Writing Specific Aims

Thursday November 7, 2019

Daichi Shimbo, MD

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Outline

- Presentation (40 minutes)
- Working in pairs to review aims (30 minutes)
- Q&A period (20 minutes)

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Writing Specific Aims

How do I structure a compelling research question?

How do I structure a specific aims page?

Writing Specific Aims

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Compelling research question

- The research question is the objective of the study, the knowledge gap that the investigator wants to solve.
 - General question
 - Should people exercise?
 - Focused question (preferred)
 - Does isometric exercise lower blood pressure for individuals who have hypertension?

Compelling research question

- Research question
 - General question
 - Does systematic changes in the electronic health record (EHR) improve cardiovascular risk?
 - Focused question
 - Does EHR alerts based on underlying baseline cardiovascular risk improve the rate of appropriate statin administration for individuals without cardiovascular disease?
- Quality assurance versus <u>scientific</u> research question

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Compelling research question

- FINER
 - F = Feasible
 - > I = Interesting
 - N = Novel
 - E = Ethical
 - > R = Relevant (timely)

Source: Designing Clinical Research, 4th ed. Hulley, Cummings, Browner, Grady, Newman, 2013.

Identifying a compelling research question

- What is known? ("Why should I care?")
 - Talk to mentors
 - Conduct an extensive literature search
 - Focus on systematic reviews, narrative reviews, and editorials
 - Use relevant search terms
 - Related article search
 - Web of science
- This takes the longest time and is difficult for most early stage investigators (in my opinion).

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Identifying a compelling research question

- Web of science (demonstration)
 - http://apps.webofknowledge.com/WOS_GeneralSearch_input.d o?product=WOS&search_mode=GeneralSearch&SID=4DOrDx4 mc31xJDz6T9Z&preferencesSaved=
 - Example:
 - Prognostic accuracy of day versus night ambulatory blood pressure: a cohort study

Identifying a compelling research question

What is not known?

- What are the knowledge gaps?
- What are the limitations (internal and external validity) of the prior studies?

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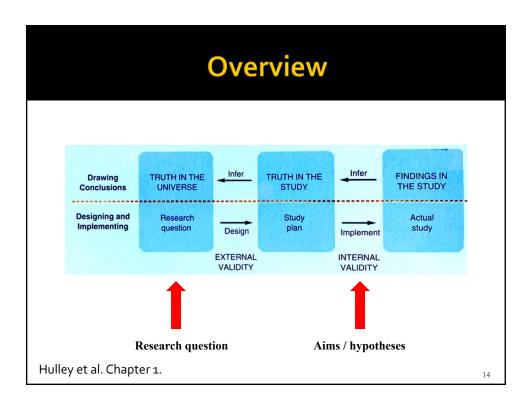
Identifying a compelling research question

What is the research question(s)?

- Should address important knowledge gaps
- Answering this question will lead to new/novel scientific knowledge
- Will influence the field, and may change current paradigms
- May lead to changes in scientific statement/guideline recommendations/conceptual models
- Avoid "me also" research questions

From research question to aims and hypotheses

- Research question
- How do we go from research question to aims / hypotheses?



Overview

Truth in the universe

- Target population: people with coronary heart disease (CHD)
- Phenomena of interest: % who take fish oil supplements?

Truth in the study

- Intended sample: all patients with history of CHD seen in cardiology clinic at CUMC for the last year
- Intended variables: self-reported use of fish oil supplements

Actual study

- Actual subjects: smaller group of patients with a CHD diagnosis in the EHR in the prior year who filled out a questionnaire about supplements
- Actual measurements: response to questionnaire about fish oil supplements

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Specific Aim

Specific Aim

- What are you specifically proposing to study?
 - Primary Aims
 - Secondary Aims
 - Exploratory Aims

Aims should be be independent of one another

- Does the failure of one aim invalidate another aim?
- There should be a logical flow of the aims

Research Question vs. Aim

Example 1

- Research Question: Does lowering dietary salt intake affect blood pressure among those at risk?
- Primary Aim: To determine whether a reduction of dietary sodium intake leads to a reduction in blood pressure among middle-aged individuals with a history of heart disease.

Example 2

- Research Question: Do multi-vitamins impact cancer risk?
- Primary Aim: To determine whether long-term multivitamin supplementation decreases the risk of total and site-specific cancer events among men.

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Hypothesis

Hypothesis

- What is your expected finding?
- A statement derived from a theory that predicts the relationship among variables representing concepts, constructs, or events (Mosby's 5th ed.)
- A research hypothesis is a specific, testable prediction about what will happen under a given set of circumstances or conditions

Hypothesis

Hypothesis

- Primary Aim
 - One hypothesis or multiple hypotheses per Primary Aim
- Secondary Aim?

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Aim and Hypothesis

Example

- Primary Aim 1: To compare the difference between clinic blood pressure and daytime blood pressure on ambulatory blood pressure monitoring when clinic blood pressure is assessed using the unattended versus attended automated oscillometric method.
- Hypothesis 1: The difference between clinic blood pressure and daytime blood pressure on ambulatory blood pressure monitoring will be smaller when clinic blood pressure is assessed using the unattended versus attended automated oscillometric method.

Writing Specific Aims

How do I structure a compelling research question?

How do I structure a specific aims page?

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Specific Aims Page

- What is the health care/biomedical research problem (topic) and how important is it. What is the unmet need.
- What is already known and accepted in this area
- What is the problem, roadblock, the unknown (i.e. the "research question")?
 - Limitations of prior studies
 - Unaddressed questions
- Long-term goal = What final "big result" will the research help achieve down the road?
- What is the <u>specific narrow goal</u> of <u>this</u> research?
 - Statement of the research question of your study
- How will your study address:
 - Limitations of prior studies and what is not known
 - The research question

Specific Aims Page

- How your study is innovative
- Statement of specific aims and hypotheses
 - If the aims/hypotheses are met, what are the implications for the unmet need?
 - If the aims/hypotheses are not met, what the implications?
- Study design
 - Alternatively, this can go above aims/hypotheses.
- Health implications (summary)

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Career Development Awards

- Mentor and mentorship plan
- Candidate description (who are you? what are your career goals? why do you <u>need</u> training? Not a personal statement per se)
- Career development and career goals
 - Long-term career goals
 - Short-term career goals (training aims)
 - Addressed by training modules (approach)

Career Development Awards

My long-term goals are to:

- Build a high productive, independent laboratory to continue my scientific investigations into preventive cardiology.
- Train and mentor future clinical researchers as they develop into independent scientists.
- Develop a strong network of collaborators within the research community.

My short-term goals (i.e. aims) are to:

- Have formal training in the design, conduct, and evaluation of clinical trials including randomized controlled trials.
- Acquire statistical expertise in the analysis of longitudinal data.
- Have further training in relevant laboratory techniques applicable to conducting patient-oriented laboratory-based research.
- Have further training in preventive cardiology.
- Refine my ability to articulate research ideas and findings.

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Career Development Awards

Training Module	Mentors	Mode of Learning
1. Clinical Trials Design	Pickering & Davidson	Graduate coursework Weekly research meetings Applied training
2. Statistics	Chaplin	Graduate coursework 1-on-1 meetings every other week
3. Basic Science Methodology	Badimon	Graduate coursework Weekly research meetings Applied laboratory training
4. Preventive Cardiology	Pickering	Weekly research meetings Clinical experience Guided reading
5. Medical Research Dissemination	Pickering & Davidson	Collaboration on submitted manuscripts and Ro1 applications

Specific Aims Page

- Typically one page in length (no greater)
- Minimum and essential for a proposal in development
 - Deciding if good science
 - Deciding if feasible (i.e. is science overambitious)
 - Deciding who is on the investigative team
 - Deciding initial statistical plan and power analyses
 - Determining if study is overbudget
- Show it people <u>outside</u> your area and get feedback
- When finalized, rest of the application will come easily

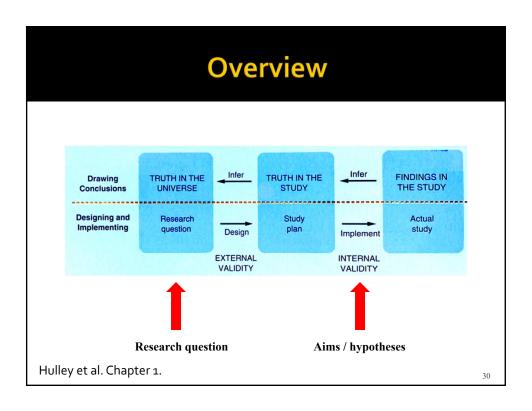
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Typical reviewer

MENTALLY EXHAUSTED

Scientific Writing – Advice

- Be concise and crystal clear
- Be somewhat redundant throughout the writing
- Speak to a more general research audience
- Highlight gaps and innovation; and state what happens when your study is done successfully



Handouts

Six handouts

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Specific Aims Page (maximum 1 page)

Your specific aims page should be structured as follows:

- What is the health care/biomedical research problem (topic) and how important is it?
 What is the unmet need (ie. Gaps in knowledge, ways this will bring the field forward)?
- What is already known and accepted in this area?
- · What is the problem, roadblock, the unknown?
 - o Limitations of prior studies
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- Long-term goal: What final "big result" will the research help achieve down the road?
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- Statement of the research question of your study
- How will your study address:
 - o Limitations of prior studies and what is not known
 - o The research question
- How is your study innovative?
- Statement of specific aims and hypotheses
 - o If the aims/hypotheses are met, what are the implications for the unmet need?
 - o If the aims/hypotheses are not met, what the implications?
- Study design (for clinical/population-based research: population to be studied, sample size, source of subjects, measures etc.; for basic science: animal model, cells, protein, experimental procedure etc.)
 - Alternatively, this can go above aims/hypotheses.
- Public health implications (summary)

Research Strategy (i.e. Significance, Innovation, Approach sections) (the page limit is dictated by the type of application you are submitting – please review NIH application instructions carefully to find out what the page limit is).

Significance: 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 are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

Suggest format: Provide background of scientific area. What is already known. What is
not known (i.e. scientific gaps in knowledge). Why do these gaps matter for human
health. Describe overall research question. How will your study address these gaps.

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel?

- Overview of study design and methods to be used, and how they are appropriate for assessing your hypotheses.
- Study design: Include strengths and advantages of your chosen design, discussion of possible alternatives and the reasons for not choosing them. Tie your choice of design to your specific aims, and why it works.
- Subjects
- Population being targeted
 Entry criteria & recruits ---
 - Entry criteria & recruitment information
 Any issues related to eligibility/attrition
 Randomization procedures (if applicable)
- Variables

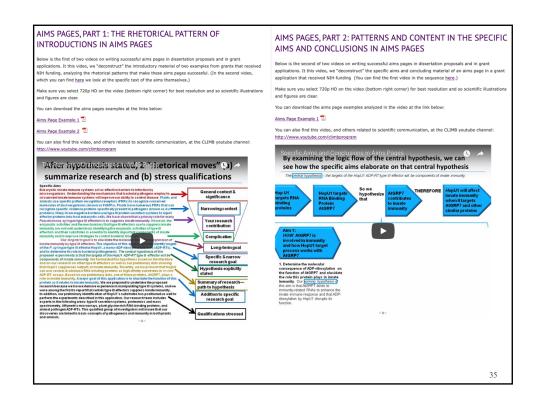
 - Exposure(s)
 Outcome(s)
 Adjustment variables (covariates)
- Statistical plan
 For each aim, describe the statistical procedures and techniques you will apply to address your main hypotheses; tie explicitly to your specific aims.
 Plans for data management (where/how will data be collected and stored)

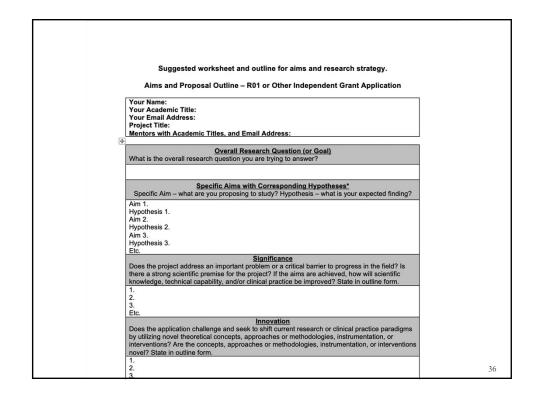
 - Sample size justification: Give a justification (power or precision) for the sample size you will employ.
- Potential problems, pitfalls, and alternative strategies
 Describe problems that you foresee and strategies for overcoming them.

 Timeline and benchmarks
 Give a timeline and possible benchmarks that you can use to monitor your

References (no limit)







Suggested worksheet and outline for aims and research strategy. Aims and Proposal Outline - K Application Your Name: Your Academic Title: Your Email Address: Project Title: Mentors with Academic Titles, and Email Address: Career Development What are your long-term career goals? 1. Training What kind of training do you envision needing to attain your long-term career goals? Overall Research Question (or Goal) question you are trying to answer? What is the overall research qu Specific Aims with Corresponding Hypotheses* Specific Aim – what are you proposing to study? Hypothesis – what is your expected finding? Aim 1 Hypothesis 1. Aim 2. Hypothesis 2. Aim 3. Hypothesis 3. Etc.

Why Academics Have a Hard Time Writing Good Grant Proposals Robert Porter Journal of Research Administration; Fall 2007; 38, 2; ABI/INFORM Global pg. 37

Why Academics Have a Hard Time **Writing Good Grant Proposals**

Significance

Robert Porter, Ph. D.

Program Development Manager, Research Division Virginia Tech 340 Burruss Hall, MC0244 Blacksburg, VA 24060 (540) 231-6747 reporter@vt.edu

This paper was presented as part of the 2006 Symposium at the annual October meeting of the Society of Research Administrators International in Quebec City, where it was awarded Best Paper of the Year.

Abstract

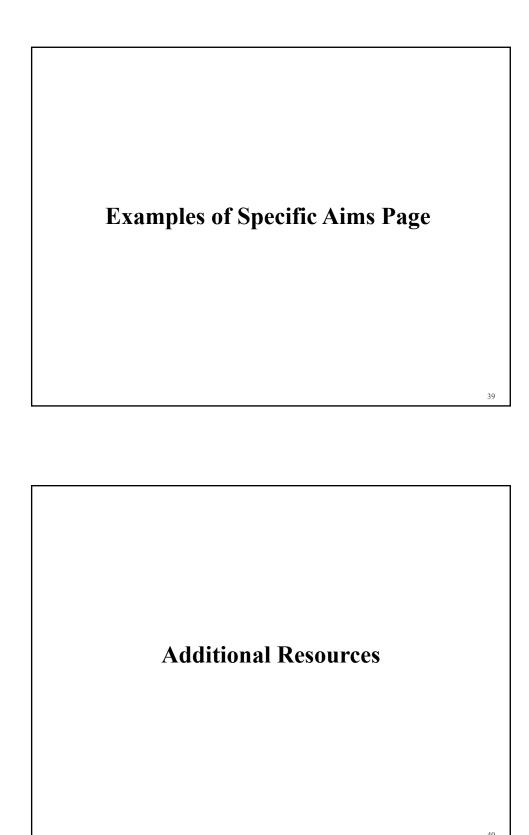
This paper discusses the contrasting perspectives of academic prose versus grant writing, and lists strategies grant specialists can use to help researchers break old habits and replace them with techniques better suited to the world of competitive grant proposals.

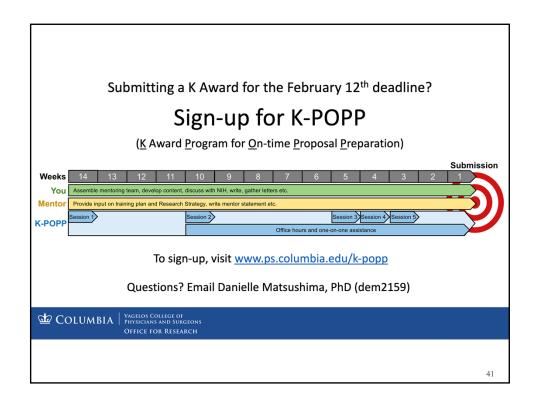
Introduction

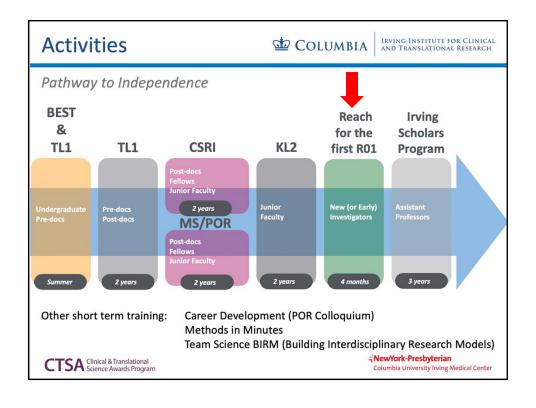
When they are new to the grant game, even scholars with fine publishing records can struggle with proposal writing. Many are surprised to find that the writing style that made them successful as academics is not well suited to crafting a winning proposal. To succeed at grant writing, most researchers need to learn a new set of

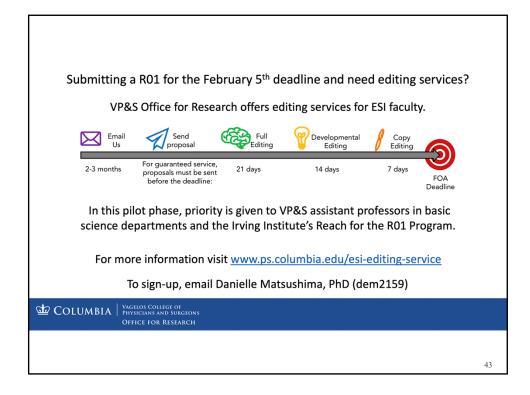
the relationship between workplace experiences and supervisor-targeted aggression. Indeed, despite the differential effects of situational and individual difference factors on aggression, it is notable that the individual difference factors exerted a consistent but relatively low-level effect on aggression across contexts,

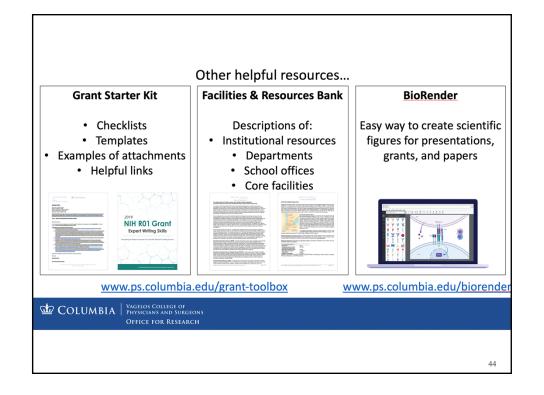
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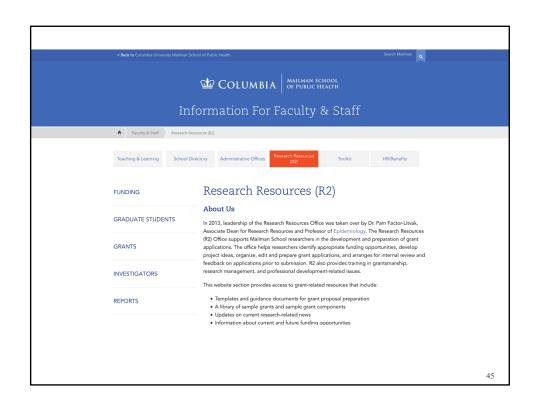












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Suggested worksheet and outline for aims and research strategy.

Aims and Proposal Outline – R01 or Other Independent Grant Application

Your Name:
Your Canademic Title:
Your Email Address:
Project Title:
Mentors with Academic Titles, and Email Address:
What is the overall research Question (or Goal)

What is the overall research question you are trying to answer?

Specific Aim – what are you proposing to study? Hypothesis – what is your expected finding?

Aim 1.
Hypothesis 1.
Aim 2.
Hypothesis 2.
Aim 3.
Hypothesis 3.
Etc.

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 are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? State in outline form.

1.
2.
3.
Etc.

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions novel? State in outline form.

1.
2.
3.
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Suggested worksheet and outline for aims and research strategy.			
2. 33			
Aims and Proposal Outline – K Application			
Your Name:			
Your Academic Title:			
Your Email Address:			
Project Title:			
Mentors with Academic Titles, and Email Address:	l		
Career Development			
What are your long-term career goals?			
T.			
2.			
3.			
Etc.			
Training			
What kind of training do you envision needing to attain your long-term career goals?			
1.			
2.			
3.			
Etc.			
1			
Overall Research Question (or Goal)			
What is the overall research question you are trying to answer?			
Specific Aims with Corresponding Hypotheses*			
Specific Aim – what are you proposing to study? Hypothesis – what is your expected finding?			
Aim 1.			
Hypothesis 1.			
Aim 2.			
Hypothesis 2.			
Aim 3.			
Hypothesis 3.			
Etc.	49		
Significance	49		
<u> </u>			

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