Revised NIH Review & Grant Proposal Format

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With thanks to

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Deputy Associate Director, NIGMS

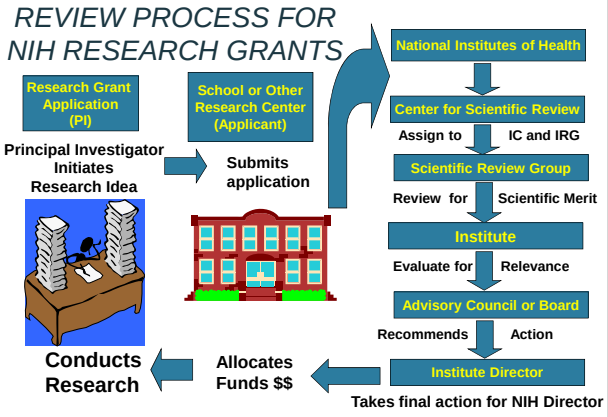
for many of these slides

NIH has revised both its grant review process (effective May 2009) and the format for research grant proposals (effective January 2010)..

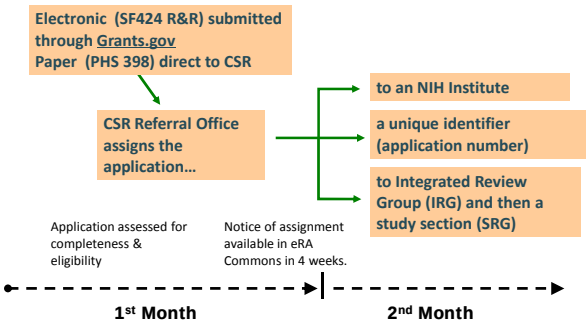
Understanding these changes will help you write more competitive proposals

While the format for NIH proposals and the review process have changed dramatically, the overall process, from inception of investigator's idea to final report, remains fundamentally the same.

REVIEW PROCESS FOR NIH RESEARCH GRANTS



Receipt and Referral of Applications



Assignment to Institutes

Applications are referred to an Institute or Center as the potential funding component:

- Assignment is based on a match between the research proposed and the overall mission of the Institute or Center
- Where applications are appropriate for more than one Institute or Center, multiple assignments are made

Assignment to CSR Study Sections

Applications assigned to study sections known as Scientific Review Groups (SRG) based on:

1. specific referral guidelines for each SRG and
2. information contained in your application

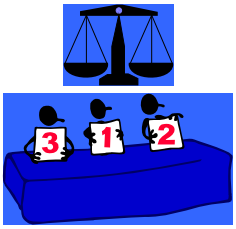
(Go to http://www.csr.nih.gov/Committees/rosterindex.asp to learn about study sections – their scientific mission and their scientific membership)

WHO/WHAT DETERMINES WHICH GROUP REVIEWS THE APPLICATION?

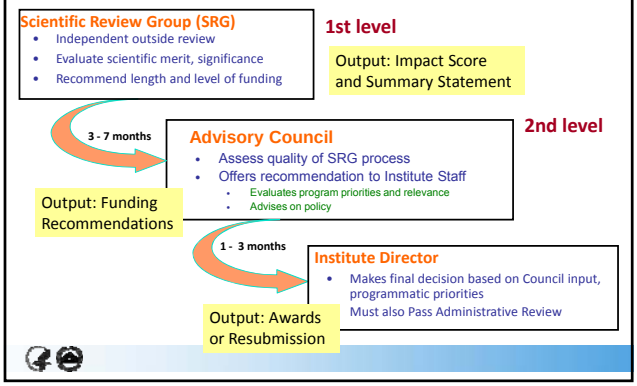
YOU DO!

- **The words in your application, especially:**
  - Your title
  - Your abstract
  - Your specific aims
  - Your approach (methods)

Understanding
NIH Peer Review



Review System for Grant Applications



Enhancing Peer Review at NIH

Changes Happening May 2009

- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Clustering of New Investigator applications
- Score order of review
- Implemented for applications submitted:
  - for Fiscal Year 2010 funding consideration

Changes Happening May '09: New Scoring System

9-Point Scale

- Reduces number of rating discriminations
- Provides rating descriptors
  - To improve reliability
  - To encourage use of the entire range
- Will be used for:
  - Overall impact/priority scores
  - Individual criterion scores
- Will be implemented for applications submitted for:
  - FY2010 funding consideration and beyond

Changes Happening May '09:
New Scoring System

New Score Descriptors

Impact	Score	Descriptor
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

Five Key Review Criteria

Significance
Investigator
Innovation
Approach
Environment

Same Core Criteria: Significance, Investigator, Innovation, Approach, Environment

Significance now includes technical capability

Investigator lists separate considerations for Early Stage (ES) and established investigators

Innovation

- highlights paradigm change in thought or practice
- asks if the innovation is discipline-specific or general
- distinguishes between refinement or completely new

Approach

- Provides special criteria for early stage projects
- Highlights human subject issues for clinical research

- A successful project does not have to be equally strong in all 5 criteria.
- "A project that by its nature is not innovative may be essential to advance a field." (Underscores by JSR)
- Significance may trump innovation.

Enhanced Review Criteria

Impact Score (formerly Priority Score) = Significance + Feasibility

- Core criteria order:
  - Significance*
  - Investigator(s)*
  - Innovation*
  - Approach*
  - Environment*
- Additional review criteria
  - *Protections for Human Subjects*
  - *Inclusion of Women, Minorities, and Children*
  - *Vertebrate Animals*
  - *Resubmission Applications*
  - *Renewal Applications*
  - *Biohazards*

Each criterion will receive an individual score

Side-by-side comparisonhttp://grants.nih.gov/grants/peer_review_process.htm

Enhancing Peer Review at NIH

Structured Critiques

- Decrease variability
- Increase quality of information in critiques
- More succinct, better organized
- Encourage evaluative statements
- Ensure that reviewers address all review criteria and considerations

Changes Happening May '09: Structured Critiques

Critique Templates

- Bulleted comments
- Scores for five review criteria
- Required comments:
  - Protections for Human Subjects
  - Inclusion Plans
  - Vertebrate Animal Welfare
  - Biohazards
  - Budget

National Advisory Council or Board Review

Council Actions

- Assesses Quality of SRG Review
- Concurs with study section action

  or
- Modifies SRG (study section) action

  Cannot change priority score

  – Deferral for re-review of the same application – no changes allowed

Makes Recommendation to Institute Staff on Funding, Evaluates Program Priorities and Relevance and Advises on Policy

What Determines Which Awards Are Made?

- Scientific or medical merit (Do you have a good idea? An important question? How good are your design and methods?) Peer reviewers judge this.
- Program Considerations (Do your priorities match the agency's priorities?) Agency officials determine this.
- Availability of funds

Happening ~~LATER~~ Now:

Application Changes

Beginning with Jan 2010 Submissions

- Alignment of applications & review criteria
- Shorter Research/Research Training Plans

*NIH released new forms in December 2009
(Note: General information was released on 9/21/09, NIH Notice NOT-OD-09-149)

Happening Now: Application Changes

Alignment of Applications and Review Criteria

Changes to three parts of application:

- Biographical sketch
- Research/Research Training Plan
- Resources

Happening Now: Application Changes

Biographical Sketch

- Personal Statement – why experience and qualifications make the applicant particularly well-suited for role in the project

Happening Now: Application Changes

Biographical Sketch

- Publications: NIH recommends list no more than 15
- May choose based on recency, importance to the field, and/or relevance to proposed research
- Do you have fewer than15 publications? may sub original research and theoretical treatises, reviews, book chapters, pamphlets, etc.
- Do not include manuscripts submitted or in preparation.

Happening Now: Application Changes

Old vs. Restructured Research Plan

Introduction (amended applications only)

Specific Aims

Background and Significance

Preliminary Studies/Progress Report

Research/Research Training Design and Methods

Research Strategy

Inclusion Enrollment Report (as applicable)

Progress Report Publication List

Human Subjects Sections….

Other Research Plan Sections….

Happening Now: Application Changes

Old Application	New Application
Background and Significance	**Research / Training Strategy** a. Significance b. Innovation c. Approach • Preliminary Studies/Progress Report woven thru these sections
Research Design and Methods	
Preliminary Studies/Progress Report	

NIH Extramural Nexus February 2010

Happening Now: Application Changes

Facilities and Other Resources

(in 424 part of the R&R Other Project Information; in 398 the Resources Format Page)

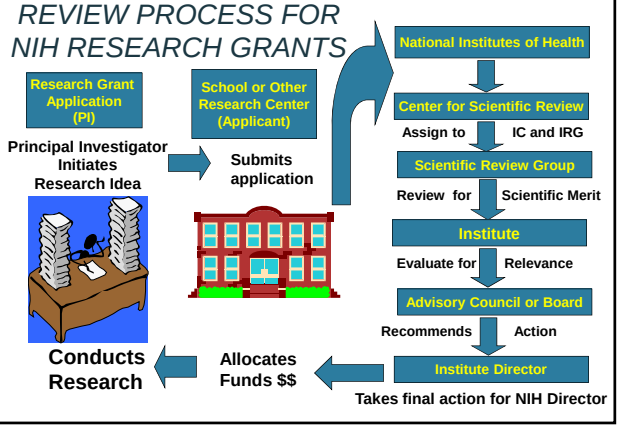
Environment - New instruction to address how scientific/training environment will contribute to probability of success, unique features of environment, etc. For ESIs, provide description of institutional investment in success of the investigator.

Happening Now: Alignment of Application with Review Criteria

Core Review Criteria	Application
Significance	Research Strategy **a. Significance**
Investigator(s)	Biosketch **Personal Statement**
Innovation	Research Strategy **b. Innovation**
Approach	Research Strategy **c. Approach**
Environment	Resources **Environment**

Happening Now: Shorter Applications

Page Limit Revisions

Introduction (to Resubmission or Revision)	**1 page**
Specific Aims	1 page
Research Strategy	
(R03,13, R21, R36, R41, R43), Fellowship (**F**)	**6 pages**
(R01, R10, R15, R18, R21/33, R24, **R25**, R33, R34, R42, R44)	**12 pages**
Career (K) (Combined Candidate Information & Research Strategy)	**12 pages**
Institutional Training(**Ts & K12**) (Research Training Plan)	**25 pages**
all other activity codes, including Cs, Ps, Ss, Us	**See FOA**
Biosketch	4 pages
Appendices	Unlimited

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