

UM-CIRHT Webinar Series

Framing a Research Question

Berhanu Gebremeskel MD MPH

Sr. Project Manager, UM-CIRHT

Michigan Medicine

“He who does not know what he is looking for will not lay hold of what he has found when he gets it”

Claude Bernard

UM-CIRHT's Research Overarching Goal

- **Inspire research culture at individual and institutional level**



UM-CIRHT Framework: Research Life Cycle

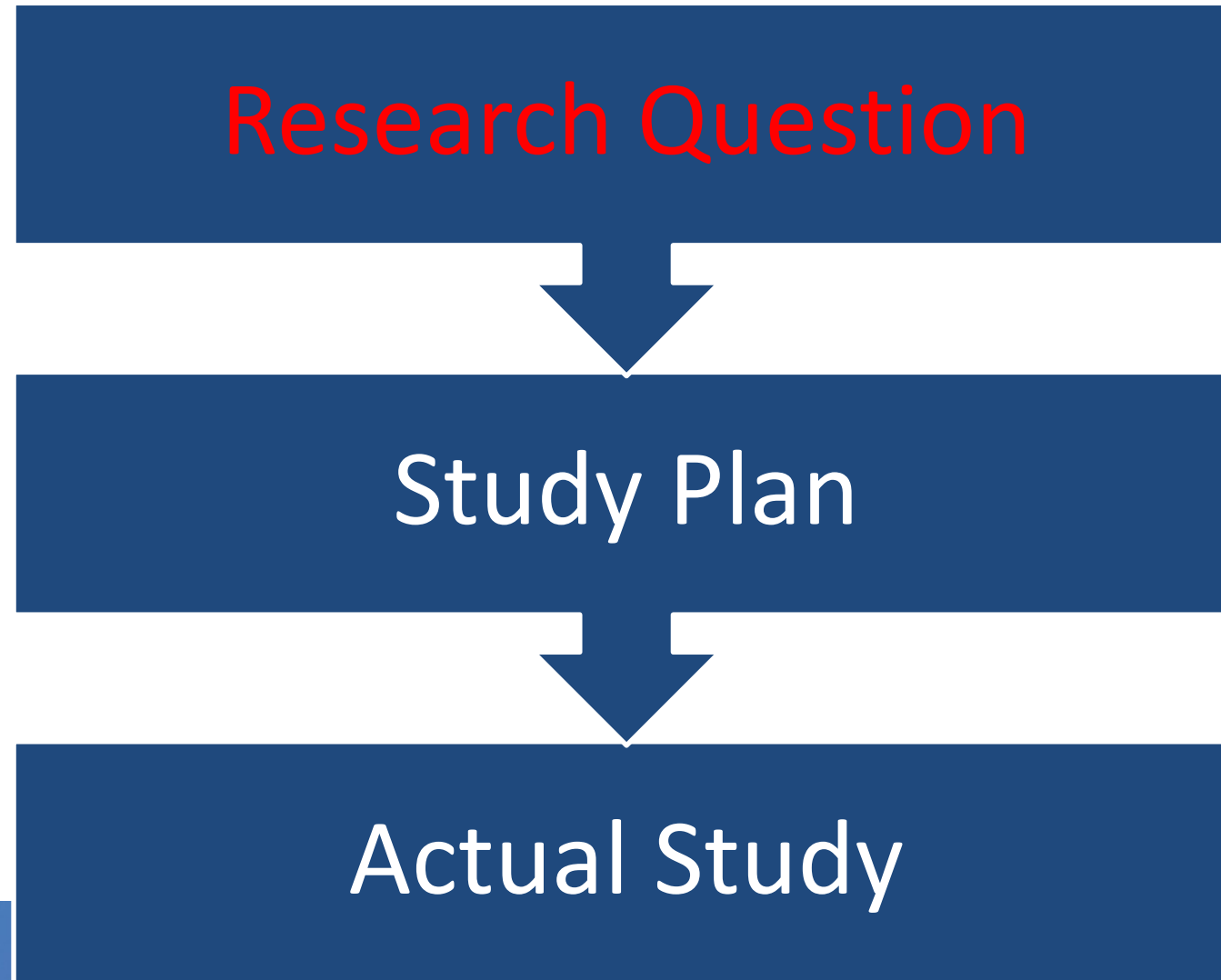


Beza et al , 2018. The UM-CIRHT Framework



Figure 6. Research Milestones to Build a Cadre of Independent Investigators at Partner Schools

Research Process



Webinar Objectives

- To illustrate the importance of framing a good research question
 - Ask **useful, answerable, valid** question
- Introduce two useful frameworks for evaluating and refining a research question
- Through this endeavor:
 - **Help investigators develop valid and feasible study plan**
 - IRB Application
 - Grant Application
- This webinar is not about:
 - Study design
 - Details of statistics



Outline

- What is research?
- What is the research question?
- Why frame a research question?
- Sources of research questions
- Characteristics of a good research question
 - FINER criteria
- Roadmap for framing a Research Question
 - PICO(T) framework
- Examples
- Resources
 - CIRHT guide
 - NIH RePORT



What is Research?

“Research means a **systematic investigation**, including research development, testing and evaluation, designed to **develop** or **contribute** to **generalizable knowledge**” (45 CFR 46)

- Clinical research vs. clinical practice [distinction very important]
 - Activity designed to
 - Test hypothesis
 - Permit conclusions , thereby:
 - Develop or contribute to generalizable knowledge (theories, principles, statement of relationships)
 - Interventions designed solely to enhance well-being of individual patient or client and have reasonable expectation of success, purpose to provide diagnosis, preventive treatment or therapy to particular individuals



What is a Research Question?

- ~ “The **uncertainty** that the investigator wants to **resolve** by performing his/her own study”*
- The objective /aim of the study
 - NIH Specific aims section
- Forms the foundation of the study
- Action oriented
 - The research question will answer the question
- Examples
 - “Is life worth living?”

*Hulley SB, *Designing clinical research*. LWW; 2013.



What is a Research Question?

- The boundary between current knowledge and ignorance
- Researchable questions come from finding the ‘*cutting edge*’ of knowledge for a problem with which you are familiar*

*Haynes R, *Clinical Epidemiology* ; 2009.



Why Frame a Research Question?

- The challenge in finding a research question is defining an important one that can be transformed into a **feasible** and **valid study plan**.
- Forms the basis of **the study plan**

TABLE 1.1 ANATOMY OF RESEARCH: THE STUDY PLAN

DESIGN COMPONENTS	PURPOSE
Research questions	What questions will the study address?
Background and significance	Why are these questions important?
Design	How is the study structured?
Time frame	
Epidemiologic design	
Subjects	Who are the subjects and how will they be selected?
Selection criteria	
Sampling design	
Variables	What measurements will be made?
Predictor variables	
Confounding variables	
Outcome variables	
Statistical issues	How large is the study and how will it be analyzed?
Hypotheses	
Sample size	
Analytic approach	

Writing the Researchable Question

- Challenging and difficult step in the research process
 - Yet: one of the most critical aspects
- A clear and carefully and thoughtfully constructed research question
 - Helps guide the research project to hit its scholarly target
 - Research is only as good as the research question and plan on which it is based
- Determines the success of a research process
 - Should drive the development of a research protocol
- **Research interest \neq Research Question**



Why Most Published Research Findings Are False

Open access, freely available online

Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

Summary

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question, and, importantly, the ratio of true to no relationships among the relationships probed in each scientific field. In this framework, a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more

factors that influence this problem and some corollaries thereof.

Model Positiv

Several pointed rate of confirm is a cor yet ill-f conclus the bas formal for a p - is not most appropriately represented and summarized by p -values, but, unfortunately, there is a widespread notion that medical research articles

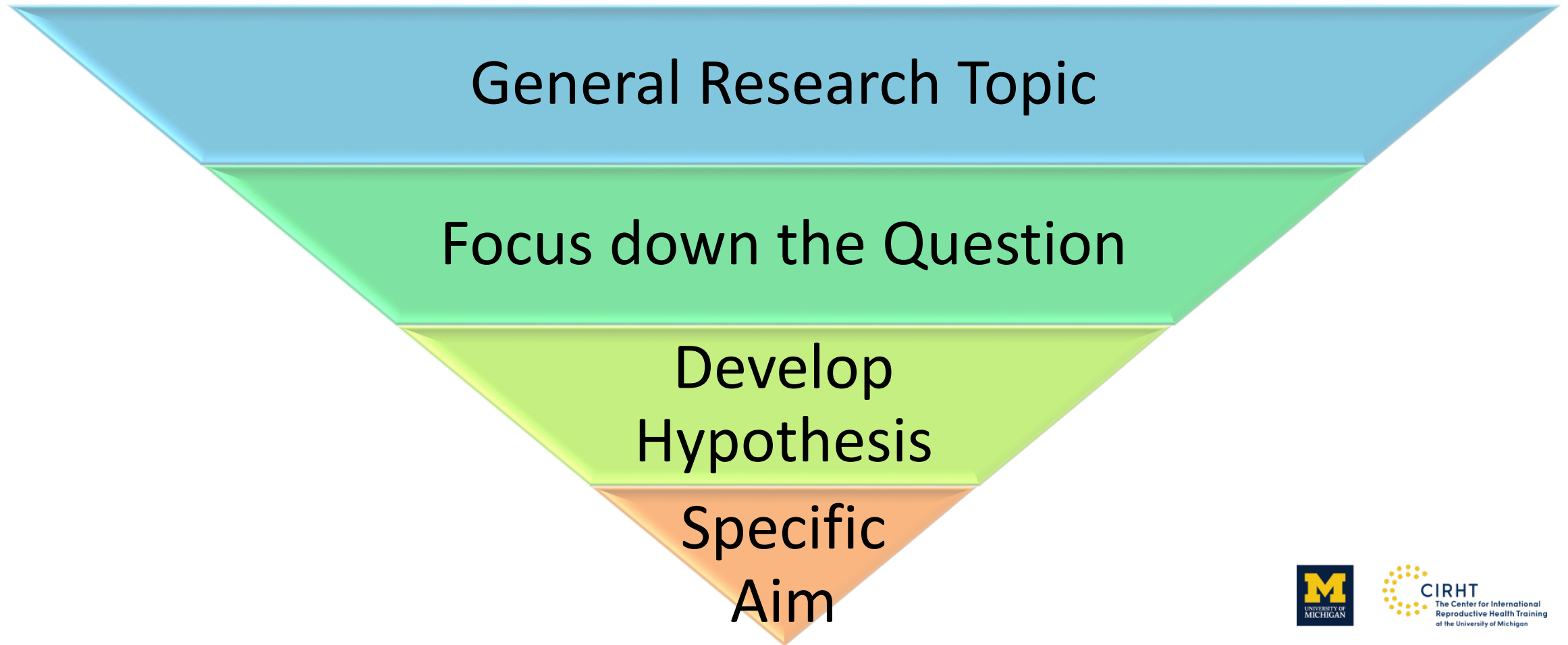
is characteristic of the field and can vary a lot depending on whether the field targets highly likely relationships

Moreover, for many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias. In this essay, I discuss the implications of these problems for the conduct and interpretation of research.

reflects the power $1 - \beta$ (one minus the Type II error rate). The probability of claiming a relationship when none truly exists reflects the Type I error



Refining the Research Question



Sources of Research Questions

- Observations in clinical practice
 - Your own research
- Quality improvement activities
- Mentors
- Colleagues
- Scientific conferences
- Scientific literature
- Use your imagination!!!



Characteristics of a Good Research Question:

FINER Criteria

Characteristics of a Good Research Question: FINER Criteria

TABLE 2.1 FINER CRITERIA FOR A GOOD RESEARCH QUESTION AND STUDY PLAN

Feasible

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope
- Fundable

Interesting

- Getting the answer intrigues the investigator and her colleagues

Novel

- Provides new findings
- Confirms, refutes, or extends previous findings
- May lead to innovations in concepts of health and disease, medical practice, or methodologies for research

Ethical

- A study that the institutional review board will approve

Relevant

- Likely to have significant impacts on scientific knowledge, clinical practice, or health policy
- May influence directions of future research

Hulley SB, *Designing clinical research*. LWW; 2013.



Feasible

- Adequate # study subjects
- Appropriate/adequate technical expertise
- Within scope
- Adequate funding



Interesting

- Getting at the truth of the matter is interesting
 - Provides the necessary motivation/ intensity of effort for the research process
- Interesting to the researcher
- Others should also find it interesting
 - Mentors
 - Outside experts
 - Funders



Novel

- A good clinical research question contributes to new knowledge
- Innovative: new
 - Concepts
 - Methods/approaches
 - Interventions
- But: need not be totally original
 - Replication: confirmatory
 - Other population



Ethical

- Must be ethical
- The first requirement of ethical research: research question must be worth asking: must have
 - potential social, scientific, or clinical value
- If unacceptable risks/invasion of privacy:
 - Other ways of answering the RQ
- If uncertain:
 - Discuss with IRB reps early on
- **Validity** is an essential element of ethical research



Research must be ethical!

- Valuable research question ethically requires **validity** and **rigor** in research design and implementation to produce valid, reliable, interpretable, and generalizable results
- Poorly designed research:
 - with an inappropriate design
 - inadequate power
 - insufficient or sloppy data, or
 - inappropriate or unfeasible methods is
 - **harmful** because human and material resources are wasted and individuals are exposed to risk for no benefit



Relevant

- Significance

- Importance of the problem
- How the project will improve scientific knowledge
- How the result will change
 - Concepts
 - Methods
 - Clinical practice



So What?

Should pass the “So what? Test!

**Will the research make a
difference?**

Roadmap for Framing a Research Question: PICO(T) Framework

PICO(T) Framework

- In order to develop and refine research ideas: useful techniques:
 - Mind mapping
 - Brainstorming
 - Focus groups
- Very useful approach to transform research idea into a research question : PICOT format



PICO(T) Framework

- **P**-Population [patient/problem]
- **I**-Intervention [exposure, diagnostic test, prognostic factor]
- **C**-Comparison [if relevant']
- **O**-Outcome
- **T**-Timeframe



PICO(T) approach: Examples

Original Question

1. What is the best way to prevent and manage spasticity in TBI patients
2. Why should we fund physiotherapy for patients following discharge from SCI rehab?
3. Why did you do a CT instead of an MRI for this TBI patient?

PICO(T) format

1. In patients with severe TBI, what is the effect of casting on spasticity, compared with pharmacological management(Rx)
2. In patients following SCI rehab, what is the effect of community-based physiotherapy on functional status, compared with standard care? (DX)
3. In patients with suspected TBI, what is the diagnostic value of CT, compared with MRI? (DX)

Another example

contraception in the United States [13]. However, there is little information about effective strategies in Ethiopia and other LMICs. In Ethiopia, contraception training traditionally includes lectures during Obstetrics and Gynecology (Ob-Gyn) clerkship but without specific skill-focused FP exposure. Cognizant of this gap, competencies for all methods of reversible contraceptives were integrated into the medical school curriculum at St. Paul's Hospital Millennium Medical College (SPHMMC), Addis Ababa, in 2012, in collaboration with the Department of Ob-Gyn at the University of Michigan. Following this, the Center for International Reproductive Health Training (CIRHT) was established at the University of Michigan with the goal of decreasing maternal morbidity and mortality through effective preservice training of medical students in FP and abortion. The University of Michigan is providing support for the integration program through various faculty development initiatives in Ethiopia.

The objective of this study was to assess if structured integration of comprehensive FP training into a medical school curriculum improves FP knowledge and skills of interns. We also investigated potential factors associated with knowledge and skills (demographics, self-assessed competencies and reported number of procedures). We hypothesized that interns from the intervention site with the structured integrated curriculum (SPHMMC) have higher knowledge and skill scores compared to four control sites with conventional curriculum.

2. Material and methods

This study, conducted in five Ethiopian medical schools, compared the intervention school that implemented a structured FP cur-

2.1. Intervention site

The structured integrated FP training at SPHMMC involved five FP didactic sessions during third year of medical school (three 1-h lectures, one tutorial and one seminar) and five simulation sessions during the fourth year to practice FP and abortion procedures [implant and IUD insertion and removal and manual vacuum aspiration (MVA)] under Ob-Gyn faculty supervision. After a fourth-year qualifying exam, students complete a 1-year rotating internship before graduation. At the intervention site, interns had service rotations at SPHMMC's FP clinic for 1 week within their 10-week Ob-Gyn rotation, performing supervised LARC procedures (Fig. 1). Faculty used a standardized curriculum ensuring coverage of all essential content and minimizing any variability in the training. The faculty supervise the interns when doing LARC procedures. This paper reports FP outcomes and does not present the results of the comprehensive abortion care training.

2.2. Control sites

The four control medical schools have existed for at least 10 years. Their Ob-Gyn curriculum comprised 3 h of lectures on FP and comprehensive abortion care topics. There were no FP skill teaching in simulated or clinical settings, and no emphasis on students rotating through FP clinics during their internship. However, interns were expected to perform supervised MVAs in the management of patients with incomplete abortion during the gynecology rotation. They were not expected to place LARC devices or participate in family planning rotations during their internship year (Fig. 1).

Examples of Good Research Questions

- Funded Research Projects from the Contraception Research Branch (CRB) of the NICHD
- (2008-2019) EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
- <https://www.nichd.nih.gov/about/org/der/branches/crb/projects?fy=2008>



Examples of Good Research Questions

- I. Understanding the lactational amenorrhea method of contraception for mothers of preterm and term infants
 - I. to compare amenorrhea rates, duration of lactation, and resumption of sexual activity among postpartum women who are breastfeeding versus expressing milk after term and preterm delivery through a prospective observational study following women through 6 months postpartum
 2. assessing the feasibility and acceptability of using home urinary luteinizing hormone test kits to detect ovulation in exclusively breastfeeding women
 3. understand decision-making regarding contraception and infant feeding practices in mothers of preterm infants using a qualitative approach with semi-structured interviews



Examples of Good Research Questions

- **RCT assessing pregnancy with intrauterine devices for emergency contraception**
 1. Our primary aim is to assess the efficacy of the LNG20 IUD vs. the copper T380 IUD for EC utilizing a non-inferiority design assessing the feasibility and acceptability of using home urinary luteinizing hormone test kits to detect ovulation in exclusively breastfeeding women
 2. assess one-year continuation and unintended pregnancy rates in women initiating the LNG20 IUD or copper T380 IUD for EC and study the mechanisms of continuation related to satisfaction, pain, and bleeding over the first year of use



Examples of Good Research Questions

- Contraceptive method and HIV risk
 1. determine whether women randomized to DMPA have more or less frequent condomless vaginal sex than women randomized to the IUD or implant during trial follow-up by comparing vaginal PSA, a marker of recent semen exposure, between randomized contraceptive groups across multiple ECHO sites
 2. evaluate whether women randomized to DMPA are more or less likely to misreport condomless sex than women randomized to the IUD or implant during trial follow-up by evaluating the concordance of self-reported condom use or abstinence during trial follow-up with PSA detection overall, and by randomized contraceptive group



Examples of Good Research Questions

- A prospective cohort of HIV-infected Malawian women on Efavirenz initiating the levonorgestrel implant or the depot medroxyprogesterone acetate injectable
 1. compare the typical-use pregnancy rates of the LNG implant versus the DMPA injectable in a prospective cohort of 1,420 HIV+ women on EFV (710 initiating the LNG implant and 710 initiating DMPA)
 2. study 240 women in a 2:1 nested case-control study of women from the cohort to determine if higher EFV concentrations in hair (a biomarker for EFV exposure) are associated LNG implant contraceptive failure. 80 women (cases) who become pregnant while using the LNG implant will be compared with 160 LNG implant users who were not pregnant after the same duration of implant use (controls)



Examples of Good Research Questions

- **Improving emergency contraceptive effectiveness in obese women**

- I. We hypothesize that increasing the dose of orally-dosed EC agents will normalize the pharmacokinetics resulting in the expected treatment effect (delay in follicle rupture) in obese women
- I. , we plan to perform detailed pharmacokinetic and pharmacodynamic studies of ulipristal acetate- based EC in obese women and expand upon our preliminary findings of levonorgestrel-based EC.



Summary

- Research question begins with an idea which is then transformed into a research question
- A research question: clear, focused, and concise statement that conveys the objectives of the research and its potential findings
- Should be expressed in a simple, straight-forward language



Before committing much time and effort to writing a proposal/carrying out a study:

- Is the research question/study plan 'FINER'?
- Funder: priority to proposals that may have **innovative** and **significant impacts** on :
 - Science and
 - Health
- Early on: RQ into one page **Study outline**, specifically describing
 - Number of subjects needed
 - How subjects will be selected
 - Measurements to be made
- Iterative process
 - Consultations with mentors/colleagues/literature
- Focus on : single primary question in designing and implementing the study



Suggested Exercises at Home

- Look for research papers in your area of interest
- Assess if the RQ is explicitly stated
- Use the FINER criteria and the PICOT framework to critic the merits of the RQ
- Write your ideal research Qn (feasibility aside 😊 for now)
- Use the FINER/PICOT to refine your Qn
- Share with your colleagues/mentors
- Visit the NIH RePORT to find funded research projects by your topic of interest



Resources

- CIRHT research guide
 - <https://cirht.med.umich.edu/resources/>
- NIH webpage
 - Research Portfolio Online Reporting Tools (RePORT)
 - <https://report.nih.gov/>



Thank You
Questions?