Developing a Proposal for the ACCP Clinical Pharmacy Challenge

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Conflict of Interest Disclosures

- Dr. DiDomenico is a member of the ACCP Board of Regents (2025-2028) and has served as a reviewer for the Clinical Research Challenge since 2019
- Dr. DiDomenico has no conflicts of interest related to the content of this presentation

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Overview

- Review the LOI Feedback with your Team & Faculty Advisor by area:
  - General
  - Background, Rationale, and Innovation
  - Hypothesis and Specific Aims
  - Methods
  - Timeline
  - Future impact and dissemination
  - Budget
- Follow Formatting Requirements – Be sure to review and follow all the requirements including the AI Acknowledgement section at https://www.accp.com/stunet/crc/eligibility.aspx#format

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Responding to Reviewer Feedback General Comments

- Reviewer feedback is intended to be constructive to refine and shape your proposal submission.
- Review this feedback as a team and with your faculty advisor.
- Address any formatting, referencing comments.
- Be sure to review document for spelling and grammatical issues.
- Ensure the document reads well as a whole.
  - Optimize transitions between sections to improve overall document flow, given multiple authors
- **Be explicit** with statements when making edits
- Incorporate and/or add specifics to the various sections of your proposal requested by the review panel.
  - Remember: LOI was an abbreviated version of your proposal.
- Strongly consider making the edits suggested by the review panel.
- Consider the inclusion of figures and or tables to add clarity
  - Examples: conceptual model, study design, timeline, etc.
- *Online examples provided by ACCP may be useful templates/guides*

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Background, Rationale and Innovation Reviewer Feedback

- Include some background that describes similar work in this area & use this to highlight what gaps exist—why your study is necessary
  - Don't want to replicate prior studies but rather elevate/improve/refine what has been done previously—innovate!
  - "The gap in knowledge is…" "…represents a gap in knowledge."
  - Knowledge gap should lead naturally to the rationale for your project
    - "The purpose of our study is…"
- Describe why your proposal is innovative compared to prior work
  - "This work is innovative because…"
- Indicate how your proposal fits with the funding opportunity
  - "Our work aligns with…"

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Reviewer Feedback – Hypothesis and Specific Aims

Hypothesis

- Have one!
- What is your overall hypothesis?
  - "Our central hypothesis is…"

Specific Aims

- Generally, have 2-3 specific aims
- Brief description of each aim follows

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Hypothesis and Specifics Aims Example

Aim 1. Explore the relationship between pharmacist board certification(s), CCP workload characteristics, and patient outcomes. Participating CCPs (n=200) across the U.S. will prospectively record comprehensive daily workload information (e.g., census, rounding) and record all patients cared for over 100 days (n=40,000). Pharmacist (e.g., training, years of experience, board certification(s)) and patient (e.g., demographics, severity of illness, outcomes) data will be recorded. We will explore the relationships of Board Certified Pharmacotherapy Specialist (BCPS), BCCCP, and multiple board certifications with CCP workload and patient outcomes and will specifically test the hypothesis that BCCCP expands a CCPs capacity for higher workload, thereby mitigating the relationship between CCP workload and patient outcomes.

Aim 2. Determine the effect of a BCCCP-credentialed CCP on mortality of critically ill patients through application of traditional and novel modeling techniques. Several methods (multi-level logistic regression, Bayesian, unsupervised ML) will be used to identify patterns within this complex dataset. First, a multi-level logistic regression model will be built to identify the relationship between BCCCP and patient outcomes. Then, Bayesian analysis will support identifying the probability of patient harm based on board certification. Lastly, unsupervised ML will be used to identify patterns of pharmacist characteristics associated with poor outcomes.

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Design and Methods Reviewer Feedback

General flow of the methods section

- Think about studies you've read/reviewed (e.g., journal club)
  - Study design
  - Inclusion/exclusion criteria
  - Study procedures (e.g., intervention & control groups)
  - Study outcomes (primary & secondary)
  - Statistical analyses

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Methods
Outcomes

- Use clear definitions for your endpoints
  - What criteria will you use to define/categorize a subject as having an endpoint?
- Select endpoints that are:
  - Consistent with your hypothesis & specific aims
  - Reasonable & feasible based on the study parameters
    - Consider the budget & timeline
    - Consider easily measured surrogate endpoints (e.g., measures of disease control [BP, blood glucose]) vs hard clinical endpoints (mortality)
    - Consider using validated tools (e.g., adherence scale, survey, QOL tool, etc.) from the
    - If you demonstrate success with these surrogates, subsequent "outcomes studies" can be proposed as part of Future Impact

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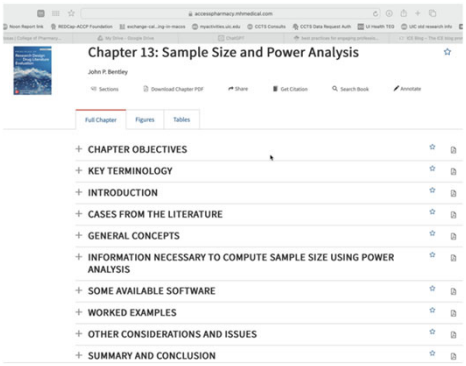
Methods
Sample Size

- Be practical based on budget & funding period
- Use of surrogate endpoints may allow for smaller sample size
- Strongly consider calculating an appropriate sample size



Bentley JP. Sample Size and Power Analysis. In: Aparasu RR, Bentley JP. eds. *Principles of Research Design and Drug Literature Evaluation, 2e*. McGraw-Hill Education; 2020. Accessed January 27, 2026. https://accesspharmacy.mhmedical.com/content.aspx?bookid=2733&sectionid=226711822

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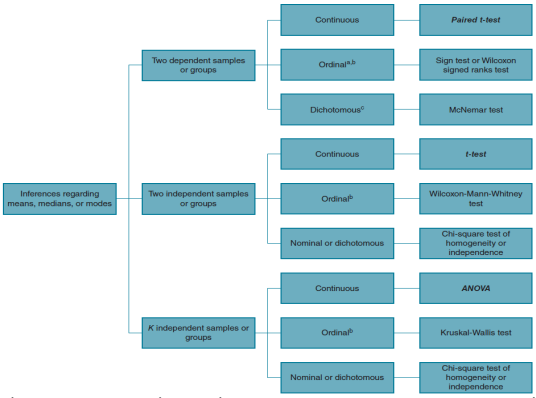
Methods
Data & Statistical Analyses

- Data handling
  - If plans are to de-identify data, it should be done after collecting study-related data.
    - De-identification before collecting outcome data will not permit you to link outcomes to baseline data collected.
- Statistical analysis
  - Indicate how you will analyze your different outcomes.



Slack MK. Bivariate Analysis and Comparing Groups. In: Aparasu RR, Bentley JP. eds. *Principles of Research Design and Drug Literature Evaluation, 2e*. McGraw-Hill Education; 2020. Accessed January 27, 2026. https://accesspharmacy.mhmedical.com/content.aspx?bookid=2733&sectionid=226711514

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Future Impact/Dissemination
Reviewer Feedback

Future Impact

- Dedicated section vs "Discussion"
- Don't simply reiterate rationale
- Describe how study may impact patient care moving forward
- Describe what follow-up studies are planned

Dissemination

- Dedicated section vs "Discussion"
- Should discuss how you will inform others of your findings
  - Scientific abstract
    - What meeting(s)?
  - Manuscript
    - Targeted journal(s)?
  - Other dissemination outlets?

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Timeline
Reviewer Feedback

All study procedures should be completed within the funding period

- Protocol development
- IRB
- Patient recruitment
- Patient follow up
- Data analysis
- Dissemination
- Abstract
- Manuscript

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Timeline
Visual Representation

Timeline: The proposed aims are discrete, well-defined, and feasible with design, IRB approval, and recruitment supporting a 12-month timeline (*Table 2*).

Table 2. Proposal Timeline by Month	1	2	3	4	5	6	7	8	9	10	11	12
OPTIM investigator team meetings	■	■	■	■	■	■	■	■	■	■	■	■
Study operations (IRBs, DUAs, REDCap)	■	■										
CCP participant engagement sessions					■			■			■	
Aim 1												
Phase 1 Data Collection		■										
Phase 2 Data Collection		■	■	■	■							
Phase 3 Data Collection					■	■	■					
Statistical analyses								■	■			
Aim 2												
Traditional analyses								■	■			
Bayesian analyses									■	■		
Machine learning analyses									■	■		
Manuscript development							■	■		■	■	■
Development of AHRQ R01 funding proposal											■	■

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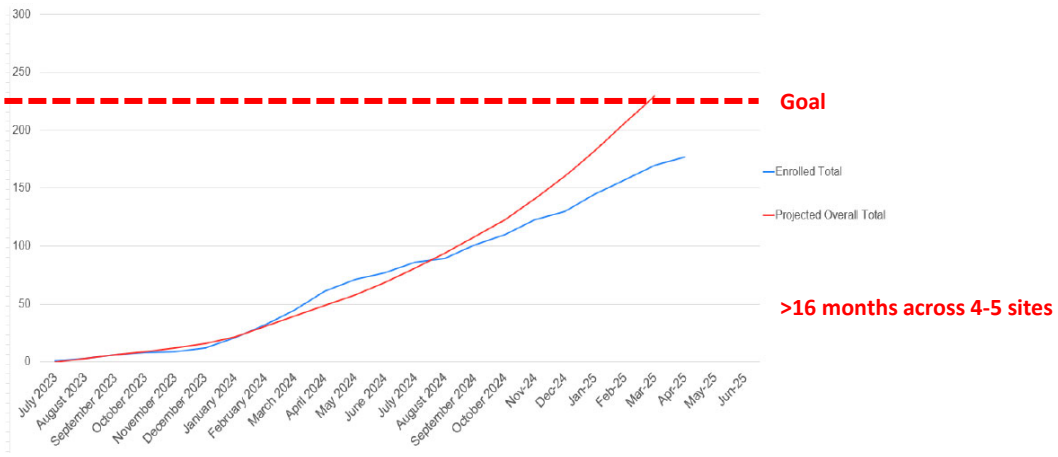
Timeline
Takes Time to Enroll Subjects



>16 months across 4-5 sites

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Budget
Reviewer Feedback

Specify how the funds will be used

- Personnel/salary support
  - Paying for their time (or portion of their time)
  - Fringe benefits
- Materials
  - Lab supplies
  - Equipment
  - Use of validated tools
  - Statistical software
- Travel support to present findings
- Manuscript fees
- Institutional overhead costs

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Evaluation of Proposal

- Each proposal will be evaluated by 3 members of the Research Protocol Review Committee and will be assigned an overall impact score.
- Reviewers will consider the following criteria when evaluating the proposal
  - Background, Rationale, and Innovation- 20%
  - Hypothesis and Specific Aims -15%
  - Design and Methods – 40%
  - Timeline and Budget Adherence – 10%
  - Future Impact/Dissemination Plan -10%
  - Overall Document Construction – 5%
- Teams achieving a rating in the top third of submissions will be forwarded to the Competition Oversight Panel for final review and consideration for the top four awards.
- Award winners are announced in June

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Evaluation Rubric

Section	Comments
Background and Rationale (Weight: 20%)	
Consider:	
How well the research problem and issue(s) are clearly identified.	
The importance, significance, and innovation of research topic and scientific approach and how well these are established.	
Whether there is a concise description of what is to be accomplished by the study and justification for why study is important.	
How relevant and appropriate the background is for current study provided and whether references are cited according to AMA.	
The degree to which there is sufficient focus on evaluation and relevance of prior research and existing literature.	Score (0-5): _____
Hypothesis and Specific Aims (Weight: 15%)	
Consider:	
The appropriateness of the research question(s) and how well it is stated.	
Whether the hypothesis is appropriate and testable as stated.	
The degree to which the specific aims are concise and descriptive.	Score (0-5): _____
Design and Methods (Weight: 40%)	
Consider:	
The appropriateness of the inclusion and exclusion criteria and whether they are explicitly stated.	
Whether the manner in which the subjects will be recruited and assigned to study groups is indicated.	
The degree to which there is a detailed description of what is to be done throughout the study duration, and in chronological sequence.	
Whether the planned subject recruitment is feasible as described.	
The degree to which the primary and secondary or exploratory outcomes are clearly stated, how appropriate their selection is for the project, whether the rationale is stated and appropriate.	
The degree to which the strategies for controlling extraneous variables are provided.	
Whether the manner of data collection, data analysis, and justification for chosen analytical and statistical methods is included.	
Whether the sample size/power calculation parameters are provided.	
Whether the study design is highly feasible to answer hypothesis.	
Whether a justification for human subjects – i.e., informed consent process addressed (or waiver of consent) is provided and how appropriate it is for the project.	Score (0-5): _____
The degree to which potential limitations are acknowledged, addressed, and complete.	
Timeline and Budget (Weight: 10%)	
Consider:	
The degree to which the study timeline/period of follow-up is feasible.	
Whether the roles and responsibilities of the study team are identified.	
The degree to which individual components of the budget are identified and allocated, and whether it is reasonable.	Score (0-5): _____
Future Impact/Dissemination Plan (Weight: 10%)	
Consider:	
The likelihood that the results of the project will have a sustained influence on the field of research.	
How feasible the plan is for dissemination of results and how well it is articulated.	
How likely the results of the project are to generate new and additional research in the field.	Score (0-5): _____
Overall Document (Weight: 5%)	
Consider:	
Whether the spelling, grammar, punctuation, and sentence structure are complete and appropriate.	
Whether the formatting requirements (page, margin, font) are met Font: Times New Roman 12 point; Margins: 1 inch; Line Spacing: 1.5; Total Page Limit: 12 pages	
Your overall impression of document construction, readability, and grantsmanship.	Score (0-5): _____
	Total Score _(calculated using algorithm)_____

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