GRANTSMANSHIP

YOUR IRRESISTIBLE IDEA!

KIMBERLY PAGE, PH.D, MPH
PROFESSOR INTERNAL MEDICINE,
DIVISION OF EPIDEMIOLOGY, BIOSTATISTICS AND PREVENTIVE MEDICINE

SPECIFIC AIMS AND RESEARCH STRATEGY

Significance
Innovation
Leaders in the field

- Who is your seminar leader – Kimberly Page, Ph.D., MPH
- Who are you?
- SEMINAR GOALS and next week:
  - Presenting your irresistible idea as a study question
  - Significance: why is this needed? What gaps will the work fill
  - Innovation: how will your work contribute to new directions?
  - The building blocks of your grant proposal including the:
    - Why,
    - Design,
    - Measures,
    - How you will do it.
- Goal: Convincing the reviewers that you can do what you say you can do

Session 1 – July 24, 2020
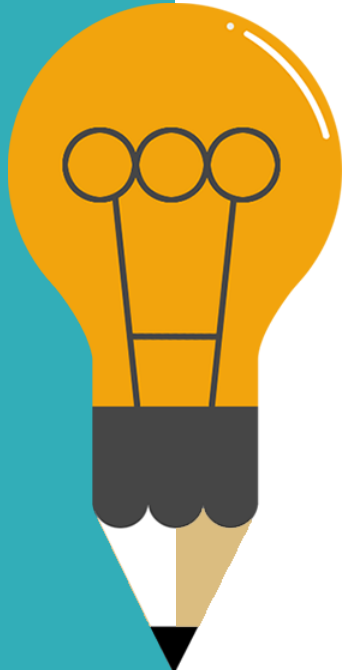
01 **Your Irresistible Idea**

Presenting that as a study question
Pilot studies: why do them

02 **Review of Specific Aims section**

Moving from bulleted outline to 1-page write-up

03 **Discussion of your aims**

What is the objective of your proposal?

04 **Introduction to Significance and Innovation**

Scientific premise, positive impact, departure from the status quo

SPIRIT (Standard Protocol Items: Recommendation for Interventional Trials):
a protocol is a document that provides sufficient detail to enable understanding of the:

- Aims/Objectives (Based on your study question)
- Background
- Rationale
- Approach:
  - Investigators
  - Study population
  - Interventions
  - Methods
    - Study Administration
    - Measures
  - Power and Statistical Analyses
- Ethical considerations,
- Dissemination plans

a feasibility study intended to guide the planning of a larger scale investigation

Answers important questions that can inform the design and conduct of a larger clinical trial, or study
- Evaluate subject availability and recruitment potential
- Feasibility of collaborations
- Evaluate safety of treatments or interventions
- Evaluate biomarker or other data in diverse populations
- Increase clinical experience with the intervention (or medication),
- Study management: assess procedures and refine protocol
- Trial case-report forms and analysis plan
- Project time, costs and help with budget preparation
- Need pilot data and publications to obtain funding

State your study question

Discussion

Study question

Guide/formula

In a population of _____, what is the association between __ <a>____ and <b: *outcome*>?

Specific Aims

1-page to concisely state goals, objective, expected outcomes, impact

Introductory paragraph

Hook, current knowledge, gap in knowledge, statement of need

Specific aims paragraph

How you will test your central hypothesis or tasks you will perform

What, why, who paragraph

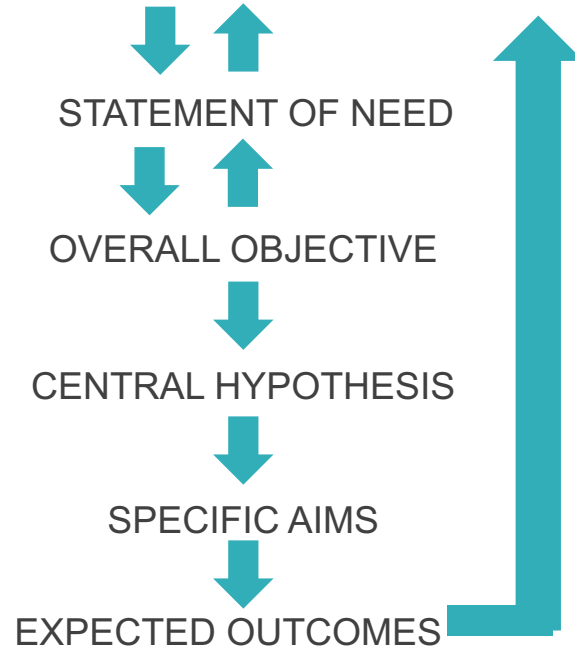Long-term goal, overall objective, central hypothesis, rationale

Payoff paragraph

Expected outcomes, positive impact

Progression – *kind of circular*

Specific Aims

GAP IN KNOWLEDGE/LACK OF SOMETHING

STATEMENT OF NEED

OVERALL OBJECTIVE

CENTRAL HYPOTHESIS

SPECIFIC AIMS

EXPECTED OUTCOMES

Expected Outcomes & Positive Impact

The expected products of the research

- Collectively, the outcomes allow you to attain your overall objective
- Advance science
- Not a restatement of the hypothesis

Provide robust estimates of efficacy

Generate important information about …

Establish the clinical and patient-centered relevance of …

a considerable advancement towards health equity

Example Specific Aims

Dissect and Discuss

1ˢᵗ paragraph

Hook   Known information   Gaps in knowledge   Need

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. About 21% of households with children are affected, as are more than a quarter of Latino and African-American households. One in eight US households is now enrolled in the Supplemental Nutrition Assistance Program (formerly known as Food Stamps). Food insecure adults tend to shift dietary intake toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally-rich foods. They also tend to over-consume during episodes of food adequacy in expectation of future food shortages. These behaviors may predispose adults to the development of obesity and diet-sensitive chronic disease. My recent work has demonstrated that food insecurity is independently associated with a higher prevalence of hypertension and diabetes, and poorer diabetes self-management. However, a number of crucial questions remain: *Does food insecurity predispose adults to obesity or diabetes? Does food insecurity alter self-management capacity, making diabetes management more difficult? There is a need to understand whether reducing food insecurity enables adults with diabetes to improve self-management capacity and intermediate outcomes?*

Color Key: Hook   Known Information   Gap in Knowledge   Critical Need

2nd paragraph

Long-term Goal	Proposal Objective	Rationale	Hypothesis	Pay-off

Diabetes is increasingly a disease of the poor; among US adults 50-64 years of age in California, the prevalence of diabetes is 8% among whites, 16% among blacks, and 22% among Latinos. The objective of this application is to determine whether obesity/diabetes   interventions implemented in low-income settings should specifically target food insecurity. My central hypothesis, formulated on the basis of my clinical experience as a general internist at a public hospital and my subsequent preliminary research, is that food insecurity negatively impacts   the prevention and control of obesity and diabetes through alterations in dietary intake and interference with self-management capacity. If this hypothesis is correct, one strategy to increase the effectiveness of obesity and diabetes prevention and control efforts in low-income communities may be to directly address food insecurity – a risk factor that has been largely overlooked and that may   be causally related to socioeconomic inequalities in the incidence of obesity and diabetes. My long-term goal is to implement and disseminate interventions at the clinic and policy level that reduce the burden of obesity and diabetes in low-income communities. By pursuing the following specific aims, I will gather data essential for a formal intervention to shift dietary intake among low-income patients with diabetes toward increased fruit and vegetable consumption (to be proposed in a subsequent R01).

Color Key: Long-term Goal   Proposal Objective   Rationale   Hypothesis   Pay-off

The AIMS

Aim 1: **Establish the extent to which food insecurity is related to the incidence of obesity, pre-diabetes, and diabetes.** To accomplish this aim, we will use longitudinal data from the NHLBI-funded Coronary Artery Risk Development in Young Adults Study (CARDIA). We hypothesize that food insecurity will be associated with unhealthy dietary intake and 5-year incidence of obesity, pre-diabetes, and diabetes.

Aim 2: **Determine whether food insecurity alters response to a diabetes self-management intervention.** We will use the infrastructure of an existing self-management intervention which has recruited 702 patients with diabetes receiving primary care in federally qualified health centers. We hypothesize that food insecurity will moderate participants' success with the behavioral intervention.

Aim 3: **Conduct a pilot randomized controlled trial of a fruits and vegetables voucher in a population of food insecure patients with poorly-controlled diabetes.** We will recruit 60 patients from a safety net clinic with a 43% rate of food insecurity. Process outcomes include success with recruitment, ability to deliver the intervention in a clinical setting, and ability to measure study outcomes. Clinical outcomes include dietary intake, change in blood pressure and glycosylated hemoglobin, and rates of hypoglycemia

Color Key: Aim Title   Experimental Strategy   Hypothesis or rationale   Outcome or Impact

Summary Paragraph

Innovation   Expected Outcomes   Impact/Pay-off

In addition to establishing the importance of food insecurity as a risk factor for difficulty with obesity and diabetes prevention and management, these studies are expected to have an important impact on the design of clinical and public health interventions to shift dietary intake in low-income communities toward more healthy food alternatives. These specific aims build logically toward an R01-level intervention targeted at patients with, or at high risk of, obesity and diabetes.

Color Code: Innovation   Expected Outcomes   Impact/Pay-off

Your Aims

What is the overall objective of your proposal?

Specific Aims

1-page to concisely state goals, objective, expected outcomes, impact

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Long-term goal, overall objective, central hypothesis, rationale

Payoff paragraph

Expected outcomes, positive impact

Significance

The impact that something will have on some other thing

> Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments services, or preventive interventions that drive this field?

Why is your project important?

Components of Significance
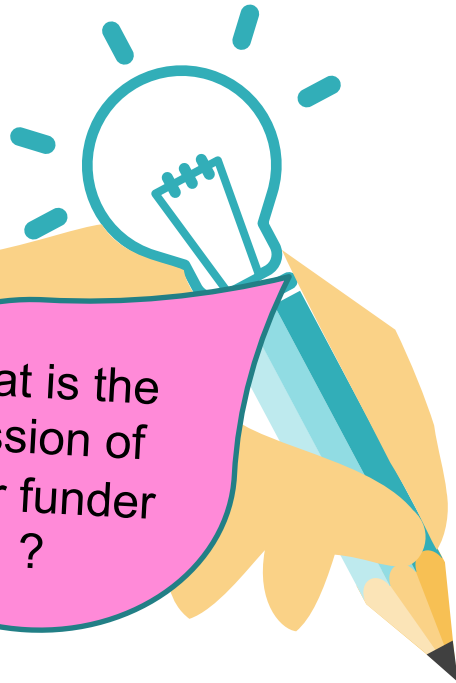
01 **Overall Scientific Premise**

Scientific foundation on which your proposal is built
Detail existence of the gap/need you plan to address

02 **Scientific Premise for Each Aim**

Select support for each aim that is maximally relevant
Explain why each aim is needed

03 **Significance of the Expected Research Contribution**

Explicitly describe the contribution you expect to make
Why the contribution will have positive impact
Relate to funding agency mission

What is the mission of your funder ?

NIH Mission: NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability

Innovation

A new and substantively different way of considering/addressing something, which opens new horizons

"

Does the application challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentations, or interventions? Are the concepts, approaches or methodologies, instrumentations, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentations, or interventions proposed?

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Departure from the status quo
Attainment of new horizons

Leaders in the field

Discussion

Research Strategy or Approach

The nuts and bolts

Details of how you will do your research
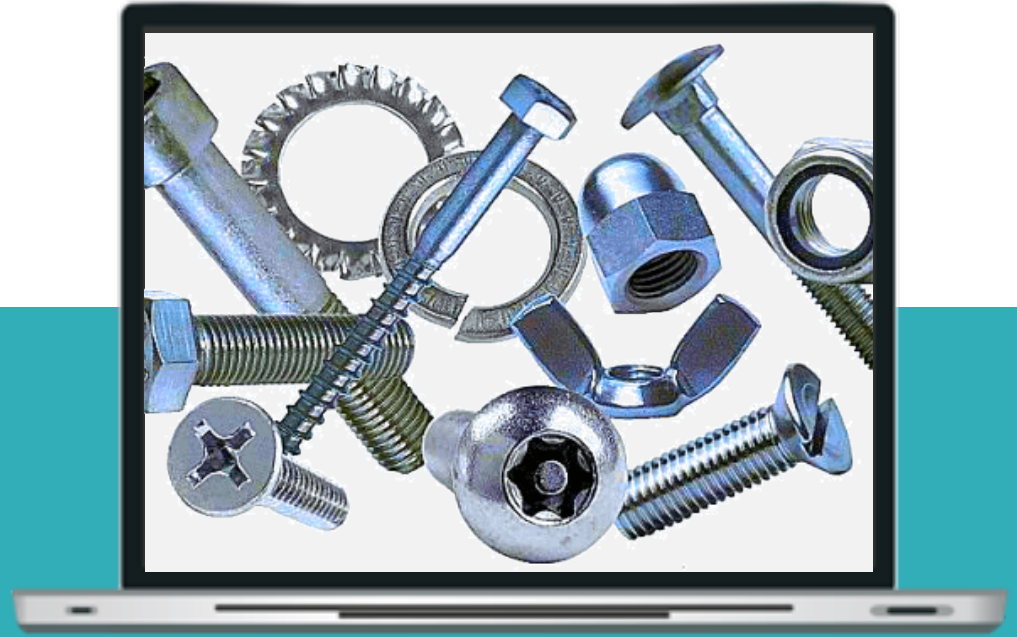
Session 2 – July 31, 2020
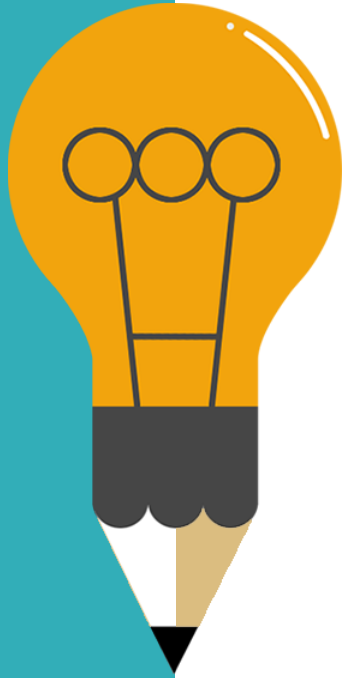
01 **The Approach/Research Strategy Section**
Nuts and Bolts of your proposal

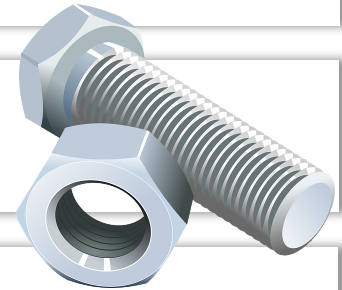**02** **Review of your Research Strategy Section**
Make an outline!   Make it flow

03 **Details, details, details**

04 **Anticipate Reviewers' questions**
Limitations, alternative approaches,

Your Research Strategy is the nuts and bolts of your application.

- Describe your research rationale and the experiments you will conduct to accomplish each aim.

How you organize it is largely up to you

In general follow these guidelines:

- Organize using bold headers or an outline or numbering system—or both—that you use consistently throughout.
- Start each section with the appropriate header: Significance, Innovation, or Approach
- Organize the Approach section around your Specific Aims.

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project

- Discuss potential problems, alternative approaches, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stages of development, describe any strategy to establish feasibility and address the management of any high-risk aspects of the proposed work.

NIH format: Single spaced, 11 point Arial font, .5 inch margins)
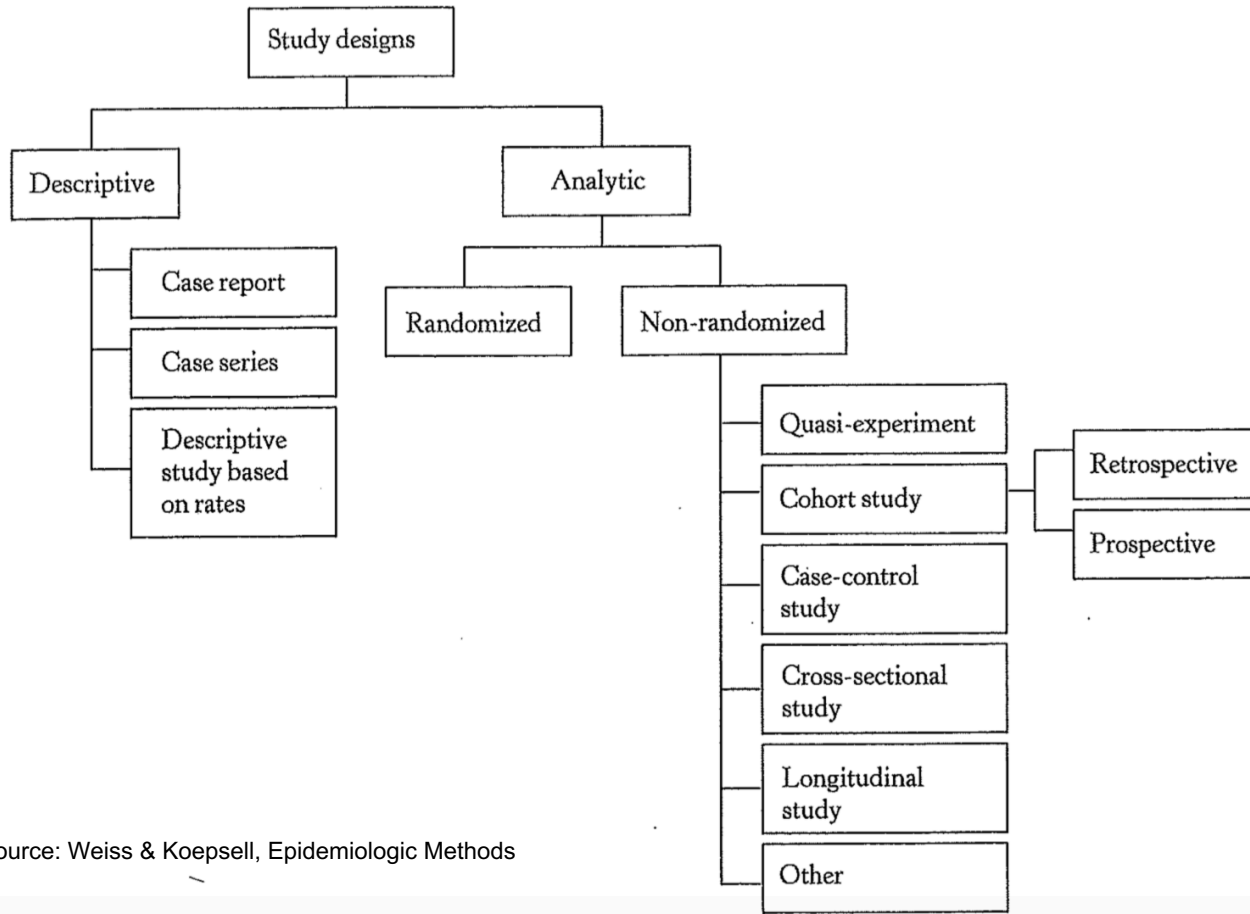
Source: Weiss & Koepsell, Epidemiologic Methods

biostatistics
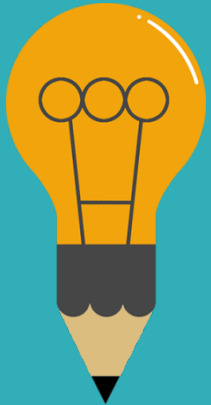
Unitary Approach

- Background
- Preliminary Studies
- Research Design
    - Investigators
    - Study design
    - Study population
    - Study procedures – By AIM
    - Study measurements
    - Data quality and management
    - Data analysis
- Expected Outcomes
- Potential Problems & Alternative approaches
- Timeline
- Future Directions

Modular Approach

- <mark>Each Aim:</mark>
  - Introduction
  - Background
  - Preliminary Studies
  - Investigators
  - Research Design
    - » Study design
    - » Study population
    - » Study procedures
    - » Study measurements
    - » Data quality and management
    - » Data analysis and Sample size
  - Expected Outcomes
  - Potential Problems & Alternative Approaches
- Timeline
- Future Directions
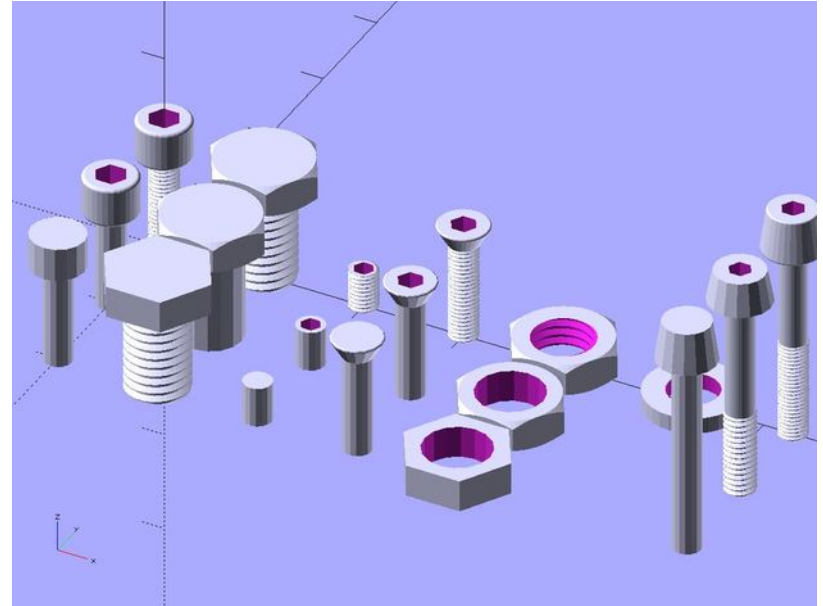
Spell out the experiment(s) or study that you will conduct to address each aim

How much detail to include

- Depends on page limits of the application
- Typically less detail than in a scientific paper, but some experimental detail is necessary
  - <u>what</u> you plan to do and <u>how</u> you plan to do it

NIH data show that of the peer review criteria, APPROACH has the highest correlation with the overall impact score

What kind of research question is being asked?

Can the investigator manipulate the exposure?

Where would the data come from?

How common is the outcome?

How common is the exposure?

Research Strategy—a description of the rationale for your research and your experiments

# https://www.niaid.nih.gov/grants-contracts/write-research-plan

1. Specific aims

2. Background and significance

3. Preliminary studies

4. Research design and methods → Approach

5. Bibliography and references cited (not included in 5 page limit)

- Convince the reader that you/your research team has the experience & evidence to complete the proposed research

- You can either include this information as a subsection of Approach or integrate it into any or all, of the three main Research Strategy sections.

- If you do the latter, be sure to mark the information clearly, for example, with a bold subhead.

Reviewers

- Will the investigators be able to get the work done within the project period? Is the proposed work over-ambitious?

- Did the applicants describe potential pitfalls and possible alternatives?

- Will the research/experiments generate meaningful data?

- Could the resulting data prove the hypothesis?

- Are others already doing the work, or has it been done elsewhere?
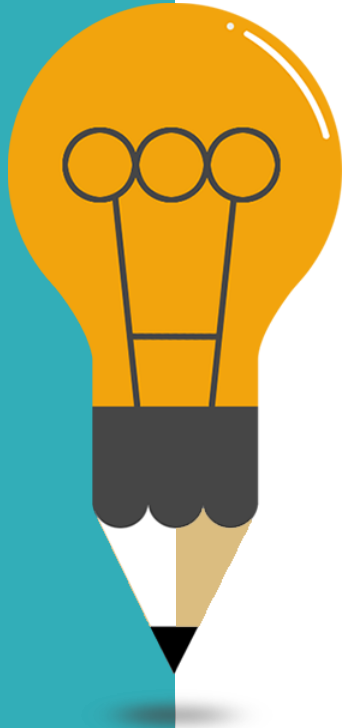
- Strategies for success

  ✓ Organization
    - Numbers and bullets
  ✓ Personal favorite: shared documents to avoid version issues. Eg., google doc
  ✓ Writing style – be clear.
    - Read the proposal out loud. Are you wordy? Are you consistent with terms?
  ✓ Use graphics: tables and figures wisely!
  ✓ Plan ahead: set deadlines, be early!
  ✓ Peer Review
    - Get critiques, feedback
    - You will have time to change things

Pagek@salud.unm.edu