## Center for Nursing Research Mock Reviews

### PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The Center for Nursing Research office *requires* that all grant applications receive an internal review prior to submission. The PI will determine who will review his/her proposal. Additionally, it highly encouraged that the PI have an expert in the field review the application and not rely solely on the required internal reviewers. It is also recommended that the PI plan the mock review early enough in the process leaving enough time for revisions and a second review by the external reviewer. An external reviewer will be paid by the CNR based on one versus two grant reviews (for information regarding external reviewer compensation, contact the Director of Research Administration in the CNR).

The purpose of the internal review is to provide a comprehensive review of the proposal to enable the PI to make potentially substantial changes to the proposal to improve the chance of funding. It is the PI's responsibility to contact the reviewers and provide the proposal documents by the agreed upon date to allow time for the review and for the PI to potentially make substantial changes to the proposal based on reviewers' comments. The Research Administrator (RA) will assist the PI by setting meetings and *realistic* deadlines based on the recommend timeline, below. It is expected that the PI will seriously consider any comments/edits provided and meet with the reviewer(s) to discuss any discrepancies.

All documents should be provided to the reviewers in word format to provide for easy use of the track changes tool.

The assigned RA will contact the reviewers to ensure adherence to this process prior to application submission. The PI's application may not be submitted without this review.

#### **Suggested Timeline**

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AIMS REVIEW:	3-6 months prior to
• PI informs the RA of the proposal and provide the Request for Proposal /	the deadline.
Solicitation.	
RA schedules an aims review.	
PROPOSAL REVIEW:	8 weeks prior to the
• PI provides names of suggested internal reviewers and the name of the external reviewer to the RA.	deadline
• RA coordinates the mock review, date, time, place that is convenient for the PI and selected reviewers.	
• PI meets with the RA to begin a preliminary budget.	
MOCK REVIEW:	6-8 weeks prior to
• Should take place at least 6-8 wks. prior to submission date	the deadline
• PI provides documents for review including Research Strategy, Specific Aims, Narrative, Biosketches, Budget Justification, Summary Statement (if this is a resubmission), and any other additional documents	2 weeks prior to the mock review
• RA sends out the documents for review and NIH score sheets to the Research Faculty, Reviewers, and Graduate Students. Watermark the proposal as	
"Confidential"	
FINAL REVIEW:	3 weeks prior to the
• PI sends the revised proposal and other supporting documents to the external reviewer.	deadline.
PROPOSAL SUBMISSION:	2 days prior to the
• PI sends final documents will be sent to the RA at least 2 days prior to the deadline date.	deadline.

• RA reviews the proposal to ensure that all sponsor guidelines are followed. If there are any issues the RA has time to address these issues and submit before the deadline. Submission 1-2 days prior to the deadline.

## **REVIEWER RESPONSIBILITIES**

The reviewer is responsible to provide timely, constructive feedback to the PI. *If at any time there are concerns with an application, please contact the Associate Dean for Research and Innovation ASAP.* 

**Eligibility:** Assess if the funding mechanism is appropriate for the PI, including eligibility based on stage of career, prior funding, and scope/theme of project.

**Application Assignment:** Assess whether the appropriate institute(s) and study section are selected. Ensure that interactions with program officer have been initiated.

**Resubmissions:** Review summary statements to evaluate if proposal sufficiently addresses the critiques. Similarly evaluate introduction (the formal response to critiques).

**Overview:** Does the investigator have sufficient internal and/or external support to be competitive for this project? In areas of obvious intellectual or technical weakness, does the investigator include letters of collaboration from experts in these field(s)? If the applicant utilizes core facilities/services, are letters of support included? Does that applicant include all necessary supporting documents (i.e., facilities and resources, equipment, resource sharing plan, vertebrate animal or human subject forms)?

**Specific Aims:** Evaluate the scope of project and appropriate grantsmanship. This section is the most important and needs to be flawless. It should make a compelling case for why the proposed work is worth doing, <u>briefly</u> <u>summarize</u> the approach and clearly describe what will accomplished by the end of the studies. Typically, there should be an overall hypothesis or driving scientific question that is not too limited in scope. Each Aim may also have one or more hypothesis or driving scientific question. How much of the proposed work is dependent on the success of the rest (i.e. does Aim 2 largely depend on the outcome of Aim 1)? This is to be avoided. Does the writer take their audience into account (i.e., if it is an NIH proposal, is there public health relevance)?

**Significance and Innovation:** Does the Significance section convincingly justify the need for the proposed experiments. This section is not a literature review and should only include information necessary to justify why the work should be done. (i.e., there is a gap in our collective knowledge or capabilities and the proposed work will fill that gap). Does the Innovation section <u>succinctly</u> describe what is innovative about this proposal? Innovation of ideas and approaches is the key to this section, not simply the application of cutting-edge techniques.

**Research Strategy:** Most of the preliminary data should be in this section. Is the preliminary data organized effectively? Should the preliminary data be incorporated into the approach (i.e. broken up for each Aim) or is the preliminary data most effectively presented in a discrete section prior to the approach? Is the preliminary data sufficient for the proposal? Is there a pitfalls and limitations section for each Aim? Are alternative approaches discussed if technical issues arise? Is there a discussion of expected outcomes and how these outcomes will be interpreted? Does it appear that the PI has decided on the outcome of the studies and all approaches and possible outcomes are oriented towards that expected outcome? This is to be avoided.

Is there a logical, detailed timeline for the proposed studies (charts/figure of timeline are often optimal)? Is there a summary that redefines why the work should be done, what will be accomplished by completion of the studies, and how this will lead to future studies?

Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Human Subjects: Applications that propose to involve human subjects must address:

- 1. The risk to subjects
- 2. The adequacy of protections against risk
- 3. Potential benefits of the research to subjects and others
- 4. The importance of the knowledge to be gained

5. For clinical trials, data and safety monitoring plan and a data and safety monitoring board for Phase III trials.

# **REVIEWER ACKNOWLEDGEMENT**

If you serve as a reviewer a minimum of one time per calendar year, you may include this as institutional service on our curriculum vitae (CV). For example, under a subheading of your CV which you would typically list extramural grant review activities, you may list "Internal Grant Review Program, Penn State Research", or something similar.