Loewenberg College of Nursing Template for Research Proposal Submission

Planned Completion Date

List Date & Person Responsible

(NOTE: While these guidelines are specific to the NIH proposal, the principles are also applicable for proposals to other major research funders)

	1. **YOUR IDEA & Identifying a Funding Opportunity Announcement (FOA)** All applications must be submitted in response to a Funding Opportunity Announcement (FOA). To browse through current FOAs, go to http://grants.nih.gov/grants/oer.htm. Use RePORTER https://reporter.nih.gov/ to Help Identify Where Your Research Fits This guide provides information for how to develop each section of the application. You should allow about a semester for proposal writing and submission.
	2. **Contact the Associate Dean for Research's Office** (ADR) by submitting an "Intent to Submit" form [enter URL for this here] with brief information, investigators, % effort (draft information OK). Request to register in era Commons, if needed.
	3. **Begin to assemble the Research Team**. Investigate opportunities for collaborating with more experienced, well-known recipients. Collaborators can fill gaps in your own expertise and resources and can assure reviewers of the competence of your proposed team. You should choose key personnel whose training and experience match the science proposed in the application. Senior/Key Personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition. You should not include technicians or junior investigators unless they are providing specific expertise or skills needed to complete the proposed research. ADR office will assist if needed.
	4. **Develop a working Title**: Title should be short and descriptive of the proposed research. Maximum space limit is 81 characters including spaces.
	5. **Write a draft Specific Aims section:** MOST IMPORTANT PART! A strong proposal is driven by a hypothesis(es) or purpose(s) that leads to clear research objectives. The Specific Aims section should encapsulate these concepts. It typically begins with a brief narrative paragraph or two that concisely states the issue or problem to be addressed, describes the long-term goals or objectives of the project and clearly states the hypothesis to be tested. This is followed by a numbered list of the Specific Aims. The aims test different aspects of the hypotheses, operationalize the objectives and provide a rationale for the experimental approach to be described later. For clarity, each aim should consist of only one sentence. Use a brief paragraph under each aim if detail is needed. Most successful applications have 2-4 specific aims. Make sure the aims are logical, achievable, and clearly relate back to the hypothesis. 1 page only.
	6. **Research Forum**: ADR will plan a research form or brainstorming session at LCON to obtain approach input and/or get suggestions for problematic or undecided pieces, *If desired*
	7. **Timeline:** Plan & develop a timeline of tasks to ensure you get your application to your Office of Sponsored Research on time - 5 business days prior to due date.

	8. **Contact NIH Program Officer** to discuss ideas: ADR office will assist. Identify the NIH IC that supports research in your area, then check the IC's Web site to determine whether your idea matches any of the IC's high-priority research areas and obtain specific information related to the IC's FOAs and specific research priorities.
	9. **Things to do early or whenever you have down time:** **a**. **Biosketches & Letters of Support**: For BS, 5 page limit each. Each Key Personnel must submit an NIH Biosketch form which requires a personal statement describing relevant experience and qualifications that makes this person well suited for the role to be played in the project. It also includes a section on publications, which can include up to 15 manuscripts in press or published articles. SEE HOW TO BIOSKETCH. https://grants.nih.gov/grants/forms/biosketch.htm **Letters of Support:** Your application should include letters of support from your institution, key personnel, collaborators, and other significant contributors. Relevant letters of support will assure your peer reviewers that your collaborations and institutional commitments are on the right track. What To Include: The letter text should demonstrate the commitment of your institution & contributors. Summarize the agreements you have in place to support your project. https://www.niaid.nih.gov/grants-contracts/letters-of-support The ADR office will assist if needed. **b. Facilities and Other Resources:** This section provides information to indicate that the environment can support the proposed research. Reviewers will use this information to assess the capability of organizational resources to perform the proposed research. Resources might include laboratory, computer, office, clinical, or other facilities. Provide information on capacities, capabilities, relative proximity, and extent of availability of resources to the project. Describe only those resources that are directly applicable to the proposed research. Discuss the scientific environment of the institution, specifically, ways in which the proposed research will benefit from unique features of the environment, including special populations and investigators, opportunities for collaboration, intellectual discussion, etc. If the research will be conducted in several places, be sure to describe the resources available in each site. Mention any start-up funds, support for a technician, and other resources provided by your institution. This is a positive indicator to reviewers of institutional commitment. For New or Early Stage Investigators, describe the institutional investment that will be made to ensure the success of the investigator (e.g., resources, classes, etc.) There is no page limit for this section. You may wish to consider the following questions. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? The ADR office has templates for UoM resources and scientific environment which you may use. BE SURE to SPECIFY & modify for your own proposal. **c. Budget:** Begin this process early so you know what the scope of your project can be (limited by the funding mechanism). The budget includes such items as investigator time/salaries, equipment, supplies, travel expenses, and the like. Salaries generally are 60% to 80% of direct costs. Begin to work with OSP budget assistance early THEY WILL HELP TO OBTAIN COSTS OF ITEMS NEEDED. All costs must be allowable, reasonable, and necessary. If you ask for too little money given the work

	proposed, reviewers will see the application as naïve. If you ask for too much, reviewers will cut the budget. **d. Budget Justification:** narrative section that describes what & why these items are needed. There are two types of budgets: 1) a modular budget, which must not be over $250,000 per year in direct costs and only requires personnel justification, and 2) SF424 budget, for requests over $250,000 or specific RFAs, which require detailed line items and detailed justifications for all items. You cannot go above $500,000 per year in direct costs without NIH Institute approval. Plan to spend time thinking through the budget and justification. If the budget is getting too high for the grant mechanism or your stage of career development, consider cutting back the specific aims or experiments. There are no page limits for this section. **e**. **Human Subjects Section**: Reviewers evaluate the justification for involving human subjects and proposed protections from research risk according to five criteria: 1. "Potential Risks to subjects" section, 2. Adequacy of protection against risks stated in "Protection against Risks" section) 3. "Potential benefits of proposed research to human subjects and others", 4. "Importance of the knowledge to be gained", 5. "Data and safety monitoring" – if Clinical Trial . ***Write subsections for each. <u>No page limit</u>*** i. Inclusion of Women & Minorities Section (separate page) https://www.niaid.nih.gov/grants-contracts/special-populations ii. Inclusion Enrollment Form (separate page) iii. Inclusion of Children Section (separate page)
	10. Research Strategy: 12 pages limit (R awards), check FOA The research strategy is organized into three sections: **Significance, Innovation, & Approach.** The assessment of this research plan will largely determine whether or not the application is favorably recommended for funding. For an application with multiple Specific Aims, the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or address Significance, Innovation and Approach for all of the Specific Aims collectively. The R01 application allows for a maximum of 12 pages, which include the three strategy components: Significance, Innovation, and Approach. Other types of applications may have different length limits. Images, graphs, and charts should be included within this section, not in a separate attachment. They count against the page limit. Investigators must use image compression such as JPEG or PNG. **a. Significance:** In this section, <u>state the research problem, current state of knowledge, and potential contributions of the research to the field.</u> Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. The background leading to the present application should be brief. It should include a critical evaluation of the literature and identify the gap that this project will fill. The literature review should provide only that information that directly clinical practice be advanced? What will be the

	effect of these studies on the concepts, methods, technologies, treatments, services, or preventive measures that drive this field? **b. Innovation**: Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **Consider the following questions**. Is the project original and innovative? For example, does the project challenge existing paradigms or clinical practice? Does it address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
	c. Approach: In this section, describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe how you plan to carry out the research. Include details related to specific methodology, and explain why the proposed methods are the best to accomplish study goals. Describe any novel concepts, approaches, tools, or techniques. Your research methods should relate directly to the specific aims. <u>This section is critical for demonstrating that you have developed a clear, organized, and thoughtful study design that tests the central hypothesis.</u> State how the data will be collected, analyzed, and interpreted. Describe statistical techniques that will be used. Include a proposed timeline for completing the work. Discuss potential problems, alternative strategies, 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. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. <u>In brief, the content of the Approach section should include:</u> **a.** **PI's preliminary studies**, data, and experience relevant to the application & design; **Preliminary Studies:** as part of the Approach section. Discuss your preliminary studies, data, and <u>or experience pertinent to this application</u>. preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of proposed project. It can also provide support for feasibility of the proposed research and for experience and competence of applicant. <u>Discuss how the previous work leads to the current proposal</u>. <u>Emphasize how previous work demonstrates feasibility of proposed methods. Accuracy is critical in figures, tables, and graphs. New or early stage Investigators should include preliminary data if they have any.</u> **b.** the overview of the **design;** **c.** a **description of methods and analyses** to be used to accomplish the specific aims of the project **d.** a **discussion of potential difficulties** & limitations and how these will be overcome or mitigated; **e.** **expected results, and alternative approaches** that will be used if unexpected results are found; **f.** **a projected sequence or timetable** (work plan);

	g. if the project is in the early stages of development, describe any strategy to establish feasibility, and address management of any high risk aspects of the proposed work; **h. a detailed discussion of the way in which the results will be collected, analyzed, and interpreted;** **i.** a description of any new methodology used and **why it is an improvement** over the existing ones.
	11. **ABSTRACT: Do LAST** https://nexus.od.nih.gov/all/2019/06/28/project-summary-abstract-and-project-narrative-whats-the-difference-and-what-to-include/ A succinct and accurate description of the proposed work; **30 lines of text or less**; Include: the project's broad, long-term objectives and specific aims, and a description of the research design and methods. Do not include: proprietary or confidential information, or descriptions of past accomplishments.
	12. **Project narrative: Do LAST** Communicates the public health relevance of the project to the public; **No more than 2-3 sentences**; Use plain language understandable by a general audience; Describe how, in the short or long term, the research would contribute to: the fundamental knowledge about the nature and behavior of living systems, and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
	13. Bibliography and References Cited: Provide a bibliography of any references cited in the project narrative and any other parts of your application. This section shows your breadth of knowledge in your field. There is no page limit for this section. The references should be limited to relevant and current literature. When citing articles that fall under the Public Access Policy (i.e., arose from NIH support), provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article.