

Enhancing Peer Review at NIH

University of Central Florida Grant Day Workshop

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Division of Scientific Review



Enhancing Peer Review

Receipt, Referral and Review of Applications

Recent Peer Review Changes

Upcoming Changes

Submission of Applications

- The old way to submit applications
 - Paper PHS 398 application form
 - FedEx@truckload
- The new way requires
 - Transition to the SF424 Research & Research-Related family of forms
 - Electronic submission of grant applications through Grants.gov

Paper or Electronic Submission

- Transitioned mechanisms require electronic submission of the SF424 to Grants.gov
 - RO1, RO3, R13, R21, R34, SBIR and K applications
- Mechanisms yet to transition require continued use of paper PHS 398 form
 - Training grant (T32) applications
 - Program project/Center grant applications

Electronic Submission Process

- Applications must respond to a Funding Opportunity Announcement (FOA)
- Unsolicited applications respond to Parent FOAs listed at the OER website
- Application package attached to particular FOA must be used
- Submission to Grants.gov
- NIH retrieval of applications into eRA Commons

Assignment of Applications

Division of Referral assigns applications to

- Scientific Review Group
 - Center for Scientific Review (CSR) Integrated Review Group/Study Section
 - Institute Initial Review Group/Review Subcommittee
- Institute Program
- Referral Guidelines
- PI Cover letter

Assignment to CSR or Institute Review Group

Applications reviewed by CSR

- Research projects RO1, R21; Fellowships F32; Small business innovation research R43, R44

Applications reviewed by Institute Scientific Review Divisions

- Career development (K) applications
- Small research grant (RO3) applications
- Institutional training grant (T32) applications
- Conference grant (R13) applications
- Multicenter RO1 applications

Types of Review Committees

- Standing Committees
 - Chartered; multi-year commitment
 - Temporary members added as needed
 - Roster available in NIH Commons
- Special Emphasis Panels
 - All temporary (ad-hoc) members

Preparation for Review Meeting

Scientific Review Officer

- Analyzes content of applications
- Recruits and assigns qualified reviewers
- Manages conflicts of interest
- Establishes the 3 phases of Internet Assisted Review
- Transmits applications and orientation material to reviewers

Review Group Orientation

Responsibility of Reviewers

- Assess scientific and technical merit of applications using specified review criteria
- Reviewers do not consider program relevance or compare applications

Review Group Orientation

- Conflict of interest and confidentiality
- Guidelines for Reviewers
 - Review Criteria
 - Grant mechanism specific
 - Additional Review Criteria
 - Human Subjects, Inclusion of WMC
 - Additional Review Considerations
 - Budget
- Recent Peer Review Changes

Review Group Orientation

- Grant mechanism specific review criteria from Funding Opportunity Announcements Section V
 - Parent Announcement
 - Institute Specific Program Announcement (PA)
 - Request for Applications (RFA)
- FOAs describe objectives of specific program
 - e.g. Research grant (RO1)
 - e.g. Small research grant (RO3)
 - e.g. RFA “Neurological Recovery in TBI”

Review Group Orientation

Small grant (RO3) applications

- Objectives
 - Pilot or feasibility studies
 - Secondary analyses of existing data
 - Small, self contained research projects
 - Development of research methodology/new technology
- Provide a clear conceptual framework & general approach, less emphasis on methodological approach, preliminary data not required

Review Group Orientation

Career Development Applications

- Mentored Research Scientist Development Award (KO1)
- Mentored Patient-Oriented Research Career Development Award (K23)
- Midcareer Investigator Award in Patient-Oriented Research (K24)
- Mentored Quantitative Research Career Development Award (K25)
- Pathway to Independence Award (K99/R00)
- K Kiosk <http://grants.nih.gov/training/careerdevelopmentawards.htm>

Review Group Orientation

- Review of applications using grant mechanism specific review criteria
- Additional review criteria
 - Human subjects
 - Inclusion of women, minorities, children
 - Vertebrate animals
- Additional review considerations
 - Budget and period of support
 - Foreign applications

Peer Review Changes

Goals

- Clearer understanding of the basis of application ratings
- More emphasis on impact and less emphasis on technical details
- Succinct, well-focused critiques that evaluate, rather than describe, applications
- Routine use of the entire rating scale

Peer Review Changes

Specific changes effective with the June 2009 review meetings

- Enhanced review criteria
- Templates for Structured Critiques
- New 1-9 Scoring Scale
- Scoring of Individual Review Criteria

Enhanced Review Criteria

RO1 and RO3 Applications

- Former Review Criteria
 - Significance, **Approach**, Innovation, Investigators, Environment
- Enhanced Review Criteria
 - Significance, Investigators, Innovation, **Approach**, Environment

Review of R Applications

- Overall Impact
- Core Review Criteria (different for other grant mechanisms)
 - Significance, **Investigators**, Innovation, **Approach**, Environment
- Additional Review Criteria
 - Protection for Human Subjects; Inclusion of Women, Minorities, Children; Resubmissions
- Additional Review Considerations - Budget

Peer Review Changes

Specific changes effective with the June 2009 review meetings

- Enhanced review criteria
- **Templates for Structured Critiques**
- New 1-9 Scoring Scale
- Scoring of Individual Review Criteria

Critique Templates

- Use of templates to promote listing of strengths and weaknesses for
 - the overall impact
 - each of the core criteria
 - other review criteria such as protection for human subjects
- Templates are grant mechanism specific
 - RPG template – RO1, RO3
 - K template – KO1, K23, K24, K25, K99/R00

RPG Critique Template

RO1 and RO3 Applications

OVERALL IMPACT	Please limit text to 1/4 page
<p data-bbox="394 625 569 662">Strengths</p> <ul data-bbox="342 686 363 862" style="list-style-type: none">•••• <p data-bbox="394 922 619 959">Weaknesses</p> <ul data-bbox="342 984 363 1159" style="list-style-type: none">••••	

RPG Critique Template

RO1 and RO3 Applications

RPG Review Critique Template

1. <u>Significance</u>	Please limit text to 1/4 page
Strengths <ul style="list-style-type: none">••• Weaknesses <ul style="list-style-type: none">•••	

2. <u>Investigator(s)</u>	Please limit text to 1/4 page
Strengths <ul style="list-style-type: none">••• Weaknesses <ul style="list-style-type: none">•••	

Review of K Applications

- Overall Impact
- Core Review Criteria
 - Candidate, Career development plan, Research plan, Mentors, Environment
- Additional Review Criteria
 - Training in responsible conduct of research
 - Protection for Human Subjects
 - Inclusion of Women, Minorities, Children
 - Resubmission
- Additional Review Considerations

K Template

Overall Impact

Strengths

-

Weaknesses

1. Candidate

Strengths

-

Weaknesses

-

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring

Strengths

-

Weaknesses

-

Peer Review Changes


Specific changes effective with the June 2009 review meetings

- Enhanced review criteria
- Templates for Structured Critiques
- **New 1-9 Scoring Scale**
- Scoring of Individual Review Criteria

New Scoring System

- The new NIH scoring system uses a 9-point rating scale for the overall impact score and the core review criteria
- Ratings are provided only in whole numbers, with “1” still being the best score

New Scoring System

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

Peer Review Changes

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Old Scoring vs. New Scoring

Item	Old Way	New Way
Criterion Scores		1 to 9
Preliminary Score	1.0 to 5.0	1 to 9
Final Score	1.0 to 5.0	1 to 9
Impact/Priority Score	100 to 500	10 to 90
Percentiles	0.1 to 100.0	1 to 100



RO1 and RO3 Critiques

- Overall Impact - **Scored**
- Core Review Criteria (different for other grant mechanisms) - **Scored**
 - Significance, Investigators, Innovation, Approach, Environment
- Additional Review Criteria
 - Protection for Human Subjects; Inclusion of Women, Minorities, Children; Resubmissions
- Additional Review Considerations - Budget

Review Meeting



Review Meeting

- Assigned Reviewers
 - Indicate initial enthusiasm for application
 - Primary initiates discussion, 2nd, 3rd follow
- General discussion
- Assigned reviewers
 - State their final scores
- Private Scoring
- Budget

Review Meeting Cont'd

- Applications unanimously judged less competitive will not be discussed
Summary Statement
 - Indicates “Not Discussed”
 - Contains critiques and criteria scores from assigned reviewers
- Applications devoid of significant and substantial scientific merit still receive a rating of “Not Recommend for Further Consideration”

Summary Statement

Contains

- Summary of the discussion (if discussed)
- Essentially unedited reviewer critiques
- Criterion scores for all applications/
Impact score if application is discussed
- Recommended budget (discussed applications)
- Human and animal subject concerns
- Administrative Notes

Available to PI only via the eRA Commons

Advisory Council Review

- Most applications are approved en bloc
- Some undergo individual discussion
 - Foreign application
 - Human subjects or animal welfare concerns
 - Other concerns
 - PI appeals
- Funding recommendations to Institute

Upcoming Changes

- Effective for applications submitted on or after January 25, 2010, i.e. the June 2010 review meetings
 - New application structure and length
 - Alignment of applications with the peer review criteria
- New application forms and instructions must be used

Changes for R Applications

Research Plan

Current	Restructured
1. Introduction	1. Introduction
2. Specific Aims	2. Specific Aims
3. Background & Significance	3. Research Strategy Significance
4. Preliminary Studies/ Progress Report	Innovation Approach
5. Research Design & Methods	Preliminary Studies Progress Report

Changes for R Applications Cont'd

- Restructured Research Plan
 - Research Strategy limited to 12 pages for RO1s, 6 pages for RO3s
- Resources
 - Section requires information how the scientific environment will contribute to probably of success of the project
- Bibliographical Sketch
 - List of selected peer-reviewed publications limited to 15 (recent, important, relevant)

Changes for K Applications

- Restructured Research Plan
 - Introduction (resubmissions only)
 - Specific Aims
 - Research Strategy
 - Includes candidate information
 - Limited to 12 pages

Important Links to NIH

Enhancing Peer Review

<http://enhancing-peer-review.nih.gov>

Peer Review Process and Changes

<http://enhancing-peer-review.nih.gov/process&changes.html>

Guidelines for Reviewers

http://grants.nih.gov/grants/peer/reviewer_guidelines.htm

Restructured Applications <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html>