

JULY 28, 2025

Mapping the Research Landscape

Ally Calderon

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



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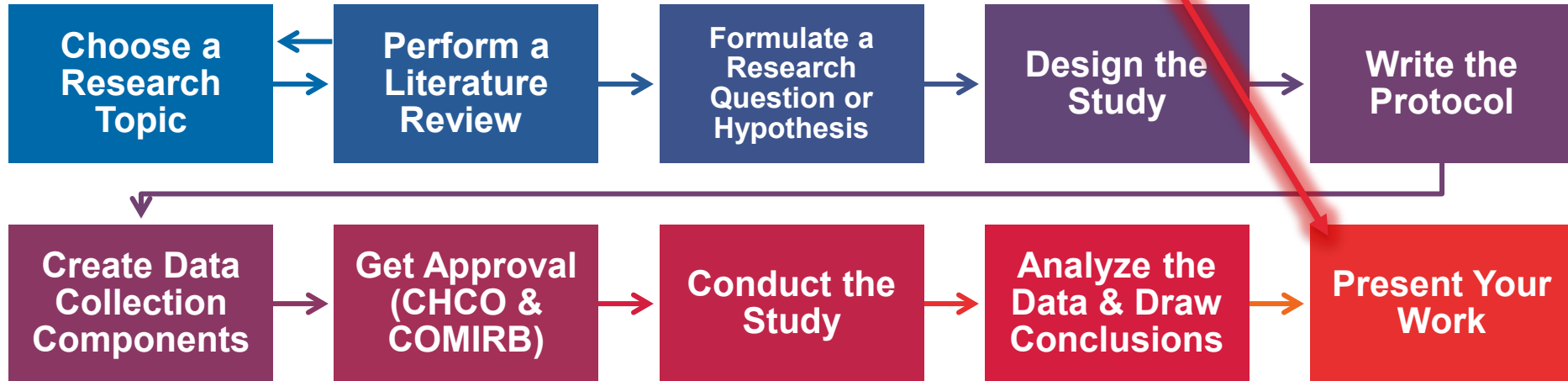
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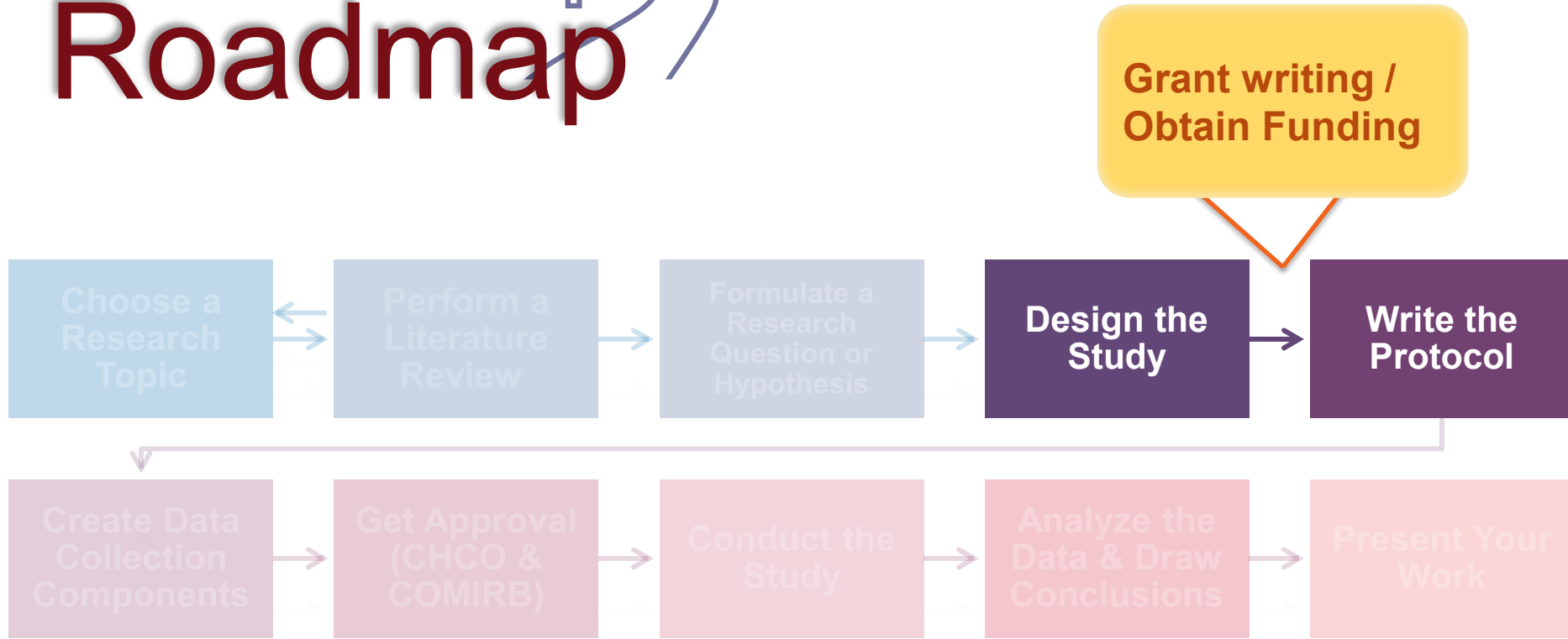
Roadmap



**Revise
your work based off
peer review**



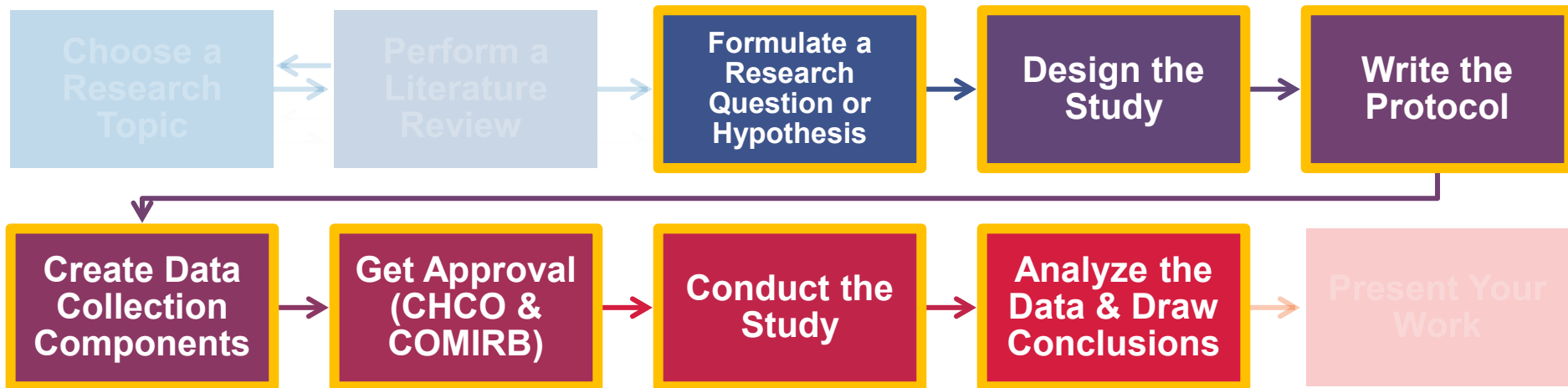
Roadmap



Roadmap



ROCS CAN SUPPORT
THESE ASPECTS OF
YOUR RESEARCH



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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RESOURCES

Colorado Child Health Research Institute SharePoint/Intranet

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

The screenshot shows the homepage of the Colorado Child Health Research Institute SharePoint/Intranet. The top navigation bar includes links for MyChildrensColorado, Resources, Actions, Departments, About Us, and For Me. Below this, the main header features the Colorado Child Health Research Institute logo, the word "Public", and a "Following" button. A secondary navigation bar contains links for About Us, Research Start-Up Resources, Operational Updates and Quick Links, Study Dashboards, Communications, and a menu icon. The main content area is divided into three sections. The left section is a large dark blue box with the text "COLORADO Child Health Research INSTITUTE" and a link "LEARN MORE ABOUT OUR CAMPUS PARTNERSHIP →". The right section is a purple box with a megaphone icon and the text "Announcement: Electronic Storage Solution for Child Health Research Study Binders Coming Soon". The bottom right section is a yellow box with a dashed line icon and the text "Research Start-Up Resources". To the right of this is a photo of two women and a child, with the text "Check Out Our New Patient Education Materials".



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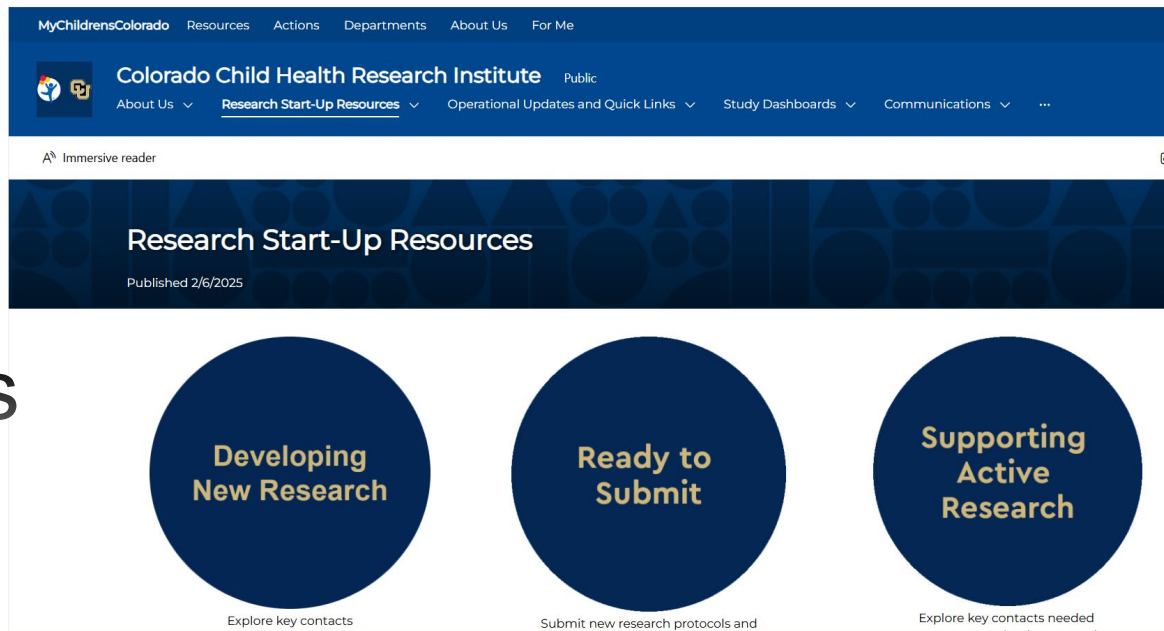
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RESOURCES

Colorado Child Health Research Institute SharePoint/Intranet

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

CHCO Guides & SOPs



RESOURCES

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

Research Toolkit

OBGYN Research Toolkit

 Onboarding for Research Faculty & PRAs	 Regulatory Processes Maps	 Regulatory Submission Process	 Statistical Support	 Scientific Editing
---	---	--	---	---

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.



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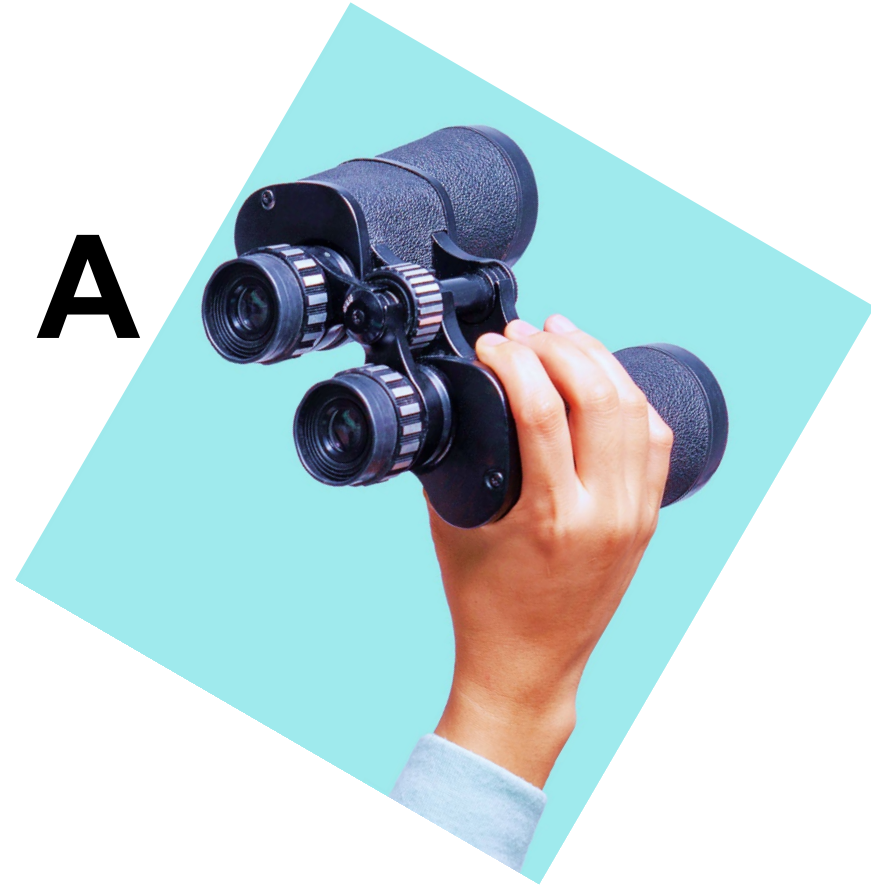
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CONDUCTING A STUDY

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)



ONCORE Training – If conducting/supporting enrolling studies



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Required Trainings(con't)

Register
in
Cornerstone



Epic Research training* If conducting/supporting enrolling studies



Research Workshops* – Hosted by CHCO/ CCHRI

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



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 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 accuracy of data



HOW TO BE A GOOD PI

A Good PI...

- ✓ Provides intellectual leadership and strategic direction for the research project.
- ✓ Ensures the integrity, accuracy, and validity of all results and conclusions presented.
- ✓ Accepts full intellectual responsibility for the design, execution, and outcomes of the work.

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



JULY 28, 2025

What Is Research?

From Questions to Protocols

Samantha Wilson, MS

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



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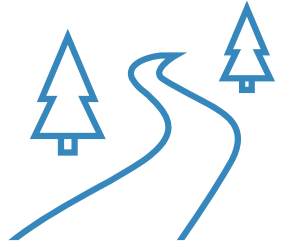


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ROADMAP



**Choose a
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**Perform a
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**Formulate a
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**Get Approval
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**Analyze the
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**Present your
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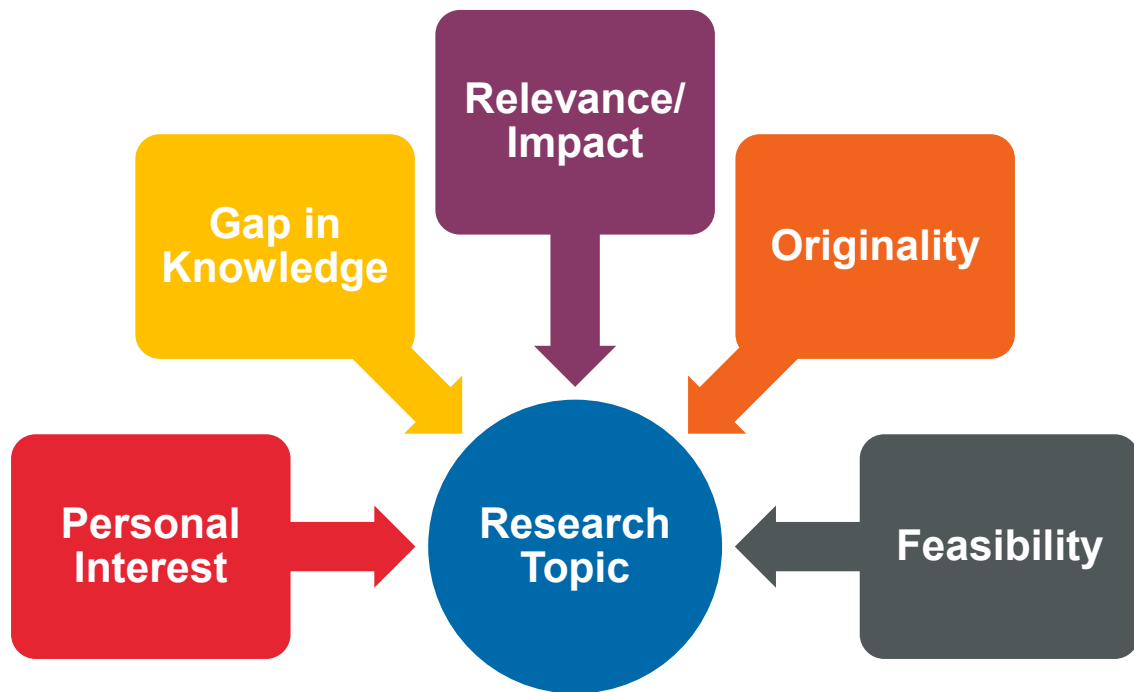
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CHOOSING A RESEARCH TOPIC



LITERATURE REVIEWS

What is a literature review?

A comprehensive overview of existing published work on a particular topic or research question.

Why do a literature review?

- Narrow down scope of research topic
- Look at what has been done before and how it was done
 - Include this in your background/introduction section
- Look for standardized techniques/current accepted practices



QUESTIONS TO ASK YOURSELF

What are people doing?  Search across many peer-reviewed publications (GoogleScholar or PubMed)

What is the current practice/knowledge?  Look at the most-cited publications

Is the research good quality?  Look critically at study design

When was it done?  Look for recent studies (last 5-10 years)



RESOURCES

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

University of Colorado **Anschutz Medical Campus** Webmail | UCDAccess | Canvas | Off Campus Access | Quick Links

Resources ▾ Help ▾ Services ▾ About ▾ Contact the Library ▾ [Building Access](#) [Hours](#) [Reserve a Room](#) [My Accounts](#)

PubMed Library Search Journal by Subject Google Scholar Resource Guides Search

Enter keyword or concept to search for articles in PubMed. [Search](#)

AskUs

Top Resources

Services

- [Interlibrary Loan](#)
- [Gadgets for Checkout](#)
- [Professional Search Request](#)
- [Request a Library Tour](#)
- [Video Resources](#)
- [LibKey Nomad \(Full Text\)](#)

Databases

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

Clinical Point of Care Tools

- [Up To Date](#)
- [DynaMed](#)
- [Micromedex](#)
- [ClinicalKey](#)
- [VisualDX](#)
- [IsabelDX](#)

Subject Guides

- [Medicine](#)
- [Nursing](#)
- [Pharmacy](#)
- [Dental Medicine](#)
- [Physical Therapy](#)
- [Public Health](#)

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

Web of Science

Quick Filters

☐	Highly Cited Papers	281
☐	Hot Papers	8
☐	Review Article	6,356
☐	Early Access	439
☐	Open Access	16,339
☐	Enriched Cited References	7,315
☐	Open publisher-invited reviews	93

jane.biosemantics.org



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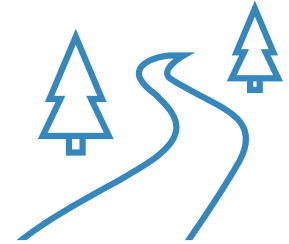
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**Conduct the
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**Present your
work**



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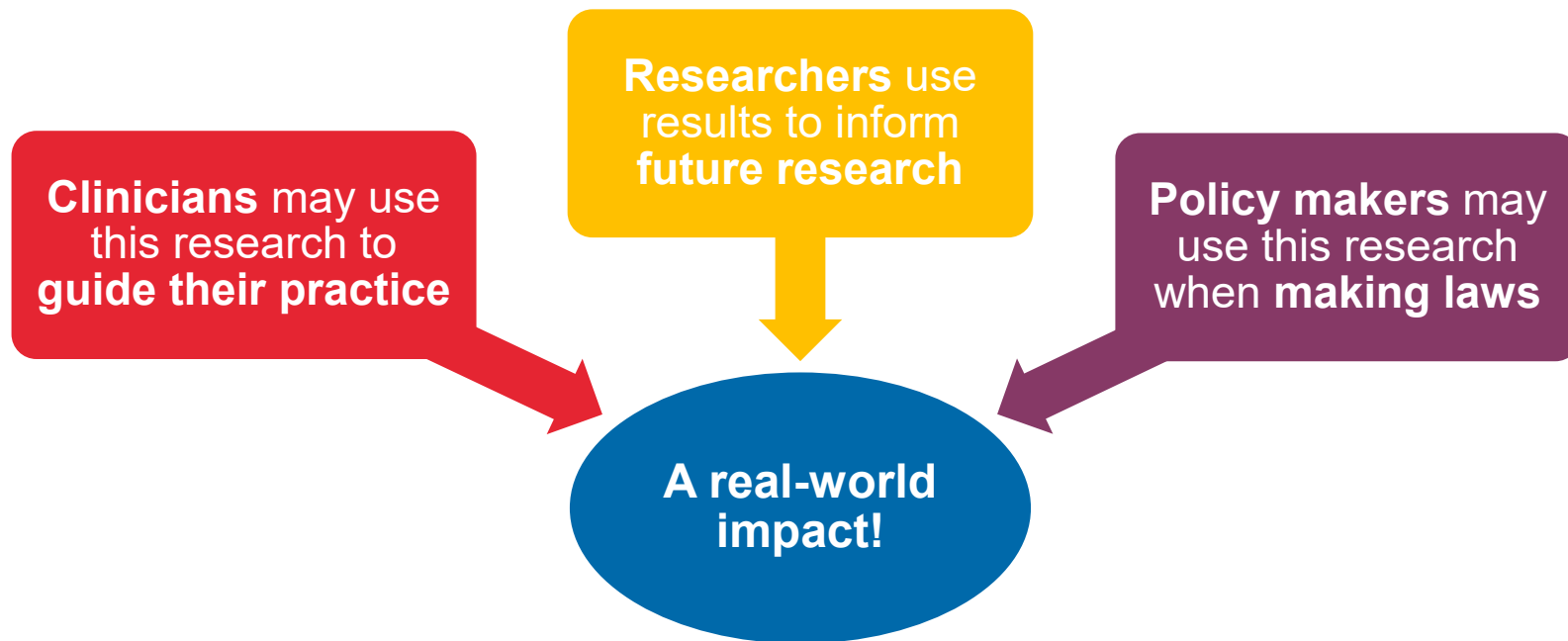
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HIGH QUALITY RESEARCH



STUDY DESIGN



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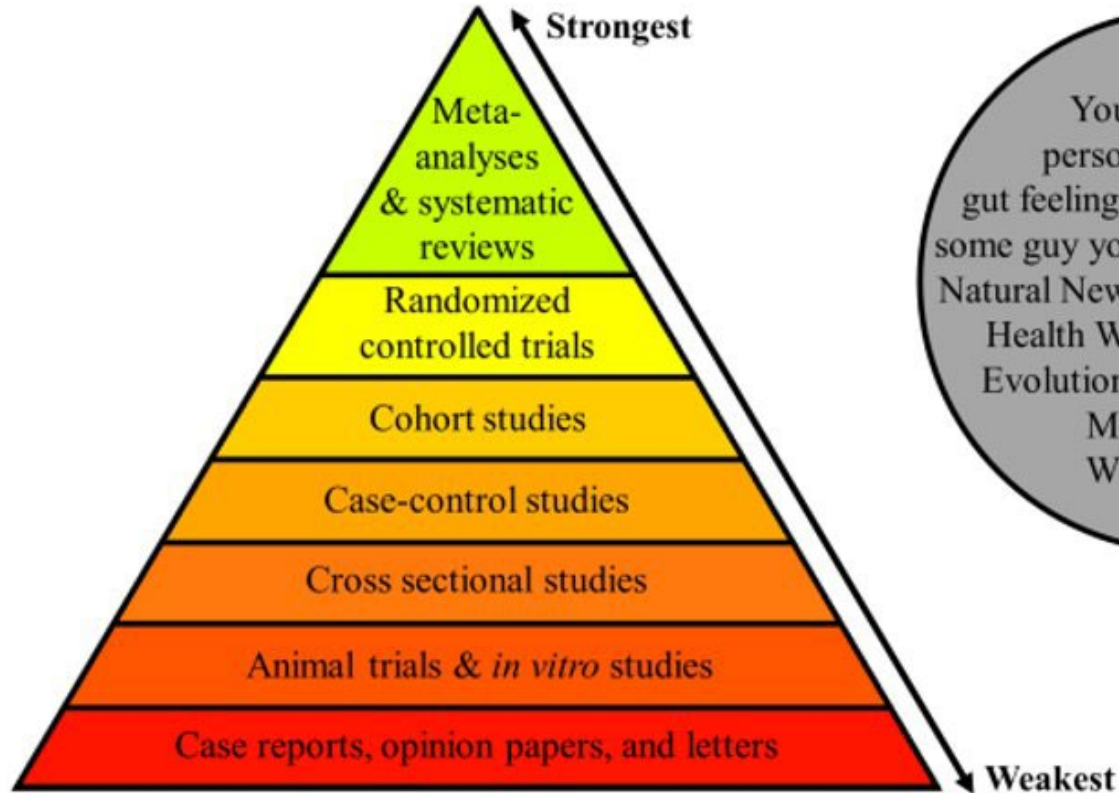
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Hierarchy of Scientific Evidence



Not Scientific Evidence



thelogicofscience.com



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STUDY DESIGN CHEAT SHEET

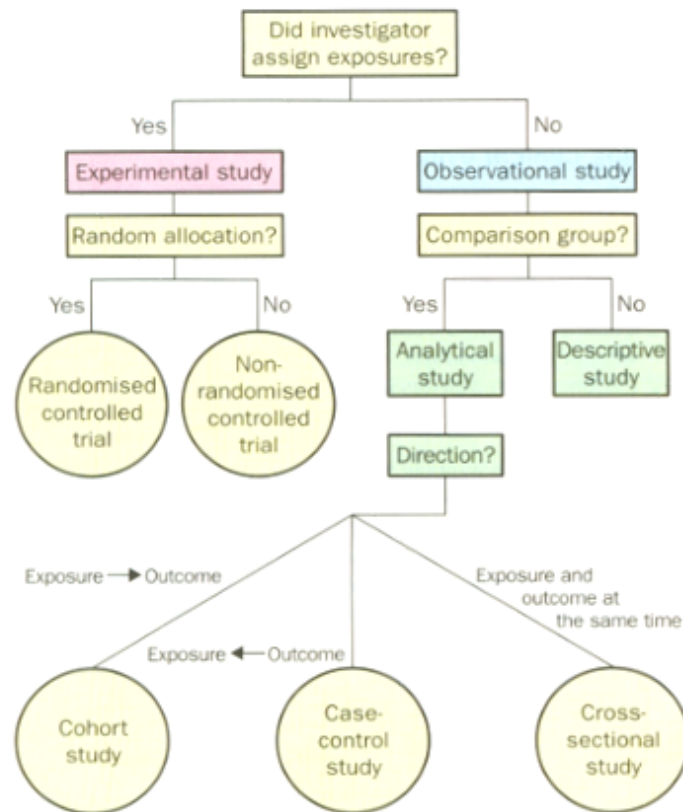


Figure 1: Algorithm for classification of types of clinical research



ROADMAP



**Choose a
Research
Topic**

**Perform a
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**Formulate a
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**Design the
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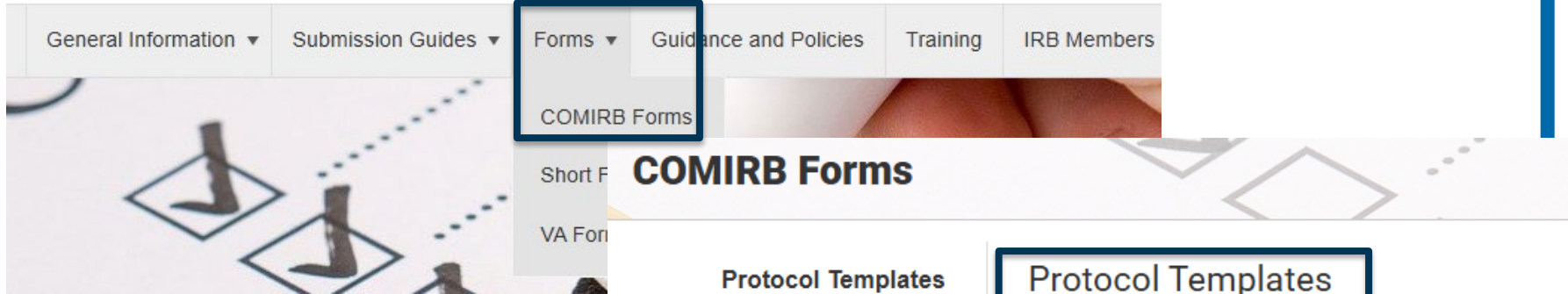
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Colorado Multiple Institutional Review Board (COMIRB)

Regulatory Compliance



The screenshot shows the top navigation bar of the COMIRB website. The 'Forms' dropdown menu is open, showing options: 'COMIRB Forms', 'Short F', and 'VA For'. The 'COMIRB Forms' option is highlighted with a blue box. Below the navigation bar, the 'COMIRB Forms' page is displayed, featuring a list of links: 'Protocol Templates', 'Applications', 'Consent Templates', 'HIPAA', 'Continuing Review', and 'Incident Reports'. The 'Protocol Templates' link is highlighted with a blue box. To the right of the 'Protocol Templates' link, a list of links is provided: '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', and 'HDE Protocol Template'.

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

COMIRB Forms

Short F

VA For

COMIRB Forms

Protocol Templates

Applications

Consent Templates

HIPAA

Continuing Review

Incident Reports

Protocol Templates

- [Therapeutic Intervention, IND/IDE exempt](#)
- [Observational or Non-Therapeutic Intervention](#)
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PROTOCOL COMPONENTS

Study Rationale

Background

Objectives (Hypothesis, Specific Aims)

Study Design

Study Population

Study Intervention, Assessments and Procedures

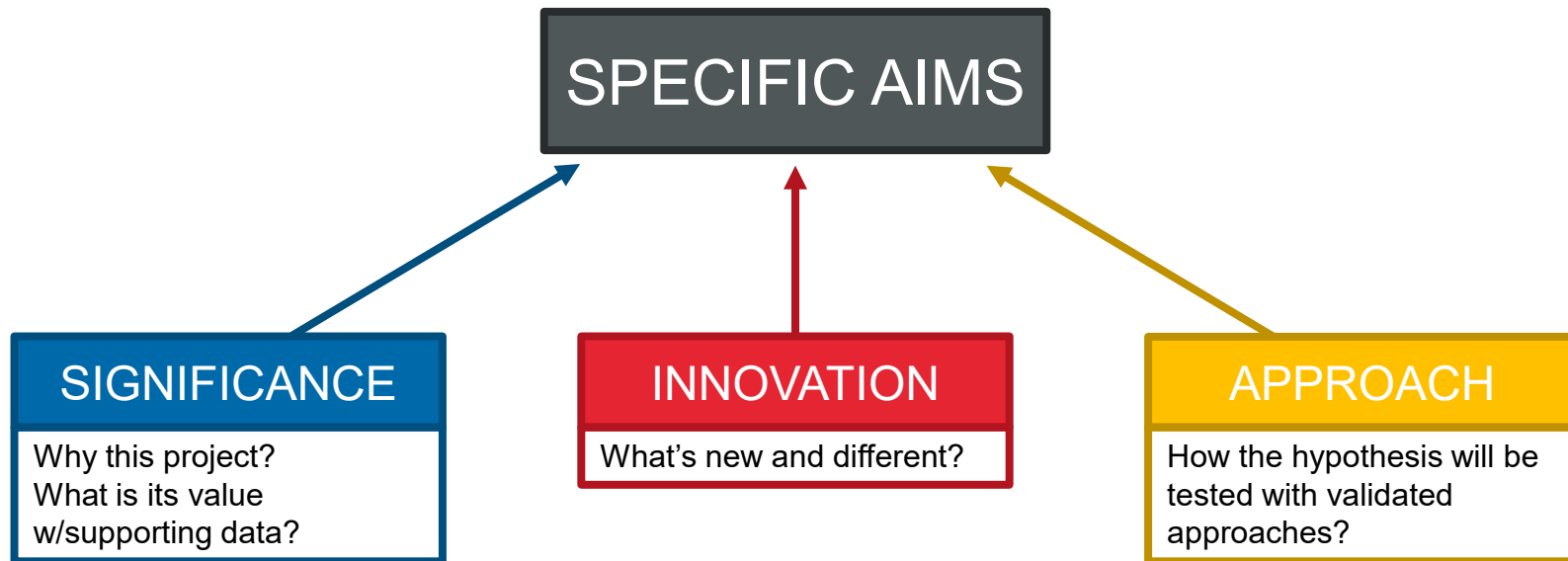
Risk/Benefit Assessment

Data Analysis/Statistics

Informed Consent



FORMULATE YOUR GAME PLAN



OBJECTIVES / SPECIFIC AIMS

Describe the study objectives. An objective is the reason for performing the study related to the scientific question(s) being explored. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate, to explore) and incorporate the overall intent (e.g., feasibility, acceptability, effectiveness, dissemination, implementation, observation, exploration).

For most projects, 2-3 specific aims is an ideal number.

The specific aims of this **pilot and feasibility study** are:

1. To examine the feasibility of recruitment and retention of adolescents with overweight/obesity, pre-diabetes, and inadequate sleep into a sleep extension intervention.
2. To assess adherence to and initial pre-post sleep outcomes of a sleep extension intervention to increase total sleep time in adolescents with overweight/obesity, pre-diabetes, and inadequate sleep.
3. To determine estimates of the mean and variability of potential intervention outcomes, including metabolomics, body composition, and substrate oxidation.



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Informed Consent



STUDY RATIONALE

State the problem or question and the reason for conducting the research. If there is an educational intervention (Exempt Category 1 only), state the name and the nature of the intervention, and explain the underlying rationale.

State the problem or question (e.g., describe the population, disease, current routine care, and limitations of knowledge or current usual care). State the reason for conducting the clinical trial. State the name and the nature of the intervention. Identify the hypothesized target(s) of the intervention, and the clinical or social outcomes of interest.



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BACKGROUND

II. Background and Significance:

Obesity affects over one-third of US adolescents and related comorbidities, including type 2 diabetes (T2D), are increasingly prevalent in youth with higher rates of T2D documented in adolescents.^{1,2} Insulin resistance (IR) is a critical contributor to the link between obesity and cardiometabolic diseases, such as T2D and cardiovascular disease (CVD).³ More than half of youth with T2D in the TODAY RCT failed primary metformin and metformin/rosiglitazone therapy by 3-years, a rate that is almost 4 times faster than seen in similar studies of adults.^{4,5} In the RISE study, pancreatic β -cell function continued to decline despite interventions effective at preventing decline in adults. Taken together, emerging data suggests that T2D in youth has a more aggressive phenotype than in adults. Focusing on the pathways underlying the relationships among poor health behaviors, obesity, and IR in adolescents is vital to improve their long-term health.



PROTOCOL COMPONENTS

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Study Design

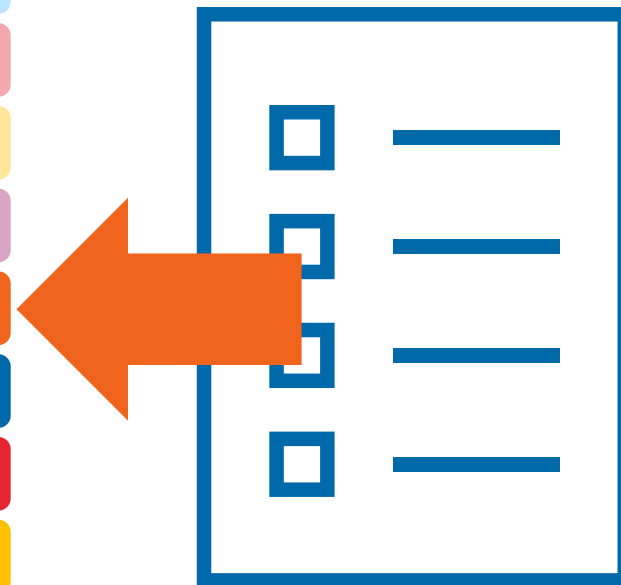
Study Population

Study Intervention, Assessments and Procedures

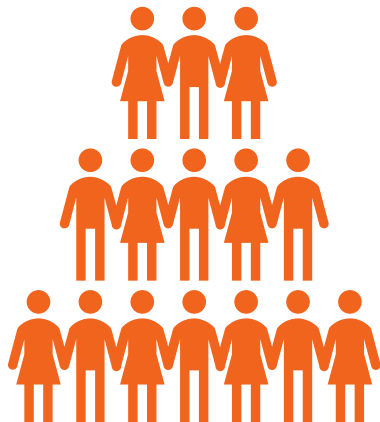
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Data Analysis/Statistics

Informed Consent



POPULATION



B. Description of Population to be Enrolled:

Participants: This study will allow for data collection on 20 adolescents. Total enrollment will be up to 26 participants to allow for screen failures and dropouts. We will conduct a chart review to determine eligible patients and approach them during their clinic visit. After providing written informed consent, participants will undergo an in-person screening interview to confirm eligibility.

Inclusion Criteria:

- 1) High school students between the age of 13-19 years
- 2) BMI >85th percentile for age and sex
- 3) Prediabetes defined as a HbA1c 5.7-6.4%
- 4) Tanner Stage 4-5 (based on breast development for girls and testicular size for boys)

Exclusion Criteria:

- 1) Any medications that affect insulin resistance or sleep (e.g., metformin, stimulants, atypical antipsychotics, current use of oral steroids)
- 2) Regular use of melatonin or other sleep aids
- 3) A prior diagnosis of a sleep disorder (e.g., insomnia, delayed sleep phase syndrome, obstructive sleep apnea) or abnormal scores on sleep disorders screening measures
- 4) Type 2 diabetes (HbA1c $\geq 6.5\%$)
- 5) IQ < 70 or severe mental illness that may impact sleep or ability to consent/assent (e.g., schizophrenia, psychotic episodes), verified through chart review
- 6) Teens not enrolled in a traditional high school academic program (e.g., home school students)
- 7) Schedules that would preclude participants from adhering to the sleep extension protocol (e.g., night shift employment)
- 8) Travel across more than two time zones in the 2 weeks prior to the study



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INFORMED CONSENT

Recruitment: Adolescents will be recruited from the Children's Hospital Colorado Lifestyle Medicine Clinics.

Informed Consent Plan: Appropriately qualified and informed personnel who have completed the COMIRB and HIPAA course requirements will fully explain the study protocol and consent form to the subject and guardian verbally in the language they understand. The explanation will be conducted in a quiet environment with adequate time given for the participant and guardian to review the study procedure before the commencement of the study. Asking the participant to explain the study in their own words will assess the participants' understanding. If non-English speaking participants are enrolled in the study, the investigators will adhere to Section 10C of the COMIRB Instructions for Clinical Investigators regarding the consent of these subjects. The qualified personnel mentioned above will then obtain written consent from the guardian and assent from the participant, co-signed on the consent form, or in participants who are 18 years or older, direct consent. The PI will make a good faith effort to obtain both parent signatures. The subject and guardian will be provided a copy of the consent form for better understanding and record purposes.

Consent/Assent Plan: Consent will be obtained from all participants in the study. Following explanation, all participants below 18 years old will co-sign the consent form in addition to the parents signing the consent form. All participants age 18 or older will sign the standard consent form.

Compensation, Incentives & Rewards: Participants will be compensated with Greenphire debit card payments at study visits. Participants will be compensated for each completed visit; maximum of \$150 for study participation.



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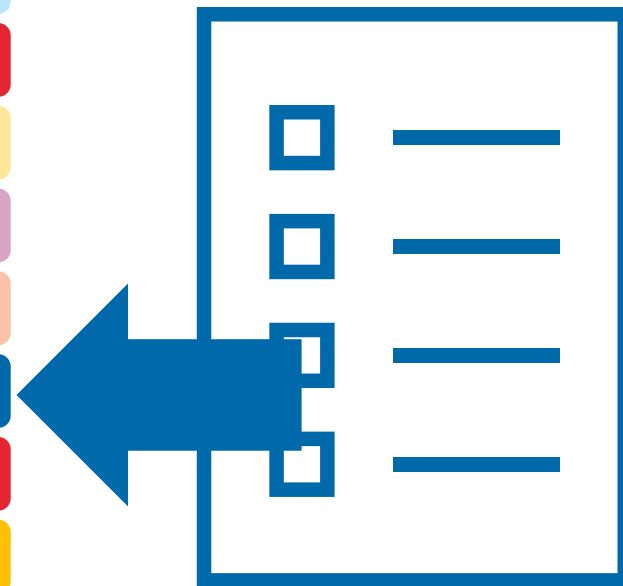
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STUDY PROCEDURES

Study Procedures. Participants will receive a Standard Care Diet and Physical Activity Education Intervention (SC) and an Extended Sleep Intervention (ES). For the SC, participants will have their diet, physical activity, and screen time assessed by study interventionist. Prescribed goals will be determined collaboratively through discussion with

Table 1. Summary of Measurements at Clinical (CV) & Research Visits (RV)

	CV Pre-RCT	RV 1 Baseline	Phone Week 1	RV 2 Week 2	Phone Week 3	RV 3 Post-RCT	CV Week 12
<u>Recruitment</u>							
Screening	X						
Consent	X						
<u>Intervention</u>							
Intervention Delivery		X	X	X	X		
Education/Goal Setting		X	X	X	X		
<u>Free-Living Measurements</u>							
Sleep (actigraphy)	X	X	X	X	X		X
Physical Activity (actigraphy)		X	X	X	X		
Diet Assessment (FFQ)		X				X	
<u>Clinical Visit Measurements</u>							
Body Composition (BMI, WC)		X				X	X
Clinical Markers of CVD Risk		X				X	X
Indirect Calorimetry		X				X	
Fasting Labs & Metabolomics		X				X	
Insulin Resistance (OGTT)		X				X	



STUDY ASSESSMENTS

Assessments.

Sleep Disorders Screening: The Adolescent Sleep Wake Scale (ASWS)²³ & Sleep Disorders Inventory for Students-Adolescent (SDIS-A)²⁴ will be completed at the first clinic visit to evaluate sleep disorders.

Sleep duration & timing: An actigraphy watch (AW Spectrum Plus, Phillips Respironics, Bend, OR) will be worn on the non-dominant wrist to monitor sleep patterns continuously throughout study. Average sleep start and end time, duration, mid-sleep time, and efficiency will be calculated with Actiware Sleep v6 software.²⁵ The actigraphy devices are well-tolerated by adolescents with good adherence in our previous studies.²⁶

Physical Activity (PA): A triaxial thigh-worn ActivPal (PAL Technologies, UK) will be used to measure sedentary, upright, and ambulatory activities.²⁷ The data will be downloaded and the device recharged at the second research visit after 2 weeks of continuous wear and then replaced for the last two weeks of the study.

Energy and Macronutrient Intake: The SEARCH Food Frequency Questionnaire will be used to assess energy intake (EI) and compare intra-individual changes in EI.²⁸ We recognize the limitations of self-reported measures of EI.²⁹

Feasibility & Acceptability: Participants will complete a modified Feasibility Acceptability Questionnaire (FAQ³⁰) following the intervention. Information will be used to further develop the intervention for testing our pilot study.



PROTOCOL COMPONENTS

Study Rationale

Background

Objectives (Hypothesis, Specific Aims)

Study Design

Study Population

Study Intervention, Assessments and Procedures

Risk/Benefit Assessment

Data Analysis/Statistics

Informed Consent



RISKS

Questionnaires

Description: Participants will complete questionnaires regarding their sleep and feasibility & acceptability of the intervention.

Risk: There is a small possibility that participants will be uncomfortable answering a particular question.

Justification/Minimization: The questionnaires used in the study are widely used in both research and clinical practice and are not of a particularly sensitive nature. Participants will be able to skip any items that they find uncomfortable. None of the items assess for suicidality.

Violation of Privacy and Loss of Confidentiality

Description: These are both risks to which research participants are exposed. The possibility of these risks increases when protected health information is collected. Every effort will be made to decrease this risk by limiting access to protected health information, storing this information in a password protected database, and identifying subjects only by a unique identifier that is kept in a separate location in a locked container, traceable only by study personnel. All of the tests involve the risk of identifying asymptomatic abnormalities. The study may include risks that are unknown at this time.

Justification/Minimization: Every effort will be made to decrease the risk of loss of confidentiality by limiting access to protected health information, storing this information in a password protected database, and de-identifying study specimens.



PROTOCOL COMPONENTS

Study Rationale

Background

Objectives (Hypothesis, Specific Aims)

Study Design

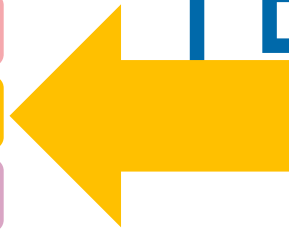
Study Population

Study Intervention, Assessments and Procedures

Risk/Benefit Assessment

Data Analysis/Statistics

Informed Consent



DATA ANALYSIS PLAN

Power analyses were conducted for detecting changes in sleep from pre- to posttest (Aim 2). Assuming two-sided α of 0.05, $n=20$ will provide 80% power to detect an effect size of Cohen's $d=0.66$ for change in total sleep time. This effect is reasonable based on research demonstrating sleep improvements of 71 minutes ($t=12.52$, $p<0.001$) in 18 adolescents following a sleep extension protocol.³⁵ Conservatively estimating 20% attrition, we will recruit 26 adolescents. The sample size of 20 will be sufficient to address study feasibility, such as alerting the research team to non-rare adverse events and establishing procedures for recruitment and retention (Aim 1). The sample size will also provide stable estimates of the mean and variability of the proposed intervention outcomes (Aim 3).

Statistical analysis will be performed using SAS v9.3. All data will be entered and managed using REDCap. Descriptive statistics will be presented using means and standard deviations for continuous variables and frequencies for categorical variables. Independent t-test and Cochran Mantel-Haenzel tests will be used to assess differences in continuous and categorical variables, respectively. Measures include (see Table 2 for further details):

Aim 1: Recruitment (rate of recruitment and proportion of consented participants with insufficient sleep measured by actigraphy) and **retention** (attrition, missing data, completed in-person versus phone call visits).

Criteria for feasibility: We anticipate that we will be able to recruit 5 participants per month and that 80% of these will be deemed eligible based on objectively measured insufficient sleep. We anticipate a 20% attrition rate; hence will recruit 26 participants in order to obtain complete data on 20 individuals.



ROADMAP



**Choose a
Research
Topic**

**Perform a
literature
review**

**Formulate a
Research
Question or
Hypothesis**

**Design the
Study**

**Write the
protocol**

**Create data
collection
components**

**Get Approval
(CHCO &
COMIRB)**

**Conduct the
Study**

**Analyze the
Data & Draw
Conclusions**

**Present your
work**



JULY 28, 2025

Getting Started: *Regulatory Basics & Study Start-Up*

Samantha Wilson, MS

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



Center for Children's Surgery

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Children's Surgery (ROCS)

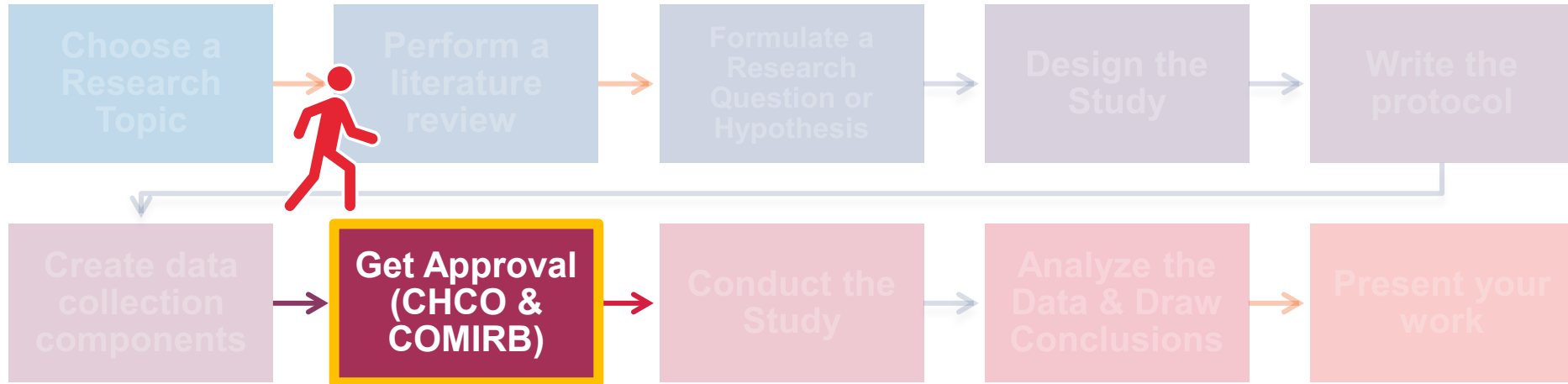
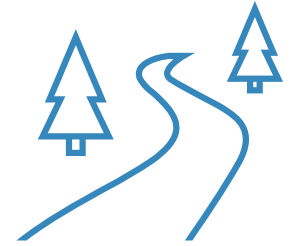
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ROADMAP



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STUDY START-UP OVERVIEW

Takes 2-4 weeks for CHCO approval

Create Human
Protocol in
InfoEd

HSR Portal
Submission

Submit to
COMIRB

Approval!

Takes 4-8 weeks for IRB approval

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



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 ▾	
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Initial Submission (Studies)

Complete the forms to submit your new study

Before you begin, please visit the [COMIRB website](#), and complete several steps. **Investigators and research staff must complete the required education courses, gain access to the InfoEd eRA website, and complete several steps.** Some steps can take several days to complete, so please factor that into your planning.

1

Determine if you need to submit for institutional approval

COMIRB's affiliated institutions each require investigators to submit for institutional approval prior to submitting to COMIRB. Please contact the appropriate institutional research office for each of the following sites involved with your research:

- CU Denver Anschutz Medical Campus, University of Colorado Hospital, Children's Hospital



**Human Subject
Research (HSR)
Portal**



Required Training



**Required
Documents**



InfoEd eRA Login



**Human Subject
Research (HSR)**



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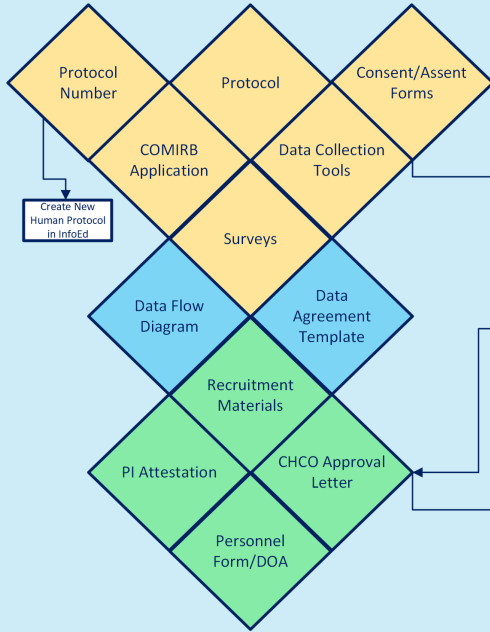
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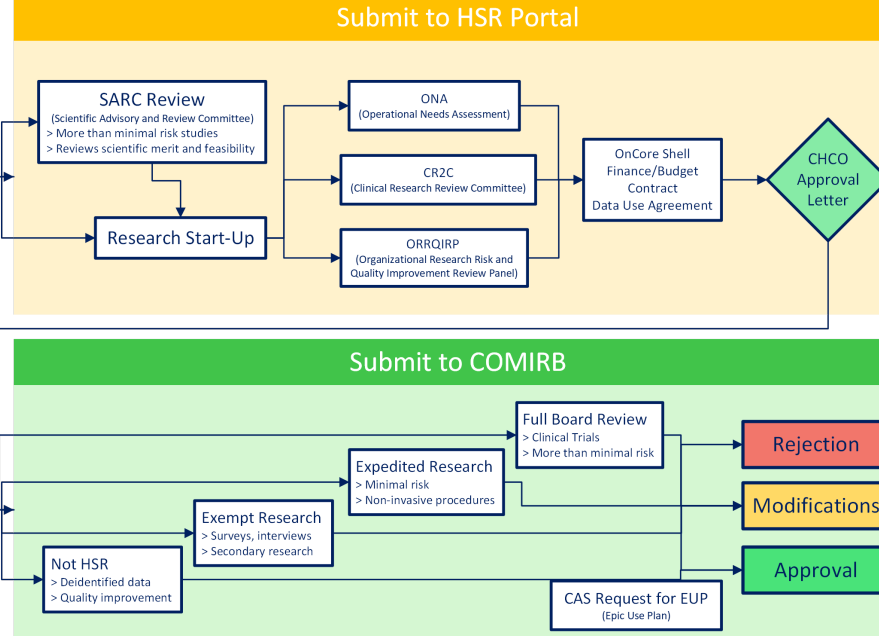
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Regulatory Process Overview

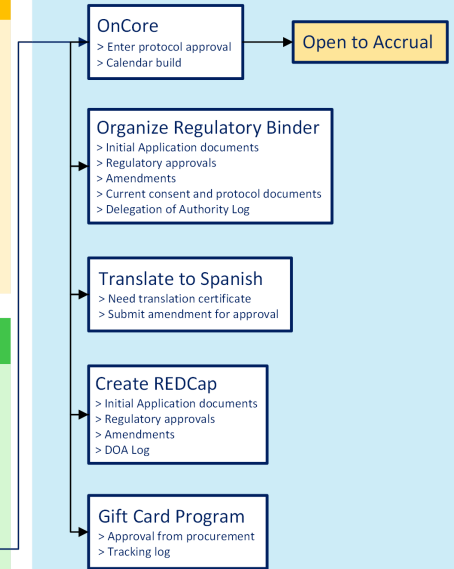
Application



Regulatory Approval



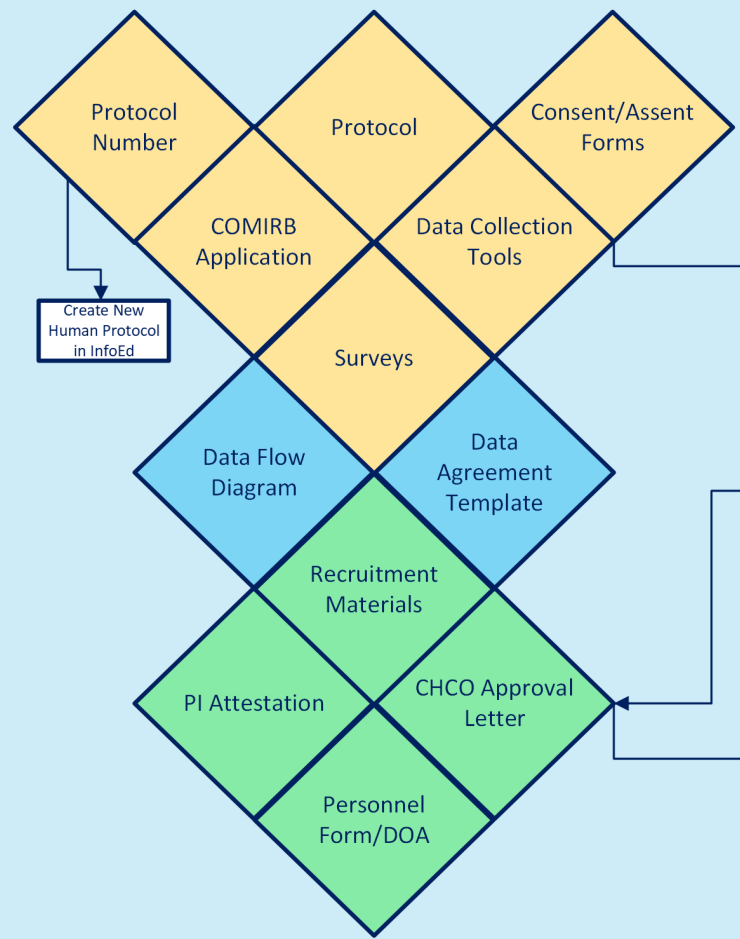
Pre-Accrual



For CHCO
Approval

Application

For IRB
Approval



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InfoEd / ERA

The screenshot displays the InfoEd / ERA web application interface. At the top, a dark header bar contains 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 features a sidebar with links to Proposals, Human Protocol, Conflict of Interest, My Projects, and SPIN. Below this sidebar is a contact box for assistance, providing the email address eRASupport@CUAnschutz.edu. The right column is titled "Human Protocol" and includes a "Create New" button, which is highlighted in yellow. Below this, there is a "Create New Human Protocol" button. Further down, the "Accessing Records/Reporting" section contains two buttons: "Search For" and "Show/List".



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Research Outcomes in
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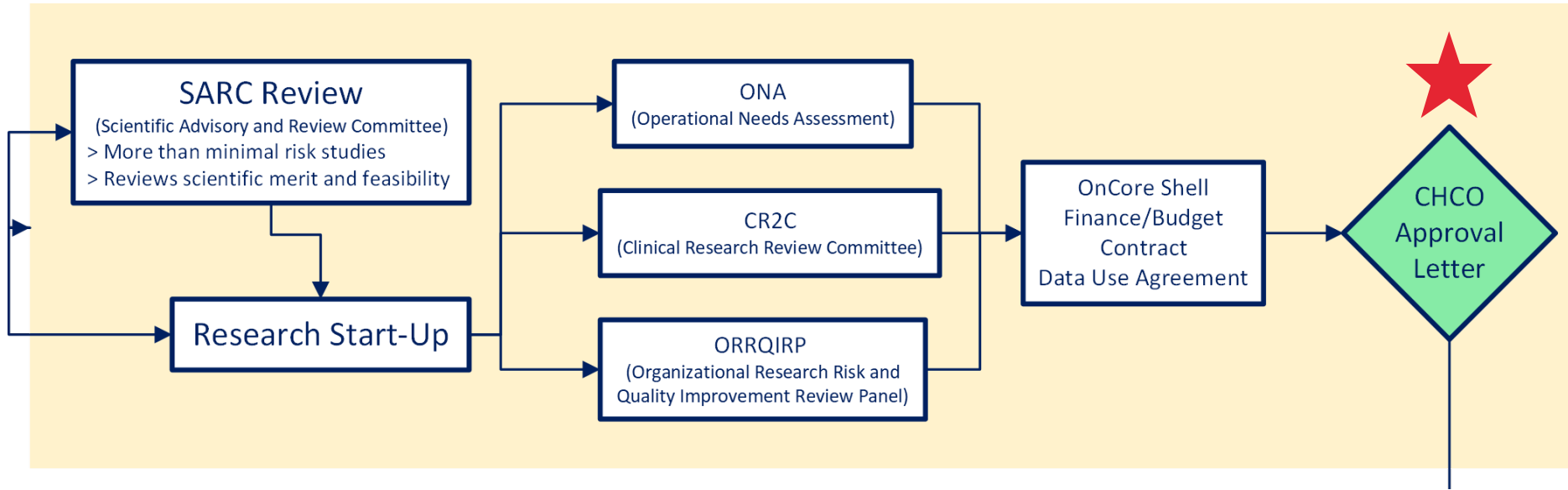


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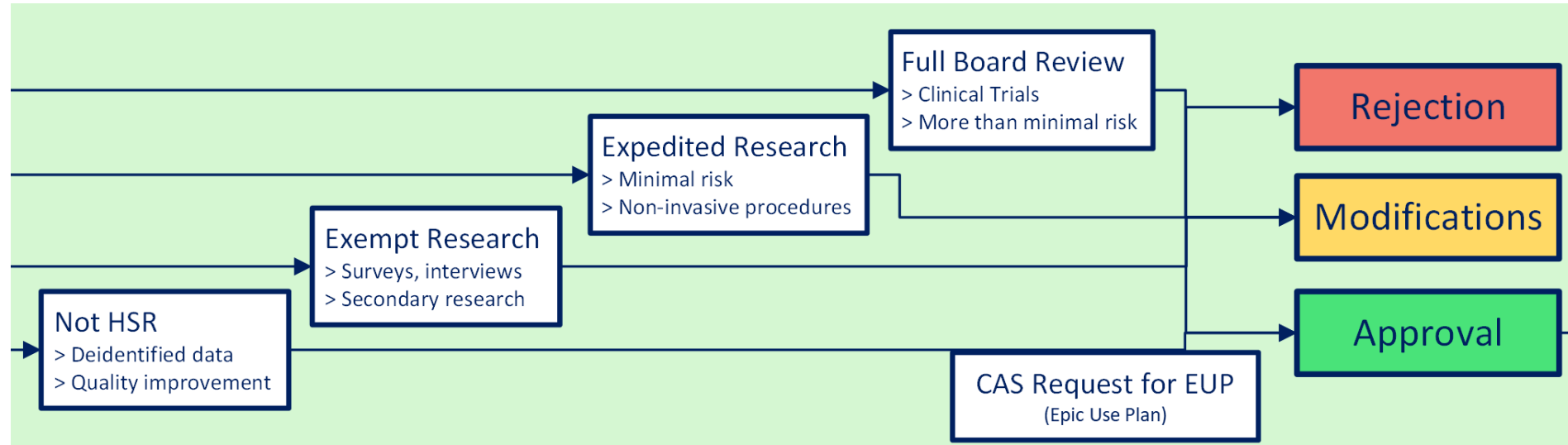
Regulatory Approval

Submit to HSR Portal



Regulatory Approval

Submit to COMIRB



Pre-Accrual

OnCore

- > Enter protocol approval
- > Calendar build

Open to Accrual

Organize Regulatory Binder

- > Initial Application documents
- > Regulatory approvals
- > Amendments
- > Current consent and protocol documents
- > Delegation of Authority Log

Translate to Spanish

- > Need translation certificate
- > Submit amendment for approval

Create REDCap

- > Initial Application documents
- > Regulatory approvals
- > Amendments
- > DOA Log

Gift Card Program

- > Approval from procurement
- > Tracking log



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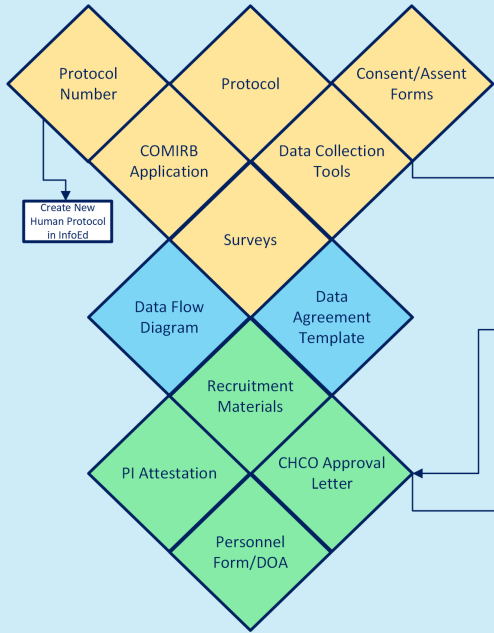


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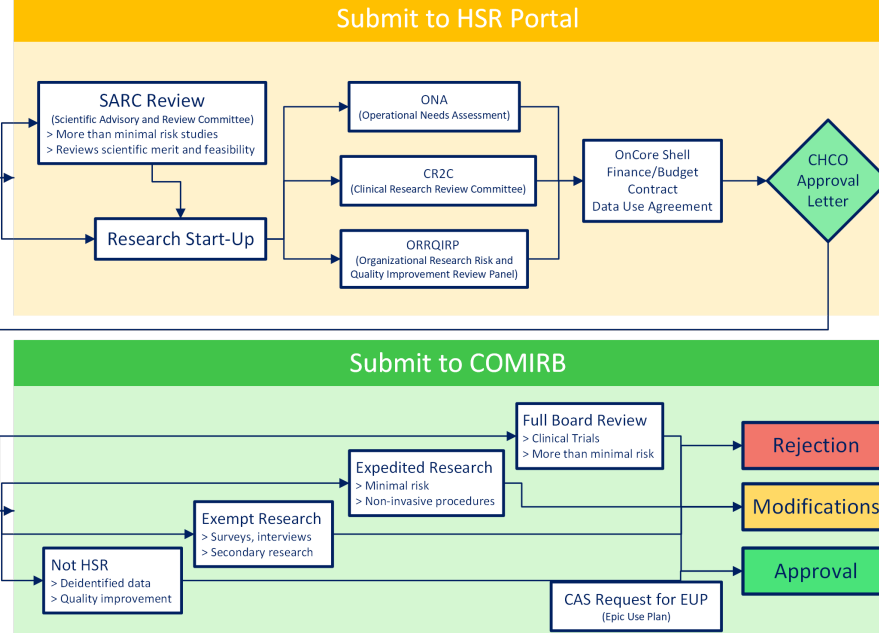
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Regulatory Process Overview

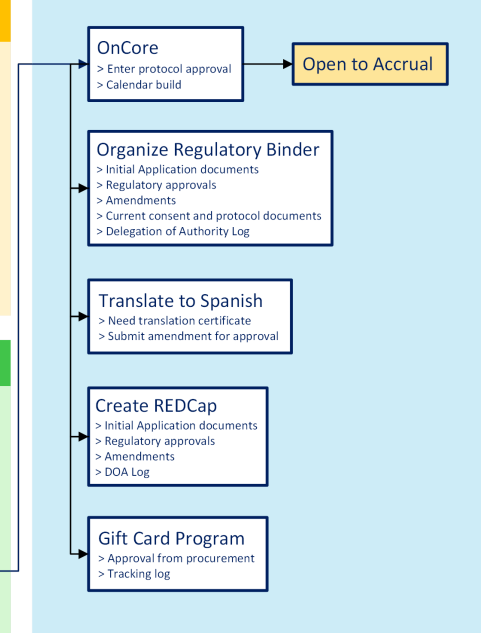
Application



Regulatory Approval



Pre-Accrual



THANK YOU

Questions?



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