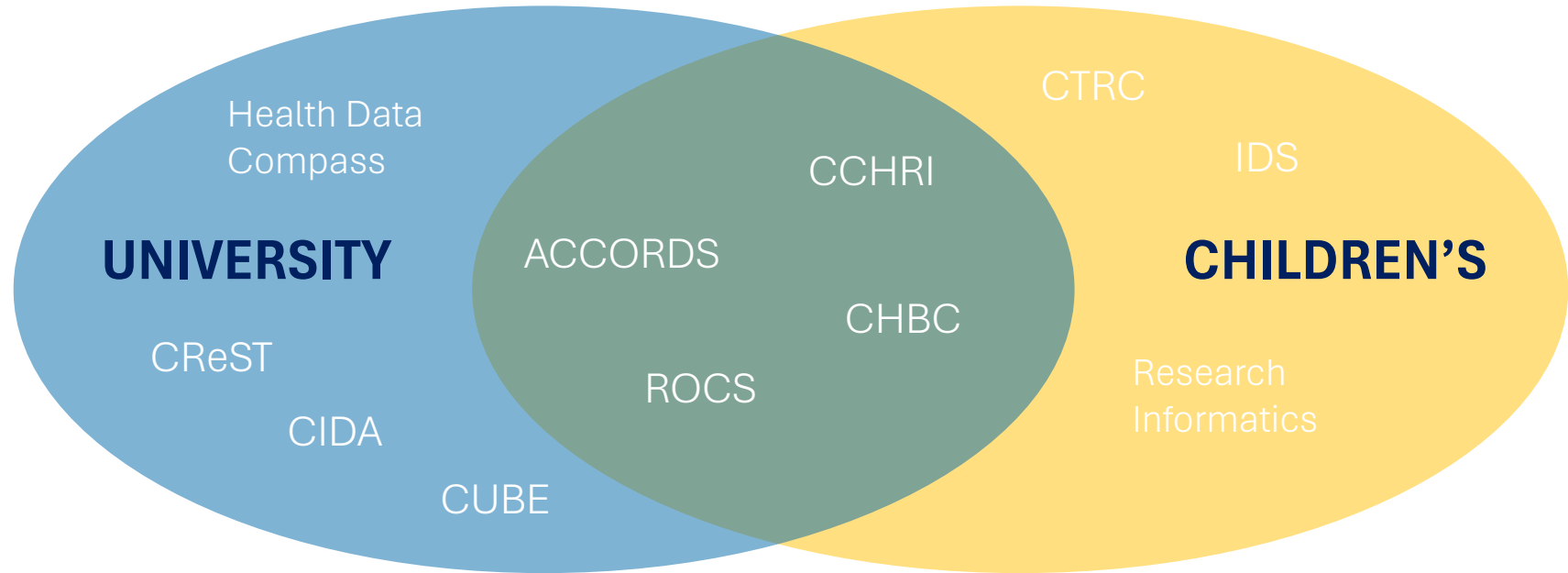
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YOU DON'T HAVE TO KNOW EVERYTHING

You just need to know how to find the right expertise.



NAVIGATING TWO RESEARCH ECOSYSTEMS



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STUDY START-UP

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Office of Grants and Contracts

CReST* (Clinical Research Support Team)

- Regulatory Support
- Budget/finance
- DSMB



ACCORDS* (Adult and Child Center for Outcomes Research & Delivery Science)

- Grant support
- Methodologic support
- Education/training

CHILDREN'S



CCHRI (Colorado Child Health Research Institute)

- Research Agreements
 - DUA
 - Budget/grant contracting
- Research Compliance
- Regulatory Support*



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STUDY OPERATIONS

UNIVERSITY

 Petty Cash & GC (PCGC)

CReST*

- Coordinator support & project management



ACCORDS*

- Qualitative & Mixed Methods Core
- Operational support



CCTSI* (Colorado Clinical and Translational Sciences Institute)

- Community outreach
- Nutrition services
- CTRC Research facilities by UHealth

CHILDREN'S

 Greenphire



CCHRI

- Coordinator support & project management*
- Education & Training
 - Julia Smith – CHCO coordinator training

Ancillary Services*

- CTRC Nurses, IDS, ECG, Lab, Radiology, & more



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DATA & ANALYSIS

UNIVERSITY

CHILDREN'S



Health Data Compass*

- De-identified UCHHealth, CHCO, CDPHE, & CO APCD data
- Free self-service option



CCHRI Research Informatics*



- CHCO Epic data

CUBE* (CU Biostatistics & Bioinformatics Ecosystem)

- Navigation tool for CIDA, ACCORDS, CHBC, & UCCC BBSR

CIDA* (Center for Innovative Design & Analysis)

- Biostats support

CHBC* (Child Health Biostats Core)

- Biostats support



ACCORDS*

- Data informatics/statistics
- Economic analysis & MarketScan data



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FUNDING

EXTERNAL

NIH

PCORI

Foundations

Professional Societies

Industry-Sponsored

INTERNAL

UNIVERSITY

SOM Pilot Grants

CCTSI Pilot Grants

Department Funding

CCS

Ponzio Awards

Innovation Awards

Quality & Safety
Awards

CHILDREN'S

Research Pilot Grants

Research & Innovation
Scholar Award (RISA)



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MORE TO EXPLORE



FIND LITERATURE

- PubMed
- Web of Science
- JANE



WORK WITH DOCUMENTS

- Adobe Pro
- DocuSign
- Florence eBinders



WORK SMARTER

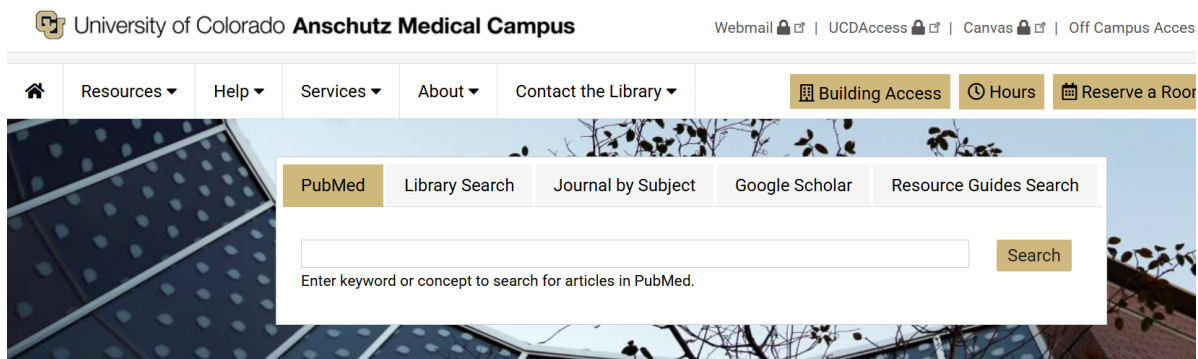
- ChatGPT
- Copilot
- Zoom AI Companion



RESOURCES

Log in to the University VPN (GlobalProtect) to view articles without the paywall

<https://library.cuanschutz.edu/>



Top Resources

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- [Request a Library Tour](#)
- [Video Resources](#)
- [LibKey Nomad \(Full Text\)](#)

Databases

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- [Ovid Medline](#)
- [CINAHL](#)
- [Embase](#)
- [Web of Science](#)
- [AccessMedicine](#)
- [Databases A - Z](#)

Clinical Point of Care Tools

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- [DynaMed](#)
- [Micromedex](#)
- [ClinicalKey](#)
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Subject Guides

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Web of Science

Quick Filters

☐	Highly Cited Papers	281
☐	Hot Papers	8
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COLLABORATION EXPANDS WHAT'S POSSIBLE

Does someone already
have the data, population,
or infrastructure I need?



Who else is working on this
problem?



Could another department or
institution strengthen the project?



Who can introduce me to the right
person?



What expertise am I missing?



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TAKEAWAYS



Great research already exists across campus



Resources are available to help you succeed



Reach out early and collaborate often



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THANK YOU!

Questions?



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