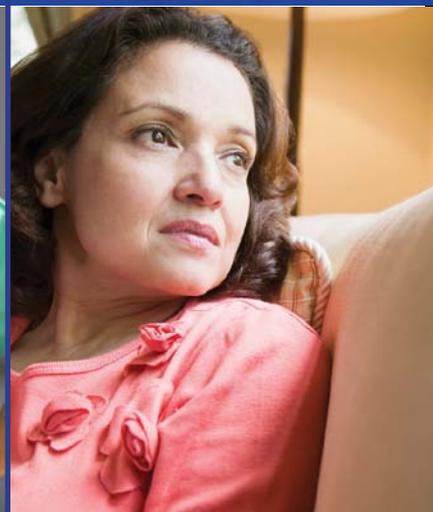




Responding to Enhanced Peer Review



Sue Marden, Ph.D.
Program Director, Symptom Management
Portfolio





Objectives

- Identify critical elements of a summary statement
 - Describe a plan for review of a summary statement
 - Discuss strategies for revising an application
-



The Summary Statement

- The official document describing the outcome of the scientific review process
 - Summarizes the discussion that provides the basis for your impact score
-



A Summary Statement

Is Not...

- An exhaustive critique
 - A teaching tool listing every point reviewers found problematic
 - A document stating what you need to do to get a better score
-

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
Jane Doe
301-594-5971/does@mail.gov

Release Date: 06/25/2010

Principal Investigator
SMITH, ANNE

Application Number: 1 R01 NR0222-01

Applicant Organization: IOWA UNIV-IOWA STATE at IOWA CITY

Review Group: ZRG1 NRCS-B (01)

Center for Scientific Review Study Section/ Nursing and Related Clinical Sciences

Meeting Date: 06/15/2010

Council: Sept 2010

Project Title: Symptom Clusters and Cancer Treatment

SRG Action: Impact/Priority Score: 27 Percentile: 13

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 2A-No men included, scientifically acceptable

Minorities 1U-Minorities and non-minorities, scientifically unacceptable

Children: 3A-No children included, scientifically acceptable

Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	267,098	434,035
2	400,000	600,000
3	325,330	450,330
TOTAL	1,000, 025	2,000, 035

NEW INVESTIGATOR

1 R01 NR0222-01
Smith, A

NRCS-B

1 R01 NR0222-01 SMITH, ANN

RESUME AND SUMMARY OF DISCUSSION: This study addresses a significant clinical problem related to symptoms clusters in cancer survivors. The study will test whether educating cancer survivors about symptoms will assist them to better manage their condition. This new, experienced investigator has assembled a strong team. The project is innovative with good institutional support. Weaknesses noted by reviewers include lack of power analysis, no report of reliability of some measures, and no plan for subject attrition. Overall, the strengths of this excellent project outweigh the weaknesses.

DESCRIPTION (provided by applicant): Cancer treatment causes many symptoms that impact quality of life and increase health care costs. As with other chronic diseases,

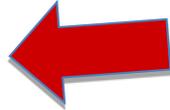
PUBLIC HEALTH RELEVANCE: Cancer survivors often suffer from multiple symptoms. An intervention to is needed to promote effective self- care of symptoms and assist survivors to seek medical treatment.

1 R01 NR0222-01
Smith, A

NRCS-B

CRITIQUE 1:

Significance: 1
Investigator(s): 2
Innovation: 1
Approach: 3
Environment: 2



Overall Impact: This highly innovative study addresses a significant clinical problem –symptoms in breast cancer survivors. The PI is experienced in research with this population. The environment provides adequate resources. A few weaknesses remain but do not limit study impact

1. Significance:



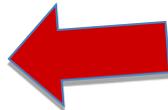
Strengths

- Proposed study addresses a clinically significant problem
- Preliminary work of the PI clearly supports the need for this study

Weaknesses

- None noted

2. Investigator(s):



Strengths

- Team members have prior experience working together

Weaknesses

- Limited effort of co-investigator

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS : ACCEPTABLE

INCLUSION OF WOMEN: Only women are included and this acceptable due to they are primarily affected with breast cancer

INCLUSION OF MINORITIES: It is unclear how a sufficient number of minorities will be recruited into this study. This is unacceptable.

INCLUSION OF CHILDREN PLAN (Resume): Only adults 21 years and older will be included. This is justified and acceptable.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested

SCIENTIFIC REVIEW OFFICER'S NOTE:



Can you Believe this Summary Statement?

“They said my grant proposal was too preliminary, not focused, too ambitious, a large fishing expedition, did not have an adequate animal model, did not provide a clear rationale, and was viewed with a low level of enthusiasm.

**And that's just in the opening summary paragraph!
There are four more pages of specific comments.**

What am I going to do?"



Can you Believe this Summary Statement?

“One critique was very realistic and cited expected holes in my application”

“Another reviewer loved the grant...quite a bit more than I really thought was deserved”

“The third reviewer totally, I mean TOTALLY, hated the application. Some criticisms were fair but there were also several obvious biases”



Attitude for Interpreting Comments?

- Assume comments are helpful
 - Be grateful not defensive
 - Be open-minded
 - Be a learner
-



Remember.....

- The reviewer is always right
 - Assume all read the same application
 - Assume more flaws exist in the application than cited
-



Can you Believe this Summary Statement?

- Read your critique thoroughly and dispassionately
 - Determine if the application is “worth fixing”
 - Respond sensibly to the queries and concerns of the reviewers
-



Is it Worth Fixing?

- Major Flaws
 - Lack of reviewer enthusiasm
 - Fixable problems
-



Major Flaws: Research Grant Awards

- Work has already been done
- Hypotheses or Questions not supported by data
- Methods are not suitable
- Insufficient statistical power
- Lack luster of past productivity of investigators
- Poor resources or facilities



Major Flaws: Training and Career Awards

Mentorship

- Mentor overcommitted
- Mentor lacks relevant expertise

Training Plan

- Lacks sufficient detail to develop candidate into a promising scientist
 - Research project is weak (unspecific aims, methodological issues)
-



Major Flaws: Training and Career Awards

- Major flaws fixable if good mentorship is available
 - Seek out a long distance mentor
 - Detail a plan for regular meetings with a mentor not at your institution
-



Lack of Reviewer Enthusiasm

If you get little criticism and a high score...

- Were the reviewers appropriate?
 - Yes...then problem not fixable
 - No...consider another review group



Fixable Problems?

- Poor Writing
 - Diffuse Aims
 - Significance is not convincing
 - Insufficient information, experimental details, or preliminary data
 - Research not feasible by proposed staff
-



Fixable Problems?

- Too much work for the project period requested
 - Insufficient attention to how data will be interpreted
 - Insufficient discussion of obstacles and alternative approaches
-



Reviewers Note Fixable Problems

- Shows they are interested in the idea
 - Indicates the application is worth fixing
-



Deconstructing the Summary Statement

- Identify most important concerns
 - Cluster other concerns by critique number
 - Organize concerns within criteria areas (e.g., Significance, Innovation)
 - Note all positive comments
-



Deconstructing the Summary Statement

- Evaluate if there is consistency of responses among reviewers
 - Choose the concerns that seem most salient
 - Seek out advice on what reviewers need to be convinced and enthused about
-

Common misconceptions

- “Read between the lines” of a statement
 - Insight into subtle differences between reviewers
 - Share notes from review meeting
-

Questions that cannot be answered

- Do notes taken match the critique?
- Were scores divergent initially and less so at the end of the discussion?
- Did one reviewer feel less favorable about the grant than the others?
- Is my score fundable?



What “Score” is Good News?

- A 20 at 9 percentile
- A 33 at 20 percentile
- An 80 at 59 percentile

Program Director always available to assist

- What the score and reviewer comments may mean
 - Budget issues
 - Resubmission of application
 - Appropriateness of your response to reviewers comments
-



What if Reviewer is Wrong?

Before you call your Program Director:

- Most common problem: Poor presentation
 - Reviewers influenced by writing and application appearance
-

What if Reviewer is Wrong?

Poor presentation can result in reviewers:

- Missing a point
- Misunderstand
- Conclude you are a careless scientist



Non-involvement of mentor



Revise or APPEAL?

" With regard to the initial review, after examining the summary statement containing the results of that review for the grant application, an investigator may have concerns about, and wish to contest a procedural aspect of the process...,
.. that the review was biased, that conflict of interest existed, that the review group lacked appropriate expertise, that factual errors entered into the review."



Revising the Application

- Revisions should be substantive
- Sources for revision
 - Summary statement comments
 - New preliminary data
 - Recent findings from others
 - Colleagues reviews of statement and application
 - Re-review of all aspects application



Revising the Application

- Training or career award: Work directly with your mentor
- Mentor not readily available?



Revising the Application: Be Mindful

“....we appreciated the recommendation and considered the approach, however, for the following reasons we choose to ..”



Introducing the Revisions

“This application has been revised in response to the XXX SS. As noted (p1), overall, reviewers were quite excited about this proposal. Critique 1 noted that the application has the potential to significantly improve knowledge about XXX.

The PI thanks the reviewers for their helpful comments. The revised proposal contains 1) findings from 8 preliminary studies (5 update and 3 new) and significant revisions to XXX. The most salient concerns from the SS are discussed briefly below”



Is it Best to Resubmit ASAP?

- Are issues raised quickly fixed?
- Are additional manuscripts in submission?
- Can colleagues review the application?
- Is the application the strongest possible?



After Revision...Remember

- No guarantee of funding even if respond adequately to criticisms
 - Summary is not an exhaustive critique
 - Risk of introducing new problems
-



After Revision...Remember

- Membership of review group changes
 - Response to prior review receiving less attention
 - Science moves on
-

Questions

