

NIH TOPICS

- 1. What is Considered a “NEW” Application**
- 2. Appeals of Initial Peer Review**

Rena Vinyard, CRA, CPRA
Associate Director / Financial Services, PreAward HSC

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NIH Limits the Number of Times you may resubmit an application with essentially the same content and scope as an earlier application.

- Initial applications are coded A0
(i.e. 1R01CA123456-01)
- Resubmissions are coded A1
(i.e. 1R01CA123456-01A1)



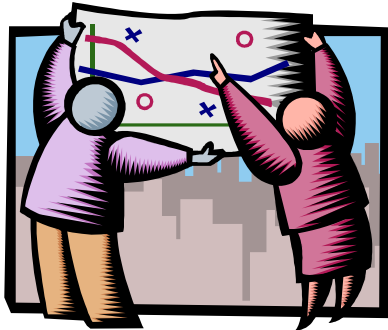
Understanding NIH Assignment

- Understanding how NIH determines whether an application is NEW or is considered a DUPLICATE is IMPORTANT.
- Applications arrive at the NIH Center for Scientific Review (CSR), Division of Receipt and Referral.
 - Where the Scientific Review Officers (SRO) are assigned to an application.

NIH CSR Team

The CSR Team compares each application and examines all parts.

They pay particular attention to:



SPECIFIC AIMS



RESEARCH STRATEGY

NIH Has Tools

- COMPARISON SOFTWARE
- Application you may think are quite different, may still be considered overlapping if many of the aims, outcomes, measures and hypotheses are the same or similar to previous applications.



Examples of Changes that Could be Substantial

- Using significantly different model systems
- Changing the disease model
- Using a similar approach for a substantially different question
- Asking a significantly different question
- Using a very different approach to address a similar issue

Examples of Changes that ARE NOT Substantial

- Rewording large sections of the application while retaining the scientific goals and objectives
- Adding one or more new collaborator(s)
- Changing the Principal Investigator
- Making changes to sections such as the Significance or Innovation but not changing the intent of the application
- Including additional preliminary data

Examples of Changes that ARE NOT Substantial cont.

- Changing the application in response to the previous reviewers' critiques
- Making substantial additions to the pre-existing Approach when the majority of the old design persists in the “new” application
- Deleting parts of the Approach such that the subsequent application is merely a subset of the old one or a concurrent submission
- Requesting assignment to a different NIH Institute/Center or review by a different Scientific Review Group
- Submitting the application to a different program announcement (PA, PAS or PAR)



Resubmission Time Clock



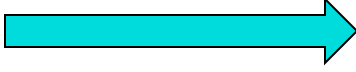
NIH has a 37-month limit for resubmissions.

If you do not submit an A1 version of the application within the 37 months of your initial submission, the future application on the same general topic will be considered a NEW application.

Given the fast pace of scientific discovery, NIH automatically expects this application to have manifested substantial changes in its scope and approach.

Unallowable Application

- If NIH suspects an Unallowable Application has been submitted, they notify PreAward and the PI.
- UNMHSC may rebut this decision to the CSR
- UNMHSC may take CSR's decision and rebut to the CSR Director. The decision then goes to the Arbitration Board for a Final Decision

NEXT 

APPEALS OF NIH PEER REVIEW

Appealing the Decision

Certain specific points must be covered in the Written Appeal of the Peer Review

1. Describe the flaws in the review process for the application in question
2. Explain the reasons for the appeal
3. Is the appeal based on one or more of the following issues related to the process of the initial peer review

Issues Related to Process

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest on the part of one or more peer reviewers.
- Lack of appropriate expertise within the SRG.
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal Letter

Appeal letters based solely on differences of scientific opinion ARE NOT accepted

Appeal letters must cover the above criteria, and be signed by the Institution's AOR (Rena Vinyard)



Appeal Letter cont.

- Letter is Reviewed by NIH Review and Program Staff to Evaluate the Merit of the Appeal
- If Review and Program ***Do Not*** support the appeal, UNM can choose to Withdraw our appeal letter or got to the next step of the appeal process
- Next step would be NIH forwards the letter to the Council for Final Consideration

2 Possible Outcomes of Final Decision

- **The Council may Agree** with the appeal, and recommend that the application be re-reviewed.



- **The Council may Deny** the appeal.

Although factual errors or other issues may have been evident, the Council may determine that these factors were unlikely to alter the final outcome.



How to Avoid the Situation

THE BEST WAY TO TRY TO PREVENT YOURSELF IN GETTING INTO THIS SITUATION IN THE FIRST PLACE –

The **COVER LETTER** in your Proposal Application



What's in the Cover Letter?

- **Identify an institute, review committee, and potential reviewers.** Start by making sure NIH has an institute that would fund the research you are considering.
- Look for a study section and potential reviewers who would appreciate your idea for a project.
- Check out study section members and their interests, and keep looking until you find a group to target your application
- Ask: are they capable of reviewing every aspect of the research? Can you identify people who could serve as primary and secondary reviewer who are excited about your project?