

Developing a Letter of Intent for the ACCP Clinical Pharmacy Research Challenge

Robert DiDomenico, Pharm.D., FCCP, FHFSA, FACC

Associate Professor; Associate Head, Faculty Affairs & Strategic Initiatives

University of Illinois Health
Chicago, Illinois



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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

- Competition Timeline
- Provided Research Environment
- Key Components
 - Background & Rationale
 - Hypothesis & Specific Aims
 - Innovation
 - Proposed Study Design & Methods
 - Future Impact & Dissemination Plan
 - Budget
 - Acknowledgement Section Disclosing any use of Artificial Intelligence
- Formatting
- Evaluation
- Tips

Competition Timeline

- Round 2: Letter of Intent (LOI)/Pre-Proposal Round
- Top 40 teams participate following the competition of the Online Journal Club Round
- LOI/Pre-proposal Due early March. Please refer to the timeline posted at <https://www.accp.com/stunet/crc/eligibility.aspx#schedule> for the current year's deadline information.
- Document must be posted online by the team's registering faculty member
- Document must be based on the provided Research Environment and conform to posted formatting requirements.

Research Environment

- Each year ACCP will provide a new and unique Research Environment which will ask student teams to demonstrate the value of clinical pharmacy service(s) in a specific area of practice.
- The Research Environment information includes:
 - Potential outcomes to be addressed
 - Specific practice site and staffing information
 - Available budget
 - Requested timeline for the research to be completed.
- Formatting Requirements are also included and are available at <https://www.accp.com/stunet/crc/eligibility.aspx#format>

What is an LOI/Pre-Proposal? Why is it Important?

Communication tool between a potential funding agency (in this case the competition review panel) & student researchers

- An "Introduction"
- Non-legally binding document
- Condensed version of a full research proposal
 - **Important step in developing a clear plan for your research**
- Designed to generate interest from funding agency (competition review panel)
- Elicit feedback & invitation to submit full proposal for Round Three of the competition.

Background and Rationale Key Components

- Develop an opening paragraph that serves as a concise executive summary.
 - LOI/Pre-proposal plans should be clear to the reviewer
 - Should entice the reader to continue

- Background & brief rationale (1 – 2 paragraphs) follow
 - Serve as a Statement of Need
 - What gap(s) in the literature will this address?
 - Justifies why this research should be conducted, who will benefit

Hypothesis and Specific Aims Key Components

- Hypothesis: what research question will project answer
 - Importance of understanding the limits of your resources
 - Is the hypothesis “testable”?

- Specific aims of the study
 - Typically, 2 – 3 specific aims
 - Primary: the main outcome measure in the study intervention
 - Secondary: additional outcome measures in the study intervention
 - Outcomes of interest could address clinical, quality, economic, or humanistic categories

- Is the work feasible?
 - Sample size, outcomes, etc. based on limitations (budget, timeline)

Innovation

- What is novel about your proposal?
 - New use of a therapy?
 - New population studied?
 - Novel service provided?
 - New methodology?
 - New collaboration?
- Be innovative and creative, think outside of the box
 - Simply replicating previous studies is NOT innovative

Study Design and Methods Key Components

Considerations

- Does the study design facilitate answering the hypothesis?
- Prospective vs retrospective
- Single vs. multi-center study
- Blinded vs. unblinded treatment
- Primary and secondary outcomes clear & appropriate in scope
- How & when will these be measured

Briefly describe:

- Who & how many will be studied
- Inclusion/exclusion criteria
- Sample size calculation/power analysis
- How will subjects be recruited
- Planned data analyses
- Timeline (duration of study, follow-up, analysis, dissemination, etc.)
- Realize that for prospective studies, patients are typically enrolled gradually over time, not all at the same time
- Limitations

Future Impact/Dissemination Plan

Key Components

Future Impact

- How will the proposed project will have a sustained influence on the field of research?
- How will the results inform or shape clinical practice?

Dissemination Plan

- How and/or where will the results of this study will be shared?
 - Poster sessions, abstracts, professional meetings, etc.
- Which journal(s) will you target for publication of the results?
 - Cannot publish same study results in >1 journal

Budget

Key Components

- Demonstrate understanding of the financial limits to fund the project
- For LOI, typically state total project costs requested & the time period for this request
 - May indicate broadly the categories of activities to be funded
 - Personnel, equipment, advertising/recruiting (e.g., stationery/flyers, websites)
 - Although specific details are not necessary for LOI, factor the following into your budget calculations:
 - Study roles for your team & how this factors into the budget (% effort/salary vs hourly rate)
 - Specific equipment needed/requested
 - IRB and other fees
 - Facility fees (e.g., “overhead”, fringe benefits for personnel, etc.)

Acknowledgement Section Disclosing any use of Artificial Intelligence – Key Components

- **Use of Artificial Intelligence (AI).** The use of tools that assisted the author(s) with generating text or images must be described. The description should include the specific tool and how it was used to create text or images used in the manuscript.
- If AI tools were used to assist with data analysis, the specific tool and description of what it performed should be included in the methods section in the body of the manuscript.
- If no use of Artificial Intelligence was employed the authors must clearly indicate so in the acknowledgement section.
- Please refer to the ACCP Web site for complete information on AI disclosures. <https://www.accp.com/stunet/crc/eligibility.aspx#format>

Formatting

Letters of Intent are to be submitted using the following criteria:

- Font- Times New Roman, 12 point
- Align text to left margin
- Margins- 1 inch
- Line Spacing 1.5
- Total Page Limit – 3 pages (This includes references which may be single spaced. The Acknowledgement Section disclosing any use of artificial intelligence WILL NOT count toward your 3-page limit.)
- Do not include any identifying information in your proposal. This includes institution name, city, hospital or health care identity, faculty or student information.
- Do not include any of the above identifying information in the title of the uploaded file containing your research proposal.

Evaluation

- Each proposal will be evaluated by 3 members of the Research Protocol Review Committee and will be assigned an overall impact score.
- Reviewers will apply the following criteria when evaluating each LOI:
 - Background and Rationale – 15%
 - Hypothesis and Specific Aims – 20%
 - Innovation - 15%
 - Proposed Study Design and Methods – 35%
 - Future Impact/Dissemination Plan - 10%
 - Adherence to Formatting Requirements – 5%
- Teams achieving the top 20 scores after the LOI round will be advanced to Round 3 and invited to submit a complete research proposal.



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Evaluation Rubric

Section	Comments
Background and Rationale (Weight: 15%)	
Consider: How well the research problem and issue(s) are clearly identified. The importance and significance 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.	Score (0-5): _____
Hypothesis and Specific Aims (Weight: 20%)	
Consider: The appropriateness of the research question and how well it stated. Whether the hypothesis is appropriate and testable as stated The degree to which the specific aims are concise and descriptive	Score (0-5): _____
Innovation (Weight 15 %)	
Consider: The degree of innovation in the proposed approach to address the research question and how well the process is described.	Score (0-5): _____
Proposed Study Design and Methods (Weight: 35%)	
Consider: Whether this study design as proposed is capable of answering the hypothesis. The ability of the proposed design to be completed within the given research environment and budget frameworks. The degree to which the primary, secondary, or exploratory outcomes are clearly state and are appropriate for the project A basic description of the design and methods is proposed including mention of subject recruitment, inclusion/exclusion criteria, manner of data and statistical analyses, and acknowledgement of potential limitations.	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 and/or impact clinical practice The plan for the dissemination of results and how well it is articulated	Score (0-5): _____
Overall Document (Weight: 5%)	
Consider: Whether the formatting requirements (page, margin, font) are met Font: Times New Roman 12 point; Margins: 1 Inch; Line Spacing: 1.5; Total Page Text align left, Limit: 3 pages; References may be single spaced. Must include Acknowledgement section regarding use of AI. The AI Acknowledgement section does not count toward the 3 page limit.	Score (0-5): _____



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Tips

- LOI should be concise, convincing, creative, & innovative.
- Avoid jargon, “fluffy” adjectives, generalized statements, and redundancies.
- Review and follow the outline provided in the Research Environment.
- Use previous studies with similar premises (e.g., implementing a pharmacy service) to guide your proposal.
 - Variables, statistics, & resources that can be translated into your own study.
- Consult with faculty with expertise in the area outlined in the research environment.
- Start early and set a schedule to meet with your faculty advisor.
- Online examples provided by ACCP may be useful templates/guides