

Getting Started in Clinical Research: Topic, Mentor, Protocol

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Outline

- Choosing a topic
- Choosing a mentor
- Writing a protocol

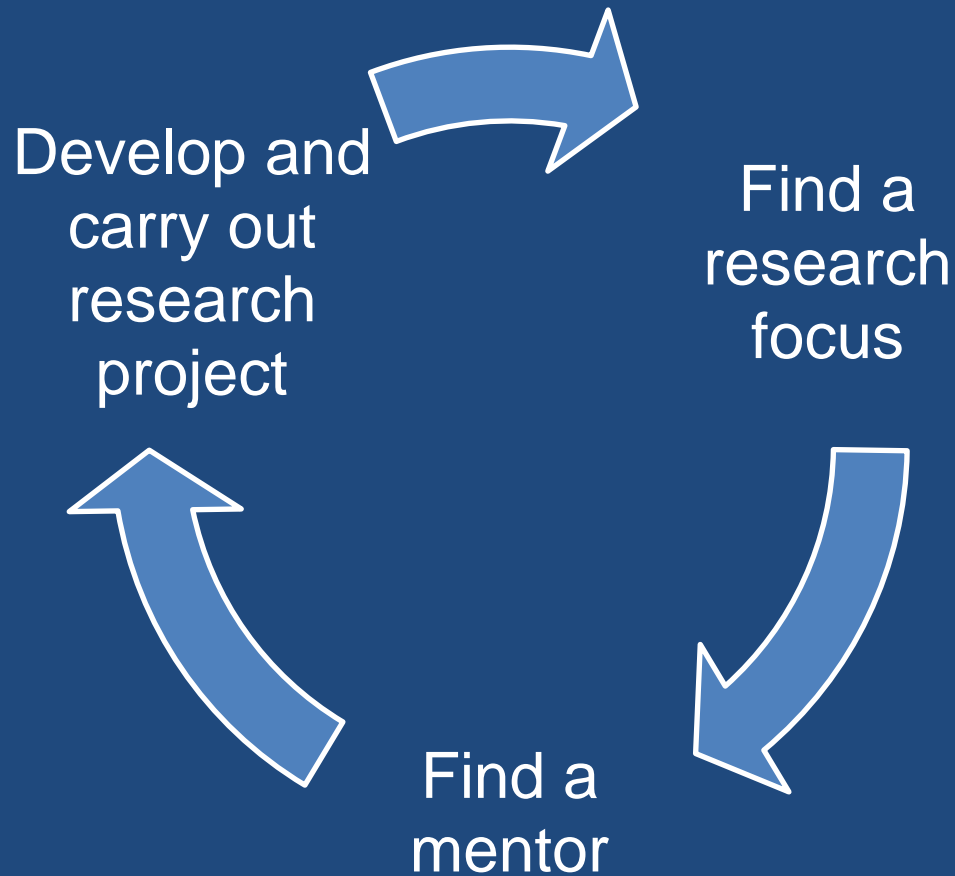
Why should I care?

- Helps develop academic skills
 - Skills in searching the literature
 - Skills in appraisal of the literature
 - Practice generating hypotheses and questions
 - Learn research and statistical methods
 - Provides exposure to academic medicine and may help define career goals

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Natural history of early research careers



Generating a research idea

- Picking a field (Locus)
 - Easier if you have a field or subspecialty
- Picking a question (Focus)
 - Is the question important?
- Assess feasibility
- Will this work in our healthcare system?
 - What other resources can I leverage?
- Define a target goal
 - Abstract, national meeting, etc.
 - Manuscript

What if you have a locus but no focus...

- Potential sources of research questions:
 - Clinical work
 - Personal experience
 - Mentors
 - Discussion sections of papers in an area of interest
 - Conferences/others' research
- Do a literature search
- Find similar research and look for a twist

Criteria for a good research question

FINER

Feasible

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

Interesting to the investigator

Novel

- Confirms or refutes previous findings
- Extends previous findings
- Provides new findings

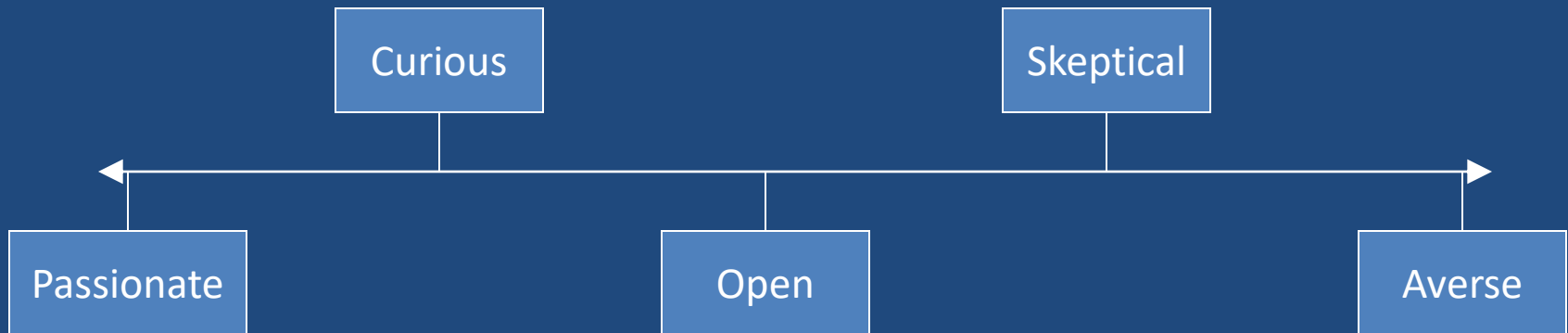
Ethical

Relevant

- To scientific knowledge
- To clinical and health policy
- To future research directions

Ideas suggested by others

- Mentors are a very good source of ideas, however..
 - **Be sure to assess how *you* feel about their idea**



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Where to look for mentors?

- Section
 - The first place to start
 - Common subject area
 - Talk to colleagues and supervisors
- Department
 - Overlap areas—best methods expertise may lie outside your immediate work unit
 - GI Obesity and Endocrine
 - GI chest pain and cardiology
- Outside department
 - Fellows often carry their mentoring relationships into faculty career
 - GI IBD and colorectal surgery
 - GI GERD and bariatric surgery
 - Not necessarily even within same institution

Choosing a mentor

- Be clear on what you need
 - Research idea
 - Methodological guidance
 - Specific guidance with a procedure, lab technique, analytical skill
 - Help with writing skills
 - Grantsmanship, paper edits
 - Navigating a new faculty position or academic center
 - Work/life balance

Ideal mentor qualities

- Senior enough to guide
 - Degree of seniority driven by experience
 - Sometimes someone a few years ahead can provide specific guidance or practicality that more senior folks cannot (e.g. promotion process)
- Has published in the area you are interested in
- Is networked and can open professional doors for you
- Has time and interest

Reasonable expectations of mentors

- Available and accessible
- Coaches and gives credit
- Pays attention to both details and big picture
- Role model for work-life
- Provides opportunities
- Recognizes potential
- Inspires to take risks
- Improves sense of identity, competence, self-awareness

Mentee expectations

- Well organized
- Takes initiative
- Motivated
- Open to new ideas
- Seeks and incorporates feedback
- Respectful and considerate
- Follows up and stays engaged

Cultivating- managing up

- Articulate your needs
- Set your personal goals and stick to it
- Be responsive and available
- Bring up issues
 - E.G. Trouble meeting goals, have mentor help reassess feasibility
- Ask for feedback on progress
- Understand yourself and your mentor

Communication

- Ask mentor about preferred style
 - Recognize that some issues need face to face meetings regardless of style
- Meet frequently but effectively
 - Come with an agenda, materials to review
- Avoid defensiveness
- Disagree when you need to—but with thoughtful, clarifying questions

Dissatisfaction happens

- Mismatch of goals, expectations
 - On both sides
- Change in interest
 - Moving away from research, or from field
- Open communication is key

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Research protocol

- The predefined written procedural method for your research
 - Specifics and details
 - Provides safeguards and ensures ethics
 - Allows for standardization and dissemination of project

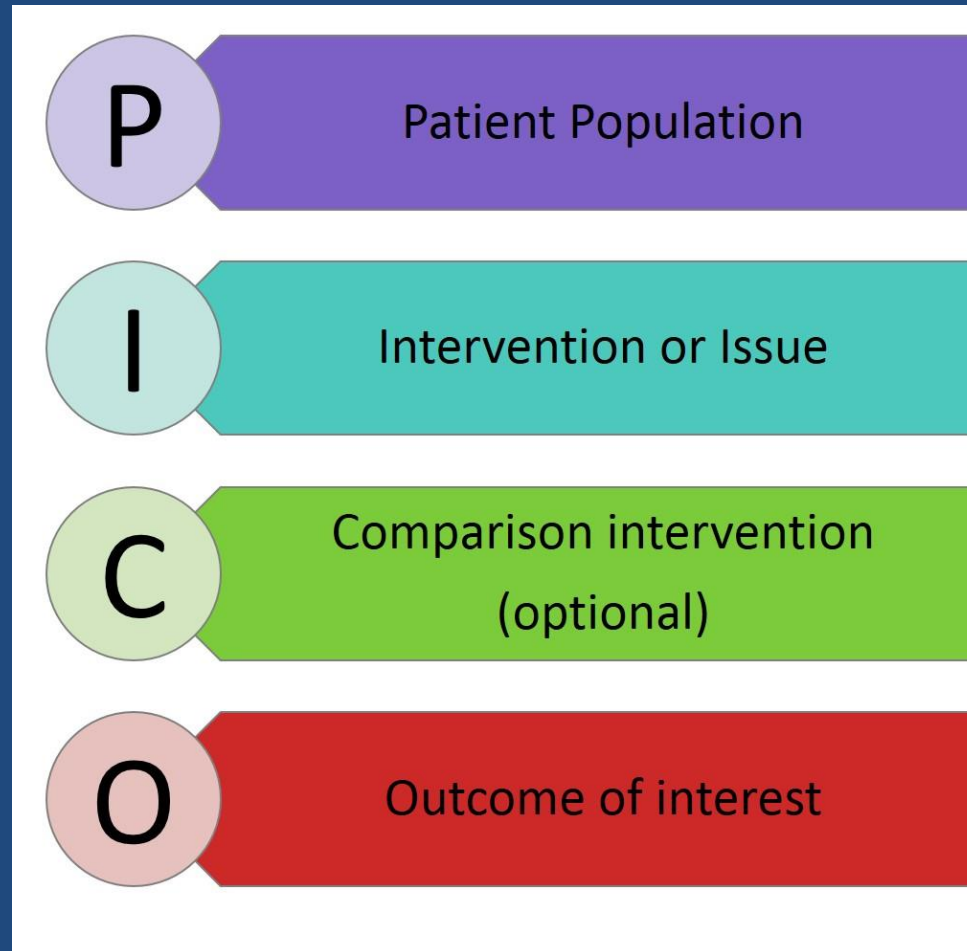
Research Proposal

- Grant applications
- Investigator-initiated studies
- Most importantly for many – IRB!

Research Proposal

- Title
- Summary/Abstract
- Aims/Hypotheses
- Rationale
- Methodology
- Ethical considerations
- References

Evidence-based medicine analysis



> [Dis Esophagus](#). 2017 Sep 1;30(9):1-6. doi: 10.1093/dote/dox056.

Abdominal diameter index is a stronger predictor of prevalent Barrett's esophagus than BMI or waist-to-hip ratio

D Baik ¹, J Sheng ¹, K Schlaffer ², F K Friedenberg ³, M S Smith ³, A C Ehrlich ³

Affiliations + expand

PMID: 28859359 DOI: 10.1093/dote/dox056

- In patients with heartburn, does abdominal diameter index, compared to BMI or waist-to-hip ratio, better predict presence of Barrett's esophagus?

> [Abdom Radiol \(NY\)](#). 2019 Jul;44(7):2632-2638. doi: 10.1007/s00261-019-02005-3.

Recent use of NSAID and NOAC medications are associated with a positive CT arteriogram

Muhammad A Shafqet ¹, Alexander Tonthat ², Paola Esparragoza ³, Butros Toro ³, Adam C Ehrlich ¹, Frank K Friedenberg ⁴

Affiliations + expand

PMID: 30949782 DOI: 10.1007/s00261-019-02005-3

- In patients who present with hematochezia, which risk factors predict a positive CT angiogram in the emergency room?

Summary/Abstract

- Just like an abstract to present your results
- Includes shorter versions of rationale, aims/hypotheses, methods
- Should be able to stand on its own

Aims/Hypothesis

- Statement of the question
- Simple and specific prediction PRIOR to the research
- Try to choose just one or two specific aims
 - Secondary goals are ok too but should be decided upon ahead of time

Rationale

- Similar to introduction in a paper
- Presents prior data
- Explains the need and puts in context

Multicenter Study > *Gastroenterology*. 2007 Aug;133(2):403-11.

doi: 10.1053/j.gastro.2007.05.026. Epub 2007 May 21.

Central adiposity and risk of Barrett's esophagus

Zoe R Edelstein ¹, Diana C Farrow, Mary P Bronner, Sheldon N Rosen, Thomas L Vaughan

Affiliations + expand

PMID: 17681161 DOI: 10.1053/j.gastro.2007.05.026

> *Int J Obes (Lond)*. 2011 Mar;35(3):409-15. doi: 10.1038/ijo.2010.143. Epub 2010 Aug 17.

Abdominal diameter index and 12-year cardiovascular disease incidence in male bridge and tunnel workers

A C Ehrlich ¹, D A Smith

Methodology

- Research design
- Subjects
 - Inclusion/exclusion criteria
 - Randomization
- Independent variables
- Outcome measures
- Statistical analyses (and power calculations)
 - Seek help on this if needed

Ethical considerations

- Risks/benefits
- Confidentiality
- Informed consent

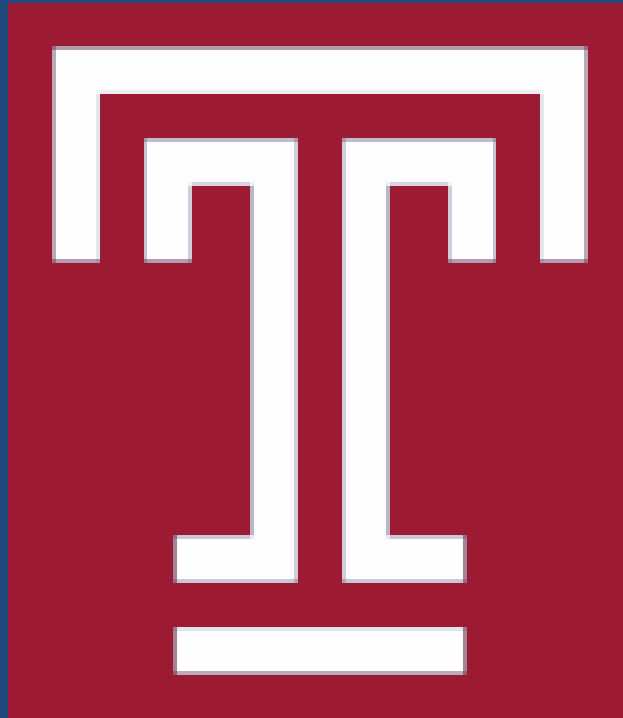
References

- References that help shape your rationale and methods

Summary

- Choose a research question
 - Interesting to you
 - Feasible (time, resources)
 - Meets your goals (abstract, paper, grant submission?)
- Choose a mentor
 - Who can fill a need (ideas, expertise, connections)
 - Who has a track record of success
- Research protocol
 - Helps guide your work
 - Helps identify flaws early
 - Generally necessary for IRB (even when a small retrospective study)
 - Ask for help and use prior examples

Thank you!



Questions?

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